HIT Standards Committee
Draft Transcript
April 17, 2013

ATTENDANCE

The following members attended the meeting:

- Dixie Baker
- Anne Castro
- Tim Cromwell
- John Derr
- Jeremy Delinsky
- Floyd Eisenberg
- Jamie Ferguson
- Keith Figlioli
- Lisa Gallagher
- John Halamka
- Leslie Kelly Hall
- C. Martin Harris
- Stanley Huff
- Elizabeth Johnson
- Rebecca Kush
- Anne LeMaistre
- Arien Malec
- David McCallie, Jr.
- Kim Nolen
- Wes Rishel
- Eric Rose
- Andrew Wiesenthal
- Nancy Orvis
- Kamie Roberts for Charles Romine

The following members were absent:

- Lorraine Doo
- Jonathan Perlin
- Christopher Ross
- Sharon Terry

Presentation

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thank you. Good morning, everybody. This is MacKenzie Robertson in the Office of the National Coordinator for Health IT. This is the 47th meeting of the HIT Standards Committee. This is a public meeting, and there is time for public comment built into the agenda. And the public comment sessions will be limited to 3 minutes each. This meeting is also being transcribed and recorded, so for the sake of the record, if you could please identify yourself before speaking. I'll now go through the roll call. Jon Perlin? John Halamka?

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

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks, John. Dixie Baker?

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

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks Dixie. Anne Castro?

Anne Castro – BlueCross BlueShield of South Carolina – Chief Design Architect
I'm here.

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks, Anne. Jeremy Delinsky?

Jeremy Delinsky, MBA – athenahealth, Inc. – Senior Vice President, Chief Technical Officer
Present.

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thank you, Jeremy. John Derr?

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

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks, John. Floyd Eisenberg?

Floyd Eisenberg, MD, MPH, FACP – Independent Consultant
Here.

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks, Floyd. Jamie Ferguson?

Jamie Ferguson – Kaiser Permanente, Institute for Health Policy – Vice President, Health Information Technology Strategy and Planning, Fellow
Here.

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks, Jamie. Keith Figlioli? Lisa Gallagher?

Lisa Gallagher, BSEE, CISM, CPHIMS – Healthcare Information & Management Systems Society (HIMSS) – Senior Director, Privacy and Security
Here.

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks, Lisa. Leslie Kelly Hall?

Leslie Kelly Hall – Healthwise – Senior Vice President, Policy
Here.

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks, Leslie. Martin Harris?

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

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks, Martin. Stanley Huff? Liz Johnson?

Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Tenet Healthcare Corporation – Vice President, Applied Clinical Informatics
I'm here.

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks, Liz. Becky Kush?

Rebecca Kush – Clinical Data Interchange Standards Consortium
Here.

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks, Becky. Anne LeMaistre?

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

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks, Anne. Arien Malec?

Arien Malec – RelayHealth Clinical Solutions – Vice President
I'm here.

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

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

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks, David. Kim Nolen?

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

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks, Kim. Wes Rishel?

Wes Rishel – Gartner, Incorporated – Vice President & Distinguished Analyst
Here.

MacKenzie Robertson – Office of the National Coordinator
Thanks, Wes. Eric Rose?

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

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks, Eric. Cris Ross? Sharon Terry? Andy Wiesenthal? Tim Cromwell?

Tim Cromwell, RN, PhD – Veterans Health Administration – Director, Standards & Interoperability
Here.

MacKenzie Robertson – Office of the National Coordinator
Ahh, thanks, Tim. Lorraine Doo? Nancy Orvis? And Chuck Romine? And just for anyone out there using twitter, the hashtag is HITStandards, and with that, I will turn the agenda over to John Halamka. Farzad Mostashari is running a little bit late today, so we'll turn it over to John to do the review of the agenda.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Great. Well thanks very much. And Jon Perlin is running an HCA activity so he can't be here today, but he certainly sends his best to all of us. Farzad was so enamored of our old hotel, the Dupont Circle Hotel, that he decided to go there this morning, but don't worry, he'll be here shortly. So today's agenda is important as we look at the work plan. And if you recall, we had a work plan, which divided up, into quarters, the priorities for the Standards Committee to work on, noting that about 12 projects were going to be done between January and March. And given that it's April, we have to do have to do a little recalibration. We had a chairs call over the last month, where we actually looked at the work plan and asked ourselves questions about what is achievable? Where are standards mature? Where are workflow processes existent? And very vocal commentary from the chairs looking at all of the work that we have ahead of us for Meaningful Use Stage 3 and for supporting the goals of ONC S&I, etcetera, and recognizing, you know there's only certain things that the Standards Committee can be effective doing.

