HIT Standards Committee
Transcript
January 16, 2013

Attendance

The following members attended the meeting:

- Dixie Baker
- Anne Castro
- Christopher Chute
- Tim Cromwell
- John Derr
- Floyd Eisenberg
- Jamie Ferguson
- John Halamka
- Leslie Kelly Hall
- C. Martin Harris
- Stanley Huff
- Elizabeth Johnson
- Rebecca Kush
- David McCallie
- J. Marc Overhage
- Jonathan Perlin
- Wes Rishel
- Kamie Roberts for Charles Romine
- Christopher Ross
- Walter Suarez
- James Walker

The following members did not attend this meeting:

- Lorraine Doo
- Kevin Hutchinson
- Arien Malec
- Nancy Orvis
- Sharon Terry

MacKenzie Robertson – Office of the National Coordinator
Thank you. Good morning, everybody. This is MacKenzie Robertson in the Office of the National Coordinator for Health IT. First, I just want to say thank you for being patient for our brief delay in the start this morning. We are having some weather and transportation issues here, so thank you for being patient.

This is the 44th meeting of the HIT Standards Committee, the first of 2013. This is a public meeting. There is two periods for public comment on the agenda. And the meeting is also being transcribed, so please make sure you identify yourself for the transcript. I'll now go through the roll call. Jon Perlin?

Jonathan Perlin – Hospital Corporation of America
Good morning.

MacKenzie Robertson – Office of the National Coordinator
Good morning, Jon. John Halamka I know will be here briefly. Dixie Baker?

Dixie Baker – Martin, Blanck, and Associates
Here

MacKenzie Robertson – Office of the National Coordinator
Thanks, Dixie. Anne Castro?

Anne Castro – BlueCross BlueShield of South Carolina
Here.

MacKenzie Robertson – Office of the National Coordinator
Thanks, Anne. Chris Chute?

Christopher Chute – Mayo Clinic College of Medicine
Present.

MacKenzie Robertson – Office of the National Coordinator
Thanks, Chris. John Derr?

John Derr – Golden Living, LLC
Present.

MacKenzie Robertson – Office of the National Coordinator
Thanks, John. Floyd Eisenberg?

Floyd Eisenberg – Independent Consultant
Present.

MacKenzie Robertson – Office of the National Coordinator
Thank you, Floyd. Jamie Ferguson?

James Ferguson – Kaiser Permanente, Institute for Health Policy
Here.

MacKenzie Robertson – Office of the National Coordinator
Thanks, Jamie. Leslie Kelly Hall?

Leslie Kelly Hall – Healthwise
Here.

MacKenzie Robertson – Office of the National Coordinator
Thanks, Leslie. Martin Harris?

C. Martin Harris – Cleveland Clinic Foundation
Present on the phone.

MacKenzie Robertson – Office of the National Coordinator
Great. Thanks, Martin. Stanley Huff?

Stanley Huff – Intermountain Healthcare
Present.

MacKenzie Robertson – Office of the National Coordinator
Thanks, Stan. Kevin Hutchinson? Liz Johnson?

Elizabeth Johnson – Tenet Healthcare Corporation
Here.

MacKenzie Robertson – Office of the National Coordinator
Thanks, Liz. Becky Kush?

Rebecca Kush – Clinical Data Interchange Standards Consortium (CDISC)
Here.

MacKenzie Robertson – Office of the National Coordinator
Thanks, Becky. Arien Malec? David McCallie?

David McCallie, Jr. – Cerner Corporation
Here.

MacKenzie Robertson – Office of the National Coordinator
Thanks, David. Marc Overhage?

J. Marc Overhage – Siemens Healthcare
Here.

MacKenzie Robertson – Office of the National Coordinator
Thanks, Marc. Wes Rishel?

Wes Rishel – Gartner, Inc.
Here.

MacKenzie Robertson – Office of the National Coordinator
Thanks, Wes. Chris Ross?

Christopher Ross – Mayo Clinic
Present.

MacKenzie Robertson – Office of the National Coordinator
Thanks, Chris. Walter Suarez?

Walter Suarez – Kaiser Permanente
I'm here.

MacKenzie Robertson – Office of the National Coordinator
Thanks, Walter. Sharon Terry? Jim Walker?

James Walker – Geisinger Health System
Here.

MacKenzie Robertson – Office of the National Coordinator
Thanks, Jim. Tim Cromwell?

Tim Cromwell – Department of Veterans Affairs
Here.

MacKenzie Robertson – Office of the National Coordinator
Thanks, Tim. Lorraine Doo? Nancy Orvis? Charles Romine?

Kimmy Roberts – National Institutes of Standards and Technology
This is Kimmy Roberts for Charles Romine.

MacKenzie Robertson – Office of the National Coordinator
Thank you. And with that, I'll turn the agenda over to Dr. Mostashari for some opening remarks.

Farzad Mostashari – Office of the National Coordinator
Thank you, MacKenzie. Happy New Year, everybody. It's been a great 2012, and I think 2013, as I discussed at the Policy Committee, the three main priorities are going to deepen in a way, moving from meaningful use to the meaningful use of meaningful use as a tool for delivery and payment reform, moving interoperability and exchange from committee and from rule making into communities, and into action, and consumerism in healthcare finding its place, not only in the standards, but in really ubiquitous empowerment of patients to participate – and their caregivers – in their care.

Now those are and remain the – really the three engines for the health IT infrastructure, and I think at a time like this, it's important for us to remember the long view, and there's been of late a lot of anxiety in the press about healthcare costs, and various ties to our country's fiscal situation. Many discussions will be had over the coming weeks and months about ways of dealing with the long term unsustainable trends in healthcare costs, and yet as we look for solutions, there will be some that look at ways of – I would say more tactical short-term ways of shifting costs from Medicare to others, whether it's to commercial payers, whether it's to patients themselves, and there will be other ways of more fundamentally bending the cost curve of healthcare costs, not just Medicare costs.

And as has been pointed out many, many times, most recently I think by both the Institute of Medicine and the Commonwealth Commission for a High Performing Health System, to accomplish that is going to need twin changes in how we deliver care and how we pay for care. I thought it interesting, the *Washington Post* had an editorial that in the print edition was entitled "The Wrong Prescription." And it looked a *The New York Times* report about the recent RAND report in health affairs.

And when you look at that sort of, you know, saying, well, healthcare IT has not delivered on the promise of the cost savings, and I think we have to take a little bit of a longer term and a little bit of a broader view of this, and various responses came to mind as I – as I read that editorial.

[Laughter]

Farzad Mostashari – Office of the National Coordinator
___ ___. No, no. I don't mean the four-letter variety.

[Laughter]

Farzad Mostashari – Office of the National Coordinator
The first was just interesting, as someone who believes in data and science – we've talked before about how various pieces of evidence mutate as they make their way through the scientific peer-reviewed press in through the public media, and just one point to – I saw this actually in *The New York Times* yesterday. They said, the RAND report found that health IT has increased costs.

[Laughter]

Farzad Mostashari – Office of the National Coordinator
Just to set the record straight of what the RAND report actually did look at on the cost side, what they said was if we set day zero as when our report was issued in 2005, and ask the question, have cost increases gone down by 1.2 percent or whatever per year every year since then compared to projections, they have not. They did not attribute that in any way to being able to say was the rate of increase in healthcare costs – what portion of that was due to health IT, plus or minus? It was looking at two graphs.

A reasonable question. Why 2005? The publication of an article is not exactly national health policy. And indeed, if we look at since 2009, say, after the passage of HITECH, the past three years, increase in healthcare costs have been the lowest in 52 years of federal record keeping. Now I'm not saying that was due to health IT. But I also don't think that there is any evidence presented or even any attempt to analyze it to say, as the *Washington Post* editorial claimed, we know what it wasn't. It wasn't health IT. I think it's simply too early to tell.

But my other response was kind of give it time. We're in – we set the trajectory for meaningful use. We talked about stages. Stage one, get the information systems in. Get the data collected. Begin to do some of the process changes. Stage two, share the information we've collected with each other, with patients. Stage three, outcomes. We're in stage one. And part of the problem we have in this country is we want a pill to make us better. I think maybe the – if the title of that editorial had been not, you know, the wrong – not the right medicine or the wrong prescription, if it had been "No Magic Pill," I would have agreed. Health IT is not a magic pill that you take two and you'll be all better.

And part of the problem we have is people start taking a pill, they say, I'm not feeling any better, and they stop. So we've got to be better than that. We've got to monitor what's going on. We've got to improve. We've got to learn. But we can't expect policy on attention deficit to work. We need to make a plan and work towards that longer-term plan.

The RAND report actually, if you actually read the report, identifies some things that have to occur, which I don't disagree with, before the full benefits of health IT can be realized. They say adoption needs to approach the levels that we've seen in countries where they do have a better ratio of life expectancy to healthcare expenditures, and they're right. We've now up to 72 percent adoption. It needs to get higher. But we've made huge progress.

They say systems need to be able to talk to each other better. They're right. And they also say stage two is a really big step in that direction. They say patients need to be able to have access to their own information, not only in PDF form, but in computable form, and they're right. And they also say that, too, is part of stage two of meaningful use. None of that makes it into the editorial pages.

But I think beyond the corrections around the evidence, what the evidence actually says, beyond the pleas for longer-term thinking and perspective, the third issue that comes to mind on thinking about health IT and cost is the issue of the context within which this tool is used. It's a tool. What are we trying to do with it? Are we trying to deliver total quality divided by total cost? Is that the incentive structure within which we're operating? If it is, pretty good bet that it's going to be an amazing tool, an indispensable tool. I don't know of any institution that has achieved higher health, higher quality, higher safety, at lower cost, that has not used information technology to the maximum extent. Maybe there is. I don't know about it.

So if we are to achieve better health and better care while cutting costs, there is no other way than to change both how we deliver care and how we pay for that care. And that is happening. The reimbursement changes that are occurring, whether it's Medicare Advantage, whether it's bundled payments, whether it's patient-centered medical homes, whether it's value-based purchasing, whether it's accountable care organizations, are tilting the reimbursement scales away from volume and towards value, towards quality, towards coordination, towards rewarding health, not just care.

How they end up we don't know. They too are a work in progress. Just as health IT is a work in progress, so too are those new reimbursement models. But what seems inevitable to me is that if we are to achieve not just lower cost, but also better health and better care while we do it, we need to twin those together tightly, how we pay for care and how we deliver care, and health IT is an essential enabler of both, of both having more sane reimbursement, more measures that matter, more outcomes, as well as to improve that care.

So while we do what we do, what we can't do is succumb to the same sort of isolated thinking rather than holistic and comprehensive thinking, short-term thinking versus long-term thinking, that is the hallmark of the very problems of the healthcare system that we're trying to solve, which sees each patient visit in the short-term, not in the long-term, which sees each part of the care delivered in its own fragmented way, and not part of a comprehensive plan.

So to the health IT community, I guess I would say what those other patriots would say. Do your job. And I'm referring, of course, to the New England Patriots. Go Pats.

[Laughter]

Farzad Mostashari – Office of the National Coordinator
And not get distracted by the editorial of the day or the week. Let's do our jobs. Thank you.

Jonathan Perlin – Hospital Corporation of America
Well said. I think that really deserve –

[Applause]

Jonathan Perlin – Hospital Corporation of America
Good morning. Welcome to the 44th meeting of the Health IT Standards Committee. I'm not going to reiterate anything, but I think we should just ride the flow of inspiration, the eloquence that Dr. Mostashari provided, because it really does frame our work.

This is an amazing time. I hope everyone had a terrific holiday season. The New Year is exciting. I think it's a moment to celebrate certain accomplishments. Indeed, as Dr. Mostashari said, the levels of adoption are really quite remarkable. In candor, these are levels of adoption that I did not believe that I would see in my professional career until this program started, and that is extraordinary. Not to steal Jodi's thunder, and of course, I've used the number 72 percent adoption, but in the materials that people have pre-read in preparation for the meeting, as of 11/30, 84 percent of hospitals registered, 68 percent paid eligible providers, 63 and 33 percent respectively as of November 30th. Those numbers are higher now, but that is quite remarkable. And before meaningful use was a concept, I don't think these levels would have been seen in our lifetime.

So it's extraordinarily exciting to contemplate the progress of information technology as an enabler for the vision that Farzad so eloquently discussed, better health, better care, better value, and that's extraordinary.

As we celebrate those achievements, there is also the remainder that there's a huge amount of work to do. What a confluence of activities. As a practitioner in the field, we're in the third year of stage one. Others may be in other aspects of stage one. But that is the operating reality of the moment. Stage two is no longer a concept, but fully fleshed, and that's something that across all of the ecosystem of healthcare, vendors, providers, consumers, every aspect of engagement with the information ecosystem has some – has a working plan.

And today, we're talking – we're focusing our efforts and conversation about the comments and request – receiving comments on stage three of meaningful use. In that regard, I think the wisdom that was just provided is also on target, is that we have to take the long view. We have to envision the system of higher quality, of greater safety, of greater compassion, of greater value, higher performance. We need to take the near term view as well, because there are certain mileposts that we need to be able to support in the mid-view. And Dr. Fridsma has really given us the metaphor of threading a needle over time, a logical progression, durable, because the standards that are used really build upon themselves to create increasing capacity for the sorts of performance that we've discussed.

So our task – our efforts today really are to provide standards to support the continuous progress. It's not our charge to re-litigate the recommendations of the Policy Committee. It is our charge to identify standards that really enhance and allow us to achieve the policy goals, but in the context of providing a logical progression, one that is built on standards that are in fact durable over time, and that allow building a more capable data and fact – data model architect and ecosystem of information for a better, improved ecosystem of healthcare.

Make no mistake, I think all of us share the belief that stage three is extraordinarily ambitious in many regards, lots of work for all of us. I want to thank all of you for your efforts, ongoing, not only in providing comments, but in organizing those comments. Indeed, my colleague John Halamka has been systematically querying Policy Committee workgroup chairs and others at the Office of the National Coordinator to create a logical framework, at least one that we asked for your reaction to, to help us parse this vast amount of work, parse our efforts logically, in support of these goals.

And Dixie and colleagues, the great work that you've provided in help us – in helping us contemplate the readiness for adoption of standards provides a logical approach to identifying – and for us to contemplate what's available now? What's available shortly? What's really going to require a heavy lift, and look at another dimension of readiness for adoption as we approach the stage three? And that's tremendously helpful.

So we have two parameters, one conceptual, around the bodies of work, the sorts of activity, quality as an example, interoperability as another, and another dimension, another filter in which to look at standards and offer standards, which is the readiness for adoption, and look forward to discussing with you that approach, as we parse our work for the contemplation of standards for stage three.

I think it's a very important agenda today. Appreciate Jodi Daniels being here. I appreciate not only Jodi Daniels and John Halamka, but all of you being here. I know that there was difficulty in transit from points around the country, but the trip from Boston, I understand, John, was equaled only by the red line on Metro, so –

[Laughter]

Jonathan Perlin – Hospital Corporation of America
So thank you for being here. But Jodi will bring us up to date on the work plan, and look forward to commentary from others as well.

I want to take a moment and note and thank Lauren Thompson for being here. Lauren's worked side by side with Doug Fridsma. And maybe just a second, if you'd introduce yourself briefly, and attach a face to a voice that's been heard on many phone calls.

Lauren Thompson – ONC Office of Science and Technology
Certainly. Thank you. Lauren Thompson. I'm the director of the Federal Health Architecture Program within Doug Fridsma's organization, the Office of Science and Technology in ONC. I've had a long career in the health field, mostly within the government health arena, both within the government as well as with information technology firms and consulting firms in the private sector, working with government agencies. So I'm thrilled to be a part of the ONC organization, and happy to be here today. Thank you.

Jonathan Perlin – Hospital Corporation of America
And we're glad you're here, and we're glad that Doug will also be online. So we'll have the full team. But thank you for all of your hard work.

Then as we move from work plan, health IT Policy Committee work plan, preliminary work plan, that Jody will review, obviously, we'll look through our own work plan, and appreciate John leading us in that discussion, and bringing together some of the conversations that I know he's had with many of you in that regard.

We then have to move spec – well, actually, before that, I want to thank Becky Kush. Becky has been reminding us about the importance of making sure that we contemplate all means to make our system a learning health system. She – her leadership of CDISC is obviously well-known, but we appreciate the insights that she'll provide. And it was interesting. I was mentioning to her before the meeting that – when I was reviewing her information, I had originally come to it thinking about the importance of all the secondary uses of data, and then I realized, stopping myself, that that's really an inappropriate characterization.

The idea is how do we build a robust information ecosystem that allows a learning health system, and that the intent is robust – a robust data that can inform policy, improve care, and guide discovery, and that's really extraordinary. And this is not just a theoretical construct. It's obviously important to all the things Dr. Mostashari said, but perhaps later in the day, if schedule permits, Chris Ross might describe some of the discovery activities that his organization is embarking upon. Mayo and Optum announced really a big discovery. And maybe three or four sentences, Chris, on just the aspirations there.

Christopher Ross – Mayo Clinic
Sure, and I'll ask Dr. Chute also from Mayo to add in as appropriate. But, you know, what we've entered into is an arrangement to combine in a de-identified laboratory environment sponsored by Optum in their Optum Lab Initiative claims and clinical data to try to mine for insights about pre and post-patterns, for example, that might lead to some clinical insights, and to look for not just, you know, episode of treatment cost, but lifetime care and encounter kind of data around, you know, can we see some things that would help us understand how to better treat a patient when they enter a particular episode of care?

We're just getting started. We're very excited about our collaboration with them. Do you want to add anything?

Christopher Chute – Mayo Clinic College of Medicine
I'd just add that it's the next logical step in what has been a century-long tradition of valuing patient information to improve care.

Jonathan Perlin – Hospital Corporation of America
And the part that excites me is not only the scale of discovery possible, but with the discussions, and I'm taking it back to ___ ____ even more broadly to the standards that this group, the Office of the National Coordinator, helped to promulgate, allows a depth of insight directly to the clinical information. One can envision the system or an environment in the future that really allows the scale of progress in improving care delivery and improving really insight into the science of healthcare in ways that we just can't even contemplate today. Just so exciting.

As we move then to the afternoon, we have another defined body of work, and that's the response to the Health IT Policy Committee's request for comments through the lens, of course, of our work as parsed among the activities that would logically associate with each of the workgroups, and appreciate each of the workgroup chairs in taking on that activity and helping to guide our subsequent effort.

We have a very full agenda, not only literally for the day, but in terms of the weeks and months ahead of us, and with that, let me turn to the first order of required business, and that is the approval of the minutes, the proceedings of our last meeting. Let me ask if there are any amendments, corrections, amplifications. As you're contemplating that, I'd just note that I thought the format of these most recent minutes was particularly useful. The bolding and highlighting of specific concepts and action items was – made it even easier to follow. Hearing no offers of – for corrections, I would consider those approved, and let me turn to John Halamka for comments, and we'll lead directly then into the work plan, both for the Policy Committee and ultimately our work plan activities.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Well, thanks very much, and good morning, everybody. And as you said, neither snow nor sleet nor metro derailment could prevent me from attending the Standards Committee.

[Laughter]

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Hey, I was only ten minutes late. So not so bad. So as you said, today's meeting is a lot about confluence, and the challenge that we have, as we're going to hear the Policy Committee's work plan for the year, we all have had the chance to go through a lot of the request for comment. We also have had the chance to give MacKenzie our own inputs as to what we think is important and are gaps.

And so the challenge is going through every one of these documents in detail and teasing out what actually the standards committee over the next year should be working on. So as Jon said, I didn't actually create any novel content. All I did was try to assemble the content you all provided, Policy Committee, your comments directly to MacKenzie, the comments and feedback on the RFC, into a reasonable set of categories and themes, and it is purely meant as a straw man for your feedback.

And then we'll hear from Doug, who has tried to align those – the categories and themes with the activities that ONC already has in process, to really understand what S&I has done or is doing and where there are new projects being launched, so we can really look at the gaps, some areas that we should work on.

And so again, as John said, the nature of the meeting today is quite rich, and what I hope comes out of it is a set of next few months marching orders so that when we're interviewed by *The New York Times,* the *Washington Post*, and these other folks, we can say, I mean, come on, look at the work that we've done, and of course it's not completed, but my God, have we made incredible progress. So look forward to the meeting.

Jonathan Perlin – Hospital Corporation of America
Well, with that, thank you very much, John, let us turn to Jodi Daniel, and appreciate your bringing us up to date on the preliminary work plan for the Policy Committee.

Jodi Daniel – ONC Office of Policy and Planning

I feel like I should have some work plans here with me. This is such a long table. But, well, I finally did make it, even though I only had about eight miles to travel instead of, you know, a few hundred. But I wanted to talk to you today just about what the Policy Committee is thinking about for their 2013 plan. What I'm going to present today was basically the same thing that was presented by Paul Tang at the Policy Committee last week. There was also rich discussion after that, so we are in the process of going back and making some revisions based on the comment we've gotten.

So this is in fact a draft work plan. We'll have a final work plan at the February meeting, so, you know, this is still a little bit of a work in progress. But I wanted you to all have the benefit of the discussion and thinking that has been going on in the Policy Committee, as you're thinking about your work plan for 2013. I'll also give one other caveat, that I don't have expertise on every single detail of every single issue that the Policy Committee is going to be taking on, so I will do my best if folks have specific detailed questions, to answer them, or else get back to you if I don't have the answer.

We also anticipate looking at the work plan every quarter and updating it, so we expect that new things will come down the pike that we will – that the Policy Committee will want to take up or that ONC will be interested in the Policy Committee taking up, that we haven't thought about, or things that make take longer or shorter than anticipated. So we will over the course of the year plan to continually update our work plan. I expect that we'll have the same process with the Standards Committee as well. We'll try to keep coming back to this periodically and making sure that we are sticking with the work plan, or if there are changes that need to be made, that we are bringing those to the committee for discussion.

So it is a pretty aggressive plan, and we have for 2013 the three overall themes that you'll hear – that you've heard Farzad talking about, and that you'll see these topics focusing on. You know, meaning – making meaningful use meaningful, how do we optimize implementation, design and implementation of meaningful use to lead to improved outcomes, focus on interoperability and exchange, and doing that more effectively, and encouraging more exchange of information, and third, focusing on consumer empowerment and consumerism and healthcare, and health IT can support consumers in being more actively involved in their own health and care.

So I will get started. So of course, you know, topic number one, meaningful use, this is – we are currently in the process of processing the RFP comments that we have gotten back from the meaningful use – I'm sorry, from the Health IT Policy Committee's request for comments. The period just closed on the 14th. And so we are in the process of just kind of pulling those all together. I don't have any details for you about the comments or numbers who commented and the like. We are still kind of processing all of that. But the expectation is that the meaningful use workgroup will be taking those comments, as well as some of the other workgroups in the Policy Committee, looking at those comments, and making recommendations for ONC and for CMS as we look at meaningful use stage three objectives, criteria, and measures.

Actually, on this, just as far as the timing, the meaning – the Health IT Policy Committee will have draft recommendations in April on meaningful use stage three, and final recommendations in May. We will keep this group informed about the discussions there, so as you're thinking about your process with respect to the standards and certification criteria, we will have final recommendations from the Policy Committee on this in May, and so we expect that the Standards Committee will have a fun summer again this year.

So as we're preparing for the – the Committee will also be starting to prepare for meaningful use stage four, and thinking about how we go from stage three of improving – measuring improving outcomes, to really supporting, you know, a learning health system. So they will be kind of starting the beginning of the year on MU3, but then starting to merge into thinking on where we go from there.

The Policy Committee will also be thinking about shared healthcare records, how patients need to be part of the team, and how to incorporate data coming out of people's homes, observations of daily living, remote devices, perhaps patient preferences and the like, and how we can start moving towards this bidirectional sharing of information between patients and providers as we look forward beyond stage three.

We will be holding a clinical documentation hearing on February 13th. The focus here is about how clinicians use electronic health records to document the clinical encounter. We know that there are a lot of shortcuts people take, like cut and paste and copy, forward, to help improve the efficiency of inputting the information into the EHR, and that this is done for – by a lot of providers, and we're looking at some best practices, and how we can make sure that as folks are using the technology, that there is proper clinical documentation to support the clinical encounter, understanding that there are these efficiencies that clinicians are using, these tools and – to create efficiencies for documentation, and that there are implications for billing as well. So we're looking for some best practices, innovation solutions, and the like, and there will be a hearing in February.

And then finally, safety enhanced design of EHRs, and I'll come back to safety in a little bit. But we're looking at ways to continue on the initial steps that were taken in the – in the 2014 edition of standards and certification criteria, focusing on user-centered design and quality manufacturing practices for EHRs in order to promote safety in the technology.

So moving on to quality measures, so we know that just measuring – just making e-measures out of the current measures doesn't answer the right questions, and we're looking for – the committee is looking at some fresh approaches to measures, including information from patients. ONC as well as the Policy Committee is thinking of some de novo ways about thinking about quality measures and leveraging data from EHRs and PHRs in doing that. The committee will be talking about flexible platforms for measuring and recording quality measures in health IT systems, so moving away from hardwiring in the quality reporting. The – our quality workgroup will also be looking at the role of inter – of data intermediaries, particularly in supporting smaller practices and hospitals, and getting useful information out of EHRs and PHRs.

And finally, we expect that the committee will be looking at connections to clinical decision support, and connecting clinical decision support with the outcomes that we're measuring, so that we have the quality improvement and the feedback loop that we can get from the technology.

On health information exchange, we will be holding a hearing on January 29th. We will be looking at where we are, best practices, what's the role of health information exchange in new payment systems. We know that with new payment models where providers are responsible for a population, there is a greater need to coordinate care and share information by the provider, so how health information exchange – how we support that through our health information exchange efforts.

And finally, looking at the role of governments and principles and models that can be suggested or that – from a variety of stakeholders, including from the federal government, or that could be developed to help everybody get a head start and to support the governance activities that are currently taking place.

So I said I'd come back to safety plan, to health IT safety. So as I'm sure most folks know at this point, ONC released our Health IT Safety Action and Surveillance Plan on December 21st. It is a draft. We have asked for public comments, which are due February 4th to us. This was a follow-on to the reports that we received from the Institute of Medicine on health IT safety, where they called for ONC to put forward a Safety Action and Surveillance Plan. So this was in direct response to the Institute of Medicine report that ONC sponsored.

And the way we're looking at this is both how we use health IT to support patient safety more broadly, as well as how we can make sure that the technology itself is safe, and that we're aware of any risks that the technology may pose so that we can appropriately mitigate those risks as well. So we look at those as our two objectives with respect to safety, using the technology to support patient safety as well as making sure the technology itself it safe.

We have asked the Health IT Policy Committee to give feedback on the plan, as well as they will be looking at – there are some safety-related questions in the request for comments, so we expect to be getting some feedback through that mechanism as well, and whether or not there's something more we can be doing in stage three meaningful use, or in our next round of the standards and certification criteria to support safety.

Excuse me. I'm still coming off of a pretty nasty virus that's been going around.

Okay. With respect to privacy and security, we are just finishing up on recommendations with respect to patient identities in cyberspace. Our Privacy and Security Tiger Team just presented some recommendations at our last Policy Committee meeting. The Tiger Team will be looking at querying response exchanges. When we move from having providers serving as the trusted entity in the middle of exchange as the surrogate for the patient, how do we transition to query and response and to other models where the provider may not be in the middle, and being that trusted broker of information?

The Tiger Team also will take on looking at challenges of implementing minors' rights in health IT and health information exchange. So there's specific and sometimes complicated rules about minors' rights to information, and parents' rights to information with respect to minors. They will not be looking at changing the policies, but rather how to – how to address the challenges of implementation that those policies raise.

So we know now that in practice, a lot of times folks who are providing patient portals or exchange of information are carving out certain categories of minors because of the challenges of implementing the policies, and so the Tiger Team will be looking at any best practices or guidance or approaches that can help to support implementing those policies without – and including the minors' information, so that they have the same benefits of access and exchange as others.

With respect to personal representatives, this is a related issue, but talking about authentication and identity proofing of personal representatives. We've talked about this with respect to patience, but wanting to also support caregivers and personal representatives in acting for patients when appropriate.

The committee is also interested in looking at how we deal with privacy and security protections with respect to cloud computing, as folks are moving more toward that. Looking at the right of access in electronic world, so we – revisiting some of the existing requirements of patient access, perhaps reducing timeframes to get patients' copies of their records and things like that, with the ease of electronic exchange of information.

And then finally, looking, as we start talking more about patient-generated data, also considering the privacy issues with respect to patient-generated data.

On consumer empowerment, so we just asked for nominations for a consumer empowerment workgroup of the Policy Committee and the consumer empowerment workgroup of the Standards Committee, and we will be sending those up shortly. Our nominations period just closed this week as well, and we're in the process of gathering together the nominations. We did receive quite a lot. So hopefully we'll have a great pool to choose from, and we'll be working with the heads of the Standards Committee and the Policy Committee as well as with Leslie and with Christine Bechtel on the Policy Committee side to try to get a good workgroup participation and good expertise on both of those committees, and then trying to make sure that we have good coordination among them.

From the Policy Committee standpoint, there are some of the areas we expect that they will start with. We at ONC have been focusing a lot on Blue Button, making sure patients have easy access to their information and can download copies of their – of their information from their clinicians and plans. And we have efforts to look at ongoing access, and – with our Automated Blue Button Initiative. There are some policy issues that have been coming up there, and we expect that our consumer empowerment workgroup on the policy side will be taking a look at those.

There are also issues about combining and sharing data from multiple sources. So we know people can Blue Button their data, but if they have multiple providers, they're going to have – they might have five different sets of information from their five different providers, even if they all do offer Blue Button option to get their data, and how do we help to make that easier for patients to manage? Issues of helping the patients and the providers managing the data and preventing data overload, how do we present the right data to the right folks to be useful? And then, of course, reconciliation of data once we are getting data from various sources. How can we make it all – how do you deal with reconciling data when there are inconsistencies?

There are also some privacy issues, protecting downloaded patient data, and the committee will also likely start talking about shared decision making. And once we talk about patient-generated data and patient access to data, how do we start thinking about shared decision making between patients and providers and the technology to support that?

And some of these, just the way we have – we will be working our consumer empowerment workgroup on the policy side. We do have a consumer engagement subgroup of meaningful use. So as there are policy recommendations regarding meaningful use, that will still be through our meaningful use workgroup, and we're hoping that the consumer empowerment workgroup will be kind of one step ahead on some of the things that may not be right for meaningful use right away, but to try to pave the path so that when we move to future stages of meaningful use, that there will be things that are right, as well as to sort of support other activities that may not have to go through our meaningful use program, but that will support consumer engagement.

The Policy Committee plans to set up another workgroup on accountable care and new models of care to look at what are some of the new opportunities and challenges that these new models of care may present for technology. We want to make sure that the technology can – that we understand what the needs are for these new – these new approaches, these new models of care, so that we can make sure that the technology can support those models of care. So we know that folks will need longitudinal data, shared care plans, and among care team as well as patients and caregivers across the continuum. And this group will be really looking at how to – how – what kind of recommendations we should be considering at HHS to make sure the technology supports those new models of care. As Farzad had said, they will be absolutely critical in the – these new models of care being successful.

And then finally, I want to talk about some of the emerging areas that we are thinking the Policy Committee will take on. The API for innovation, as additional program demands are added to EHRs, we want to think about how we could foster information – I'm sorry, foster innovation to share information and receive intelligence from other EHR applications, or non-EHR applications, and how we can have applications and services that can be built on top of the data architecture that already exists.

We currently, with the Policy and Standards Committee, we have typically two approaches for getting input. We've been either – you know, we form a workgroup or we hold – and have workgroup deliberations, or we hold hearings. And for some of these emerging areas, what we may want to do, and we're thinking about how we can – how we can make this work, is to try to find some external expert who can come – you know, can pull together some information and present to the full committees in order to start the thinking about a particular emerging topic, and then figure out where the committee might want to kind of take on some piece of that. So for a lot of these emerging areas, we're going to be looking outside for some experts who may be able to come in and present to the full committees on the topics, and then think about what our next steps might be. So not necessarily punting these to a committee or to hold hearings on these, but we'll – ____ sort of beginning to take these on.

As I mentioned before, quality improvement, looking at how we can better connect clinical decision support and quality measures with a focus on quality improvement. Somebody just said this yesterday, I love this metaphor, that you can't – you can't fatten up a calf by weighing it. So we have to come up with techniques of taking the data that we learned from the measurement in order to actually get to the outcomes that we are seeking.

This is another one that we have actually – that ONC has suggested we have better connection between our advisory committees and some external work. There is a lot of effort going on now with patient-centered outcomes research and the Patient-Centered Outcomes Research Institute. And we'd like to make sure that the Policy Committee and the Standards Committee are aware of the activities that are going on with PCOR, and particularly with PCORI. They are putting out lots of grants, and they will be doing some RFPs in the near future on infrastructure to support patient-centered outcomes research.

And we will have PCORI come and present to the committee so that all of you have a better sense, and the Policy Committee has a better sense, of what they're doing and what they're thinking, as well as to help make sure that the folks who are at PCORI understand some of the work we're doing, so that we are building on what we've already – you know, the successes we've already had, rather than having folks going off in different directions and duplicating efforts. So we're going to try to bring this issue to the committees and make sure that we have both a dialogue with the PCORI folks, as well as think about where ONC – and get recommendations from folks on how we can help support the infrastructure for patient-centered outcomes research.

Another topic in this emerging area is looking at continuous learning of health professionals, how we can use maintenance of certification or other efforts with respect to professionalism of clinicians in order to support meaningful use and health IT adoption among clinicians.

And then finally, leveraging big data. You know, this is a concept that we keep coming back to. It's something we haven't spent a huge amount of time on, but particularly as we are moving toward talking about a learning health system and using data to support some of the new care models, getting a better handle on how health IT can be used to support big data and analysis of multiple data sets, etcetera. So again, this is an emerging issue. This is something that we'll just be starting to think about as we're looking forward toward future stages in a learning healthcare system.

So finally, and I hope everybody has a copy of this. I made sure I brought a bigger version of this, because last time I couldn't read it. So this is just sort of a quarter by quarter breakdown of the – of the work plan. I'm not going to go through this in detail. But it goes through quarter by quarter, by topic area, by workgroup, basically, what we expect to be covering when – just – I'll give a couple of highlights. As I mentioned, the final meaningful use recommendations will be in the second quarter, so April, May timeframe. We will be having – I mentioned the couple of hearings that we're going to be having early on. We'll be having a safety plan review now, because the comment period is open, but there may be some future work in that space as well.

Privacy and security, they're finishing up, like I said, some of the issues with patient ident – trusted identities in cyberspace, and talking about query and response authorization. And then starting to move more into the personal reps and minors issues, and then kind of later on, cloud computing and the like. We expect the consumer empowerment workgroup will probably kick off before the end of the first quarter, so getting them started on – early on, we'll be having them talking about Blue Button.

One thing I didn't mention, we will be having – one thing they also will be looking at is disparities. Our consumer – our consumer eHealth program is holding a roundtable, it's called the eHealth Equity Roundtable, that will be looking at disparities in health IT, and so we will expect our consumer empowerment workgroup to be looking at some of the discussions and findings that come out of that roundtable and following through on that.

The accountable care workgroup we expect will probably start off in Q2. We're going to kind of stage them, so consumer empowerment first, then accountable care. So that will be not necessarily a long term committee. I think that that might be a time limited committee, but they will be kicking off their work in Q2 and going through the year. And then kind of once we get through the meaningful use crunch, we'll start dealing with some of these emerging issues that we talked about, some on the earlier side, PCORI, because they will be coming out with an RFP sometime I think in Q2, and the APIs for innovation, to understand if there's anything we should be thinking about for our next stage of standards and certification rulemaking. And then kind of moving down into – down later in the year into things like clinical decision support, the professionalism, and big data.

So that is a quick nutshell of what the Policy Committee is thinking. It's quite an ambitious agenda. If we get through three-quarters of all of this, I'll be thrilled. But knowing the way they work, they'll probably pull it all off. So – and we look forward to working collaboratively, Doug and I, in trying to combine the work plans between the Standards Committee and the Policy Committee, and making sure that we have good handoff and good communication as dialogues are going forward, so that where it's necessary for the Standards Committee to weigh in, or where you all think it would be helpful to weigh in, we will do that, like we'll be doing later this afternoon with the RFC comments. So with that, any comments, questions?

Jonathan Perlin – Hospital Corporation of America
Well, thank you for an encapsulation of a year in 20 minutes. That was an incredible tour de force. The fact that this is available, and in fact, the next discussion really did prove that ONC does stand for the Office of No Christmas, it's obviously been a very busy time. I'd like to suggest that we take this moment for questions of clarification and use it to set the stage and really have a discussion about these activities through the lens of our Standards Committee work plan as they relate to these activities in the next block of time, which will be substantial and substantially interactive.

So in the spirit of clarifying questions and comments, let's have a moment here, but really reserve the breadth of discussion for the next session. So Dave McCallie, your card was up first, and then John Derr next.

David McCallie, Jr. – Cerner Corporation
Yes. This is David McCallie. Jodi, a lot of the activity that you described would happen after meaningful use stage three requirements have been set. What's the target thought for activity and capabilities that are discussed that would be after meaningful use stage three?

Jodi Daniel – ONC Office of Policy and Planning
I'm sorry. Say that again. What are the –

David McCallie, Jr. – Cerner Corporation
So there's activity that goes all the way through the year, but the meaningful use stage three criteria will have been set before much of this activity happens.

Jodi Daniel – ONC Office of Policy and Planning
Correct.

David McCallie, Jr. – Cerner Corporation
So where does the – where do the ideas that come out of post-meaningful use stage three land in terms of policy levers and so forth? Is there a stage four –

Jodi Daniel – ONC Office of Policy and Planning
Well, yeah. I mean, right, so there's stage four –

David McCallie, Jr. – Cerner Corporation
– at some point –

Jodi Daniel – ONC Office of Policy and Planning
You know, the meaningful use program doesn't go away. So we always talked since we started about one, two, and three, but there – the program continues, and we will continue to iterate the requirements. There – I think on some of these, we were finding in the Policy Committee that there were some things that folks wanted to push the envelope on, and we were – the push back that they got was that some of these things weren't ready. They were too new, they were too emerging, they weren't – there wasn't enough experience, standards capabilities, etcetera.

And so some of talking about these, you know, things down the pike beyond stage three is to start putting them on the plate so that people can start looking ahead and, you know, working on – doing the standards work, or, you know, having folks start to develop those capabilities so that we can move toward it in another stage. So we are still looking at this as, you know, we will continue to iterate on capabilities, on standards, on policies that support those capabilities, and we will have, you know, future – you know, future stages to incorporate those into, as well as using whatever other levers we can to support – to support that progress.

So for instance, you know, like we have the Blue Button work. It's not – I mean, we have view/download/transmit, but, you know, somebody doesn't have to do Blue Button if they don't want to. They have to make it available. They have a different capability, you know, there's – there are people who are – we have our pledge program to get folks to promote Blue Button. You know, there are lots of different ways that we can promote certain activities or certain objectives. We have our challenge program. So for instance, if there's an area that's emerging that – where we haven't seen a lot of development in a particular area, but the Policy Committee, for instance, thinks it's incredibly important, we could conceivably do an innovation challenge to start getting progress in a particular area.

So we can use lots of different levers to start moving the ball forward on some things, and then when they're ripe, we would consider them for meaningful use and for standards and certification.

Jonathan Perlin – Hospital Corporation of America
John Derr?

John Derr – Golden Living, LLC
Jodi, just a – this is John Derr – a clarification. Where do the providers who are not included in the HITECH Act and for vulnerable – broken record, I know, but where do they fit into this? I don't see that. And you headed up a roundtable that we had last May, and a report was put out in July. Where does that fit in so we can start incorporating the skilled nursing and home care and hospice and all that?

Jodi Daniel – ONC Office of Policy and Planning
Yeah. You know, I think – the way I think about it is that I think that's – we're going to try to address that through the accountable care activities, because that's where there will be a need for connecting various providers that may not all be covered by the meaningful use program, particularly long term post-acute care. And so I think that that would be a perfect place to have those conversations, because there will be a need for those activities to – those connections to take place, and that might be a great opportunity to have that dialogue and to figure out how to make that work.

So that would be where I would focus the efforts, and to – I will take a recommendation that I think you might make, that it may be – it would be great to have somebody representing those communities that serves on that workgroup, so that – so we can make sure that perspective is addressed.

John Derr – Golden Living, LLC
Could you maybe add it to your matrix here sometime to put LTPAC and behavioral health there, so people don't forget it? Thanks.

[Laughter]

Jonathan Perlin – Hospital Corporation of America
Thanks, John. The –

Jodi Daniel – ONC Office of Policy and Planning
Thanks, John.

Jonathan Perlin – Hospital Corporation of America
Just to make –

Jodi Daniel – ONC Office of Policy and Planning
You always keep us honest.

[Crosstalk]

Jonathan Perlin – Hospital Corporation of America
Dixie Baker, and then we'll go to Jim Walker, and then –

Dixie Baker – Martin, Blanck, and Associates
I noticed that on the work plan, patient-generated data is under both privacy and security and consumer empowerment.

Jodi Daniel – ONC Office of Policy and Planning
Yes.

Dixie Baker – Martin, Blanck, and Associates
And first of all, I'm really pleased that you've called out the genomic data, because that is an issue with patients going to get genetic testing on their own –

Jodi Daniel – ONC Office of Policy and Planning
Right.

Dixie Baker – Martin, Blanck, and Associates
– etcetera. So I think that – that's good. My only question is will the two workgroups be working together on that topic, or independently?

Jodi Daniel – ONC Office of Policy and Planning
So it's a good question. We're not quite sure yet. What we – right now, we just kicked off an effort with NEHCs. They will be pulling together – they have an expert panel to talk about patient-generated health data from a policy perspective, and what are some of the – because we heard in the patient-generated data hearing that there were a lot of concerns about patient-generated health data with work flow, with liability concerns, privacy concerns, all of these things, these policy issues. And, you know, it kind of – it was kind of the wall that was holding back the ability to move forward on patient-generated data.

So we just asked NEHC to convene a group of experts to talk about patient-generated data and identify where there are some best practices out there, and where some guidelines might be helpful, and help us basically think about a policy framework. Whatever they present, we would be bringing to the Policy Committee. They will initially focus on meaningful use, whatever – the provisions in the RFC that talked about patient-generated data, in order to kind of narrow their focus and to help support the meaningful use workgroup in thinking about patient-generated data and meaningful use stage three.

And then beyond that, you'll notice that it's listed twice in two different quarters. So that was because they'll start with meaningful use, and then they will be looking kind of broader at some things that may not be ripe for meaningful use stage three. But same concepts. What are some best practices? What are some areas for guidelines? Where are some of the roadblocks? You know, are there some things that would help make, you know, workflow issues, etcetera, to help support the – you know, more widespread use of patient-generated data beyond meaningful use stage three.

Dixie Baker – Martin, Blanck, and Associates
Yeah. I didn't even notice it was – yeah, it's under – yeah, meaningful use –

Jodi Daniel – ONC Office of Policy and Planning
So, now that said, as NEHC is talking, we expect that there will be privacy issues that come up as well as other policy issues, and since we have the privacy and security workgroup, we wanted to – we kind of put it as a placeholder in there for whatever issues come up from the NEHC discussion, and we would bring that to the privacy and security workgroup. So I expect that the work will be – we'll have separate issues on patient-generated data that go to the different workgroups, but it'll all funnel up through the Policy Committee, and we'll just have to kind of curate that behind the scenes and make sure that there's good coordination.

Dixie Baker – Martin, Blanck, and Associates
Great. Thanks.

Jonathan Perlin – Hospital Corporation of America
And last comment from Jim Walker.

James Walker – Geisinger Health System
This is – so there are good reasons that in phase one of all of this we focused on physicians and hospitals, and now in the last year or so we've been sort of going back and saying, okay, but for the patient to get really high quality care, high – and cost effective care, and convenient care, we need to include the entire care team of the patient, obviously always centering on the patient and the patient's lay caregivers. And John keeps reminding us appropriately of LTPAC. I propose that Policy Committee needs to take this opportunity and say, okay, MU3 is sort of the end of phase one, and now we're going to really define the patient's care team, and, you know, maybe we say in phase two of all this we focus particularly on patients and their lay caregivers and on LTPAC, but we know what the whole care – we've agreed what the whole care team is, and we have a plan for how the whole care team will be brought into this game in some kind of systematic, orderly, accountable, transparent way, so that instead of sort of piecemeal, saying, oh, God, we forgot first responders, or whoever it is we forgot, we have a plan that everybody can look at and say, okay, I'm not in this year, but I'm on the plan.

Jonathan Perlin – Hospital Corporation of America
Thanks, John. And that's actually an ideal segue to really the standards discussion, because we're not – we're not leaving the Policy Committee work plan, we're just rechanneling activities in terms of – or our discussion in terms of our own activities and their relationship then. I think the points that both you and John have made is that these conventions that we adopt to create communication across an ecosystem need to include all members of the ecosystem, and we need to work with our colleagues on the Policy Committee to make sure that we are broad and inclusive in that process. So terrific sort of segue into the next – Jodi, again, brilliant encapsulation of a huge amount of work.

Speaking of brilliant work, I am – I never cease to be amazed by the bandwidth of my colleagues to assimilate information from multiple channels simultaneously, and that really – it's such a privilege to work with all of you. And John has just been, you know, really reaching out to each of the groups and bringing – together with ONC – the structure or hopefully the platform for structured discussion about our next set of work. And I hope – we all hope that it's helpful to really facilitate that discussion and to parse our activities both by concept – Dixie and other workgroup chairs who've provided insight into the adoptability and the ____ plan for gaining adoptability of standards provides another dimension for those discussions.

So let me now turn to John, and appreciate all of your efforts.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Great. Thanks. So if you look at our last year's work plan, we actually achieved just about everything that we had suggested, except working on image standards. That was one thing we just didn't get to. But hey, there were many other things that came across during the year that we got to sufficiently.

So here's our challenge, is that we've just heard from Jodi the Policy Committee work plan, and we need to be reactive to that, deciding what elements of it can be done with existing standards or standards over the next 18 months, but at the same time, Jon, you used the term threading the needle, and we have to be proactive, if you look at some of the things that we want to do in stage three, stage four, unless we start working on them now, there's just not going to be the foundation that's necessary to make them happen.

So as I said in my introductory remarks, what I tried to do was take every detail that Jodi just presented, plus every comment in the RFC, plus every one of your comments, plus commentary from all the emails, and thanks, Wes, you always give me those very thoughtful emails, and put them into a list of categories and themes, some of which may take multiple years. But unless we categorize where it is we're going, we're never going to get there. So let me just start off with the broad categories: quality and safety, health information exchange, consumer empowerment, ACO population healthcare management as a body of work, and privacy and security.

So you'll see that many of these themes underneath the categories match some of the gaps that have been identified by ONC in stage three standards, and many of the comments that Jodi just made. So we hear, you know, Jim, over and over, that on the quality and safety side we need a platform. You know, we don't want to have numerators and denominators that are hardcoded and baked into EHRs. And we know we heard from our friends at CMS that they aren't going to just retool existent quality measures. They're going to come up with completely new measures from scratch. We just heard from Jodi. EHR and PHR data elements are going to be used in novel ways.

So the broad statement on the Standards Committee is we need standards that support flexible platforms for measuring and reporting quality. There have been notions like the query response aspect, the query help, the QRDA, HQMF approaches. So whatever it is, it's clear that it isn't just going to be what we've done in the past. It's got to be a novel approach, and it's a platform, this threading the needle idea.

We've heard a lot, especially in the press, about EHR usability or lack thereof, and there's a lot that has been published by ONC, like in your safety plan, about the notion that NIST is working on some objective measure of usability. And everyone I talk to says, oh, you can't measure usability. You know, that's too hard. Well, if NIST is working on it, and ONC has put it in their safety plan, it's probably something that we should ask ourselves. Can you objectively measure usability?

Standards which address content gaps. So Dixie already mentioned representing genomic data in the EHR. That's a content gap. I mean, there's work in HL7 on this stuff, but let's take a peek at that.

We know there are such things as polishing that's been done by Clem McDonald and others on making sure version two lab orders and compendia are standardized. Formulary downloads. You know, this is certainly a debate that we've had, as exactly – do we do the NCPDP 3.0, the 4.0? Is that something that all EHRs will now receive formulary data in a standardized format, as opposed to today, it's spreadsheets, quote/comma delimited, and God only knows what?

We talked in this forum, I think, Jim, you brought it up, about the problem with e-prescribing from hospitals at discharge, because the cancel transaction isn't widely adopted. So we'd better think about that. I mean, it's NCPDP 10.6, but the ecosystem out there with Surescripts and pharmacies doesn't seem to use it, so how is this all going to work?

Defect reporting. Well, again, reflecting back on the safety report that ONC issued, I mean, it's a question we should ask. Are EHRs the right vehicle by which to report EHR-related defects to PSOs? Maybe yes, maybe no. What are the standards that should be used to report those defects? Just something we should answer. I'm not suggesting that the EHR somehow can automatically say, an error has occurred. Would you like to report to the PSO? Click here. But maybe in fact there is some sort of function by which if we discover doctors are writing for medications inappropriately because of a misdesigned screen that puts Atenolol and Ativan, you know, on a pull-down, and a slip of your finger on the mouse, and suddenly instead of treating somebody's high blood pressure, you're giving them an anti-anxiety medication.

And then I think – gee, I think it was Jim also that – you suggested this, that as we start doing more health information exchange, we're going to run into this interesting problem of copy/paste, forward, redundant data, I'm going to send a copy of the patient's data to the patient, the patient's going to send that data back to me, and before you know it, the same information is replicated 400 times in the record. How do we start dealing with redundant data identification and reduction? That may be a multi-year consideration. It's just I worry that we'll all have 100 percent adoption of EHRs, 100 percent adoption of HIEs, and then every storage device in the entire planet will fill up in 7 minutes because everybody is copying everything to everybody else. What do you do?

On health information exchange, we know that – we've tried to tackle this, Dixie. How do we do provider directories in a query format that HIEs can simply use? And we've looked at all kinds of different standards, and we sort of declared that nothing was quite ready for primetime, and yet we have – I mean, I don't know if folks read the AHA's response to meaningful use stage three that came out a couple of days ago, but it highlighted the fact that there isn't a robust infrastructure in this country for health information exchange, such as querying provider directories that enable the routing of messages to an intended party. So somehow we've got to tackle provider and patient identity.

The AHA response also suggested that we, the Standards Committee, Marc, revisit again your work on the accuracy of matching patients, and make sure we make appropriate statements as to if we are going to have things like not just push but pull health information exchange, how are there master patient indices that do probabilistic statistical matching in a way that the country accepts isn't perfect, but is good enough? So just make sure that we've made statements in that regard.

Record locator services. If we are going to have a model by which – oh, sorry. They've given me the button. Record locator services so that as we do move from push health information exchange to pull health information exchange, I show up unconscious in the emergency department, my wallet is extracted, and I see name, gender, date of birth, zip code, whatever, and then suddenly after providing such information, I get as a – say the physician gets a list of all the institutions my data happens to reside at, and maybe where I have opted in or whatever disclosure consent you want, because I recognize it can be very variable by state, for which the data can be retrieved.

And in fact, that very question of how consent is going to be managed is a tough one. I mean, I hear models all over the place. I've heard really interesting ideas that new, third party cloud hosted consent management firms will arise, and that I can declare, these are my preferences. I've heard, oh, I actually want to push the consent with the request. I mean, I've heard all kinds of things. And, you know, every state has a different set of requirements. Massachusetts is particularly interesting, because it's an opt-in consent to disclose, except if there's HIV data, and then it's opt-in consent to view per episode of care, and, you know, then you start getting into things that from an IT perspective are actually impossible to implement. So how is it we are going to think through some of the standards around consent?

Wes has written some very thoughtful commentary, and Arien has also written thoughtful commentary on improvements needed to the consolidated CDA to ensure that it can be parsed in an unambiguous way, and that we recognize that it has a great set of improvements on the CCD, but there's still some ambiguity in it. And one of the things that Wes has suggested, HL7 is going to work on a project where we're really going to tighten up templates and examples, and have XML structures, etcetera, so that we all can pull from a library, and even though our EHRs may have different schemas, we can represent the data over the wire in a way that's going to be comparable across organizations.

Whether it's the CCDA or other construct, we also have heard from the Policy Committee about the need to have longitudinal record extractions. Really hard problem. EHR to EHR transitions, these sorts of things. So how do we think about longitudinal and not episodic record sharing? And how is it that we go from say just one person's record to a 4,000 person panel, and how do we represent that? Is that 4,000 different CCDAs, or is there some kind of bulk sharing format?

And we never got it, as I said, last year, standards to support image exchange, and I don't mean just DICOM. I mean, there are all kinds of interesting and novel models for image exchange that are cloud-based, and some engage the patient. And I actually just received a URL the other day from a demonstration site that uses HTML5 as a means of creating pan, zoom, and windowing on images that in fact does not require a DICOM viewer at all to look at high quality images via a browser. So, you know, that's, again, sort of ____ we can consider.

On the consumer side, we heard from Jodi a fair amount about patient-generated data. Now is Jamie on the phone? Okay. And so Jamie, I promised to highlight this for you. Consumer device data does await the UDI clarifications from the FDA. Again, this may be a multi-year question as to how exactly we gather, parse, store, manipulate consumer device data, but there's a body of work there. I wrote in my own blog a couple of days ago about the interesting ways I'm monitoring my own parents' health remotely. It's a strange proxy, but I operate the weather station for the town they live in, which includes a monitor of the temperature in the building, their house.

So I can actually on cold days see if they have the heat up, and on hot days if they have the air conditioning on. I'm monitoring their ambient environmental temperature as a measure of their health. Strange, but, you know, it's the kind of thing that I imagine in the future – Consumer Electronics Show demonstrated the idea that ADT as a security provider might tell us whether – just a lesson here, be nice to your kids.

[Laughter]

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
You might imagine that the refrigerator is going to tell, you know, the home health monitoring system it has been opened, and that the TV's been turned on, and that, you know, the lazy – the easy chair has been sat in, or whatever. So there's a body of work on figuring out how to gather this data.

We always talk about standards as content, vocabulary, and transport, but when we consider the consumer, my guess is the average consumer doesn't wake up thinking SNOMED, CT, and LOINC. And so, I mean, I know that they should, but –

[Laughter]

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
So how do we represent consumer terminologies, and is this something that uses the convergent medical terminology from Kaiser? Is it something that the NLM curates? How do we deal with that?

Transport of data to and from patients. So this Automated Blue Button, and we talked about that. There are other mechanisms, and I'm just finished doing an Automated Blue Button implementation at Beth Israel Deaconess that takes some of the trust bundles provided by the ONC on their Blue Button project and enables patients now to provide a direct address and send data to the location of their choice.

Advanced directives and care preferences, care plans and care teams. So how do we even represent that stuff? I don't know of any – I mean, sure, CDA may evolve to represent an advanced directive. I'm not quite sure how to represent desired outcomes and care preferences, or how exactly to place a care plan with details, goals, timelines, or representing the whole care team, but yet I think the policy committee is asking for such stuff.

And as we think beyond the individual patient and the individual provider, then we have such things as how do we deal with this new construct of the ACO? Global capitated risk plans, new payment models, just at the time we're implementing ICD10, so that we can more granularly describe encounter diagnoses. We're not going to be paid on diagnoses anymore. We have to actually rethink outcomes, quality measures, population health, and those sorts of things.

And supporting that are a whole variety of other technologies. I mean, you saw in the request for comments the notion that the Policy Committee had that maybe we should have something called a smart problem list, that even though we have not declared as providers that the patient's a diabetic, the fact that they've had hemoglobin A1Cs measured every month for the last ten years is probably something we should think through. Does that indicate diabetes?

And as we document, you talked, Jodi, about the challenge we have of clinical documentation accuracy. Doctors are not very good at documenting unstructured text in support of a diagnosis. So do you have technologies that are somehow going to say, oh, well, if you're going to describe a fracture, you probably should talk about laterality, distal proximal, open, closed, comminuted, simple, I – how is it that we get the appropriate detail in clinical documentation to support new payment models and decision support?

We heard about structured data capture, and we'll hear from Becky a little bit about some of the work that she in her organization has done on structured data capture in support of research. But there's a whole variety of ONC activities around making sure we have structured data capture standards.

I believe that clinical operations workgroup and probably also the quality workgroup in the past have talked about the use of SNOMED and LOINC as ways of asking questions and answers for structured data capture, but don't know that we've really instantiated that in any kind of specific regulation.

I hear a lot about closed loop referrals. You send a person to a cardiologist, they never go. What do you do? Or the cardiologist seems them, but you never get a response back. What are the standards necessary – because sure, I mean, we can bounce documents back and forth. We can do various kinds of X12 transactions to support referral off, but there is no notion of how to close the loop on that whole referral process with standards.

I talked a bit earlier about having the consolidated CDA templates, the XML library, to ensure comparability across various data streams and various EHRs. That probably depends on the CIMI work, on detailed clinical models, because one problem I have is allergies are described in such different ways by every EHR, and the data streams, even with the model, Wes, that HL7 creates, it's only going to be as good as the data that's captured, and maybe we need a detailed clinical model implementation.

Standards for clinical decision support. This is a very tough one, right? Do we try to represent knowledge in a standardized fashion? I mean, it's been tried for years with Arden Syntax and GLIF and other models, and not exactly completely successfully. Or do we try and represent APIs by which a knowledge source can be queried and a response can be gotten, and therefore it's not the knowledge that is actually transacted into the EHR. It's just some mechanism of querying.

Finally, on the privacy and security side, we talked about genomic data. You saw on the Policy Committee's work plan the notion of protecting consumer downloads. And this is sort of an iffy one. It's just, you know, we'll – it's in their work plan, and they want some comment on it, and I have the challenge today of I can't reach out to every consumer's device and ensure it's appropriately encrypted, so, you know, what do we do? What are the recommendations we can make?

APIs supporting modular application integration. As we talked last time, Dixie, about some of the issues of how do you ensure that the combination of modules provides enough security as a whole that we actually adhere to the guidelines that have been laid out in meaningful use? You're probably going to need to make some commentary about how these modules interact with each other.

We've heard from the Privacy and Security Tiger Team about the notion of data segmentation, and I'm often asked, well, why is it that you only do opt-in consent per institution? Why can't you have segregated data on HIV, sexually transmitted disease, domestic violence, substance abuse, and mental health? The answer is, I have no way of segmenting that data in the record, other than applying some metadata that doesn't exist in the standard yet.

And we recognize that especially as we share more data with more people for more reasons, we are going to have to have some assurance of identity. Who is it we are sending data to, or who is requesting data? And I've asked several of you, because I'm challenged by several EHR vendors and working through meaningful use stage two requirements, when I'm just told, trust everybody, yeah, it's going to be great, you know, there's got to be some mechanism beyond an EHR vendor decides it's going to be the gateway to every user of its EHR for all direct transactions, and you just do a certificate trust at the root level of every single user of that EHR, hmm, including Joe's Endoscopy Shack. Right? And then digital signature, as we think about data integrity and provenance.

So this I recognize is a broad list, but again, this is just a straw man that is based on the policy committee work, the RFC, all the things you said – I think I actually ticked and tied every recommendation that every one of you made. So if I missed anything, please let me know. But I know we have as a second part of this presentation some information from ONC as to how it dovetails into current ONC work, but John, should we take a break now and start gathering comments?

Jonathan Perlin – Hospital Corporation of America
Absolutely. Why do you –

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay. Wes?

Wes Rishel – Gartner, Inc.
So I hope I'm not remiss in not having submitted this, but an area that I have substantial concern about is the orderly evolution of standards in an environment where not everyone can change their system at the same time. And I – we have a great example of the difficulty of that in looking ICD10 adoption right now. You know, the more I've thought about this, the more I realized it's not going to be done within the standard. It's going to be done by some extra-standard type of administration. And I really think we need to find a way to focus on that, find the people who've been thinking about this, and get some sort of advice by the end of 2013 that might even be useful in the transition to stage three.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
So Wes, you were correct. You did submit that to ____.

Wes Rishel – Gartner, Inc.
Okay.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
It was not your fault. It's exactly as you said. I wasn't sure that was a standard or a process, and so it probably belongs under health information exchange as a category.

Wes Rishel – Gartner, Inc.
Right.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
But Wes, we'll call it the asynchronous adoption of various levels of standards.

Wes Rishel – Gartner, Inc.
Yeah.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
You use HL7 2.31. I use 2.51. How do we avoid an impedance mismatch?

Wes Rishel – Gartner, Inc.
Right.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
So that is duly noted.

Wes Rishel – Gartner, Inc.
And just as a – as a general comment that came up several times in your presentation, we are at the level of finding ourselves at the point, by being asked to define a standard for people who want to change the behavior of clinicians, capture more data, things like that, and I think that somehow with – in conjunction with the Policy Committee, we need to think through what is that? In general, in – over the life of the meaningful use program, we have – we have a – we've seen a pattern of make something possible and then make people do it, as opposed to trying to make it possible and get them to do it at the same time. And I think we need some sort of a – of a way of looking at specific topics that follows that general pattern.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
That is a very good point. So ICD10 is this perfect example. I've had endless hours of meetings with my clinicians, who say, I can't even get 25 diabetes codes right. How am I supposed to do 400? And you know what? IT will solve this problem.

[Laughter]

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
And so maybe that's right. It's – the physicians have demanded, instead of my pushing it on them, they are pulling it as a set of technologies and standards to do their work. So let's see. We have David, we have Leslie, we have Chris, we have Jim. So David?

David McCallie, Jr. – Cerner Corporation
Yeah. So this is David McCallie. This is a great list of things to tackle. It strikes me that many of the items on this list already have some kind of a standard out there available, but the fact that those standards for the most part aren't being used because these things made this list as things we see as gaps suggest that the existing standards have a lot of problems. And I think the struggle that we'll face going forward is figuring out what is the right standard and what's the right way to develop that standard, if we don't have one on the books?

So, you know, a couple of things that I've seen recently that worry me, one is the – you know, the struggle to get the CCDA right. Anyone who monitors the HL7 structured doc list has seen remarkable disagreement on how to even communicate simple, common boundary conditions, like no known allergies to medications, but they do have an allergy to latex. You know, there's five different opinions on the right way to say that floating around on the list. So we've got a standard that's not working very well. At least, it's not constrained well enough, which I suggest is a flaw in the standard design. We've put a lot of energy or a lot of hope that CIMI might fix some of that. The trouble is, or the question, or the point is, really, that doing a standard right is hard.

In the other direction we've seen the Health eDecisions group put together some standards for communication of clinical decision support for trial, pilot use, that are based on older HL7 standards that have never been implemented by anyone. So you're building a new layer of standards on older standards that have never been implemented. No vendors participated to speak of, one or two maybe early on in that debate. So we ended up with something that's already even in HL7 ballot that the vendors are paying essentially no attention to. So it's a process that's really hard to get right.

So I urge us to figure out as much – put as much energy on the right way to develop these standards as on what's in the list of standards to be developed. And if I had a great suggestion, I would make it. I don't. I think it's a really hard problem. I think there's bits and pieces of stuff that have worked really well. Some of the S&I framework has worked really well. Some of it has not worked well at all. Some of it has engaged vendors early and aggressively and with enthusiasm. Some of it has left the vendors out or they just aren't paying attention or they don't believe in it or – or it's too complicated and they don't think it'll ever amount to anything, so they don't invest the time. It's a hard problem. We should not overlook that we can do better.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
And this is just an extraordinary point. So Dixie looked at the whole provider directory question of using HPD and LDAP and all these other things. The standards exist. Well, and Massachusetts came to the problem of how do I implement a provider directory. We said, well, a provider actually has a name, an address, a specialty time. You know, there are probably 15 data elements. And we can develop a RESTful query using simple XML for a provider directory for the 20,000 users of the commonwealth, and put it live in about a week, and there weren't any issues of firewalls or implementation guides or complexity, and we ended up publishing an implementation guide two pages long.

And so you asked exactly the right question. I mean, standards might exist, but if they haven't been adopted because they're too complicated or too hard, should we consider other alternatives before rushing ahead? Agreed.

David McCallie, Jr. – Cerner Corporation
Thanks.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay. So let's see. We had Leslie next.

Leslie Kelly Hall – Healthwise
So sort of building on that, I think identifying where standards have overarching impact as we introduce new players into the ecosystem, like patients, caregivers, and so forth, so there's work being done in HL7 on the patient-generated note, for instance, and Jodi talked a little bit about that. But I think Jim's point on who is the care team, how are they defined, what's the role to play, to include the patient and their care team, as well as professional, non-professional, that overarching author, roles, responsibilities, is something that I think is worth considering that crosses the ecosystem, and not just now looking at it at every single interaction that we have, is one comment.

And then the other comment is as we interoperate with more expert systems that may not have direct – require direct reflection inside the EHR, or downloading of information, what standards do we have that will allow those kinds of linkages to be persistent in an asynchronous, upgradeable way? Because we can't sustain having everything we look at downloaded into an EHR. But they are material, both to the patient, or material to the provider, so some sort of referential system that allows for the ongoing view and persistence of data over the long haul is I think another area that you've touched on, especially around imaging, but is – I think worth some – again, more of a horizontal view in both those areas.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Right. And so to your point, Bob Kahn, you know, ____ one of the foundational folks who architected the internet, asked this question. How do I assign, without downloading every object in the world to a single server, some sort of persistent, canonical representation of that object that I can access in the future? So it's beyond healthcare. Chris Ross?

Christopher Ross – Mayo Clinic
So the topics all look like they're incredibly important, and there ones that are, you know, not perfectly well-defined. I guess I had a little sidebar conversation with my implementation workgroup co-chair, Liz, around the issue about, you know, if we just look at these topics, they feel like they could be interpreted as additive to what we already have, and there's still work to be done to improve and iterate the core. So I would hope that our focus for this year, at least it will be for the implementation workgroup, to a large degree, is around iteration and improvement of the core, in addition to accreting additional topics. And we'd like to see that included as part of our work plan, if that makes sense to the – to the co-chairs.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Right. And as a next step, I mean, Doug Fridsma, and Jon and I talked to Doug yesterday, was going to take a stab at taking this list, taking the existent work in progress, taking all of those S&I initiatives and other ONC initiatives that you see, and actually developing a quarter by quarter schedule for us to review at the next meeting.

Christopher Ross – Mayo Clinic
Perfect.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Because we want to get out of the – all of your input, we didn't feel like – exactly your point. We could just come to you and say, yeah, this is what we're going to do.

Christopher Ross – Mayo Clinic
Yeah. I guess our concern or question or concern or our charter is, you know, we have probably – whatever the number is, 72 percent adoption, but those 72 percent have probably adopted 50 percent, you know, which means aggregate, we've got about 35 percent of kind of total penetration of standards and adoption. You know, what do we need to do to kind of move that along to a higher level?

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Right. We also have to be realistic, as I think about the implementation workgroup, of how much change can be adopted how fast. And some of us feel like we've been running a marathon for five years, and, you know, there's a point at which I need to consolidate my gains.

Jonathan Perlin – Hospital Corporation of America
Exactly. _____. I don't know if Doug is online. Do you want to comment now? Or Lauren? But we'll have ample discussion on this topic later. But I think there is – ____ understanding, this is both a philosophical point about how one approaches it constructively, as well as a practical matter of what needs to occur.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Let's see. We had Jim Walker.

James Walker – Geisinger Health System
Thanks. So I had one proposal and then a couple of cautions. It may be there somewhere, but it seems to me that we have been and will increasingly bang up against the need for a really comprehensive, standardized patient profile that includes a tolerance to risk and locus of control and literacy and psychosocial support and identification of who's their primary lay caregiver and advanced – it just goes on and on. There's probably 40 or 50 elements that if we could come up with a standard what are the 50, or 44, and what are standard characterizations within those that would mean the same thing or something close to the same thing across the spectrum of care, I think we would advance the ability of patients to be engaged, because all of the people on the team would sort of know what kind of patient they were engaging, and have a sense at what level to start engaging. I think that would be critical, and I think we could do it.

[Background voices]

James Walker – Geisinger Health System
No. Go ahead.

Leslie Kelly Hall – Healthwise
– saying, and build upon existing work in standards, and the opportunity as we insert patient-generated health data to this, to make us look at this, because we have now a new body of evidence, the evidence that the patient presents about themselves. I bring to the table a context that is now – it is my evidence to this, and it is not a conflicting opinion. It's an additive opinion. And so the more that we have, I think Farzad said, isn't it better to know? You know, and how do we quantify that and qual – you know, identify those things, I think is a huge step, and I – a very important body of work to do.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
And we've seen in stage two the common data set, the idea that it incorporates a set of elements that are subsuming a lot of the individual content standards, but then our friends at the Policy Committee have asked for new things to be added to that common data set, such things as occupation. Okay. Maybe that's relevant. You know, if you develop silicosis or if you've got asbestos exposure, you know, that's probably important. They've also suggested things like gender identity, sexual preferences, and those sorts of things. Well, the standards for that are maybe a little harder. And somebody has to decide what's going to be in that set of initial common data elements that are going to represent – you know, it's not everything, but it's maybe enough to get started with the patient.

James Walker – Geisinger Health System
And it's probably obvious, but we will need research on how patients can enter these things themselves.

Leslie Kelly Hall – Healthwise
Absolutely.

James Walker – Geisinger Health System
So, you know, can we create instruments that are usable enough that to a large extent patients can do this themselves? Anyway –

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Right. And there's going to be some very interesting metadata around them, too, so Dixie, from a privacy and security standpoint, what if the common data set includes sexual preference and sexual identity, and there are elements that I might provide, but I don't want everybody to know? And how do you deal with that? It gets to be really interesting.

James Walker – Geisinger Health System
And then just some quick cautions. The only research I know on consumer-friendly language is that consumers feel dissed by it. It's only one paper that I know of. But I think we ought to be careful about consumer-friendly language and make sure it's actually tested to be euphoric, not dysphoric, to consumers, and to really communicate.

[Background voices]

James Walker – Geisinger Health System
A comment about micromanagement. We have some mental models, like Dashboard, which I don't think their cognitive psychological scrutiny – I don't think what patients need for themselves or for their clinicians to have is a dashboard, you know, 12 things that are always the same, but rather a much more flexible and also a system that doesn't bring anything to anyone's attention unless it needs attention.

Leslie Kelly Hall – Healthwise
Right.

James Walker – Geisinger Health System
Part of the problem with the dashboard, it's always there, whether it's relevant or not. And so I think we just want to be – I think we sort of all know what we mean when we say dashboard. We mean a way that the care team can know what's happened, what the patient may need, what the patient may want, and when it's their turn to do something.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Right.

James Walker – Geisinger Health System
But dash – if we are very literal about dashboard and put that into reg or standards or something, we will have some – we will have created something that's already obsolete before we get it standardized.

[Background voices]

James Walker – Geisinger Health System
Same thing with Blue Button. You know, maybe there will be services where a person can say, here are all the places I've ever received care. You, whoever you are, go to all those places, get all that information, rationalize it all, and then provide it to this set of addressees that I want it to go to.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Right.

James Walker – Geisinger Health System
And so there again there's something we want to accomplish. Maybe Blue Button for some period of time is the right way to do it, in some context, but I just think we want to make sure we say it to ourselves in a way that when the next iteration comes down the road, we're not stuck with one that nobody wants to use anymore.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Yep. Okay. We've got a couple more comments, and then John, I know we're running a little bit tight on time, so I think it – well, Dixie Baker, ___ Jonathan Perlin's card up, and then we have Jamie, and we have Walter. And David, you –

[Background voices]

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
So Dixie –

[Background voices]

[Laughter]

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Go ahead.

David McCallie, Jr. – Cerner Corporation
____ rationalize is the part that bugs me.

Dixie Baker – Martin, Blanck, and Associates
Okay. Two things. Thing – oh, I'm sorry. Thing one, I want to strongly agree with Leslie. We have to come up with a better way to persist ___ linkages without continuously downloading data. This is a privacy issue as well, because, you know, you're downloading and duplicating data all over the place.

Secondly, I wanted to relate back to David McCallie's comment about using standards that maybe have existed for a long time, but are not widely used, etcetera, and I would like to point out that the recommendations of the NwHIN Power Team for evaluating the readiness of standards and standards that the standards use would address this issue. So I certainly hope that as Doug Fridsma has said before, that the ONC plans to use those criteria, I certainly hope that that's happened.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Great. Thank you. Jamie Ferguson?

James Ferguson – Kaiser Permanente, Institute for Health Policy
So actually, I don't have a comment, but Doug who's here with me I believe does.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay. Well, I hope things are great in Phoenix. I hear that it's actually colder than Anchorage, Alaska.

[Laughter]

Doug Fridsma – ONC Office of Science and Technology
And that is true. So we're – this is just HIT Standards Committee West. We've got a room full of folks here. I actually was going to roll my comments into the time that we'll go through all of the various analysis that you've done, John, and then be able to sort of comment specifically on all of the different work that's been presented. I know Walter did have a comment, though.

Walter Suarez – Kaiser Permanente
Yes. Can you hear me?

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
We can.

Walter Suarez – Kaiser Permanente
Oh, good. Okay. Thank you. So one of the items that I did not see on the work plan, and that I think is very, very critical, is the next level of discussion around data provenance. I think, you know, we've been having some very interesting discussions here in the HL7 security workgroup and in other venues about the issue of how do we really implement and how do we take to the next level the implementation of provenance, the metadata.

And while we know and we have seen provenance metadata included in the CCDA and in some of the other HL7 messages, I think there is some very important new developments around this in other fields. The W3C has developed an eight-point provenance set of domains that are quite valuable, and I think will be important to consider.

So I was going to suggest that perhaps this would be something that could be incorporated into our agenda for this year, certainly, and so look at how do we incorporate, how do we address this issue in the implementation phase of both meaningful use stage two and three, into the future.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Right. Well, so – when you look at some of the themes in privacy and security, like data segmentation for privacy, digital signature, there are a variety of metadata-related topics. I was having dinner with a vendor the other night, and the vendor was complaining, well, the CCDA is just fine, but as we use Automated Blue Button or DIRECT and I send a package from here to there, I can't figure out what's in the package unless I open the package, and maybe I actually don't want to open the package. I want to route it especially – you know, oh, it's a radiology image. Oh, it's not just CPDA. It's actually an HL7 2.x, you know, public health transaction, whatever.

So Walter, I think your comments about, well, what is in the package and who sent it, what is the provenance, might there be privacy flags associated with it, these are elements that do need to be addressed. Well, Jon, I think we are a little bit behind schedule, but I think we've got some very rich comments, and –

Jonathan Perlin – Hospital Corporation of America
I think that was terrific discussions, and I don't consider this an end to the discussion. The whole day threads through, so if there was a point that you didn't get on the table at this point, we'll dovetail through that.

I'd like to take a prerogative. Let's – one of the most important parts of our entire process is public comment, so I'd like to query on – MacKenzie, for any public comments at this point. ___ to the two public comment periods in our schedule, and then we'll come back to Becky Kush on CDISC if the time actually is open.

Doug Fridsma – ONC Office of Science and Technology
Jon?

MacKenzie Robertson – Office of the National Coordinator
We still have Doug's presentation.

[Crosstalk]

Jonathan Perlin – Hospital Corporation of America
Oh, I apologize. I apologize.

Doug Fridsma – ONC Office of Science and Technology
We haven't finished this presentation yet.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
You're right. You see, Doug, we started a little late today, and so what I had just made the comment that, of course, Doug, you have promised to take all of the input that we have provided as well as your presentation on what projects are already in process and produce a straw man calendar for what we might work on. So, I mean, Jon Perlin, given the time, do – can we get a very compressed statement from Doug?

Jonathan Perlin – Hospital Corporation of America
Let's do that, and – yeah. And MacKenzie, are we okay in terms of opening the lines for public comment after this?

MacKenzie Robertson – Office of the National Coordinator
Sure.

Jonathan Perlin – Hospital Corporation of America
Okay. Great. I apologize, Doug. Please go ahead.

Doug Fridsma – ONC Office of Science and Technology
I – somehow I always get scheduled right before something that has to happen at a particular time.

[Laughter]

Doug Fridsma – ONC Office of Science and Technology
So we – if we can go to just the first slide that we've got – yeah, thank you. So I'll try to go through this very, very quickly. And to Jon and John's point, part of what we want to do is to give you a sense about what work is currently underway. This is by no means a complete list, but it essentially takes each of the statements that John Halamka presented, and sort of relates that to some activities that are sort of ongoing. Many of these activities aren't things that are starting from scratch, but in fact, we've had them in the works for a while, anticipating that these things may in fact be important. And I think it's important for folks to understand that as we're thinking about what priorities are and what is the work plan for this year, to recognize that there are some things that are going to be in flight or things that we can actually get a fair amount done, and other things that – for which there's going to be some challenges.

So the first one is the standards for flexible platforms for measuring and recording quality measures. One of the things that we are working on is standards that will support flexible platforms for capturing structured information. And so over the course of the next couple of weeks, certainly by the end of the month, we will be having a launch of a new initiative called the structured data capture initiative, and it's an effort to actually capture additional structured information, both extracted from the electronic health record, or structured data that comes from some other source that will allow us to supplement the information that's in the EHR, as well as extract that, and then use that to support a whole host of things, like adverse event reporting, clinical research activities, case report finding with the CDC, and to help with any additional information that might be necessary for doing quality reporting and the like. So look for that. It's in the works, and we intend to launch within the next two weeks.

John did talk a little bit about standards to support measurement of EHR usability in the works that the Office of the Chief Medical Officer is doing with NIST to try to create those sorts of standards. Standards to address current content gaps, and that means lab orders, formularies, cancelled transactions, all of the things listed there.

Now we don't have activities in all of those areas, and we certainly are going to have to think about priorities and what are the next kind of incremental steps that we need, but over the course of the last year, one of the S&I framework initiatives has been to create a lab order initiative as well as a lab resulting initiative, and associated with that is a lab order compendium called eDOS. And the hope is with this standard for a lab order compendium, a way to order labs electronically, and a way to result those back, we can actually do the entire 360 process of laboratory orderings as well.

And so that's something that currently is at HL7 going through some of those ballot processes. And so that's something I think that we should have ready coming into meaningful use stage three.

Standards which support defect reporting to patient safety organizations, again, this notion of structured data capture also allows us to capture that kind of information as well. Standards which support redundant data identification and reduction, there are some ways that we could approach this. I don't have a specific initiative, but certainly we've been working with CMS to come up with digital signatures, which provide unique hashes, if you will, for sections of a document that have been signed. That supports the ability to sort of figure out where the data is, and if there's exchange of data, and now you've got two copies of the same thing, there's a way that you can then sort of harmonize those.

One of the things not listed on the quality and safety, but there is work ongoing, is the – is the prescription drug monitoring program, and this is an effort to really make sure that there's a linkage between electronic health records and the prescription drug monitoring programs that exist, so that we can begin to monitor that for safety and make sure that people are doing the right things with the medications that they prescribe.

Next slide. Standards which support query response to providers' and patient identity in directories. There are a host of NwHIN IHE profiles that are being used by eHealth Exchange, the CCC, and others. I think this is something that we probably need to revisit, to see what of this we might be able to take a look at. I think one of the things that we may consider is rather than having broad broadcasts of a query and getting a response from multiple organizations is to see if the next incremental step is a targeted query, in which you know the organization that you want to ask the question, and you just simply send the query to that. So we need to talk through what that incremental step might be.

Standards that support record locator services. We don't currently have some initiatives there, but that would be something to get advice back from this particular group on. Standards which support consent in a query response. Again, that's a – the NwHIN IHE profile that we may want to take a look at, and the like.

We've got improvements to the consolidated CDA standards to facilitate unambiguous parsing, longitudinal record sharing, and bulk record sharing. I think there is some work to look at long-term care record sharing, and we have the consolidated CDA initiative there, and the LTPAC group that's been working on shared care plans.

I think we do need some additional conversation about what a longitudinal record is, because a longitudinal record is not necessarily a CDA, but it's really just an interlinked set of all the data that a patient has over the lifetime of that patient. And so it may be that an incremental step is to begin providing a way for patients to be able to get a copy of all the relevant information, even if it's not a longitudinal record, but contains all their summary documents, laboratory tests, radiology and imaging, and allow them to have that, and then over time I think it's going to be something that we do want to build towards a longitudinal care record.

Standards to support image exchange. Again, I think we need to review the things that we've got to – you know, the DICOM image standards and others. We have brought this up on multiple occasions, and I think this summer would be a tremendous opportunity for us to really bring some closure to that and set a path forward for how images should be shared both between electronic health records and with patients and others.

I'm now on slide 8, so our HIT Standards Committee West stream isn't updating, so I just want to make sure you guys are advancing slides.

This slide is about category three, consumers. So standards to support representation of patient-generated data, including consumer devices. One of the things that Leslie Hall has been working on is extension of a consolidated CDA to allow a patient to be the author of record. It's an easy sort of way for patients to be able to be an author of record of information, and then I think we need to think about other ways in which we can collect and gather patient-generated data, including the consumer devices.

Devices is a little tricky. There's some work that needs to be done around unique device identifiers, and that work is I think in the stream, but whether or not it's going to be ready for meaningful use stage three I think is going to be not clear, and we are just going to have to sort of evaluate what's out there and what the next incremental step is.

Standards to support transport of data to and from patients. We've got a whole series of transport standards. DIRECT, we've got web services, and we've had pilots on RESTful approaches that have been driven by the Federal Health Architecture. I think this committee can help us provide some advice about what's the best transport standards to use for patients so that they don't have – they have simple and mobile and other ways that they can access their data and be able to take a look at that. Certainly work within the Blue Button and ABBI projects I think can be instrumental here as well.

Standards to record care plans and care teams. That, again, is sort of the LTPAC shared care plan activities, and they've been working very, very diligently on that. It would be something important to present back to this committee so that they have an opportunity to review that.

And, of course, the ABBI Blue Button standards and implementation guides that have been worked on over the course of the next – of the last couple of months I think have really been working towards developing this ecosystem of innovation so that people have access to the data and can do things that are helpful for patients as they manage their own health and healthcare.

Now I'm on slide 9. So standards needed for registry support, including structured data capture and transition – transmission to third party repositories. Again, you see this come up again and again, this notion of structured data capture. We're trying to create a single suite of standards that can be used for a lot of different purposes, and I think it's going to be important if we can get that accomplished to really be able to tick off a lot of other questions that we have, or a lot of the things that we might be able to do in the future.

Closed loop referrals. We're completing the 360x pilots that have been done out of the state HIEs, and I think we're learning a lot about how to do that, including things like asymmetric certification testing, and how do we get to that sort of asymmetric incrementalism within interoperability? So I think that's going to be helpful for us. And we also have the LOI, eDOS, and LRI suite for labs that allow us to order, have a compendium, and also get the results back in an electronic way.

Standards to support data comparability against entities, including detailed clinical models. I'm sitting next to Stan here, who is the leader of the CIMI project. I think one of the things that's going to be important for us to think about is that the CIMI project has been working very, very diligently, but what is the incremental path? There's still work that needs to be done, and how do we get there, so that we're taking that path of least regret that allows detailed clinical models to exist in this ecosystem in the future, and that we're building towards that as well?

Standards for clinical decision support, knowledge representation, and API for query response to knowledge resources. Again, the S&I initiative around Health eDecisions, and there's been robust discussions here at HL7 this week to really advance that and make sure that quality measure standards and clinical decision support standards have some consistency, at least harmonization, between them, because it's really different sides of the same coin.

Category five, around privacy and security. Obviously, there's a lot of work here, and Joy Fritz has been instrumental in looking at data standards and adopting the best practices from NIST and others. Standards for application programming interfaces. We're going to – one of the things that we're considering is this notion of a data access API based on existing standards. I'm calling it the data spigot, for lack of a better term, and I'm sure there is a better term, but basically, what this is intended to do is can we use our existing standards, develop a extension of query health or, you know, a simple version of query health that allows us to ask a question of an EHR, and based on our existing standards, get a consolidated CDA or a collection of consolidated CDAs, laboratory information, or other kinds of information? And what would that look like? Is there a way that we can get that kind of access?

So if you take a look at the structured data capture as a way of getting structured data in that is more flexible and resilient, if you will, using common data elements and others, and then a way to get data out using a standard data access, we might be able to actually begin allowing that data to be used for learning and for the learning healthcare system.

We've got work on the data segmentation for a privacy pilot. That work is actually in pilot, and we need to, again, have that reviewed by this committee to see where we are with regard to its readiness. There are standards and certification criteria that anticipate NSTIC adoption. We have looked at OAuth and eID standards as part of our REX pilot, and that was the RESTful approach to information exchange. And we've also got work that is nearing completion with the esMD initiative with CMS that is to develop a standard to support digital signatures.

I'll go to the last slide here. And I put in a couple of other activities, because I didn't see it on the list, but it's something that I worry about, and that is that we really need to think that when we – when we have a standard adopted in regulation or it's implemented in a system, our work is just beginning. It hasn't just ended. And in some sense, and I was talking with Keith Boone the other day, and, you know, our regulatory process is sort of as if you had taken 500,000 lines of code, you visually inspected it to make sure that it's absolutely okay, and then what you do is you compile it and you put it in a regulation and you hope that it runs the first time that you've compiled it.

We know in fact that there are going to be things that we can do better, that there are going to be errata and other things that need to be improved. There are going to be patches, if you will, that need to be applied to the kinds of interoperability specifications that we put out there. And so we need to be able to find ways that we can on an ongoing basis feed the implementation experience back into the standards and the testing and all the other infrastructure that we have so that we can achieve interoperability.

So if two organizations that have certified technology are unable to interoperate, it could be that we need to make sure that our testing is more robust, and that we don't provide – that we make sure that people have the ability to receive lots of different kinds of standards, but when they send it, that they send it that conforms specifically to a set of specifications.

It could be that our implementation guides need to be more tightly constrained or applied in a different use case, and so we need to improvement the implementation guides. Or it could be that we have our standard that needs a new attribute or a different value set or something else that needs to be included. So when it comes to implementation and sort of the pre-certification testing, we need to be able to be responsive to the implementations that are going on out there, identify bugs, fix those bugs, and provide a mechanism that we can fold that back into the right place in the process, testing, or implementation guides, or value sets, or standards, so that we can maintain over time our existing portfolio of standards.

So with that, I thank you for your indulgence. I know that you guys are running a little bit late. And our goal now, and I'm on the last slide, slide 12, now what we'd like to do is sort of, based on the conversation that we've had in this committee, and as well as the work that John has summarized and articulated, we're going to come back and try to come up with a more detailed plan about the things that need to be presented to this committee, and update the ongoing work, and so that we can try to be as helpful as we can supporting the work of the HIT Standards Committee as we make – as you guys make recommendations to ONC.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Well, Doug, thank you very much. Again, my apologies for miscompiling the code in terms of time. Let's take some discussions now. We have two cards that are some. Marc Overhage, I think you've had your card up for a bit, and Dave McCallie to follow.

J. Marc Overhage – Siemens Healthcare
Thank you. This is Marc Overhage. The question I guess I have is, looking at this list, is obviously Doug has a voracious appetite for taking things on, and we appreciate that energy and the willingness of all the volunteers and things that we have to engage in these things. Frankly, I'm very worried that we're not going to be successful at any of this if we spread our efforts this broadly. And this is such a broad, ambitious agenda that – so I guess I'm wondering if, Doug, as you're thinking about priorities and plan, if there's some level of, you know, these are second tier things that we're going to touch lightly, or we're going to spend some energy on, but here's the five or ten or four or whatever it is that we really think we need – are critical to make progress on.

Because we've got so many. We've done some great work over the years. HL7's done great work. The S&I framework's done nice work. There have been a lot of volunteer effort put in and artifacts created. But most are not being consumed today. And so I fear much of this effort will be wasted if we're not thoughtful about which pieces demand answers now, and which are things that we can – we can do some thinking, looking at, and consideration for the future.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Yeah. I didn't produce this whole list __ ____. Some of these are multi-year efforts. So I think, Doug, his comments are well-taken. Obviously, we want to be successful on a few rather than superficial on the many, so as we put that schedule together, we should just recognize, let's leverage what it is you're already working on. Let's take into account the thoughtful comments from Chris and Liz on the maintenance of what exists, and decide what's realistic.

Doug Fridsma – ONC Office of Science and Technology
So yeah, I would agree. Much of the work that we have here is work that's gone on in the last year or so, and the things that would be helpful form my perspective is for this committee and others to take a look at the work that's gone on with the lab orders, and the work that's gone on with the shared care plans, and the work that's gone on with, you know, some of the other projects that are here, and give us a sense of are these ready? Do they need finishing school? Or is this part of a multi-year effort? And I think that's helpful for us, to be able to see where we want to invest our resources. So much of the things that we have here, it's just a mapping of where the priorities or where the list is, and some of the ongoing activities.

There's only really two things that are considered on here that might potentially be new things, and that is the notion of a data spigot or a data access API, and this notion of structured data capture. Those are sort of the two that would be new. And I think part of the issue there is for all of these things, we need to make sure that we are deliberative in what we – what we work on and what we do. And it may be that it, as you say, it would be better for us to take a longer time to get it right than to have so many things going on all at once.

Certainly we will be closing down or transitioning into a maintenance mode much of the current work that's in the standards and interoperability framework, and so those are sorts of things that I think will also make it a little easier to kind of get through the various activities, because there will be a number of things that we won't be doing in the future, just because of the work the S&I framework currently is being funded.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
David McCallie?

David McCallie, Jr. – Cerner Corporation
Yes. It's David. Doug, I want to sort of restate what I said earlier before your presentation. I didn't realize you were scheduled to come up, so I should have saved my earlier comments. And also to echo Marc's comments, that, you know, there's a lot going on, and you will never have any trouble getting a group of people together to work on a new standard, and in fact, they'd probably be happy to leverage it over standards that they had worked on in the past. The question is can you get people to be involved that will actually use the standard and will commit to really building it out at scale in our, you know, nationwide community of users?

And so I think that the real challenge is not to come up with these good ideas or to find people who can help work on them, but to make sure you have the right people engaged, and sometimes that, you know, is actually recruiting vendors to be a part of the process. And if you can't get the right representation present, then something is wrong. Either the standard's timing is wrong, or its scope is wrong, or the vendors don't understand what you're trying to do. But if they're not showing up for the meetings, it'll probably not do well in the long run.

So I come back to the Health eDecisions work as an example. There was an attempt to recruit some vendor membership. It didn't work very well. There weren't very many vendors who showed up. The process went forward. And it has produced a standard that I think the vendors will find very difficult and even very confusing as to why it's even there, much less try to implement it.

So I wonder if, you know, that project should have stayed on the launching pad until there was a guaranteed sufficient representation of the people who would actually be deploying it before it went forward, rather than just once you had a number of bodies who show up and volunteer to contribute, you started. So I don't know, it's just a notion, but these things are so hard, and our time is stretched across lots of difficult things to go do. If you don't have really strong vendor commitment to one of these initiatives, it's probably going to struggle when it comes time to build it out.

Doug Fridsma – ONC Office of Science and Technology
So David?

David McCallie, Jr. – Cerner Corporation
Yeah.

Doug Fridsma – ONC Office of Science and Technology
I didn't make this list.

David McCallie, Jr. – Cerner Corporation
Yeah.

Doug Fridsma – ONC Office of Science and Technology
This list came from the HIT Standards Committee, and that was the work that John had presented before. What I tried to do is take that list and say, what are the things that are currently underway that could potentially support those activities. So I think your point is incredibly well-taken, but the conversation that we had just before this was this is a huge – this is a big list of activities. All of it is really important. We should certainly be working on it. So then I presented what it is that we are working on, and now people are concerned that we're working on too much. So –

David McCallie, Jr. – Cerner Corporation
Yeah. Yeah. That – great point, and I think this is a great list, and there's nothing on here that should be taken off. But I think it has to be prioritized. And then the things that are addressed should be – you – it's not – it's not sufficient to just put a posting in the Federal Register that there's going to be a new standard development to address some new, complex capability, launch it, and get going. You're going to have to work harder to get – to make sure the right people are engaged, and in the right sequence. Not all of these can be done in parallel. Not all of them could be – should be done urgently. Some of them are longer-term thoughts.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
And so I think to your point, the next body of work is to take this list and, just as the Policy Committee did a quarter by quarter work plan, again, there was no notion that this would all be done this year and it all could be done in parallel. I think it's – we have to be very, very judicious about what gets done first, second, third quarter, and beyond.

James Ferguson – Kaiser Permanente, Institute for Health Policy
This is Jamie. I've got my card up.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay. Well, Jamie, I think we have Wes, and Jim, and Chris. Go ahead, Jamie.

James Ferguson – Kaiser Permanente, Institute for Health Policy
Okay. Well, just briefly, just to react to Doug's comment that he didn't make this ambitious list, it came from the Standards Committee, I think that, you know, the Standards Committee actually made this – these comments and this list in reaction to the – what we got from the Policy Committee. And so in fact, you know, if we – if we look at the vast expansive scope of ambitious things that are on the Policy Committee's wish list, I think that's kind of where this came from. And so we're reacting to that.

So I think, John, you said it exactly right, that, you know, this should be staged out in a multi-year work plan so that we can take a – perhaps a more thoughtful approach to what to do when, and how to focus resources at the right time.

Jonathan Perlin – Hospital Corporation of America
Jamie, this is John. Thanks for this thread of conversation. My opening comments, I made the point that really we weren't going to try to reinterpret the Policy Committee. That's beyond our purview. That said, I think this conversation is extremely helpful, because the simple reality is that as we identify standards, we've had a conversation about threading the needle and trajectory and durability, that the prioritization will occur not only with guidance from Policy Committee and ONC in terms of those things that are more important from your perspective, in terms of those things that seem to have priority within the context of standards, but the simple reality of the availability of standards, those that are present, ready to go, those that are on the precipice of readiness, and those that really require longer-term development.

So I think this is a very broad agenda, and certainly, you know, there's been a lot of discussion in the comments about the breadth of the agenda. With that in mind, it is the agenda that we're seeking to identify the match of standards and the need for standards. And I think in large part, that will help us really provide useful feedback to the Policy Committee about the aspirations, allowing all to achieve some early wins, some things that are really near term, and those things that are going to require work.

And I think this group is particularly – and the colleagues working through the workgroups – particularly well-suited, because I think concomitant both in terms of those things that can be achieved, but also really support a discussion about building a model that's durable. Some good comments earlier today that, you know, really, there's iteration and refinement of a number of the core elements, as well as the accretion of new elements. And so I think our feedback and input has to be thoughtful in those regards.

So I think this is a terrific point. Let's put that one – I think there's resonance with everybody, and need to prioritize will really accrue through the lens and part of the availability and the logical go forward approach. Let's come to other comments. Let's me turn back to Jon to moderate that.

Jonathan Perlin – Hospital Corporation of America
I think I see the profile of your card, Wes.

Wes Rishel – Gartner, Inc.
That's right. Yeah, yeah. It's encrypted. Okay.

[Laughter]

Wes Rishel – Gartner, Inc.
The – I think it's wonderful – I think if we just think about what the fundamental implication of this just last discussion on priorities has been, which is somebody out there actually thinks that standards matter. You know, we – four years ago, we could get all kinds of people to work on all kinds of standards, and they were done when they published them. And two years ago, we began to rely on them, and people of good, solid mind, but – were having a new experience, which was it doesn't matter just have I adopted this standard. Do I understand it better, or anything like that. I'm not in a race here. We're both in the same rowboat. We've got to all – it matters to me how well other people can understand and adopt the standard.

And so we are recognizing a point about the evolutionary process of a standard. No more – you know, you can look at USB. You can look at TCP. You can look at Bluetooth. You can find that they only got to the point where they were acceptable to the consumers at about version three, and they struggled with a push by dare I say the marketing folks to get more features in. We've got to have more features in this version, and things like that.

We at HL7 created the notion of a DSTU, a draft standard for trial use – thank you – that – with the understanding that there would be – issues arose during the implementation of the DSTU, there would be a quick path to resolutions for those standards, for those DSTUs, and the resultant final standard would take those issues into account. It might not always do exactly what the interim resolution was, but it would take it into account.

We have really, with the CCDA, we are taking a DSTU and rolling it out as if it were – as if it had been through that evolutionary and maturing process. And I think there are great reasons to do it, but we have to expect that we'll need to be more – doing more debugging among more people at the same time and so forth than we would need to.

The lesson that this goes back to, and this is something – you know, I've heard from Doug as well – is we need to seek the opportunity to go through a DSTU process before a standard is encoded in a regulation. The sort of sociology of that is very difficult because most of the implementation experience with standards come from vendors, not all. There are – there are some academic medical centers and some other locations, like agencies, that have done a lot of implementation on their own, but most of it comes from those centers. And vendors tend not to look beyond the next stage of meaningful use. They put – they rightly, in my opinion, put all of their energy into what is the most definite and what is going to impact their clients and their bottom line, you know, next year.

So we have, with the Policy Committee, I think, a joint requirement to identify issues requiring new standards long enough in time and in a context of implementations that allows a feedback cycle on a draft standard of trial use before it becomes a standard. And I used HL7 terminology, but I think the same concept applies to every kind of standard we could possibly have. Thanks.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Wise advice. Jim and Chris.

James Walker – Geisinger Health System
Just quickly, I want to propose something that I'm not sure we've been explicit about, as we think about if we were going to prioritize these standards. The technology adoption model is supported by a large body of experimental evidence that concludes that the two things that drive adoption of technology are usability and usefulness. And I'm not sure that we've been as explicit about usefulness, about do the people that we would need for these standards to be adopted by have a felt need that this standard would help them address? Because if they don't, it's extraordinarily difficult to – I think that explains a lot of what David's talking about. It's extraordinarily difficult to get people to use something that doesn't meet a need, and obviously involves cost and effort.

And so maybe if we were a little more explicit about, you know, what is the environmental ____? What is the felt need for all of these things? Maybe that would help us identify some that we could get quick wins, we could, you know, sort of start to achieve something. Since we can't do them all at once, we could maybe do the ones – some of the ones first that there's really a felt need for.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
And I think your point is well-taken. I see all of the hospitals associated with Harvard buying commercial products for image sharing because the body of standards, just simply do it at an EHR or PACs level, easily, cheaply, quickly, aren't quite there yet. I know people will argue with me, but why is it that companies like lifeImage, Accelarad, and others are selling so much product, if the standards are perfect? There's a demand there. Chris?

Christopher Ross – Mayo Clinic
Well, so we blame Doug and then the Standards Committee and then the Policy Committee. I figure let's not stop here. Let's blame President Obama and call it creeping socialism.

[Laughter]

Christopher Ross – Mayo Clinic
That seems to be in vogue. What the hell. I guess the only comment that I would give is that, yeah, again, going back to implementation committee, we're planning to have some hearings probably in the March timeframe, so I think what we're looking for is a venue where we can get some honest feedback from the industry around the balance of ambition and execution, because I think that's what it comes down to. I think we would invite comments or feedback from anyone on the Standards Committee about how you think we ought to organize that, so we don't get it at odds with either what Doug is leading or, you know, the rest of the committees' agenda.

The other issue is, you know, if we have a vendor panel, you know, what vendor is going to say, oh, yeah, we're going to have problems with that implementation? Everybody's going to say, we can do everything, most likely. I'm looking at David. I'm hoping he can give us some insight.

[Laughter]

Christopher Ross – Mayo Clinic
So in any case, I just wanted to note that it was our intent to try to get feedback from the community around pace of change, and would invite feedback, you know, like Wes's or anybody else's, as we assemble that agenda.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
And I think summarizing your comments, Wes's comments, Jim's comments, there is a January 29th all day HIE hearing by which we are going to ask these questions, of what are the gaps, what do you need, what is the maturity level, where is the pain? So I think that will be gathered then. Well, turning it back to you – oh, did you have another?

Christopher Ross – Mayo Clinic
Just one tag comment onto Wes's comment about the draft standard for trial use. I think there's a step even prior to that that maybe I was trying to fumble my way through describing, which is it's some kind of getting vendor buy-in in a virtual sense, that this standard is important, relevant, we'll contribute to it, we'll engage with it, so that when the DSTU appears, you have vendors already prepared to do something and test it. You can get all the way through a balloted DSTU and have no single implementation anywhere in the world, and that doesn't do anybody any good. And there's a number of standards out there on this list that are past that step of the ballot process that have never been implemented. And I – so I think there's a – there's a virtual buy-in step that has to happen, and it unfortunately, ideally would be purely voluntary. You know, you'd post a notice, people would sign up, and you'd go forward. But you may have to do some recruiting.

Jonathan Perlin – Hospital Corporation of America
I see a debate emerging about the – about the STU. I think this is a good point to break for lunch. One, I think it's been a robust discussion. Two, I think there have been some great new ideas surfaced. Three, I think there's universal consensus this is an ambitious agenda. Four, I think we have two dimensions that have been established in terms of the parsing among different workgroups in terms of the body of work, second, the readiness for adoption. And I think this concept not only of use – adoptability, that is a part of that readiness for adoption, includes a number of dimensions in terms of both usability and usefulness.

My only request in terms of the usefulness is that I think we do need to be sensitive to the difference between the Policy Committee and the Standards Committee, and I think our purview is to comment ___ usefulness of the standard, and that likely has implications as to the policy intent of that as well.

This is not a completed conversation, of course. It's an ongoing conversation. We'll dovetail back. And I apologize, Doug, because when you said I'll defer till later, I thought you meant to the ONC update, because indeed, we'll thread through that conversation as well.

If we have a miraculously expeditious discussion in the afternoon, we'll hear from Becky Kush on the CDISC. I – Becky and I side-barred. I think it's just a terribly important body of information in terms of contemplation of stage three and stage four. The material are in your packages, so at a minimum, I'd like to ask that everyone become familiar, and if the schedule allows, we'll do that. Becky has been gracious not only to speak to CDISC, or willing to speak to CDISC today, but she is traveling internationally, presenting internationally, concurrent with our next meeting, and would not be able to return then, in worst case, will return to CDISC in March ___ a mechanism between the meetings for discussion of CDISC.

I think – I know that all of us are united in a passion that this is a public process. We've deferred, and I apologize to members of the public that we're 40 minutes behind, but we do have two public comment periods. Let me turn now to MacKenzie to open lines for any public comments before we break for lunch.

Public Comment

MacKenzie Robertson – Office of the National Coordinator
Thanks, Jon. Operator, could you please open the lines for public comment, and if there are any members of the public in person that would like to make a public comment, if you could please come up to the table now.

Operator
If you'd like to make a public comment and you're listening via your computer speakers, please dial 1-877-705-6006 and press star 1, or if you're listening via your telephone, you may press star 1 at this time to be entered into the queue. And we do have a comment from Robin Raiford.

MacKenzie Robertson – Office of the National Coordinator
Thanks. And Robin, before you go, I'll just note that public comments will be limited to three minutes.

Robin Raiford – Public
Okay. Thanks very much, MacKenzie. I have a stopwatch, so I'm aware. Thanks, Jonathan and John, for being late, because if you'd done this at 11:00, I wouldn't be on the phone. I would just say that I've been profoundly sick in the last 30 days, and 2 weeks ago got told there was no medical reason why I was still alive, because of a missed – a missed diagnosis of obstructive sleep apnea with O2 sats to 69. I am absolutely convinced I'm alive today to say ___ this mission, be on this committee, help this committee get this right so we don't kill people.

I seem to have survived these O2 sats of 69 with no heart attack, no stroke, and no brain damage. And yesterday, I found out I had adrenal insufficiency, with a pressure of 58 over 30. So just know that I'm just trying to get this out, after – what you're hearing. First of all, you've all made my heart race in the last 30 minutes. I'm on so much Prednisone, so I will get off the phone after this, before Judy Murphy personally kills me. But I've had three admissions, four ER visits, and seven rescue squad events in the last thirty days.

When I hear your talk about what should you do next in the way of standards, and the ambition and the level of effort, I think, Wes, you were spot on about what vendors do. They get to the next cycle. They get to the next certification. My suggestion would be having been now through this cycle from the nurse call button all the way to discharge and follow-up, is to go after the people that did meaningful use in 2011, go after those vendors who helped them first, as per that Data.gov list that had a lot of – a lot of the software as a service vendors putting it out, because they didn't have to do client server upgrades, like the bigger vendors. But go to vendors who've got the most 2011 folks, because they have to do it, and they have to test it.

I think Wes is spot on with draft standard for trial use, because you find problems when you implement, because when vendors build it to get certified to stay in business, if they don't have their customers in that cycle, and they're pushing it off to 2013 and 2014 to miss payment adjustment, it's the 2011 starters and the 2012 starters that are going to figure it out. So I agree with that.

And John Halamka, for the where is the pain, I would prioritize where is the most pain for the patient. And I will tell you, before I found out I had adrenal insufficiency yesterday, for two weeks I went to follow up visits, two doctors with EHRs, but they did not have the patient kiosk. And to be sitting there in early adrenal insufficiency without knowing it, with a stack of 12 pieces of paper, and I hadn't figured out, if you're short of breath chewing, probably your adrenals are not working, but I wasn't figuring that out. I wouldn't fill it out. I had – and then they wouldn't help me. They were too busy. A stranger in the waiting room was helping me.

And then I found out they had an EHR and entered it on the back end. So I just like – when I – I thought, if I ever get rich, I'm going to buy them a kiosk for the lobby. That's just crazy. And so I'm three minutes and I want to stop, but I want to help, and I did put in to be on the HIT standards patient engagement workgroup. Thank you.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Robin, as you know, we don't typically respond to comments, but on behalf of the committee, all of us send you our best wishes for your good health, and take away from your comments not only the specific advice but also the reminder that this is about the patient.

Robin Raiford – Public
Thank you so much, John. Thank you.

MacKenzie Robertson – Office of the National Coordinator
And seeing no public comments in the room, are there any more public comments on the phone?

Operator
There are no comments at this time.

MacKenzie Robertson – Office of the National Coordinator
Okay.

Jonathan Perlin – Hospital Corporation of America
Okay. Let's take a break. It is now a quarter of 12. Let's take a break. Let's try to compress to about 12:10, and we'll do ___ ___, please, let's bring our stuff back to the room and let's resume. And I know we will have a terrific and robust discussion this afternoon. Thanks, everybody.

[Lunch break]

MacKenzie Robertson – Office of the National Coordinator
If everyone could start taking their seats, we'll try and get back on time with the agenda, fingers crossed.

[Pause]

MacKenzie Robertson – Office of the National Coordinator
Okay, operator, could you please open the lines back up?

Operator
Lines are open.

MacKenzie Robertson – Office of the National Coordinator
Thank you. I will now turn the agenda back over to Jon Perlin.

[Crosstalk]

MacKenzie Robertson – Office of the National Coordinator
Jon?

Jonathan Perlin – Hospital Corporation of America
I'm going to resist. I'm moving –

[audio glitch]

MacKenzie Robertson – Office of the National Coordinator
I'll now open the agenda back up and turn it over to Jon Perlin. Thanks.

Jonathan Perlin – Hospital Corporation of America
Actually, we're going to jump past the _____. Good afternoon, everybody. Thank you for reconvening. Let's jump right into the agenda without further ado. I'll turn actually to John Halamka to walk us through our workgroup perspectives.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Great. So MacKenzie has organized this in a very structured fashion so that we are going to have 12 minutes per workgroup to hear the general overall tone, the responses that your workgroups made at a high level. We recognize that the RFC itself was so lengthy that if we were to go through every single sentence, we would probably not get beyond about page 3. So you're going to have 12 minutes each. We're going to go through workgroup by workgroup by workgroup, and then we will have an hour at the end for general discussion and reaction. So let us start with the clinical quality workgroup.

James Walker – Geisinger Health System
All right. Do we have a timer?

MacKenzie Robertson – Office of the National Coordinator
We have a timer on the screen for you, projected in the room.

[Crosstalk]

[Laughter]

MacKenzie Robertson – Office of the National Coordinator
And then I'll just ask, since everyone has their own slides, just to say next slide, and we'll have them advanced for you.

James Walker – Geisinger Health System
Okay. So –

[Crosstalk]

MacKenzie Robertson – Office of the National Coordinator
And all questions we'll just hold to the end, as John mentioned.

James Walker – Geisinger Health System
The clinical quality workgroup actually came to remarkable consensus on most of these. If I don't say anything about that, it represents almost universal consensus. There were some that we identified significant – more difference in perspective than disagreement about fact, and I'll try to note those.

So the first, we felt clearly that we need to retire attestation as a way of satisfying measures. Number two, in terms of the care plan, we think it's critically important – we felt that both content and terminologies, we need standards for expressing it. As was mentioned earlier in the meeting, we probably need a conceptual framework to even start that work. We think there are some things early that are so important and are relatively well-characterized, that they could be a useful at least first phase of care plan, things like diagnoses, patient goals, back to that idea of a patient profile, advanced directives, and identification at least of the core care team members, PCP, specialist, care managers, lay caregivers, patient, you know, those sorts of things.

On three and four, while we – there's absolutely, complete support for measures that address population status, we felt that both to get there logically, and also to create clinician and patient support, that quality measures ought to focus in the – in the first phases on efficient, evidence-based care processes, and on interdisciplinary cross-venue care processes, so things that actually are visible to patients and clinicians, and then improve care at the outset. And I think there's belief in the workgroup that if we could do that, we would find that many of those do apply at a population level, with maybe some modest modification.

Strong feeling that we need to standardize a data model and authoring tools for quality measures, number five. Number six, on core measures was one of the ones where we had considerable difference of approach. Perhaps we thought there would be some measures that would represent realities so important that they really should be core. It doesn't probably matter what kind of provider you're seeing, you probably want shared decision making, adequate pain control, and so while we're cautious about it, we do think it's worth thinking about whether – that there are some.

Wider input, we thought that states are engaged in important activities that learned societies could clearly provide useful input. And then other sort of newer methods of getting information, doing focused, semi-structured interviews with important informants that don't have the resources or the time to come somewhere and testify, and then also even more virtualized sort of crowd sourcing methods.

Number eight – oh, I'm doing well. Number eight, we think patient input is critically important, but felt that standards clearly are in an early state of development about that. And one thing I think may not be – we may not always say clearly, there is – there's patient input in terms of the patient's expression of their perception of things, which is critically important. We try to teach young doctors that 85 percent of diagnoses come out of that information, before you do anything else.

But also, we're interested in the idea that the patient input could be structured and codified itself, and that we could do research to identify patient input that can be – can be so accurate that it's as accurate as clinician-generated input, and could feed directly into semi-automated care processes. So it's sort of a two-layer sort of approach to patient input, and particularly that second layer would need standards development. And again, we thought that there's some core things that the patient clearly knows that nobody else knows that would be good places to start, partly because from a clinician standpoint they represent a felt need, clearer understanding of patient symptoms, finding out about them within a few days of when they occurred instead of six months later when they come back to see you, those sorts of things.

Number nine, we thought that there certainly are now validated instruments for patients to provide codified, structured input, like depression scales, that are already in production and use. Clearly, we need more of them, validation of more of them, and testing to really understand how to put them into processes so that they work for patients and their team.

Number ten, we clearly thought in response to those questions, CMG9 and 10, you have to look at them, you know, as a sort of – which wing of the airplane do you want? Do you want process measures? Do you want outcome measures? We believe clearly what is needed is coherent sets of process and outcome measures, particularly because many of the units of measure, single clinicians, small and medium-sized practices, even medium-sized hospitals, are – don't have the kind of patient population that would make many outcome measures reliable and actionable. So enough said on that.

Number 11, then, next slide – oh, thank you. You're so good. We feel that it makes all the sense in the world to align quality measures of meaningful use objectives. And maybe we didn't see the depth of that question. It seems sort of obvious to the workgroup, and we might have missed something, I guess.

Number 12, transitions of care are very high priority for – you know, because they impact patient experience and outcomes so powerfully, and because of the well-documented problems with them. And because they really stress standards and make interoperability, at least at basic levels, just critical.

Number 13, this was one where the discussion was – there was slightly less unanimity. We think that the idea that different – I said local there – entities, learned societies, care delivery organizations, and I guess if you think about it carefully, patient groups, might, you know, create or – yeah, create quality measures. We think there's value in that, but it seemed to the group that the management of that to make sure that it really was evidence based, that it really could be built into high quality care processes, and so on and so forth, would be complex and expensive, and I guess it wasn't clear to the workgroup that the final cost would be less than having a central set of groups or group that did it in a more structured way, and maybe received input on topics to address.

And then 14, our feeling was that population management platforms at this point aren't standardized enough to do much beyond sharing best practices about how to build them and use them.

[Background voices]

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
And although I'm sure there are many comments we all want to make, we are going to march through these, so write them down. We'll save your comments till the end. So next we will move on to the privacy and security workgroup. Dixie?

Dixie Baker – Martin, Blanck, and Associates
I'm an extremely compliant person, so when MacKenzie said one slide, I have one slide.

[Background voices]

Dixie Baker – Martin, Blanck, and Associates
Yes. With 4.5 type. Yes.

[Laughter]

[Crosstalk]

Dixie Baker – Martin, Blanck, and Associates
No. Now you're taking my time here.

[Crosstalk]

MacKenzie Robertson – Office of the National Coordinator
Now, now.

[Laughter]

Dixie Baker – Martin, Blanck, and Associates
Some of the – some of the same questions were asked of both the privacy and security workgroup and the NwHIN Power Team, and so I kind of divided it between the two. First, both groups were asked about the directory standard, and we felt, both groups, in fact, feel that in most cases, directory stan – directories are part of a larger solution. You know, vendors usually don't – or providers don't usually go out and just buy a directory, but rather you acquire your directory as part of your communication solution, or part of your security solution. And we think it's inappropriate to externalize directory as a separate entity outside with a separate certification criterion, but rather, we think that the approach that the meaningful use standards have taken so far of embedding the directories within the standards, as in the case of the direct transport standards or the exchange standards, is the right way to go. So we don't – we don't support it being a separate standard.

The safety risk assessment, it called – it asked – they asked whether we thought there was a need for an IT safety risk assessment, and we agreed on the need, especially since the HIPAA risk assessment only addresses protected health information, and many safety risks are related to information that's not PHI, like clinical decision support rules, and clinical guidelines. So we agreed that there should be a general measure for safety assessment, and let the standards and certification criteria evolve over time.

The biggest – the question that generated the longest and most in depth discussion in both of these groups, actually, was the question that asked for standards for patient consent for sharing categories of information with special legal protections. And we thought it's very, very clear that there's a need to really look at access control solutions for both protecting, enforcing laws relating to special categories of information, and access controls that enforce patient consent preferences that have been expressed.

Now these are two different things, and the intelligence community and the DOD community and Department of Energy, lots of areas have separately addressed them for years and years, so there is technology to address what's widely known as mandatory access controls, which is like categories of information that by law have to be protected, and then there are access controls for discretionary access rules, like – which are very similar to what a privacy consent might indicate. So we suggested that the standard should really capitalize on work that's been done around mandatory access control and discretionary access control, as well as some of the foundational work that's been done at the Veteran's Health Administration.

The ultimate solution needs to be able to enforce access rules that are based on clinical labels or metadata attached to special categories of data, as well as rules that are – that are defined to implement patient consent. This is a – and needs to be scalable to the national level. This is a big issue, big issue that needs a lot of work.

The – I don't see my little clock there. Oh, there it is. Okay. I'm fine. There's a question about reconciling EHR certification with the National Strategy for Trusted Identities in Cyberspace, or NSTIC, approach of using third party credentials. And we thought the two were not only compatible, but are actually quite complementary. And we suggested that the certification criteria start with the requirement for multi-factor certification – multi-factor authentication. And, you know, even for stage three, we think that it's ready for that, but to not require NSTIC compatibility at stage three, but to wait till the NSTIC certified credentials are ready, and then make them an acceptable standard when they're available.

We – also, we noted that it's likely that consumers will start using NSTIC certificates before providers will, and so we urged ONC not to lock the two together and require that they progress in lockstep in – but they be allowed to progress independently.

And then finally, two of the questions from the Tiger Team related to calling out specific HIPAA requirements as meaningful use measures, and in both cases, our – the privacy and security workgroup suggested that no single HIPAA requirement be called out as a separate meaningful use criterion, but rather that, you know, the approach of just requiring HIPAA compliance is correct, that none should be highlighted as more important than any of the others. So with that –

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay. We are all beating the clock here. Okay. Well, Jamie, I know you are on the phone, so if you could go through the deliberations of the clinical operations workgroup?

James Ferguson – Kaiser Permanente, Institute for Health Policy
Sure. Happy to do that. So the clinical operations workgroup was assigned over 30 different line item comments, and I think we added in responses to a couple of the general items for good measure, so ending up with approximately 3 dozen different comment areas. So I haven't listed what all of those are, and they – they're extremely wide-ranging. So what I've tried to do instead is to categorize them to show the breadth of different kinds of responses that we had from the workgroup discussion.

The first being there were a number of items that we agreed with, and we said, yes, this is a good idea. You can either do it with the existing standard, or here's an additional or new standard you can use. So the examples that I've listed here are for lab results using existing standards, or adding the NCPDP formulary and benefit standards for formulary transmission we think is possible.

Then there were a few items where our response was, well, we really need to get more specifics. We need clarification, or there's a modification to the approach that we would recommend. We think it's a good idea, it can go forward, but that some slight change is needed. So the examples that I've got here are the need to define pertinent information for an office visit, or high priority conditions, where those things have to be listed.

There was a suggestion to add radiation dose to a visit summary, and so we thought, no, instead of just putting everything in one place, really, that – the place that that belongs is in a radiology report, and that that – but that's also very doable. It's just a different way of approaching it.

There were a few things where we disagreed with the proposed direction, and so the example that I've got here is there was a proposal to drop demographic data collection requirements, but we felt that these are foundational data, that even though the measure may have been achieved, it's a good idea to continue collecting demographic data.

And then we move into two other kinds of responses, one of which really relates very much to our previous discussion in this committee meeting, about things that require more work. And so this – these are areas where we commented that the standards are immature or standards or processes require more work that likely would take it beyond stage three of meaningful use to really get to a workable implementation. One of these example that I've got here is the reconciliation of problem list and medication allergies. Our discussion noted a number of problems with data integrity, validity, and reliability that need to be resolved in order to be able to do that kind of reconciliation with those data from multiple sources.

And then also the idea – the other example I've got here is the idea that you could require downloading decision support rules from a central repository. We don't know of any cases where that exists and is working that we could look at as a national model. So that is something that also we felt would need more time and more development.

And then the last category that I've got here is one where we found that there were some items that we thought needed to account for different dependencies, or just should be reconsidered or recast as a different kind of approach to achieve the same objective. One of these had to do with filtering data in the patient record to identify candidates for clinical trials. We felt, and we discussed this and talked about the fact that in fact this is a very complex set of filters that would have to be applied, and it ends up applying to very few patients. And it could be in the short term you could really achieve the objective by just requiring a very simple link to ClinicalTrials.gov, and then let the state of the art evolve further before trying to apply those complex filters actually in an EHR system.

And then the other example that I've got here is the device data integration, which John had mentioned earlier in his presentation. I think we expect to have the FDA UDI final rule out – on their calendar I believe it's showing as a May final rule. So within a few months we expect to have a final rule with a set of very important device data requirements that would have to be incorporated, so we didn't want to try to recommend standards for something that would have to be redone almost immediately. So the dependency on the UDI we thought needed to be accounted for, and that after we get that final rule, we can understand how better to integrate that set of device information requirements with the requirements for EHR standards and certification. So that's my summary of all our different range of responses.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Let me, as party to this discussion, I would just add overall, I think the themes of our discussion were – well, I've received several emails from folks like Arien and some of you, that there were some things on the Policy Committee's roster that represent technologies unlikely to be available in the timeframe of meaningful use stage three, and so I think Jamie has outlined this very well, that it's not that they're – I mean, they're fabulous ideas, but there's an implementation reality that says, oh, we are going to require this, but no standard exists, or the standard if it does exist is so embryonic that there's not ever been an implementation guide, any successful example of it. So, you know, we didn't want to, in all the comments that you'll see in the detail, be, you know, the naysayers raining on the parade. We just wanted to suggest maybe you're going to have to push some of this thing off to a stage four or a future stage and allow such things as, oh, well, FDA has to get the UDI work out, and that is a foundation for then moving forward with devices.

Well, Jamie, we have also exceeded the expectations on the clock here, so this is a good outcome measure. So Dixie, back to you for NwHIN Power Team.

Dixie Baker – Martin, Blanck, and Associates
Okay. Again, I have one slide here.

[Laughter]

[Crosstalk]

Dixie Baker – Martin, Blanck, and Associates
Okay. The first one has to do with a query of a central repository for clinical decision support rules. It's – it was unclear to us how the business model would actually work for this. They suggested a central repository for decision support rules, but we didn't know of any that existed, and it wasn't really clear what they were suggesting. So it's clear that there – a business model needs to be defined, but we think the EHR vendors are likely to welcome the availability of repositories that they can draw standard CDS rules from.

We think – the standards for CDS data are more mature than standards for the business logic or the decision support rules. So we recommend further definition of the business model for the repositories, and standards for CDS data, but then to defer standards for the business – for the logic – business logic to the CDS rules.

Second, there is a – there's a proposed complete process for doing query – oh, no, the second one was query for clinical trials. Arien suggested here, and I thought it was a pretty insightful observation, that for stage two, there's a requirement for the Infobutton standard to look up, you know, related information about – to assist in involving the consumer, actually. And we think that that Infobutton standard, and perhaps even certification criterion associated with it, should support query for relevant clinical trials as well. So our recommendation is to review the criterion and the associated test scripts to make sure that they're sufficient and appropriate, they have the right data elements in them, to support query for relevant clinical trials. And we suggested that ONC perhaps work with CDISC to do that.

The third one, bullet, has to do with the query for outside – of an outside entity for patient information. And the specific question that we were asked is – relates to the patient identity standards, and I think everybody on this committee knows that the lack of a reliable patient identifier is a huge challenge to care quality. So we wanted to reiterate that.

The proposed measure is step by step prescription about how you do an external query for a specific patient's information, and we felt that the measure should not be that prescriptive. It should rather say, this is what needs to be done, but not say exactly how it needs to be done.

The – there are a number of efforts already working on what some refer to as directed query, where – analogous to the DIRECT protocol, where you know exactly the name of the patient whose information you're looking for, and you're querying for that patient's information. So we suggested that ONC support the development of these effort – support these efforts, and also support the development of new models of using voluntary and other identifiers and authentication methods. And this question was asked of the privacy and security workgroup, and they agreed with this recommendation.

Then the last one I have here had to do with switching between EHRs. And at first, I for one thought it meant, well, how do go about changing from one EHR to the other, but we sort of narrowed it down to how you – how you migrate data from one EHR to another EHR, and we suggested that it really focus on migrating the data and not migrating everything between the EHRs.

We suggested creating a new standard CCDA template for data export. There's already a requirement for data export for – to support transitions of care, and we suggested that it build on that CCDA standard and add other elements as necessary. And Nancy Orvis brought up that Canada Infoway and the National Health System in the UK both are working on developing standards for transferring records, the Infoway with respect to transfer between provinces, and NHS with respect to transfer between providers, and that these may be helpful in developing this kind of a standard.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
And we did make some comment in the clinical operations workgroup on the appropriateness of consolidated CDA for that purpose, so certainly when we get to the discussion phase, Jamie may have some comments there. Okay. See, MacKenzie, we should have only offered these people six minutes. You know, they're exceeding expectations. Okay. And then lastly, we have the implementation workgroup.

Elizabeth Johnson – Tenet Healthcare Corporation
Thank you. This is Liz. What we did is we provided very clear comments on each one of the questions as asked, and those are in the grid. But we wanted to bring back to the Standards Committee and then to the Policy Committee some overlying guiding principles about the way this should move forward, and that's what we've illuminated in the slide.

First of all, we really would like to see an assurance that the plan recognizes realistic timelines for new and modified measures. So we've had this discussion on other occasions, and we recognize that the timeline that we're talking about here is from the time a measure is actually approved and goes into the Federal Register, we have to have vendors that then create software, modify it, get certification. We have to see an implementation inside of the provider environment. And then we actually have to collect data and submit for attestation.

So we are asking that, you know, as we've talked about in the past, there's some timeline between 18 and – 18 months and 36 months that that whole process takes place in, and we need to continue to put that on the forefront as we put these measures out there in the timelines. Can we make it work in a real – in a real world?

The second thing is the concept that we need to – and we've talked about it many times, the balance between ambition for change and the ability of the industry to execute. There is absolutely in our workgroup, and we believe in this committee, a clear desire to move forward and to continue to improve care, and we believe this has been a monumental way of getting that to happen. But we get very enthusiastic in our suggestions for new measures and new opportunities, and if we lose our way in terms of being able to execute, we won't achieve the ultimate goal.

And then we need to really look at, as we propose expansions or additions, that we're aligning them with a workflow of the clinicians, the physicians, other clinicians, and that we are ensuring that we're using their time and resources appropriately in conjunction with the EHR functionality. We've had some very telling conversations in this room and in other rooms about the fact that we've created new templates and new flow charts and so on to capture a piece of data simply for the purposes of reporting, not to improve care. And so if we take into consideration the way a clinician executes their workflow, and we capture the data as a byproduct of that workflow, then we'll have a significantly improved care process while collecting data to help us improve the care process for the future.

We really want to continue to encourage and allow innovation by recognizing standards and state of the industry are just good enough to get started. In other words, we've heard often innovation is the way to the future. If we don't wait for perfection, but instead get started, we will see progress faster. So we need to always keep in mind, innovation is critical to our success, and we need to provide the support for that in terms of our ability to recognize good is good enough, and it's a challenge that we'll always face.

More of – a little more specifically, and we had lots of conversations, and I always have to say to my workgroup – Chris and I's workgroup, I thank you. I mean, three, four hours every week was spent on this, and it was remarkable, the amount of dedication to the process.

But one of the concepts that came up that I thought was very intriguing was that summary reports are often enough to give us the important clinical information that we need, and that sometimes requiring original data or the image is more than we need. And we have a number of physicians that would speak out and say image is not diagnostic quality to start with, and we really do look at the report. It's not that we're objecting to the image being available, but the recognition or the slowing down of having the report available is important.

It's equally as important to understand that patients want the image, and we're perfectly in favor of that, recognizing their ability to interpret the image is a ability that will have to be worked upon, and we'll have to give them resources for interpretative purposes. So we want them to have it, but we need to recognize what we're actually giving them.

Again, we want to talk about keeping current provider workflow in mind when existing – when raising existing thresholds. We need to think about going toward the goal, and not discourage with unrealistic expectations. One of the comments specifically that came up here is if you are moving an item from menu to core, is it necessary to also raise the threshold? There may be people that have done the – have never done the menu item, and now you're taking it to core and you're raising the threshold. So again, the pragmatic side of what do we really want to do with this going forward?

And then finally, from a comment perspective, we wanted to point out that at this point in – as we're commenting on stage three requirements, we really don't have any idea how people are going to react and comply with stage two. So we want to keep in mind that we want to maintain vigilance on that stage two compliance, and then decide is it the right time to raise the threshold, add a new – and it's a timing issue. It's a very sensitive timing issue. But many of us are already preparing for stage two, so I think we can add some color and knowledge to that so we can make better decisions in the future.

So those would be the comments from the implementation workgroup.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
And of course, Arien Malec did email the two of you and me and Wes, and emphasized two themes I think you've captured well, but one is we all think meaningful use is wonderful. It's just the collective burden of ICD10, meaningful use, value-based purchasing, affordable care, all simultaneously, will get to the point where a doctor can see one patient a day. You know, so, hmm, we do need to reflect on the collective weight of everything we're trying to ask.

And the second, and you've said this, but the cycle time to get this done is much more than creating software, certifying software, installing software. It's culture change. It's workflow change. So what Arien said I thought was fairly thoughtful, was you really need about three years from the point at which your regulation is finalized to the point at which you're really held accountable for doing it, which means stage one is 2011 through '14, stage two is '14 through '17, stage three is '17 through '20, because at that point, and I know Farzad may not want to hear that, I mean, basically what you've done is balanced a set of behavioral changes and technological vendor realities such that you can get the gains you want, and there's time enough to consolidate those gains.

So in a sense, what Arien concluded was similar to what we discussed in the past, that maybe stage three should be more like a half step, you know, that is, move us forward, but do it in a way that allows us to consolidate our gains. So _____.

Jonathan Perlin – Hospital Corporation of America
Well, thanks for the comment. And I just might add a point. There's – in all of my past environments, there is Perlin's rule, which was that you can't hang the ornaments until you have the Christmas tree. And the point of this is is that we've been talking about this, and really, I just want to offer this comment before I turn back to John and get into our general conversation, is that I think the standards are so critically important in terms of this development iteration cycle. If you have a set of standards that supports a purpose, and then you move to a different set of standards for a related purpose in the next iteration, there's a lot of churn.

If, on the other hand, we can work with the Policy Committee aspirations and build – inform the use of standards that allow expanding functionality, and there's something that's durable and logical for all involved, then that's really where my enthusiasm rests in this process. How do we inform the aspirations with standards, present, near available, aspirational, that allow functionality now and expand the capacity of the data model over time? And look forward to how we inform that.

So John, let me turn back to you. I want to thank all the presenters, and more importantly, we are very sensitive to knowing how much time and how much conversation between meetings went into these very succinct presentations, and thank you.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Well, I am hopeful you all kept notes of your questions. So why don't we start and cycle back with the clinical quality workgroup, and any comments or feedback on their individual recommendations? Wes, I see your card is up. Wes?

Wes Rishel – Gartner, Inc.
Yeah. This is a little – a little ill-focused, but it comes up here and in a comment I'm going to make on the implementation comments, too. But what – when do we think that market conditions are driving the need for quality measures more than meaningful use? That is to say, we have been – we have been in an environment where we're trying to get people to do what they ought to do when it wasn't necessarily in their short-term interest to do it, and meaningful use has been a particularly effective way of doing that.

At some point, however, if we are continuing to push that wheelbarrow, and people are trying to run alongside with other wheelbarrows, we're actually in the way. And I'm not saying we're there yet, but I'm saying particular emphasis on methods for creating and local quality measures ensuring them in some kind of a collaborative framework are probably as important as specific clinical quality measures. And so that was just a little pushback on the way that was phrased in your report. Thanks.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Great.

Wes Rishel – Gartner, Inc.
I'll be back.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Well, ___ to comment on that, 60 percent of Beth Israel Deaconess patients are in global capitated risk plans, and so of course we are a binary ACO, but we also have the Blue Cross Alternative Quality Contract. Our reimbursement is not based so much on diagnosis procedure codes. It's based on quality measures. It's based on process and outcomes. So in fact, we are being driven to do exactly what you say, which is, you know, you look at the ever-growing list of quality measures that every government agency seems to want of us. It's dizzying. But if there are those that are necess – that are absolutely part of the revenue cycle and part of our successful contracting, those tend to get a fair amount of attention.

So yeah, I think we've had the discussion multiple times today about push versus pull, and as the industry says, oh, new reimbursement models are going to force us to measure quality in ways that is going to impact patient care and our revenue cycle depends on it, we'll get adoption faster than just meaningful use stage three, here's 100 you have to do. David?

David McCallie, Jr. – Cerner Corporation
Yes. David McCallie. Jim, you – Jim Walker coined the term – phrase – I think it was your – you originated it, of evidence-based document. Can I give you credit for that properly? Because if you didn't, I've been giving it to you anyway. But, you know, I think that, you know, one of the things around the quality measures and anything else where you need a bit of structured data to drive that measure, if we could begin to see the shift away from documentation for the purposes of justifying the ENM code towards documentation to justify the reportable quality measures, that that would be an incredible transition and advance, because as it is now, we structure a ton of stuff to determine how much you should get paid for the visit, but the structured data is more or less thrown away, and we may have to go back and re-ask questions that are relevant to quality, but which had nothing to do with the ENM efforts, so we didn't ask them as part of the ENM structured conversation.

So I think we have a radical shift in the way we capture clinical information. I know that's one of these S&I upcoming workgroups. If we – maybe that's the right place to have this – to explore this conversation. But to Wes's point, you know, people will capture things that matter. Let's make sure we structure the things that matter so that they're captured easily. Anyway, just to be ____ –

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
And ___ ___ highlighted in our work plan that for new reimbursement methods, we are going to need new mechanisms of structured data capture, and whether those are computer assisted coding that takes that structured data and puts it into structure – whatever it is, it is no longer going to be possible to simply write a litany of unstructured notes and somehow be able to justify the quality measure numerators and denominators. Very challenging.

David McCallie, Jr. – Cerner Corporation
Nor will it be possible to have 100 structured fields that are relevant to somebody, and have that be the note, and no narrative. I mean, there's tension between losing the narrative, which is turning out to be more and more important in causing downstream qualities of care, because you lose the story in the – in the forest of structured data elements that need to be captured. So it has to be data that matters, that's structured. The rest of it is narrative that needs to be carried along.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Right. And this is a hard body of problems that I've been trying to work through it myself for our own ACO activities and ICD10 activities, etcetera. And what I use as a – a unstructured data set, and it's – if any of you would like to parse it, it's okay, my wife has given permission, is my wife's entire cancer treatment record from start to remission, which contains this vast array of complex, unstructured terms from oncologists and radiation therapists and surgeons, etcetera. And so we have run it through several engines to say, turn this unstructured mess into a set of structured data elements for quality measurement.

And here's the problem. One of her physicians wrote, she has had no experience of hot flashes post her chemotherapy induced menopause. And of course, what comes out in the quality measure is hot flashes. Well, because no experience of, well, it's not exactly negated as doesn't exist. You know, so – but then do you require every physician to, for that particular example, have a structured data element? They'll never get through a single note.

David McCallie, Jr. – Cerner Corporation
Right.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Yeah. Liz?

Elizabeth Johnson – Tenet Healthcare Corporation
So two other words of caution. As a consumer, when I go in to see the doctor, if they can name that tune in two notes and tell me what I've got, I want them to name that tune in two notes so I can spend the rest of my time having a discussion and narrative. So I think we have to also be mindful of what the patient wants when they see the physician, and allow for time for discussion.

And I would also suggest that narrative is how we live, and clinical competence is often reflected in the narrative and nuance. So we can't structure the nuance, the storytelling, the rich experience, out of the clinical encounter for the sake of data collection. So this is a very tough thing, but keeping in mind that the records are not only to reflect quality and to document an encounter. They will become the narrative of care that a patient sees. And in fact, that quality event narrative might contribute to the most to that patient's ability to understand, comprehend, and adhere to care plans.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
And so Jim and I know this from the study that we did over the last two years with sharing the narrative with the patients that it's fascinating. If you gave the patients a bunch of structured data, you know, that's not going to tell a story. It's not going to give them that subtlety of what the clinician was thinking. So one of the things we all have to be careful of, because many of our groups have pushed back a little on these meaningful use stage three measures, is there are different users with different value cases for every one of the things that's suggested. And by solving one problem we create another.

Okay. Well, that's quality. Where there any other comments on quality before we move on to – yes? Go ahead.

Christopher Ross – Mayo Clinic
Just quickly on the evidence-based documentation, both are critical, and we've got to remember that a patient comes in with new back pain, there are 16 questions that are incredibly reliable for distinguishing whether if they don't get emergency XRT, x-ray therapy, they'll spend the rest of their life in bed, and a patient who doesn't need any radiology exams and the attendant risks, but to go about their life as they're able to.

So, you know, those 16 questions we need to capture 100 percent of the time when someone comes in with new low back pain, at the same time that we need to capture the narrative because of its incredible power in informing care. So it's – it's both.

[Crosstalk]

Christopher Ross – Mayo Clinic
And that's the evidence, is what contributes? So we don't ask – the ideal would be we don't ask a single question that doesn't contribute to the patient's care, and we never fail to ask the very few questions, as it turns out, that actually do inform a patient's care.

The other thing I just wanted to raise that sort of cuts across all of these, but ours, too, I think we are clearly in a world where there are haves and have nots, and I think it's a different group than we have identified before, in terms of clinicians and the patients whose care teams they are. There are two kinds. One works in a work system where as we create new requirements of documentation or reporting or whatever it is, the organization is robust enough and committed enough that it will hide all of that from the clinicians and the patient. It will absorb the turbulences. It will create and test processes that actually work. It will figure out ways to capture the information in ways that are maximally cost effective and usually acceptable to patients and clinicians.

And that group, all we can do is increase their cost of doing business. Okay? But the other group, and it's a very large group of patients cared for by a very large group of clinicians, are not in that kind of robust work system. And it's them that we risk knocking out of the box, of making their work unpleasant and then unfeasible. And so I think – and part of the problem, of course, is that everybody around the table is from one of those types of organizations, and so we really need to be very careful, I think, because we could be coming to a cliff where the people with not very robust work systems have sort of kept up. You can – you can pedal faster. You can grit your teeth and document more stuff. But we could run into a situation where we have exhausted their reserves and things really turn nasty.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Thank you. And John Derr?

John Derr – Golden Living, LLC
Just a slight comment to probably add another problem area, and that's the language barriers that a lot of our physicians ____ that have different ways of expressing and different language – come from different social backgrounds. And I know sometimes when I've gone in to my cardiologist, I can't understand him and how he uses the terminology. So I think that's another thing, when we get to the consumer, how we bridge that language type of ____, pidgin English.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
There we go. Good. Well, let's move on then to comments and questions on the privacy and security workgroup. Was the font too small?

[Laughter]

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
No comments? No questions? Directory standards, safety risk assessment?

[Background voices]

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Yes, sir. Chris?

Christopher Ross – Mayo Clinic
Never mind. It's –

[Laughter]

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Yes. Please go ahead.

Elizabeth Johnson – Tenet Healthcare Corporation
Dixie, on the – this is Liz speaking. On the health risk assessment that we talked about, in other groups that I engaged in to create comments, there was a lot of – no one objected to it, except for is there a standard, is there – the worry again was more work to be done related to an MU standard and what was the value to it. So do you believe there is already something out there that we could promulgate as a way of doing the assessment, or what are you thinking?

Dixie Baker – Martin, Blanck, and Associates
Actually, I know quite a bit about this area, because I used to do software safety assessments in my previous lifetime. And the methods – the formal methods that are used for safety assessments are like reverse Petri net analysis and fault tree analysis, are generally geared toward software controls, controls or hardware, right?

Elizabeth Johnson – Tenet Healthcare Corporation
Okay.

Dixie Baker – Martin, Blanck, and Associates
They're not geared for this type of – they're talking about information systems, I believe, which is more akin to the methods we use for security assessment, except you're not just restricted to protected health information, right? You're looking at all kinds of information.

But actually, in reporting it to you guys today, it occurred to me that I think my workgroup and I all assumed that we would be looking at, you know, information I don't even think we talked about, like software safety analysis, which is another where you look at the executable code, that you could actually be doing it there, too.

So there are methods for software safety analysis. There are methods for security risk assessment, which is what they reference, right? And it's really not clear exactly what they're talking about. So maybe our recommendation to have a general requirement to do safety assessment might be a good place to start, and then let the methods evolve over time.

Elizabeth Johnson – Tenet Healthcare Corporation
Rather than trying to get a clearer definition at this point? Is that what you're saying? Because that's our challenge. In trying to respond, it was what are you asking us to do absolutely, so then we can respond to you absolutely.

Dixie Baker – Martin, Blanck, and Associates
Oh, now I think they do have to define what they're talking about. Whether they're talking about a safety risk assessment that's analogous to a security risk assessment –

Elizabeth Johnson – Tenet Healthcare Corporation
Right.

Dixie Baker – Martin, Blanck, and Associates
– or whether they really are talking about software safety assessment, which is really a different discipline.

Elizabeth Johnson – Tenet Healthcare Corporation
Very different. Okay.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
And so an analogy for you, Leon Rodriguez of course oversees the Office of Civil Rights, as its director. He's the HIPAA enforcer for the country. And we had the opportunity recently to do back to back keynotes in Washington and Boston and exchange some ideas. What Leon will tell us that in effect OCR is looking at maturity of organization security programs as opposed to their effectiveness. And what I mean by that is as follows.

If you have a breach, does that mean that you are an immature organization? Not necessarily. Right? Maturity is a function of process and policy and documentation and all – yeah, culture, etcetera. And so in fact, the most mature organization could still have a breach. And so what OCR is doing is actually trying to measure process maturity, documentation, these sorts of things, as they do audits. And KPMG was hired to do 160 audits, and they found, well, it may very well be that, hey, hospitals put up firewalls and intrusion detection and encrypted their mobile devices, but they didn't have policies, procedures, guidelines, directives, culture, and all the rest, so they would be immature.

So I just use that analogy here because what does, you know, safety mean exactly? Does it mean that your software was developed of ISO9001 criteria, and it's just absolutely, you know, wonderful quality, or that you've developed culture, process, procedures, supporting mechanisms, review mechanisms? They may be different.

Elizabeth Johnson – Tenet Healthcare Corporation
Yeah.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
So I think your point basically on the safety risk assessment is we have two choices: go back to the Policy Committee, what do you mean?

[Crosstalk]

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Or start with the general and let the specific evolve.

Elizabeth Johnson – Tenet Healthcare Corporation
Yeah.

Dixie Baker – Martin, Blanck, and Associates
But I think a good place to start would be to look at safety critical data that you have in your system, because it is very analogous to a security risk assessment.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Very good. Well, Jamie – oh, we have two others that popped up. Yes, David?

David McCallie, Jr. – Cerner Corporation
This is David. One comment on the safety thing. You know, there are a number of conversations underway outside this group in response to the IOM report on safety of EHR systems, and then of course ONC's response to the IOM report. And one of the things that seems to be consistent in the groups that I've been involved in that are discussing this is the notion that we should – we should come up with ways to identify the highest risk software, and focus on those high risk components. And we have a device manufacturing strategy that segregates devices by their risk. We could probably do something similar to that with respect to software.

So it may well be that the targets should be identified through a process that says, these are the highest risk components in an EHR system, or a complex of applications that together perform EHR functionalities, and put the energy in focusing on those highest risk ones first. Because, you know, theoretically, any mistake anywhere could lead to some harm, but most of the mistakes are really low priority, low risk, and unlikely to lead to harm. But in some cases, you know good and well that it's going to be very high risk if something goes wrong. So stratify the effort around the highest risk.

Dixie Baker – Martin, Blanck, and Associates
Well, that – what you just described does have standards around it, because the aerospace industry and the energy industry have been doing that for decades.

David McCallie, Jr. – Cerner Corporation
Yeah. It's just –

Dixie Baker – Martin, Blanck, and Associates
So it does have formal methods.

David McCallie, Jr. – Cerner Corporation
It does. It's just we have to translate that to software systems in hospitals, because it's not quite obvious how you map those over.

Dixie Baker – Martin, Blanck, and Associates
Right.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Dixie, if you look at NIST 856 or NIST 853, I mean, do you see those as the kind of things that would be helpful – well, it's the –

[Crosstalk]

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Exactly.

Dixie Baker – Martin, Blanck, and Associates
Oh, okay. ____ –

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Come on. You live this stuff every day.

Dixie Baker – Martin, Blanck, and Associates
That's security risk assessment, right? So defining the critical elements, you have – HIPAA requires you define the most – the most security critical elements. You do have to do the same kind of thing for safety critical elements. But beyond that, there's different methods.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Well, let us move on. Jamie, clinical operations. So again, the sort of general tone of the group was there were many things we agreed with, but other things that we felt were immature, and that were wonderful aspirational goals, but probably will take a couple of years of foundation building. Got to buy the Christmas tree. So David?

David McCallie, Jr. – Cerner Corporation
Yeah. First – or just – I'll just drill into one specific thing, which is around the clinical decision support. I was glad to see that Jamie's group reached the same conclusion that the NwHIN Power Team group did on that requirement. But I want to stress that I think there is low-hanging fruit in some standardization around clinical decision support. Dixie referred to it as data. I would – I might call it content.

So for example, order sets, you know, there are many different vendors of order sets, all of whom use different XML standards to encode their order sets, and the vendors have to write data import tools for each of those vendors of order sets. That's an area that is obviously ripe for some standardization that I think would be welcomed by all parties, as opposed to the logic that would affect workflow of clinicians as they move through a patient case, which is much, much, much harder to standardize, because the vendors take different approaches, and are in fact still experimenting with the best approach to optimizing workflow around clinical decision support. It's – the era of pop-up alerts is hopefully waning, and we're going to do better jobs in that.

So it would be silly to go codify standards to enable more pop-up alerts, which is kind of what they did. So there's a baby in there with the bathwater. We just have to toss – get the baby.

James Ferguson – Kaiser Permanente, Institute for Health Policy
Yeah. So if I could just respond to that. So David, thank you. I think, you know, we agree, but we didn't see that as being uniquely really in the decision support arena. I think that the – there's no – absolutely no disagreement, there's low hanging fruit in terms of the potential for orders as part of content to be developed. But our focus really was on the aspect of the proposal that talked about the representation and integration of consistent rules across disparate systems, as well as requiring the application of those rules in a consistent way. And so that's really essentially what we were objecting to, but no disagreement, the content can – development can continue.

David McCallie, Jr. – Cerner Corporation
This is David again. I totally agree about the rules. That was our response as – in our workgroup, as well as our corporate response, that that's not ready for primetime.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay. John Derr?

John Derr – Golden Living, LLC
This is John Derr. I wanted to comment, Jamie, on – in your first point there on the formulary transmission can use existing NCPDP standards for formulary and benefits, that it's really the standard is a representative formulary that's in the EHR, and this causes the provider, who doesn't have the specific patient's formulary and benefits, to use e-prescribing, and leads to a lot of – as a pharmacist myself, to a lot of phone calls to find out exactly what that person's benefits and formulary is. And I would encourage maybe that we take a look at that, and just don't bless the pure thing, but say we need to get the person-centric formulary and benefits down to the provider, and not just a generic.

James Ferguson – Kaiser Permanente, Institute for Health Policy
Yeah. So just to clarify, because this summary doesn't express really our full comment on it, we did not address individual level formularies. What we did say essentially is that the current crop of NCPDP standards actually are used for payers – between payers and providers today, and can be used for that purpose, but at the same time, because of the need to allow for variation in generic substitution and other substitutions, that strict adherence to any transmitted formulary like that is not recommended.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Right. And so as an example, you may give doctors latitude to choose generic equivalents that are appropriate to the patient, that are effective and all the rest, but they may not be on formulary.

John Derr – Golden Living, LLC
Right.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
And so what – as Jamie just said, we recognize there's a problem in the country today, and that is everyone who implements e-prescribing in their EHR may very well get formularies from various parties in different formats. There's value in standardizing the format. But then the workflow may require some latitude as you get personalized to an individual patient's prescription.

John Derr – Golden Living, LLC
Okay.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Other comments? I see Leslie Kelly Hall.

Leslie Kelly Hall – Healthwise
So I just wanted to say thank you, Jamie. Great work. And we agree that – much discussions happened, both in the Policy Committee and patient engagement and elsewhere, around the demographic data collection not being dropped, because as we start to look at patient-generated health information, new psychosocial kinds of information being added, being done in a structured way can actually enhance this idea of an overall patient context with which all of us can address. So I think that's great work, and thank you for that recommendation.

And then also with regard to formulary, if we think of these things as just another expert system, a source outside of the EHR, rather than prescribing always that something come into the EHR, we can actually foster more innovation and available systems outside. So I just would encourage us to look at things like formulary and drug-drug interaction checks and other things and ways that a standard to approach expert external systems retrieves what's been selected in the EHR, but not mandate that the EHR be the bucket of all knowledge. So that's my comment.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Great. And Liz Johnson?

Elizabeth Johnson – Tenet Healthcare Corporation
Thank you. Jamie, on the – for the implementation workgroup, on the demographic section, I wondered if y'all have had a chance to talk about either sexual orientation and the ability to codify that and how that would be managed, and disability status? We had lengthy conversations around what constitutes disability status, what's – do we have – it doesn't call for it here, but it might be critical, when did disability status get assigned? We've listed, and you can see them in the grid, a whole host of questions. I wondered if the clinical operations group had had a chance to talk about that.

James Ferguson – Kaiser Permanente, Institute for Health Policy
So actually, yes. Thank you, Liz. That is another thing we did talk about. It is actually part of our comment, but it's not represented on the high level summary. We ended up deciding to recommend that the sensitive data for sexual orientation and disability status should not be part of the – of the requirement. So we recommended that those items should be omitted. We had talked about the lack of standards available for sexual orientation, and, you know, generally, a desire to omit some of the sensitive data categories from this kind of broad collection. So that was our recommendation.

Elizabeth Johnson – Tenet Healthcare Corporation
So Jamie, is there an opportunity – because I think all of us recognize, particularly on the patient care side, that those are – that's information we need to care for our patients. So it is something that we want to consider as a standards group saying, maybe that's for a later stage? It's not that we disagree with the concept? Or do you think the sensitivity is great enough it shouldn't be – we shouldn't even go there?

James Ferguson – Kaiser Permanente, Institute for Health Policy
Well, certainly on the sexual orientation, if the – if it's desired to standardize that terminology, then some standards work is required that likely would go beyond the initial cutoffs for meaningful use stage three standards. And then – but I – you know, I really think it's more of a policy question on the inclusion of sensitive data, but since it was posed to us, our workgroup felt that it should – that the sensitive data in both those areas should be omitted from the broad collection, which would indicate that it would typically be available to a – you know, to everybody, so –

Elizabeth Johnson – Tenet Healthcare Corporation
Okay.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
So as Jamie just said, we didn't attempt to rule on the politics or policy. What we simply said was the metadata doesn't exist, and the standards don't exist, so requiring this at this time seems premature.

Elizabeth Johnson – Tenet Healthcare Corporation
And then what we did was – and I think we added to your thought process in just saying, if we're going to do it, here's all the questions we can't answer.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Right.

Elizabeth Johnson – Tenet Healthcare Corporation
Yeah.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Now Clem McDonald did have an interesting point I just want to share with all of you, and that is, he said, if you decide everyone's achieved demographics, let's retire, suddenly what you're going to do is create a situation where everyone runs the marathon, and one foot from the finish line you'll say, never mind. That is, wouldn't it be better if you somehow kept a few of those in there so that you reward people for the hard work they've done?

[Crosstalk]

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
And so we thought demographics was both important enough to retain for the reasons you suggested, and because we wanted to recognize the hard work everyone's put in, that we would save that one. We didn't necessarily decide to save every one of them that had hit this threshold.

Elizabeth Johnson – Tenet Healthcare Corporation
Yeah. That's interesting, John, because we weren't as concerned about getting – having them leave the meaningful use measure, because we all collect them and use them every day. So it's interesting to hear your perspective. It's accurate. But our sense of not – of retiring had nothing to do with the lack of value.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Right.

Elizabeth Johnson – Tenet Healthcare Corporation
It had to do with more work for people to continue to collect information that we'd get. But I think your points are well-taken.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Great. Thanks. Now any other comments on clinical operations? Okay. Well, Dixie, we've come back to you for the NwHIN Power Team comments. Any comments there? See, Dixie, you always present so well that no one ever has any burning questions for you.

[Crosstalk]

[Laughter]

James Ferguson – Kaiser Permanente, Institute for Health Policy
Well, so this is Jamie. I guess my card is up on this one.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay, Jamie. Go ahead.

James Ferguson – Kaiser Permanente, Institute for Health Policy
All right. So I did want to come back, Dixie, to your last bullet on the use of the CCDA. I think, you know, and we did discuss this in our group. I think there's strong recognition and agreement that standards for representation and transmission of longitudinal record information is important, needs to be developed, and can be included in future stages of meaningful use.

At the same time, we felt strongly that the existing CCDA and CDA template standards are snapshots that are inappropriate for that purpose. And so I think sort of the analogy is, you know, if you have a hammer, every problems looks like a nail. Or a different – a different analogy is thinking of sort of in San Francisco, we have bicycle messengers, and there – you know, documents still go – legal documents and so forth, back and forth by bicycle messenger. And you can add a basket to the bicycle so it carries more, but there's a point at which that's not the right, you know, mechanism for containing large record sets. And it's just not intended for that purpose.

So we think that it's important to recognize that one tool isn't the right solution for every problem, but that it could be important foundational work for figuring out how to represent longitudinal records, and certainly, you know, multiple snapshots without any changes to the standard, multiple snapshots can be used to export information from one system and import it to another, that actually doesn't require any change to the standard, but that's also not building a patient record in another system, and don't – so don't pretend that it is.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay. And so I think , Dixie, in the comments that I made early on with our work plan, there is absolute concurrence, there needs to be work on a standard for longitudinal medical record representation, bulk extract representation. It remains to be determined if the CCDA is helpful in that body of work. And Jamie documented a comment suggesting that maybe CCDA is the bicycle messenger you probably don't want to overload, when in fact what you need is a Fedex truck. So I think your comment is correct. It's just the CCDA template piece that Jamie might disagree with. Other comments?

Dixie Baker – Martin, Blanck, and Associates
So I guess – and this is a question about what happens next. Before we send – I assume this committee's going to send our recommendations over to the Policy Committee, so should we – are we go to back and – am I to go back and edit our – you know, our response? How does that –

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Well, so MacKenzie, here's a question for you. There's two bodies of work. It's very, very – I mean, I look at all the comments that everyone made. They're almost all internally consistent. It is rare that you would say go left and we would say go right or whatever. But if there are subtleties, like, oh, all ____ we've asked ___ say create an appropriate standard, as opposed to create an appropriate standard as opposed to –

Dixie Baker – Martin, Blanck, and Associates
Yes.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
– CCDA template, you know –

[Crosstalk]

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
– Dixie makes that edit. But also, there are elements in the entire RFC that were assigned to HITSC that haven't actually had complete comments from anybody yet. So any thoughts on either of those points?

MacKenzie Robertson – Office of the National Coordinator
So I would say at this point if we want to talk about any other items that were specifically assigned to the committee, we could do that now. I think in terms of – the plan was to have the combined RFC document with everyone's input by item sent over to the Policy Committee, so in their workgroups they could actually refer to it, because I know at the workgroup level, each of the Policy Committee workgroups do refer back to this item by item, and looks at the input. So I think this will be a really helpful document for them to refer to. So I do think we should transfer over the full RFC with all the workgroup comments included. But if there's anything that we want to add from this discussion, you can send that to me, and I'll incorporate that.

And then at the next Policy Committee meeting, John is going to present just the overarching themes that he heard here and the discussion that he heard here to the Policy Committee in person.

Dixie Baker – Martin, Blanck, and Associates
Right. I think Jamie made a really good point. So it's easy for us to incorporate that into our response, given what David has to say.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Yeah. So I agree with – certainly with Jamie's point. This is on the export format, that the CCDA as it exists today is an inadequate template. I think our suggestion was to expand that template as necessary, to build on it, so that you could capture longitudinal records –

Dixie Baker – Martin, Blanck, and Associates
But he's saying it's not even appropriate to build on.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Well, and that's – so that is my question to Jamie, is are you saying that it – it's a bad starting point, in which case you just make the problem a lot harder for the vendors who put a lot of energy into building CCDA export and import tools. Now if it's just not the right starting point, then we have to start over, but that just makes the problem a lot harder.

What we were hoping for is – and I don't think our committee had done any deep research on this. We'll be quick to tell you that these are fairly superficial opinions. But that if we could leverage the work done by the vendor community in CDA template-based exports, that might be the way to go for a bulk export. No one really cares how big the file is. It's going to be computer processed. So –

James Ferguson – Kaiser Permanente, Institute for Health Policy
So, I mean, I think the gist of our discussion was it is a good starting point, but it also requires some fundamental rethinking to move from a – an episodic care snapshot to a longitudinal record that – so you certainly could start with – I mean, even today, without any changes to the standard, you can have multiple snapshots for bulk export and import. And that's a perfectly good starting point. Our point is just that more rethinking is needed, so that you don't end up with one, you know, sort of Swiss Army knife tool that absolutely does everything for every possible purpose, and that while that is a good starting point, other substantial changes may be required. I think we don't know.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Yeah. And I'm comfortable with that. I think our group would be very consistent with that.

Dixie Baker – Martin, Blanck, and Associates
Yeah. We would be –

[Crosstalk]

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Thanks.

Dixie Baker – Martin, Blanck, and Associates
Yes.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Now we'll of course move on to the implementation workgroup in just a second, but since of course MacKenzie wants me to present the entire collective comments on this entire, you know, 35 page document, Jamie, there are just a very, very few SGRPs that the clinical operations workgroup didn't comment on, so for example, record electronic notes in patient records for more than 30 percent of office visits within 4 calendar days.

[Crosstalk]

Elizabeth Johnson – Tenet Healthcare Corporation
Where are you?

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Oh, that's SGRP120. So no one has – so MacKenzie, I'm just looking at where there was no comment from any workgroup? Because obviously I will – if clinical quality made a comment, you know, if clinical operations made a comment, I will leverage those.

Elizabeth Johnson – Tenet Healthcare Corporation
And this is a menu item, correct?

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
So the menu objective, recording notes in patient records and/or at least one electronic progress note.

Elizabeth Johnson – Tenet Healthcare Corporation
Yeah. So the assumption would be it would continue as a menu.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Right.

Elizabeth Johnson – Tenet Healthcare Corporation
You think?

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
So I hear one comment, it continues as a menu item. Sounds okay?

James Walker – Geisinger Health System
Yeah. I believe that would – that the quality workgroup ___ addressed that would agree.

James Ferguson – Kaiser Permanente, Institute for Health Policy
Yeah. I mean, I would agree with that as well.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay. And so MacKenzie, I am just looking through and seeing if there are any other SGRPs that aren't commented on.

[Background voices]

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
They're on the next page, I think. So SGRP – I am on 127, ability to maintain up to date interdisciplinary problem lists inclusive of versioning to support collaborative care. And I think – just looking here, the comments from the implementation workgroup I think referred to the previous ones. So SGRP127, 125, 308, they're all on the same page, and the document doesn't have page numbers on it. So maintaining up to date interdisciplinary problem lists, medication reconciliation to accept data feed from PBM, retrieve external medication refill history.

Elizabeth Johnson – Tenet Healthcare Corporation
One of the things, John, from the implementation workgroup – this is Liz. One of the things we talked about, and I don't know that this is the appropriate tie, but we had some real concerns about fill and dispense information, and where was it coming from, and what did it really tell us? And what I mean by that is that if we collect that data and it goes back to an ___ provider or a hospital, who's going to deal with the data, and does getting your prescription filled mean you did anything with it? Just as sort of food for thought. It wasn't – no one objected to the fact that that would add to the quality of data. It was could we get the data and what would we do with it, which sort of kind of goes back to this filling thing.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Right.

James Ferguson – Kaiser Permanente, Institute for Health Policy
Yeah. So actually, John, I would also say on that particular one that on a different item, where we talked about the external data source reconciliation of problem list and medication allergies, I think it was there that we said that incorporation of external data for fill status from external data sources raised issues of data integrity and validity that needed to be resolved first, before the standards were required. So I think, you know, we could reference that one here as well.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Good. That's very useful input.

Leslie Kelly Hall – Healthwise
John?

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Yes.

Leslie Kelly Hall – Healthwise
The reference to PBM – this is Leslie. The reference to the PBM information, though, I think in the meaningful use workgroup we were discussing that we needed information from – standards from that side of the industry, that we didn't have that embedded in the knowledge of the workgroup. So that was one of the discussion items.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Let's see. I'm looking at 401A, submission of vaccine contraindication and reason for substance refusal to the current objective of successful ongoing immunization data submission. Any comments on – I'm allergic to duck eggs, right? Can't – sorry, can't have a flu vaccine. I'm allergic to duck eggs. Does anyone even know that we have a appropriate set of standards for contraindications, adverse reactions?

[Background voices]

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay. Fine. So you've given me what I need there.

[Laughter]

Elizabeth Johnson – Tenet Healthcare Corporation
John, I don't – you may – because we don't have page numbers, on 204D, which is providing the patients the ability to request an amendment, again, no objection to it, but it's new. And again, do we have the standards to allow an amendment from a patient into our records?

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Right. Okay. You're right. I –

Leslie Kelly Hall – Healthwise
And ____ an addendum versus an amendment.

Elizabeth Johnson – Tenet Healthcare Corporation
An addendum. Correct.

Leslie Kelly Hall – Healthwise
So I think the language is not – I mean, that's what we talked about at one time.

Elizabeth Johnson – Tenet Healthcare Corporation
Right.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Yeah.

Leslie Kelly Hall – Healthwise
Now we have the structure in the – a clinician offering an amendment to a – or addendum to a record today.

Elizabeth Johnson – Tenet Healthcare Corporation
Right.

Leslie Kelly Hall – Healthwise
Just is that applicable for patient-generated data?

Elizabeth Johnson – Tenet Healthcare Corporation
Right. Well, and the thing is that today we accept amendments or addendums to our records – you can bring it into our place of care, whether it's an office or a hospital, and we will add it. This is saying to be able to record this online.

Leslie Kelly Hall – Healthwise
Right.

Elizabeth Johnson – Tenet Healthcare Corporation
Which is a different – it's the same concept, but it's a different mechanism for transmission of information.

Leslie Kelly Hall – Healthwise
Mm-hmm.

Elizabeth Johnson – Tenet Healthcare Corporation
Your ____, John.

[Crosstalk]

Dixie Baker – Martin, Blanck, and Associates
___ ___ last meeting, that we have a standard there for stage two, and they're adding the measure for stage three. I think there's already a stand – I could check it, but I think that that –

[Crosstalk]

Elizabeth Johnson – Tenet Healthcare Corporation
And ___ for an amendment?

Dixie Baker – Martin, Blanck, and Associates
That they – yeah. I think it's there.

Elizabeth Johnson – Tenet Healthcare Corporation
I don't know. I don't remember it. But then when you're looking at one, two, and three simultaneously, occasionally things get blended.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
So there are three related measures to ask you guys about. SGRP404 –

Jonathan Perlin – Hospital Corporation of America
John?

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Yes.

James Walker – Geisinger Health System
I'm sorry. Just a moment. On allergies and contraindications and so forth, to David's point about prioritizing this stuff, if we're going to be serious about patient safety, about patient input, about a whole raft of things, we have got to recommend to whomever that whomever commissions whatever is needed to create a set of standards that captures allergies and contraindications to medication and other substance exposures. That just –

Elizabeth Johnson – Tenet Healthcare Corporation
And can I just –

James Walker – Geisinger Health System
It's almost unbelievable.

Elizabeth Johnson – Tenet Healthcare Corporation
Yeah, it is.

James Walker – Geisinger Health System
That we keep saying we don't have this, and don't do anything about it.

Elizabeth Johnson – Tenet Healthcare Corporation
And Jim, I would add to that – a friendly amendment would be I think it's apparent, but I want it stated. We've got to get to severity, because the challenge is not just capturing the allergy. It's understanding, because we all know we get side effects, and so we don't have to have that whole discussion, but severity is critical.

James Walker – Geisinger Health System
Yeah. I think – let me just add, my PhD is pharmacology, and ___ endorse the general thrust of it, but when you look at improving safety, quality, and value of healthcare, medications are stopped for any number of reasons, and it goes even beyond allergy. I think we would agree clinically that there's a rationale for those things for which there's the physiologic allergy, are in one bucket, where you just don't want to repeat something that's inherently dangerous. On the other hand, there is the social imperative to understand why medication is terminated. The absence of standard vocabulary, value set around this, is problematic.

And it also I think is a case example, an object lesson, in terms of not doing something in the near term that would be replaced subsequently by something else. What we really want to do is support a process where we understand the aspiration of the Policy Committee on this. I want to support the coherent evolution, so that each successive stage builds and expands the capacity.

[Crosstalk]

Dixie Baker – Martin, Blanck, and Associates
So what are we – are we going to make a formal –

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
And so I think the formal recommendation that I'm hearing is that I will tell the Policy Committee, you know, it is a gap, but we actually think it's a gap that needs to be filled. And I actually had many conversations with the Policy Committee in the past about adverse events, contraindications, I mean, there's a difference between allergy and an adverse event or contraindications, and that's where have –

James Walker – Geisinger Health System
This is Jim. I think the operative thing is reasons that a medicine should not – or that a clinician should think very carefully before prescribing a medication. It may be an adverse effect that is not an allergic adverse effect. It may be just that the patient is convinced it's going to kill them. That is a reason not to give a medication. And in clinical practice, while maybe we can distinguish the different buckets, the operative issue is why should I stop and think real carefully before I prescribe this for a patient? And we just have got to get to where we can communicate that.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
So that would be my recommendation. So –

Dixie Baker – Martin, Blanck, and Associates
But that's the recommendation to ONC, though, right? To develop –

[Crosstalk]

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Well, I'm going to be reporting back to the Policy Committee what you guys said. And so at that point, obviously, as we do the work plan, it will reflect in there. But I'm just synthesizing everything you guys say.

James Walker – Geisinger Health System
On 302, clinical ops workgroup said defer this item while also recognizing all the discussion we just had. So are we going to take forward also their recommendation to defer and do this work? I'm looking at SGRP302.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Right. So I would think that what is said is we will not make the excuse that the standard doesn't exist, so we will just give up, that in fact we will work on the standard, and when the standards are ready, then we will move forward with the appropriate menu set of core items.

[Crosstalk]

M
John, ____, right – I'm sorry to interrupt, but right at that point, identifying the use case, the reason specifically is so critical around this one, and I'm beginning to think the things that Jim made, it's not just a standard for communicating it, because on the one hand, we're going to want to be incredibly detailed. On the other hand, we'll want to be able to accommodate the rather unstructured stuff that patients tell us. And without an understanding of why, maybe multiple reasons why, but without that, it can't – we'll go in circles.

[Background voices]

James Walker – Geisinger Health System
This is Jim. Just to be clear, our proposal is not that we try to implement standards that aren't mature, and they aren't, but that we quit using that as the reason we don't do something, and somebody commissions the work that it would take to create standards that we could then test and then start to use.

[Background voices]

[Crosstalk]

Rebecca Kush – Clinical Data Interchange Standards Consortium (CDISC)
____ John has a good point, and that allergies are different than adverse events. But if you look at adverse events and severity, there are standards for those in the clinical research space, quite a few of them, and they've all been harmonized into one model, and I wouldn't start over. I would use those.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Great. Thank you. So then there were a couple – yes.

Elizabeth Johnson – Tenet Healthcare Corporation
When – just while we're doing that, making sure that we're accommodating the patient's voice in there, because I think to Jim's point, if the patient just says, no, that's good enough, and so it could be religious preferences, it could be personal, and so let's make sure we accommodate that.

David McCallie, Jr. – Cerner Corporation
And one more, please, ___ many of the discussions on the HL7 lists where questions have come up about CCDA have been around how to capture some of these subtleties of allergy. And I would hate to, in deference to the fact that we're not solving the full problem, that we don't at least make some progress in the ability to communicate specific, known, even if they're un-described, potential allergies. So I think we still need to nail down something that's stage two, and – or, yeah, stage three, CCDAs, are adherent with, until such time as we have a deeper model. And – because –

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
As you can imagine, a detailed clinical model or an XML example –

[Crosstalk]

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
But we may not have the full vocabulary necessary to control –

David McCallie, Jr. – Cerner Corporation
There are probably 27 ways to use a CDA to communicate an intolerance or an allergy and an associated response to it, but if every vendor just makes something up, we will have done a great disservice, when we are – when we should be able to at least push an RxNorm drug-drug, generic drug, or a drug class, and say, there's something about this that you should think about twice, even if we don't know any other details. Otherwise, we will – we'll be missing a huge opportunity.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
And Stan Huff, I see you've raised your hand.

Stanley Huff – Intermountain Healthcare
Yeah. It's really just to second or, you know, contribute to the discussion. This – while there aren't standards in the sense of, you know, something that's been adopted and widely implemented, there – as Becky has pointed out within clinical trials, as well as within given institutions, there are in fact models in place in practice that, you know, accommodate the use cases. And we're sort of in this discussion recapitulating, you know, what the experts have been doing in this area for the last five years, and that it hasn't come to – you know, to a balloted standard, but it really is known, and I think there are in fact already existing models that incorporate everything that we've talked about. And it's just a matter of bringing that information forward, educating people, and doing it.

But I – yeah, it'd be nice to start simple. In fact, I think we – it will take time to get this to a consolidated approach. But there's a – there are great starting points. We're not starting from scratch.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
We've heard that from Becky as well. Well, the last just couple, and then – because I know we want to both finish up with the implementation workgroup, and maybe we can squeeze in a few minutes of Becky – we'll see, we'll try – and that is participating in mandated and non-mandated registries as a menu set item. Yes?

Rebecca Kush – Clinical Data Interchange Standards Consortium (CDISC)
Do you want comments around that to put into here? Because there are ways to use standards to populate registries, and they were announced at some of the hearings that we had, and retrieve form for data capture is one of them, which is what Doug refers to as structured data capture, and those exist.

[Crosstalk]

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay. These are menu set items.

Elizabeth Johnson – Tenet Healthcare Corporation
Yeah. The only comment I would make, Becky ____, I agree with that, and I think we want to continue that evolution down the road toward progress, recognizing that most often, once a menu item occurs, one stage, the next stage, it becomes core. And where I become concerned was when it says un – it's not required, it's not mandatory, that we – how we would judge in even trying to meet the standard, much less – not from a value set perspective, but actually do a test, if it's not required. You see where I'm going? It's – all those that are mandatory are in the menu. Fine. But those that are not mandatory, if we put or, then I just – I'm concerned, how do you –

[Crosstalk]

Elizabeth Johnson – Tenet Healthcare Corporation
– write certification criteria and get vendors to build a – I'm struggling with it. Because you saw it said both, not one.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Other comments?

[Background voices]

Leslie Kelly Hall – Healthwise
Which one –

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
This is SGRP404, 406, 408. There's a cluster of these, submit to registry a mandated and non-mandated –

Elizabeth Johnson – Tenet Healthcare Corporation
Yeah. The mandated ones are pretty straightforward. It's the non-mandated ones – again, not that we shouldn't participate, but how do you translate that into certification criteria and standards for the future?

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Yep. And obviously, I mean, what a great point. Here's a non-mandated registry that is submitting shoe size to Nike.

Elizabeth Johnson – Tenet Healthcare Corporation
Right.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
What's the standard? How do you test it?

[Crosstalk]

Wes Rishel – Gartner, Inc.
So I would argue that I'm a little less concerned about shoe sizes to Nike than lung disease in West Virginia, but there is a way to give people most of the standard that, you know, if in fact we know that most standards record clinical observations and record certain things – or most registries record those, we can get to the point of saying, here's how to do it. Plug your specific kind of information in here. It may not work for every registry, but it gets us out of the – out of the problem of some programmer in a back room making up a format for a message and a way of sending it that's different for no good reason from one place to the next.

So I think there's a way to in effect create a skeleton submission or something like that that would be very helpful.

Elizabeth Johnson – Tenet Healthcare Corporation
So Wes, here, I'm not objecting to having a standard and doing it right.

Wes Rishel – Gartner, Inc.
Yeah.

Elizabeth Johnson – Tenet Healthcare Corporation
What I'm concerned about is when it's non-mandated, how do we then create the certification criteria and so on for the non-mandated piece?

Wes Rishel – Gartner, Inc.
Well, I would say we – I would say we create a certification – we create a use case, give them the solution, the codes that they need to identify it, and say, submit this to this mythical, you know, testing registry to see –

Elizabeth Johnson – Tenet Healthcare Corporation
And the compliance threshold would be what? Meaning if that's a menu item, how do I put a compliance threshold on the measure for non-mandated?

Wes Rishel – Gartner, Inc.
Now you're asking about compliance rather than certification.

Elizabeth Johnson – Tenet Healthcare Corporation
Correct. _____ –

Wes Rishel – Gartner, Inc.
I would say that someone should only be able to elect a menu item if they really have such a registry to submit to, and then the compliance threshold could be some nominal number, ten percent or something. I mean, you know, but I think you shouldn't be able to say, I choose this menu item, and by the way, I don't have any of those, so I get a waiver, right?

Elizabeth Johnson – Tenet Healthcare Corporation
Sure. Absolutely true. Yeah.

[Crosstalk]

Dixie Baker – Martin, Blanck, and Associates
Yeah. I think we could – we could accommodate this through using the same standard that we used for sending a patient's data to a third party, which is already a requirement. This is a third party. We use the same standard, which is CCDA. And it's using DIRECT – that's what the standards are.

I also wanted to mention that I did check, and stage two does have the – a certification criterion to be able to append patient-supplied information in free text or scanned directly to a patient's health record, or by embedding an electronic link. So it's already – they implemented the standard and certification criterion before they implemented the meaningful use measure.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Yeah. Okay. Now – Jim, did you have a comment?

James Walker – Geisinger Health System
Very quickly, stupid question. Do we know what mandated means? Is that legally mandated? To Liz's issue, I mean, I think we will stumble there. If we mean legally mandated, then that probably – they've got to do it. Anything else –

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Right. And mandated is definitely a squishy word, so our surgeons send lots of data to a repository which they think is important for their professional development, and if they don't, what are the consequences? I mean, they will tell me it is mandated. You know, for benchmarking and these sorts of things. So – yeah. Anyway, but I think one of the things Jamie did is – and, you know, comments you'll see that there are – the definition of several words from the Policy Committee, like the word mandated, it's unclear.

Wes Rishel – Gartner, Inc.
Wes, and I just want to check where we are in the agenda. You've been going through the items that had no comments. Is that right?

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
So where we are is that just because there were a number that were kind of quasi-related to the clinical operations workgroup that had no comments of any kind from anybody, I wanted to just gather those. But now we are on the implementation workgroup –

Wes Rishel – Gartner, Inc.
No, I think Dixie had commented on the – in the NwHIN Power Group, Power Team, and when you interrupted that, I had a comment for her, and then –

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Oh, please. Yes.

Wes Rishel – Gartner, Inc.
So when you make a list, you know, you –

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Yes.

Wes Rishel – Gartner, Inc.
So you – there were some comments on consent, and talked about solutions that were scalable nationally. I think you may have been addressing my concern, but I want to double check. There have been a set of – there's implementations of policy engines and a set of protocols around them that are certainly technically feasible, but it has always been my concern that they rely on a vocabulary of concepts that are not widely used, and these are concepts that are part of the operations of healthcare institutions. They're not just arbitrarily made up content.

So I want to be sure that nationally scalable meant implementable in the Lizard Lick County Hospital as well as at – yeah, at –

Dixie Baker – Martin, Blanck, and Associates
Yeah. The solutions have to stand up to the same test the NwHIN Power Team ___ for any kind of – any kind of standards to be adopted, has to be in broad use, and implementable, scalable, etcetera.

Wes Rishel – Gartner, Inc.
And just one comment. We have almost never adopted a standard in broad use. Okay.

Dixie Baker – Martin, Blanck, and Associates
That's not my fault.

Wes Rishel – Gartner, Inc.
No, I – I'm just saying that –

[Laughter]

Wes Rishel – Gartner, Inc.
Of all of – of all of the things that we – that we took as a good idea, when faced with the requirements of the – of the – sort of the forward grinding of meaningful use stages, we've had to back off on that. So I think we need to have another lever to look at that same issue.

Dixie Baker – Martin, Blanck, and Associates
Yeah. And I think we should always – and David would agree – we need to look at all of our standards that we recommend through that – through those criteria.

[Crosstalk]

Wes Rishel – Gartner, Inc.
I'm saying we adopt –

[Crosstalk]

Wes Rishel – Gartner, Inc.
We have found that that is one of those criteria that makes us feel good when we say it, and we never act on it. So I think we need to find a different ____.

Dixie Baker – Martin, Blanck, and Associates
I agree. I do. I agree. I agree.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
So let us finish up with the comments for the implementation workgroup. Any notes that people took there?

Wes Rishel – Gartner, Inc.
Same old hand again.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Oh, yes. Go ahead, Wes.

Wes Rishel – Gartner, Inc.
In a couple of places, the issue of standards as being anti-innovation or standards supporting innovation came up, including some of the comments from this team. And I just want to make it clear that all economists will tell you that all standards inhibit innovation. And there is some truth to that. There's also the rare cases where a standard sort of narrows a playing field just enough to create – to spur innovation, but that's more unusual.

We – I think we need – as we look at this whole issue of the evolution of a policy concept, a Policy Committee comment, to something that's certified and implementable, we need to work with the Policy Committee or I might go so far as to dare to say the Policy Committee needs to do this, but I'll be careful about that, that if you want to spur innovation, you almost need to carve off an area and say, okay, we're not going to develop definitive standards in that area for some time. We're going to – we're going to let alternatives develop, and those won't be the same standards that you measure for meaningful use. I mean, that's just – that's just the fact of life around this. Thanks.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
Well, thank you. So Jon Perlin, I would like to turn it back to you, and unfortunately, I have to fly back to Boston. The State of the Union address in Massachusetts is happening tonight, and I have to go sit in the House.

Jonathan Perlin – Hospital Corporation of America
___ ____.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center
I guess IT is a big topic this year.

Jonathan Perlin – Hospital Corporation of America
Dr. Halamka has been invited to be testament to the benefit of interoperability, and that is absolutely terrific, because I think it's, again, a demonstration of the impact and progress. So John, travel safe. We hope your trip to Boston is faster than your trip on Metro, so good luck with that.

[Background voices]

[Laughter]

Jonathan Perlin – Hospital Corporation of America
For the online audience, the comment was that Dr. Halamka can acquire a tie at the airport.

[Laughter]

Jonathan Perlin – Hospital Corporation of America
Indeed. Let me thank everyone for a very robust discussion. As I think about this discussion, there is the specific task, the response back as requested to the Policy Committee, and I think, you know, a lot of work between meetings and in this discussion, and the ONC, many technical points have been captured. I think thematically two things have been captured. One is the sort of evolutionary intent that we've spoken of in great detail, and two is the clarity, clarity around the specific use case, and clarity and precision of the words. Mandate as an example is a word that we need to understand, to be able to support with standards, as well as obviously in practical terms, although we're trying to comport to different stages of meaningful use.

So I think it should be a good discussion. Appreciate MacKenzie and the ONC team synthesizing both the discussion and the work in between. With your agreement, with the modifications based on this discussion, this will be the sense of the committee to transmit. Any objections to that process? Terrific. I appreciate all the work. Really it's such a privilege to work with all of you and hear your insights into this very complicated area.

Let me just check if Doug is online, and Doug, if you go through your materials and we have excess – if we have resid – remaining time, we'll come back to Becky, which would be terrific, because in some of these discussions, there is a body of work in the research domain – or that has been in the research domain that would inform certain very practical problems, such as any variety of reasons for stopping a drug, ranging from adverse event to true allergy to lack of effectiveness. So Doug, are you ready?

Doug Fridsma – ONC Office of Science and Technology
I'm here. So thanks. Is Lauren Thompson there as well?

M
She is.

Doug Fridsma – ONC Office of Science and Technology
Okay. Great. Great. Lauren Thompson is the director of our federal health architecture, and has been tremendously instrumental in really working with all of our federal partners around issues related to interoperability, the standards for the sort of interoperability architecture that's shared among the federal agencies in the healthcare space, and I'm delighted that she's a part of our team. It's been tremendous.

So I'm just going to go through a couple of the ONC standards updates. Some of this stuff we've already talked about a bit, but I wanted to give just a brief overview of some of the activities. I will try to minimize the activities so that David doesn't get too upset, but we'll just sort of run through all the things that are currently going on and what are plans are for the next couple of – couple of months.

So if we go to the next slide, obviously, you've seen sort of this diagram before. I think what's important to note is that the – that the activities on the top there, all of them have been balloted through HL7, and have been adopted really as part of the meaningful use stage two criteria. We have a number of other activities, too, and some of them have moved further along than others. We are in the process right now of doing an analysis across all of our S&I framework activities to make sure that we have some mechanism to continue those activities for which the community is engaged, but for – but are not necessarily part of the priorities for meaningful use stage three, and just make sure that for ongoing work we have a place for the work to continue, as the ___ funds will probably be diminishing and essentially gone in the course of the next six to eight weeks.

If you go to slide 2, I – yeah, I guess this is slide 3. I apologize. We've got SDO activities. There's an implementation guide for laboratory results interfaces and ToC that were balloted. We're working right now this week with the HQMF ballots, and we've got a number of activities at HL7 this week with regard to the Health eDecisions ballot and some of the work on clinical decision support.

The initiative that we are continuing, esMD around digital signatures and some work on structured data capture, we have activities on the LOI and the eDOS – and the eDOS, the compendium. Query Health, we've got a – got some pilots, but I think we're trying to leverage the work that we've got with Query Health to see if we can responsive to some of the priorities that we have for the HIT Standards Committee and the Policy Committee with regard to query and response. And then we've got the longitudinal care coordination team that's really trying to make sure that the long term care facilities are included in the information exchange that we have as part of meaningful use.

The PHRI, the Public Health Reporting Initiatives, they've done a number of really good work in developing a whole series of use cases. I think we're at a point right now where we'd like to reevaluate those use cases, see kind of what is the low-hanging fruit, and then figure out a path forward that could be responsive to some of the public health priorities coming up in the next year or so.

ToC, LRI, and Provider Directory are initiatives that are completed, and we're really right now working on figuring out a way to coordinate with HL7 and others to make sure that we're supporting those initiatives in the – in the long term, in sort of a maintenance mode.

And we're – we've been working very closely with our Office of Certification and with NIST to develop a lot of the test data that we need for meaningful use two activities, and have been working with our BEACON communities to help to transition from the C32 standards to the consolidated CDA, and developing some tools and resources that will allow that transition to happen more smoothly.

The next two slides are probably the ones that we've been focused on, and I think it's one of the areas that I have a – have some concerns about. You've all seen this before, which is sort of the current state of the standards environment, and that – kind of the first four boxes, where we talk about use cases, harmonization and implementation specifications, it's probably driven among experts who understand the clinical problem and how to translate those into standards that the standards development organizations can ballot and implement.

And then the remaining three are about pilot demonstration projects, reference implementations, and sort of the certification and testing. And part of what we had tried to do I think in the S&I framework was to begin bringing those people who would do the implementations and who would do the demonstrations up front, so that they could help us with defining the use cases and the implementation guide. And I think what is clear is that in many sense, vendors have a lot of things on their plate. They don't really oftentimes engage early in these activities. In fact, some of the feedback that we've heard is that until we get our testing scripts out, people really don't know how to work on the code that needs to be developed so that they can pass meaningful use stage two requirements.

And so it hasn't been a 100 percent success in engaging the implementers and the vendors in the process from the beginning, and it may be that these just represent very different communities, that there is an implement – implementers community, and there's sort of a standards development community, and they need to coordinate and communicate. But they're fundamentally different, and are addressing or asking different questions.

So one of the things that we're proposing to do as we go into 2013 is that we're going to continue the work that we've done with the use cases, harmonization, and implementation specification at a much, much lower level of activity. We won't be able to spend as much time or energy in trying to accelerate the standards efforts. And I think that will mean that some of the things that we will probably propose with regard to priorities are going to be focused on extensions of existing standards, and maybe a few very selective activities to develop some new functionality.

The criteria for the new initiatives are going to be really to what degree do these satisfy multiple use cases, and sort of the biggest bang for your buck, and also whether or not we have funds or other sorts of resources that can help support those kinds of activities as well. But in addition to that, we think that we really do need to have an implementation and testing or precertification environment that will help those people that are now taking the standards and implementing them, because I think given the optionality that we have in many of the standards and the varieties of ways in which you can pass certification, choosing option A versus option B, it is entirely conceivable, and I think we're beginning to even see evidence of that, that a certified product, you know, certified product A may not be able to interoperate with certified product B, because they've chosen through the certification process different options to implement, and that leads to challenges in value sets, challenges in what options are there, and things like that.

In some sense, we need to be able to then incorporate that information and understand where is the best place for us to be able to solve the problem. We talked a bit about this as well, which is, you know, do we need to change the way we do our testing? Do we need to change our implementation guide? Do we need to change our standards? And so we're in the process of standing this up. We've got sort of a soft launch already around some of the quality measure activities, because the same problem exists there. If a quality measure isn't calculating what you'd like it to, you don't know if it's because the logic is wrong, the value sets aren't complete, or if something about the standard needs to be enhanced so that you can actually capture that information effectively.

And this is the way we believe that we can sort of triage many of the incoming problems and make sure that we choose the right tool to solve the problem. And this week, while we're at HL7, I mean, we are continuing the conversations with HL7, because of their expertise in consolidated CDA and some of the other standards that have been adopted. It will be incredibly important for us to make sure that we work with those organizations and coordinate so that we've got the best information and the best minds helping the implementers as they discover problems.

And then we can then use this as a way of creating best practices and guidance so that folks can say, if you've got a certified product, that's great, because that's kind of your version 1.0. But in fact, there are some security patches and bug fixes that you may need that are kind of 1.1 and 1.2, things that we've recognized through the process of implementation, and that these are ways that you can enhance your ability to get the interoperability using those certified products as well.

And so we intend over the course of the next couple of weeks really to begin supporting this, because we think the need is urgent, and that there are people that are going to begin having lots and lots of questions, and having a place to go, and tools that they can use will be – will be important.

So some of the things that we're looking at, we're taking a look at the – let's go to the next slide. We're working right now at examining the public health reporting activities and seeing how we can enhance functionality there. The Health eDecisions implementation guide is being balloted this week. We're going to be launching the PCOR Initiative, which is about the structured data capture, given some resources that we received from PCOR, and that have been supplemented by work that AHRQ has been interested in. And we've got work that's being directed out of the Office of Policy and Planning to develop standards around prescription drug monitoring programs.

We've got some cross-S&I framework activities as well that we hope will help us do a better job of making sure that we've integrated things, and there is a lot of work that's going on within NIEM right now. We're trying to make sure that that activity is aligned with the Federal Health Information Modeling and the – our Clinical Entity Data Dictionary that's part of the S&I framework, because we really at this point I don't think have semantic consistency across these things.

And again, working to develop quality measures to support the Office of the Chief Medical Officer, and working as well to try to get some test data sets that people can use to test and look at whether or not they're – they – kinds of documents they're producing as part of their meaningful use activities conform to the – to the various standards as well.

So let's go to the next slide here. So in addition, and this is slide number 6, we have been able to, over the course of this last year, take the NwHIN activities and launch that as the eHealth Exchange. And so that has been a – really I think a tremendous effort to try to continue this public/private partnership, to be able to continue information exchange, and that group has been robust, and has really done a great deal of work to kind of – to create a sustainable business model that will allow the federal partners and the folks that are members of the eHealth Exchange to be able to support health information exchange using these query response mechanisms, and really to continue that great work.

So then the next slide, slide 7. I can't take any credit for this. The person who's sitting in the room there, Lauren Thompson, is the person who really I think has been tremendous in coming – bringing together the Federal Health Architecture and our federal partners to support meaningful use and interoperability among our federal partners.

In the course of the last year, Lauren has set up a new governance structure that creates strategic alignment across the federal partners and enhances the transparency and communication. They have sort of refactored much of the work, making sure that it's aligned with the original intent of the Federal Health Architecture as an E-Gov line of business.

In addition to that, they're launching a strategic planning activity right now that is nearing completion, and to try to make sure that it is something that can support the strategies that we have for this Federal Health Architecture.

With regard to the interoperability architecture as well, they're looking at current and planned data exchanges integrating the Federal Health Architecture activities into the HealthIT.gov website, and really working to align the standards harmonization efforts with the standards and interoperability framework as well.

Other successes include some of the early work on developing RESTful pilots, using something called RHEx, and we've leveraged some of that activity as we've continued the work around the Blue Button Automation or the ABBI Project, to take a look at some of that work as well.

Slide 8. We've done a lot of work as well on the standards around some of the innovation. We're continuing to work with the CONNECT Project. There's a new release that's coming out this year. It has been refactored and streamlined and really focused on the core essentials that the original architecture had.

We continue to work to try to get this into a more open source community in which it can be driven by the community as well, and we're navigating the various hurdles that are thrown in place, but it certainly is part of our goals and objectives to make this a resource that others can leverage and use.

And finally, we've got the RESTful Health Exchange. We've done – we did two pilots, one with TATRC, which is out of the Army, and then another with HealthInfoNet, to demonstrate really how this might work in terms of using RESTful exchanges as well.

So there's been a lot of activity over the course of the last year. We're in kind of a regroup mode right now, trying to identify those critical pieces that need to main – be maintained, setting the stage so that we can continue to learn from the implementations and refine the work that we do, and then identifying those high priority items around extensions to the consolidated CDA, structured document capture, because it covers so many use cases, and then making sure that we leverage Query Health and the NwHIN portfolio of standards so that we can create a consistent access to electronic health records information, using and leveraging our existing standards.

So with that, I can take any questions, but then I'll turn it over to Jodi for the ONC program updates on some of the other activities ONC has been working on.

Jonathan Perlin – Hospital Corporation of America
Thanks, Doug, for a terrific – not only terrific presentation, but what a terrific amount of work. The floor is open for any questions here before we go to Jodi, or comments.

t:Are you asking for questions?

Jonathan Perlin – Hospital Corporation of America
Yeah. Anything that relates directly to this, let's take a moment and – on this topic. David McCallie?

David McCallie, Jr. – Cerner Corporation
Yeah. Hi, Doug. It's David. I think that you made a comment that maybe sometimes vendors don't engage because they just want to wait and be told what to do, or at least that's how I heard your comment. I don't think that all the vendors will fit into that categorization. Maybe there are subgroups of vendors, some of whom would be very happy to engage up front in active development of these standards, when those vendors understand clearly the use case and the market case and the business case for developing a new standard. There may well be some vendors who would prefer to just wait until the standard is finished and then implement it, and certainly an approach that makes sense, but not all of us want to approach it that way.

And I would note that, you know, a number of the successful standards that you're pushing, or a number of the more promising standards that you're pushing, you know, originated in the case of DIRECT and RHEx both, completely outside of existing standards bodies, and were driven by vendor or by, in the case of RHEx, contracts supported some by vendors. So, you know, it's hard for me to reconcile the notion that vendors are just waiting to be told what to do with what's actually happened.

And then second, I think some of the standards that seem to be going forward full speed ahead in the standards space still don't have very much vendor support, and in particular, I'm thinking of the Health eDecisions one, which, you know, the two separate committees today that eval – that responded to the MU stage three question that relates to Health eDecisions both said, you know, not ready for primetime, and yet it's already in ballot. So there's a disconnect there that – I don't know how to resolve it, but there's a disconnect. It's moving forward, and yet we've had feedback that says it's not really ready. So I – again, I'm a little defensive, but I understand how hard this stuff is, and I know that when we all work together, we get a lot of good stuff done. So it's just a comment that, you know, please engage the vendor community, and we'll work together to get these things done.

Doug Fridsma – ONC Office of Science and Technology
Yeah. No, David, I appreciate that. I think you and I both share a desire to really make sure the kinds of standards that are constructed meet the needs of the vendors, and that are supportive of the use cases that we have. I'm not being defensive. I'm being just sort of frankly honest about things. I think the vendor community is fairly heterogeneous, and there are some that really are looking towards what the testing scripts are going to tell them, because that's their way of interpreting really what the specifications are or the requirements are.

It could be that we need to make sure that as part of an implementation guide, a fully fleshed out implementation guide includes a testing plan, so that we can get that information up front, and have more of a conversation about that that would be helpful.

I want to make sure that we engage the vendor community. I think that's where we're going to have success with this. And I will try any and all means that I can to try to – try to support that. And so in some circumstances, I think you are right. There are some – there are some initiatives that have been directed in large part because of policy objectives or goals that we have to create new functionality, and it may not be ready for primetime, but we need to think through how to do pilots and get them ready for those sorts of things.

We also need to make sure that we figure out ways to engage the vendor community as well. And I think there are a number of vendors that have come to the table that have participated in our pilots and have done really a remarkable service, if you will, to help us advance the standards, and then others that have taken different approaches to being able to sort of get to the points of having certified products as well.

So I am welcome and all ears to try to figure out a way that we can engage the communities. I'm hopeful, and part of the reason for the implementation and kind of pre-certification testing environment is to see if we can't focus some energy on that community, the implementers and the vendors and the folks that are using the technology, so that we can learn from that experience, be more engaged with that community, and then use that to help inform much of the work that we do on both the standards and the implementation guides and the other things.

So I think I share your commitment to trying to do a better job of engaging that vendor community, and if there are things that we can do that would be helpful, or things that we can do that you think that would accelerate that, I would really be welcome and open to those kinds of suggestions.

Jonathan Perlin – Hospital Corporation of America
On the points, let's, from the lens of the Standards Committee, really think about how to engage, as ___ point of the continuing conversation, you know, limited time left. We have Wes and Dixie and Jim, is your card up, or is that – okay. I wasn't sure.

Wes Rishel – Gartner, Inc.
That's a leftover card. This is Wes Rishel. I would note that the vendors that don't participate early on will feel no inhibitions in criticizing the standard later. It's just human nature. And I think working with the standards group, we need to look at this issue from two sides. One is what can we do to get vendors involved. From the point of the view of the Standards Committee, it's what can be done to create standards that are responsible to the community needs, and the vendors are one of the channels of identifying the community needs. Often they bring a lot of expertise in interpreting what users needs.

I was involved in the policy making in HL7 around the draft standard for trial use, and I pushed for, didn't get, but I think it's a concept that's worth modifying and figuring out how to use, I pushed for the notion that nothing could proceed – no DSTU project could be launched unless there were at least two vendors that were committed to implementing it during the trial period – and two implementers, not necessarily vendors. It could be two hospitals or a hospital and a vendor.

But that level of having people that are thinking through the issues and thinking about the implementation issues really contributes – it's harder to kick a can down the road when you realize you're going to be the one down the road. And I still think – I still think that there's – there's a corresponding principle that I didn't think of that the folks who ran the DIRECT project did, which is those who are going to participate, having committed to participating, get to make the rules, that rather than make an equal vote among people who are having to go out and work on implementing it, and those who have an intellectual interest in the standard, there's some differential of authority, particularly during the DSTU phase, to those who are going to implement.

I think various activities going on from ONC have recognized this important principle, and the next job is to sort of create a synergistic view on process in standard development organizations with the ONC. Thanks.

Jonathan Perlin – Hospital Corporation of America
Thanks, Wes, and Doug, I think it's good, you know, food for thought, roles of endorser, endorser implementers, good conversation within ONC to contemplate that. Dixie, do you want to come in on this before we move?

Dixie Baker – Martin, Blanck, and Associates
Yeah. Hi, Doug. It's Dixie Baker. I just want to point out that the conversation we just had and the inputs that you just heard from Wes and David, that's what I was proposing that the NwHIN Power Team address for you moving forward, is how to get these kinds of inputs, how to get the vendor engagement early on, so that the – so that standards can move more quickly to meet those criteria that the NwHIN Power Team set forth. So I wasn't clear, but I just wanted to clarify for you – in my email, but I wanted to clarify, that's what I was proposing to you.

Doug Fridsma – ONC Office of Science and Technology
Oh, that's great. That's great. I know – you know, my – the DIRECT project, which really did have vendor engagement, was the model that we tried to use in many of the standards and interoperability initiatives that we launched. We had some success in some of them, and we had other places, it was – it was a bit more challenging and stuff. So it's a constant learning process. We have to continue to refine it and to be able to make modifications and, you know, accept criticism, and try to do a better job.

But we have tried, I think, to figure out and crack the nut, and I'm not sure we're there yet, but anything that you guys can do to help, I think that's – that would be great.

Jonathan Perlin – Hospital Corporation of America
Well, thank you, Doug. Any additional comments that you'd like to offer, or for Lauren Thompson? Appreciate your being here, and your leadership in FHA. Just anything you'd like to close with?

Lauren Thompson – ONC Office of Science and Technology
On behalf of FHA, I would like to say I think we've – we have made tremendous progress over the next – over the last year. We do have our strategic plan approved by our governing board, so we will be unveiling that in the last – in the next few weeks. And it's very focused on aligning the Federal Health Architecture with what is being discussed here today, and hope to align much more closely with the S&I framework and initiatives going forward.

Jonathan Perlin – Hospital Corporation of America
Terrific. Well, thank you, and Doug, thank you so much, to all the folks who've been participating from Phoenix. Let's move now to Jodi Daniel for a ONC program update. And Jodi?

Jodi Daniel – ONC Office of Policy and Planning
Great. Thank you, Jon. I'm just going to stay here, if that works.

Jonathan Perlin – Hospital Corporation of America
Sure.

Jodi Daniel – ONC Office of Policy and Planning
So what I wanted to do was do sort of a 2012 year in review, just going over a variety of our programs and some of the – some of the accomplishments in the past year, just give sort of a flavor of a lot of the activities we have going on, and then, you know, over the course of the year, I might do some, you know, give a little bit more detail on particular programs as appropriate. But kind of wanted to give that overview, since we're starting a new year.

So some of the data that Jon already mentioned at the beginning of the meeting, these are our slides that show the progress that we've made on meaningful use, both for professionals and hospitals. And as you can see, at this point, the total number of professionals that have been paid is over 173,000, which is a third of the eligible professionals, and those registered for the program is 65 percent. So we've made significant progress in adoption, and greater success than – exceeding our goals for the past year, and we expect to exceed our goal for this year as well.

If you look at the hospital numbers, again, really strong adoption numbers here. The total hospitals that have been paid is 68 percent of the total eligible hospitals. This is – I think this is as of November, as of the end of November. And then we have 84 percent of all hospitals that have registered, eligible hospitals that have registered for the program. So again, exceeding expectations, exceeding our goals, and really showing strong progress with respect to adoption.

When we look at the incentives program and the incentives that have been paid, this is as of November, these numbers, but it's over $9 billion that has been paid out over – through the Medicare and Medicaid programs, incentive programs, and Rob Anthony from CMS at the Policy Committee meeting said that they anticipate by the end of the year, once they get those numbers, it would be over $10 billion.

So this isn't just by coincidence that all of this has happened, and that we've had such great adoption. We've been working really hard at it. We have our Regional Extension Center programs all across the country that are working with providers, significantly with primary care providers, to help them to adopt and become meaningful users of certified EHR technology. Over – at this point, over 132,000 primary care providers have been working with RECs, which is about 40 percent of all of the primary care providers in the US. We also have had a very strong engagement of rural providers and of SQHCs, so hitting some of the folks that really need the greatest assistance in adoption and coming into implementation for meaningful use.

A couple of points of note. I'm not going to go into all the details in this slide, but there was a GAO report, and the GAO report found that 47 percent of providers who received AIU payments were working with a Regional Extension Center, and they also found that Medicare providers that were working with Regional Extension Centers were over 2 times more likely to receive payment than those who weren't working with them. So again, just demonstrating all of the hard work that the Regional Extension Centers have been putting in to trying to promote adoption and help providers to get to implementation and meaningful use, and it's due to both the hard work of some folks at ONC, but more importantly, to the dedicated work of the folks out in the field who are, you know, kind of pounding the payment every day and working with providers individually to help this – help this success, and to help the numbers that you've seen before.

Shifting to our health information exchange efforts, just, again, a couple of notable and exciting statistics here. At this point, we have 94 percent of pharmacies that are actively e-prescribing. With respect to directed exchange, 43 states and territories have directed exchange, and 6 – over 60,000 clinical and administrative staff nationwide have access to directed exchange. I found these Q3 2012 numbers staggering, both with directed and query-based exchange. But during Q3 of 2012, there were almost 80 million directed exchange messages. So really huge, huge numbers and huge progress in moving exchange and in having folk using the standards that we have been pushing for.

With respect to query-based exchange, 20 states have statewide query-based exchange, and 12 additional states have query-based exchange within regions, although not statewide as of yet. With respect to clinical and administrative staff nationwide that have access to query-based exchange, it's 71,600. And again, during Q3 2012, there were 2.8 million patient queries through these exchange efforts. There are only four states and four territories that report not having any directed or query-based exchange at this time, so really making huge strides across the country toward exchange of health information.

Also of note, in the past year we put out consent guidance that went out all the state HIE grantees based on the recommendations from the Health IT Policy Committee, so following through on some of the recommendations that we've heard, and putting – getting them into implementation at the state level.

Our BEACON community update, so we've had great success in the BEACON communities as well in the past – in the past yearly. Early results have featured improvements in quality, cost, and population health, with all of the 17 communities having at least 2 measures trending positively. We've launched new exchange capabilities in communities such as New Orleans and San Diego, where in New Orleans they are facilitating exchange between safety net clinics and hospitals, and they will connect with the state HIE as well.

And in San Diego, the focus is on connecting ED notifications and providing information to county public health for syndromic surveillance purposes. And again, these efforts will be connected with the state HIE efforts in California.

There has also been collaboration between eight BEACON communities and six EHR vendors to advance interoperability and exchange, and there's been a lot of positive activity as a result of that. We do have a series of fact sheets demonstrating progress reached in the 17 BEACON communities, so I invite folks to go to our website if you are interested in specific BEACON communities, or in seeing some of the great progress and the great activities that have been going on in those – in those programs.

With respect to workforce training, we have our community college program and our university-based training program. In the community college program, as of November 30th of 2012, we've had 16,228 students successfully complete the training. Some previous experience in IT or healthcare is a requirement of enrollment at all the schools, so a lot of the students have a number of years of work experience before enrolling in the programs, and the schools are seeing a wide range of educational backgrounds in their students, including folks with bachelor's degrees, nursing degrees, and even in some cases masters and PhDs.

The one area of opportunity that we have heard over and over again, both with this program as well as with the university-based training program, is the ability to get hands-on experience with EHRs as a critical need for the students. They've been currently using Vista to provide experience in these trainings, and folks have universally asked for more internships or hands-on experience in order to be able to get better placements when they're done.

With respect to the university-based training, we've had 828 students as of October that have graduated with 1,685 anticipated to graduate by the end of the funding period. Again, there's been a lot of satisfaction with the quality of the curriculum, the assignments, and the group activities, but again, the desire for more hands-on experience has been noted.

In our consumer eHealth program, we've talked about this before, we have the three As, access, action, and attitudes, and there's been a lot of progress in this. Not only have we made a lot of progress, but we moved from having no focus on consumer eHealth to having a consumer eHealth lead to now having a consumer eHealth program, so that's huge progress. That's only in two short years, and the program did start last year officially.

With respect to access, 88 million Americans have access to Blue Button. One point four million Blue Button downloads have occurred, and we have 454 organizations that have joined our Blue Button Pledge Program to either pledge to make information available, or to encourage folks to access their health information using this capability.

Under action, we've had – we have launched our Automated Blue Button S&I framework initiative, the ABBI initiative, and we have 68 organizations that are participating in that initiative. Others are welcome to join. It is open. We had – we did a health record design challenge which got I think the most submissions of any challenge we've done so far. We had 230 submissions, and this was – instead of a technology challenge, it was a design challenge to try to redesign the health record in a way that was more usable, both to providers as well as to patients. And my understanding is that that will – we will be actually developing software to – in line with the design winner, which would be openly available.

We had a Blue Button Mash-Up Challenge where we challenged folks to connect Blue Button data with other types of data to make it available to consumers, and we had three winning apps for that, and you've heard Farzad talk about using the – one of the Blue Button apps, the winner app for – with his parents, and I've done the same. So I encourage anybody who has – who is on Medicare or who has a family member or friend who is on Medicare to sit down with them and help them access their data.

And then we have been working to get organizations to adopt our model PHR privacy notice, and it is something that we're looking at leveraging for purposes of the Blue Button activities as well, to support trust framework.

On the attitude side, we've had – I'm not going to go through all of these, but we've had, you know, thousands of views of our video contests. We ran six video contests. We have our Health IT Animation video, and I encourage folks who haven't seen this to go and look at it and link to it if you can. It's – I think it's pretty good, and it's not your typical government brochure. So it's pretty accessible.

We had our consumer health IT summit, and the – our annual repeat of our consumer IT summit. And we have had a number of roundtables, one on cancer care, gaming, and a patient access summit. Just one thing coming up, we are starting to look at modifying and updating our strategic plan. We are trying to use an interactive approach to get broader input into our strategic planning process, and we are starting with the consumer strategy, because it's one that we think there may be broader interest in by folks who don't necessarily pay attention to our work on a regular basis. So look forward to that coming in February.

On the policy side, so of course we put our final rules for meaningful use stage two, and the 2014 edition standards and certification criteria, as well as putting out the request for comment for meaningful use stage three for the Health IT Policy Committee. As I mentioned earlier, we released our Health IT Patient Safety Action and Surveillance Plan, and are looking for comments, and we will be coming up with a final plan that incorporates some of those comments.

We used the information we received from the RFI on governance for nationwide health information exchange, and there's a word missing here, to develop a non-regulatory approach to looking at governance for nationwide health information exchange. We heard loud and clear that it was not the best approach for the federal government to move forward on regulations at this time with respect to governance of a nationwide health information exchange, and we are taking action to both work with other parties that are engaged in governance. At this point, we have out a notice of funding availability for this right now, and we will be launching some other activities, and we'll keep you posted.

And we've made progress in making PDMP, prescription drug monitoring program information available electronically, in real time, for prescribers and dispensers, and we will be developing tools so that others who were not part of the pilots can hopefully piggyback on this great work. And anecdotally, we've heard that it has made significant impacts on doctors sitting with their patients that are about to make prescription decisions, and have changed their prescribing decisions or helped their patient get treatment that they needed because they were able to target the PDMP data in real time with the patient sitting in front of them.

Okay. Certification. So we – ONC transitioned to our permanent certification program, which is great. We completed development of the 2014 edition test method materials in close collaboration with NIST. I'm not going to go through all of the details of this, but we have – we did multiple waves of draft test procedures, test data and test tools, got a lot of public input into this process, and revised the materials per that input.

It's probably hard to see this, but just a couple of notable points on our – with respect to the CHPL. This is the website that folks can access in order to see what products have – are certified. Just as a note, we have 2,910 certified products. About half of them are complete EHRs. About half of them are modular EHRs. And what I find amazing is the number of page views that we have to the CHPL. As of – the total usage in 2012, there were over 1.8 million hits to that website.

With respect to e-quality measures, our long-term goals are to align the measures, simplify data submissions, standardize components, and empower quality improvement. All of the efforts that have taken place in 2012 were designed to do these things as well as to try to standardize and build on common components for logic and value sets.

I'm not going to go through all of these. We have developed a lot of CQM developer and implementer tools, with the assistance of NLM, ONC, ARQH. You can peruse these, but I think that they've been very helpful. We also have provider tools for a quality improvement population dashboard through PopHealth. The providers can see patients levels used of the e-measures.

And last but not least, we have redesigned our HealthIT.gov website. If you haven't gone lately, please come and check us out. We're continually improving it, so if you do have any comments for how we can make it better or information that we can provide that would be helpful to folks, don't hesitate to let us know. We have tried to provide a lot more information, keep it more up to date, provide easier ways to access some of the most important information that folks have been wearing for, and so please come and check it out.

I also want to note that we have some health IT dashboards that have some great data for folks, that you should take a look at, if you are interested. We do have regular updates. You can see here that there is the section updates from HealthIT.gov, and that stays up to date. So if you just want to see what's new and exciting at ONC on health IT, you can just go and look at that, and you'll at least get the top few items of interest.

And with that, I will wrap it up and take any comments or questions.

Jonathan Perlin – Hospital Corporation of America
That is a terrific amount of information. Congratulations on just extraordinary accomplishment. Tim Cromwell, you have your card up.

Tim Cromwell – Department of Veterans Affairs
Yeah, there's one more initiative out of your office that you may not know about. I wanted to draw attention to it. There's a Pressure Ulcer Mobile App Challenge that is out of ONC. It's a prize, and it's a collaborative effort between ONC, ANA, the Department of Veterans Affairs, Kaiser Permanente. There was a domain analysis model that was balloted through HL7 last year, and now what we're doing is offering a prize for a – someone to build a mobile app using that domain analysis model and the terminology bindings, trying to get in front of the wave of mobile apps that are being developed that aren't going to foster interoperability, thinking that build one of those based on an information model will foster interoperability.

I'm very proud of the work that nurses have done, the nursing terminologists have done, to bring this forward. Pressure ulcer risk assessment via a mobile app appears to be a future – a future capability. When we transfer a patient from a hospital setting to nursing home care unit to the home setting, we will need ubiquitous nursing pressure ulcer assessments that can be interpreted by everybody, and we think this is a way to approach it. So there's a webinar next Wednesday that will be providing more information about this challenge.

Jonathan Perlin – Hospital Corporation of America
Terrific. Thank you for identifying that, the plug, and I'm sure among those who follow the Standards Committee and the broader community there will be many participants in the challenge. It's such an important clinical problem, but what a great index opportunity. And what a great point, that a challenge of that sort can occur, given the context that – the work that Jodi Daniel so eloquently described. Just exciting.

Let's do two things. Let's move to public comments, and if there's additional time, we'd love for Becky Kush to introduce us to her CDISC presentation, recognizing that we may need more time to come back to give it the time it deserves. But let me turn to MacKenzie to invite public comment in the room or online, and we'll go from there.

Public Comment

MacKenzie Robertson – Office of the National Coordinator
Thank you. Operator, can you please open the lines for public comment on the phone? And I'll ask anyone with a public comment in the room if you could please come to the table.

Operator
If you'd like to make a public comment and you're listening via your computer speakers, please dial 1-877-705-6006 and press star 1, or if you're listening via your telephone, you may press star 1 at this time to be entered into the queue.

MacKenzie Robertson – Office of the National Coordinator
And while we're queuing up the phone public comments, go ahead.

Darryl Roberts – American Nurses Association
Good afternoon. Thank you for the opportunity to provide public comment on these very important initiatives that are moving forward. First, my name is Darryl Roberts. I am a senior policy fellow with the American Nurses Association. I'm responsible for the confluence of health IT and quality and advocacy for the American Nurses Association.

First, I want to echo the comment made by Tim Cromwell. The American Nurses Association is strongly supporting the app challenge that's going forward. But also, I want to reach over and pat Judy Murphy on the back for making sure that this moves forward the way that it did. Judy has been instrumental in making this a possibility, and she deserves a great deal of thanks from the nursing community, and also from the patient community that will benefit from this app. So thank you, Judy.

Additionally, I want to direct these comments – Dr. Walker earlier in the day had made a statement about the EHR capture of patient information regarding allergies, previous problems, and preferences, and it is not something that is a nice to be, as Dr. Walker made it very clear. This is a must be. I am the American Nurses Association's representative on the National Coordinating Council for Medication Error Reporting and Prevention, blessedly called NCCMERP, because who would want to say all that?

And I can assure that there are multiple models that are available to make this a possibility, to capture these important and imperative patient allergies, to capture things that are not necessarily allergies, but most assuredly negative outcomes related to drugs, and most importantly, I think, even above the value of that capture, is patient preferences. If I choose not to take an aspirin product, I choose not to take an aspirin product. It doesn't matter if I'm allergic to it or not, and it should be documented in a meaningful, representable way in my chart, and as a patient, I should have an opportunity to add to that, or if I change my mind later, because I've learned that through education opportunities through my provider that it is important that I take it, regardless of the fact that I don't really like it, I want to be able to change my mind and later say, you know, I didn't want to take aspirin before, but I do want to live longer, so I'm going to take aspirin now.

And it is important that standards or no standards, we make representation of that information available in the chart. We make it possible to amend those representations. And if we must have standards to do it, there's a gentleman at the other end of the table that can help us support development of those standards and movement of those standards forward. Thank you very much for this opportunity.

Lindsey Hoggle – Academy of Nutrition and Dietetics
My name is Lindsey Hoggle. I'm from the Academy of Nutrition and Dietetics, and I just wanted to comment on the discussion of allergies, to make you aware that we have supported for about 18 months, 2 years now, what is being – occurring right now in HL7 in Phoenix, and that is a ballot for the patient care working group, allergies and intolerances ballot.

And exactly – we feel the same way. It's an important list, and there's been quite a bit of discussion over the comments the gentleman made just a few minutes ago, is that whatever it is, regardless of if it's a true allergy or a preference of the patient, that it should be captured in what they have designated as a list of items, and that there should be standards and ways to communicate that across care. So thank you for your attention to that.

MacKenzie Robertson – Office of the National Coordinator
And are there any public comments on the phone?

Operator
We have no comments at this time.

MacKenzie Robertson – Office of the National Coordinator
And seeing no more public comments in the room, Jon, I'll turn it back to you.

Jonathan Perlin – Hospital Corporation of America
Well, thank you. We have seven minutes left, and I know it's not adequate time to go through CDISC in detail, so let's consider this a teaser, an introduction to home study, and we may come back later in the season and – with that, let me introduce Dr. Rebecca Kush to introduce us to the materials on CDISC, and at least set the stage for future –

Rebecca Kush – Clinical Data Interchange Standards Consortium (CDISC)
I would actually ask if we wanted to defer this to another time, but there are two people from the Food and Drug Administration today who have been sitting here all day to not hear me talk about CDISC, but to hear your comments on what has been done in the research space around standards. And I don't consider myself a representative of this committee for CDISC, but rather for research as a whole. So this is not necessarily a CDISC talk. It's what have we done in the space of clinical research standards, and it's been 15 years' worth of work, and I thought I had 15 minutes to do it, but I have 5.

So I will just lead you through this presentation really quickly, and I'd hope that we could come back to a few of these topics at a future meeting, maybe March, because I believe that they're totally relevant to meaningful use three and four, and I hope that it can help launch and give us a glide path into those, and maybe we don't have to start from scratch on some of these things. And for one thing, I just got a email that I saw from Dixie, and I haven't even responded, but Doug's reference to a structured data capture is actually something we've been working on for the last ten years.

So can I just flip through the slides, and I'd really like a few comments, because Ronset Smart and Mitra Loca are here from FDA, and they're very much responsible for a lot of this work, and would like to hear the committee's comments at some point. And I have faith in this committee and the tirelessness of all of you, and I feel like it must be death by PowerPoint at this point in the game. But I know you'll bear through just a quick run through of a few slides.

So the whole idea here is for research to use healthcare information and feed it back into clinical decision support, which is terribly inefficient, and some say 17 years – some of the questions we've tried to answer are how could every patient provide some sort of research information for future generations? Because that isn't happening today. And how can we make sure that the data from patients who participate in clinical research are used wisely and effectively? Because that's why they give us their data for this purpose.

This is actually a slide that we did before we started CDISC, which shows you the opportunity to optimize the clinical research process. Even in those days, we felt that it was through what we call electronic source, which is never entering the data onto paper. And that was a scary thing in 1997, especially because everybody documented everything on three-part NCR paper, and it was horribly cumbersome. People re-wrote things four to seven times. And so this was frightening.

And the other piece of this, though, that's kind of out there, was that we certainly didn't have the adoption of EHRs that we have today, but this is something that was one of our vision slides. And this is what we were dealing with, is this is an active research site. And you ask about those three computers, and they'll tell you the other nine are in the back room, and every single sponsor asks for research data a different way. So this was the problem we were trying to solve, and that's what we set about doing.

This is what I call the plight of the site, and because most investigators do one research study and say forget it, unless they hire a coordinator instead of a whole research arm, it goes overseas. It's outsourced. It's very global. So the requirements for research standards were that they be used around the globe, and that they are flexible, because every research study is different. You wouldn't do a research study if it wasn't answering a new question, unless you don't have the data that somebody else already did that study, and that's a shame.

So this is the definition I was using. I'm not just talking about regulated research. These are some flow charts that were – we published in a CenterWatch book about eight clinical trials in 2003, and you can see the opportunity, because one is the paper-based process. I call the computer where they reentered data from medical records into the computer as kind of a Band-Aid. It's not a whole lot better than that paper process. But if you can take the eClinical, where the data aren't ever entered on paper, you get the process at the bottom.

So these are the standards that are available at this point, and we started in 1997. We have a suite of global consensus-based standards to support the exchange of what I call common data, and those are data that are common to all research studies around the world, that we can represent those from protocol through data collection analysis and reporting, for study report publications or submissions. We have a model that harmonizes all the research standards together and provides a link to healthcare. We have controlled terminology.

We have the documentation for using EHRs, or what I call e-source, for the purpose of research. We also use eDiaries, which would be patient-generated data. We've been doing that for a number of years. People found long ago that paper diaries aren't a good way to capture what's going on with a patient. And we have integration profiles that have been developed and tested, and that's one of the ones that's the structured data capture.

I'll just leave you to go through this. CDISC is a global standards organization. It's a 501(c)(3). It was founded in 1997. We have organizational members, because we feel like standards is an organizational commitment, not an individual commitment. We have Liaison A status with ISO TC 215, which Chris now is the chair of. We have a charter agreement since 2001 with HL7, and started a working group there called ARCRIM, and also work with another one called clinical interoperability. And we led the Joint Initiative Council, which is a group of SDOs, global SDOs.

And we have 90 countries participating and downloading standards. They are free. They are openly available through our website. And we have a vision of informing patient care and safety through higher quality research. Now that's CDISC, but we believe in collaborating with all other organizations, and not reinventing the wheel.

So these are some of our important collaborations. IMI is a product of the European Union and EFPIA, and their default standard for their projects is CDISC. If CDISC standard doesn't exist, they will partner to develop a new one. We are part of the SHARP grant with Mayo Clinic that Chris leads. We have worked with Duke for years on a number of standards. We work with the Critical Path Institute in Arizona. We work with the Translational Research Informatics Institute in Japan, which requires that CDISC standards be used for all of the studies that they fund through the Japanese government, through this organization.

And our – I'll talk about the NCI in a minute. And I didn't put FDA up there because they were a given in my head. These are examples of the ones that you might not know about. But FDA has been asking us to put standards together to improve their review of submissions for new products, since '97 we've been working with them, and also with the European Medicine Agency.

This is our website dashboard. You can see the standards and how they relate to each other. So we have foundational standards. We have an XML exchange standard. We have semantics, and we have what we call implementations, which are – one of them is our Healthcare Link, which is how do we put research and healthcare together. So the ones circled in yellow are the ones I thought were most relevant, and I have a couple of slides on each of those, and then I'll wrap up with the Healthcare Link piece.

But we have what we call a BRIDG model, which harmonizes all of our standards. So we don't publish a research standard that doesn't work with another research standard through CDISC. All of CDISC standards are harmonized through the BRIDG model, which is – looks like this. It looks a lot like an HL7 standard. It's a domain analysis model. But if you read the words on it, people doing research understand the words, and so those are the sections of the BRIDG model. And you'll see study design is right in the middle, but we have patients and subjects and all the things that we deal with. This was harmonized with the HL7 RIM so that we could make a link with healthcare.

And over there you'll see adverse events. We've modeled five at least adverse event models into the BRIDG to harmonize them, so I hope that anybody who needs an adverse event standard will just take it from the BRIDG and use those elements that they need to make that standard, and – or use one of the standards that we've already harmonized.

This is what we do with our vocabulary. It's all in the Enterprise Vocabulary Services metathesaurus at the NCI. Actually, I went to Chris about, what, eight years ago, and said, I don't know what to do, because everybody wants terminology, and we haven't done it. And he said, why don't you talk to NCI? And they agreed they would do our terminology, and that they didn't have to do just oncology. And you can see on this slide that they have provided a repository and a metathesaurus that puts 76 national and international sources into the database, including SNOMED, LOINC, and the MedDRA, which is pretty specific to clinical research.

This is an overview of CDASH, and all I'll say about that is that it is a core minimum data set that has been created to be what do you absolutely require for every single research study around the globe? And so it's a minimum data set. So if you start with this minimum data set and add to it, then you can create your protocol or your design for your study, and so this is a very important I think standard that people – it's harmonized with all the NCI's common case report forms, and it just forms a base to start with.

And these are the domains. Some of these only have three or four data points, but it's what's considered essential per the regulations around the globe for doing a research study. So it's – adverse events is at the top of the list, concomitant meds, demographics, those are the domains that are in it. And we have examples for the case report forms that go along with those, and then ways to carry them in what's called ODM.

This is what ODM looks like, and the important thing about this slide is it shows the audit trail. And this is a requirement for regulators to see an audit trail for how the data are collected, if they're changed, when they're changed, why they were changed, and by whom. And that goes along with 21CFR11, which is the regulation around electronic record keeping for clinical research. So that's kind of the clinical research HIPAA, if you will, and that's – our standards meet those requirements.

And then this is the initiative that got us really a lot further in terms of creating something that links research with healthcare. And actually, the FDA, a group there asked us to put together a mutual forum to look at how could we facilitate the use of electronic technology in the context of existing regulations without having to change those regulations? And that is eSource, that's eDiaries, patient reported things, electronic health records, to make it easier for clinicians to conduct studies and to collect data once, and not reenter it, and to improve data quality.

So we have a document. It's about 120 pages posted on our website. But there's 12 requirements that are important. It's referenced by EMA in their guidance. FDA just came out with their eSource guidance. And it forms the basis for what we call Retrieve Form for Data Capture, which is an integration profile that we created, and that is I think what Doug's referencing when he says structured data capture. The important thing is you can have a remotely managed forum, and it can be pulled into the environment of an electronic health record. Certain fields can be pre-populated. You can enter the rest of the fields, and then send it back to who requested the form. So this is a very powerful but very simple way to collect a core information data set.

These are some implementations of it. It was used by the CDC for H1N1 reporting. It's been used in Japan for EHRs for research. It's being used in Europe. So far, there's a couple of academic studies, and the people in the US I think are afraid to use it, even though the FDA has said go ahead, use it. And it's been used for adverse event reporting, and it's a major workflow enabler, because when these doctors were not reporting adverse events before, implementing the RFD at Harvard when a drug was discontinued, all of a sudden they started reporting them, and you can see it went from 35 minutes down to a minute, and it was happening. And this was published in *Lancet*.

So this is also the basis for a use case or a value case that went through HHS during the HITSP days, and it was not funded through the government because they had no more money, because it was the last use case to ____ forward. So contributions from 32 interested organizations and 6 government agencies funded this, and Dixie, for your sake, this was considered to be the common core data set that could be exchanged between EHRs and research to form a basis for future work that might help accommodate pharmacogenomics, patient eligibility, other use cases.

So it's there. It looks like this. It goes – the HITSP IS is to use the CCDA, which we've mapped to what we call a clinical research document. We use the RFD for the workflow enabler. We use CDASH as the core data set, and it's carried then through with ODM. So it enables collection of a core research data set in a 21CFR11-compliant what that is interoperable. So that's sitting there, available. It was ratified at the beginning of 2010.

And these are the other integration profiles that we've been working on to complement that in terms of confidentiality and security, and I'll leave that with you. And I'll close by just saying we started by doing a core research data set, and now everybody says, now you need standards for every therapeutic area. And so these are the therapeutic areas we've been working with and collaborating with a lot of other groups to get those done, to do implementations around those areas. And this is one of the PDUFA requirements for FDA now, is to produce those standards that would accommodate those about 50-some therapeutic areas with those standards, for a use case at least of trying to make sure that they get the information in FDA that they need.

These are the ones that IMI is doing, that synch up with the ones that we're working on. And TRI is using the Alzheimer's standard for research in the study with China, and CPATH has a database now with 6,000 Alzhimer's patients' data that people can do modeling and look for new therapies with that database.

So the last thing I'll say is we've learned through doing these therapeutic area standards that we can work with common data elements, but you can kind of see up here that nobody's agreed to what is a common data element. There's four different definitions for this. We ran into trouble because common data elements satisfy maybe what a clinician would collect, but they don't satisfy how you take them downstream and analyze them and figure out what's going on with the study. So it's very important to take the whole thread and look at how common data elements work.

So One Mind for Research is actually doing that, and there's the map of what it looks like when people just want to work with common data elements. It's frightening, and I would reference this paper to all of you. It's actually posted on our website, but it is produced by One Mind for Research, and it's a position paper on navigating the CDE landscape, which I think is very relevant to taking some of this work forward.

And because we need a place to house all this stuff electronically and not on paper, we're trying to create something that we call SHARE, which is Shared Health and Research Electronic Library. And I know CDISC needs this. I frankly think everybody around the world needs something like this to be able to access electronic standards more easily and more readily, because on spreadsheets it's not going to work forever.

So this is a little hard to see up there, but the – all – this is my last slide, is just showing that there's an important healthcare space, there's an important research space, and we've been trying to create these things in the middle to bring these back together so that we have BRIDG, SHARE, and this RFD profile. That's it.

Jonathan Perlin – Hospital Corporation of America
That was a terrific tour de force, and I know it's generated a couple of comments. We're over time, but I think that was just terrific in terms of identifying a set of standards and resources that are available to us. Leslie and Chris – Leslie Kelly Hall?

Leslie Kelly Hall – Healthwise
I just want to thank you, Becky, and also point out that I think there's a natural nexus point between the patient now entering in the ecosystem, research, and the business of healthcare, and an opportunity to harmonize by having the patient come in is very important. Specifically, the work that CDISC has done around consent is worth looking at, and then perhaps we should look at the CDASH work around what is the minimum data set, and look and see how that also is relevant to patients as they participate, because this is where in medicine patients have been active participants, not just subjects. And so I think it's an important opportunity for us to see how these data can integrate more easily. So thank you.

Jonathan Perlin – Hospital Corporation of America
Thanks, Leslie. Chris Chute?

Christopher Chute – Mayo Clinic College of Medicine
Thank you. I also appreciate your comments, Becky. I can say as a card-carrying NIH investigator that the importance of research standards is unquestionable in terms of having efficient conduct of research. However, now this is important, what has happened in healthcare, I have enough gray in my beard to have played in enough sandboxes that I saw the quality community essentially reinvent infrastructure and tools and resources that were completely analogous to what the research community had been doing for many years.

I'm starting to see that again. We're starting to see the emergence of the dreaded analytics community, not that they're fundamentally bad, but they're reinventing a lot of the infrastructure, a lot of the methodology, a lot of the techniques, a lot of the data structures that, oh, by the way, the clinical quality community had been doing, and oh, by the way, the research community had been doing for at least 15 or 20 years in a relatively formalized way.

My plea as a member of the HIT Standards Committee is that we not reinvent yet another set of standards, but we look very carefully – and I should disclose that I was a member of Becky's board, an unpaid member, for three years, but nevertheless, it gave me significant insight into what that community has been doing, and the formalization that has been achieved, and the parallels with the quality community are striking and largely redundant. And I'm starting to see the same kind of activity in the analytic community that is at some level disturbing, because we are having a fragmentation and yet another creation of disparate standards. Thanks.

Jonathan Perlin – Hospital Corporation of America
And Dixie Baker, then Dave McCallie with the last words on this topic.

Dixie Baker – Martin, Blanck, and Associates
Thank you, Becky. This is really incredibly interesting, and I'm sorry you were – you did have your time limited.

Jonathan Perlin – Hospital Corporation of America
Well, she actually had 20 minutes.

[Laughter]

Dixie Baker – Martin, Blanck, and Associates
Okay.

Jonathan Perlin – Hospital Corporation of America
Just for the record.

Dixie Baker – Martin, Blanck, and Associates
Earlier you heard – you know, we had a brief, you know, exchange here where, you know, we considered the proposed measure for sending data to a registry, and I suggested that perhaps the – we could use the same standards that we used for – to enable a patient to send their data to a third party for that purpose, and it sounds like maybe the CDASH standard might be considered for the data elements that would be in that as well. And I was just kind of wondering what you thought about it. I mean, that standard happens to be the CCDA, but it's, you know, to send the patient's data to a third party where the registry would be the third party. And I was just kind of – before I send the details to John, I thought I'd run it by –

Rebecca Kush – Clinical Data Interchange Standards Consortium (CDISC)
Some of the – some of the best registries I think that I know of are the ones that Gendon started around some of the orphan diseases, and they've built those around the BRIDG model, and they're using methods that you could look at that they're getting the data and using standards that are consistent with this. So I would look at that before you start over. There's also Outcome –

[Crosstalk]

Rebecca Kush – Clinical Data Interchange Standards Consortium (CDISC)
– Outcome Sciences, which gave a testimony, recommended using RFD to the HIT Standards Committee. I think they've been now purchased by Quintiles. But they have capabilities. The RFD actually has been endorsed by the EHR Association. There's a letter on our website. Most EHRs have tested for RFD, and can do that. It's –

Dixie Baker – Martin, Blanck, and Associates
So they would retrieve a form first before they sent the data ____ pushing ____ –

[Crosstalk]

Rebecca Kush – Clinical Data Interchange Standards Consortium (CDISC)
Well, and so the – so the registry would have whatever form, but you could start with a set of core elements and then add what you need to those, and that's what we do. Even for the adverse event reporting, the adverse events were reported with a standard that was based on SNOMED, went through the ICSR, converted into MedDRA, but it was – all used RFD.

That was the core integration profile that – and I need to give credit here. The person who was the brains behind RFD when I went to him and said, we're having trouble linking clinical research and healthcare ten years ago, is Landon Bain, who was the CIO at Ohio State. Then he went to Duke. He implemented the first EHR at Duke University. He's now retired from Duke and working full-time with CDISC, and he understands both communities now, because I asked him to go look at it all. And he was the brains behind that powerful integration profile. And Dixie's tried it out.

[Crosstalk]

Jonathan Perlin – Hospital Corporation of America
David, the last, final word. Brief final word.

David McCallie, Jr. – Cerner Corporation
That's a contradiction for me. Yeah. No. First, Becky, thanks for incredible coverage of a lot of ground in short order. And I just will raise this as a question for some future discussion. I was struck by your clinical data – or common data element slide, and the difficulty of harmonizing those approaches. And I think that's where we run into problems in integrating into the clinical workflow, and this is true – even if you don't take research into account, it's true amongst different clinicians, who have different levels of granularity for what they need documented.

And if you don't get enough granularity, it might be useless data to the downstream clinician who needed more granularity. If you try to capture the additional granularity from someone who doesn't need it, they get really mad at you for wasting their time capturing data that's not useful to them. And it's a huge problem that I don't think anyone has solved.

Rebecca Kush – Clinical Data Interchange Standards Consortium (CDISC)
I do think this might be a conversation for the future, because I know Chris has dealt with it through SHARP, and we're looking at the CEMs and CIMI and detailed clinical models.

David McCallie, Jr. – Cerner Corporation
Yeah.

Rebecca Kush – Clinical Data Interchange Standards Consortium (CDISC)
And what we call ours is Research Concept. At some point I think they're the same thing. It just depends on how you shape them. And I think that's where we're going with SHARE, and we want to link it up with healthcare. There's no point in keeping it separate.

Christopher Chute – Mayo Clinic College of Medicine
If I could respond to David, this is Chris Chute. It's really the concept of data salvage more than data collection, if you appreciate that distinction, in that one is presumably harvesting data that has already been collected. It's not protocol-driven research, observational research, and you have to understand that distinction, so that the requirement to explicitly collect data is not there. But if the data happens to be available in an opportunistic way, then it's the issue of having comparability and consistency in the way that it's recovered.

David McCallie, Jr. – Cerner Corporation
Yeah. I think – this is David. I think that's a – that's a great point. I was focused more on the if somebody downstream wants a particular detail of granularity and you try to push that onto the data capture process so that you have it downstream for salvage, it works as long as the person who's capturing the data has value in capturing that additional granularity. But if they don't, you get into the tension of asking too much of the clinicians.

And that's – you know, we get beat up if we make our applications too complicated. You get beat up if you don't have enough data to drive the research. So it's a tension that we have to figure out. We – we've tried.

Rebecca Kush – Clinical Data Interchange Standards Consortium (CDISC)
And I think another tension that's related that we brought up earlier is how much structured data do you capture versus narrative, and that's been something in research –

David McCallie, Jr. – Cerner Corporation
Right. Right.

Rebecca Kush – Clinical Data Interchange Standards Consortium (CDISC)
– forever that we've discussed. And FDA will tell you, you know, they want structured data so you can analyze it, but they also want the narrative around an adverse event so that they know what really happened.

[Background voices]

Jonathan Perlin – Hospital Corporation of America
I think this note of enthusiasm and continuing discussion is a great note to end on. So Becky, you asked at the beginning what would the reaction be, and I think the reaction is very vigorous, in the positive sense, positive really in three ways. First, this question of the use cases and really understanding them, and to – how does one achieve the greatest compatibility between use cases in a learning health system? As Dr. Mostashari keyed up at the beginning, phase four, literally, the meaningful use, is really about that learning health system.

So as we move forward, this is particularly important. I think this discussion also highlighted that this is not value neutral. There are philosophies behind how one approaches a use case, and that's terrific. And last, I just note, you know, in our organization we joke about the NIH syndrome, not National Institutes of Health, but Not Invented Here.

And I think what you just highlighted for us, and appreciate the FDA colleagues' presence, support, and your leadership, is really that we need to make sure that we're really informed about all of the resources that in fact do exist currently in the environment, and really map them to both the use case, the philosophy of approach. That was notable in the public comments as well, the reference to NCCMERP, an organization that happens to be one of the systems we use for recording adverse events.

But throughout the course of the day we've had not only discussion on that, but about the precision – the precision of patient preference. It intersects directly with not just the adverse event discussion, but the reason for cessation, the recording of information, and so this is – this is so multifaceted.

I want to thank everybody not only for the hard work, but their indulgence. I know we ran over, but we've just really been addressing our agenda for the year. We've been addressing really that trajectory, that threading the needle of stages two, three, and four, in the areas where there's clarity, in the areas where there remains ambiguity, and look forward to that future work with you. So travel safe, hope your new year is off to a great start. Many thanks to ONC, to the members of the public who participated, and to everyone here who's worked so hard, whose work will shape this next stage. Becky, thanks for a terrific presentation. We stand adjourned.