So if no standards exist of any kind, there may be a limited amounts our workgroups can accomplish. We actually – Doug I think some meetings ago, had described there are those things that require an initiative, like the Direct Project Arien ran. There are those things that should be done in an S&I framework kind of activity and there are those things that are widely assigned to the Standards Committee, such as review of the landscape, a pulse check, getting testimony from industry. And so our chairs call gave ONC and Doug some very significant input. So what we're going to hear from Doug is, now that he's heard that input, how can ONC best support us? How do we take a body of work, triage it into the next month ahead? How do we ensure that we get the specificity we need, the use cases that we need, because if we're given a task like, "Hey Dixie, can you secure things?" "Well gee, that's wonderful, but what do you mean?" "Can patients get at them? Well what do you mean?" And so we'll hear that specificity from Doug this morning with some truly very concrete, go forward next steps, and we'll ensure that we don't get a bulk of work that puts 12 tasks into the month of June, that they're spread out over the course of the year.

We'll hear updates from ONC on some of their current projects. We'll hear a structured data capture presentation, very important as we look forward to Stage 3. Probably the last thing that we want to do is come up with a new standard for every single instance of needing to capture structured data, especially from patients, and Stan you're in over there. We'll have two public comment periods, one before lunch and one at the end of the meeting. Important agenda clarification, Mickey Tripathi will be joining us by phone today, talking about the Policy Committee comments on the CMS/ONC RFI on interoperability and exchange. It is not a request for the Standards Committee to make its own comments on interoperability and exchange; it is to listen to Policy Committee comments. So whew, don't worry, no extra task assigned to you today, and Mickey has some very thoughtful comments as to what ONC can do to accelerate interoperability. We'll hear a presentation with Mary Jo and Kory on governance, some of the grants that they have given and some model governance activities and information sharing activities. Lunch will be in the restaurant today, where there are pre-orders at your places and then we will all gather at one large table hopefully.

Administratively, there is one task MacKenzie has asked from us, and that's the approval of the minutes from our last meeting. So I know you've all reviewed those. Were there any edits or comments on the minutes? Okay. Well MacKenzie, none being heard we will approve the minutes by consensus. So since Farzad will be here in just a couple of minutes, we will go ahead and start with Doug and then we will return to Farzad for opening comments. And Doug, as you're getting seated of course, from an IT perspective, as the guy in Boston who has to, over the last 48 hours, dealt with many aspects of communication triage, emergency care delivery, I can tell you the impact of healthcare IT over the last 48 hours was very clear, as my hospital had to deal with 21 victims of the bombing, seven critical, and deal with information exchange and ingoing and outgoing communications. So, got a chance to really use all the things we create in this committee, so certainly thank you for your work supporting that. Doug.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology

Thank you. What I'm going to do is this is sort of an iterative refinement of the work plan that we've got. I think we've got some, probably over the next couple of months; we have some sense about what's going on. I think there is flexibility in terms of where we want to move with some of these things, but again, we've taken the initial work that we got from the Policy Committee, which then we translated into activities that could be done in the Standards Committee, and then after the chairs call, we've refined that down into a smaller subset of activities that are ongoing.

So the way in which I'm trying to frame a lot of the work that we do and the things that need to be teed up is, how can ONC support the conversations that need to occur in the HIT Standards Committee regarding the topics that are listed in our summer plans. And what I mean by that is that sometimes we need you folks to kind of get together and help us clarify between alternative standards perhaps, or to help us assess whether something is ready, or to give us some of the background about what's happening in the environment. Sometimes it's that things aren't quite ready to where they need to be, but we need your early input and feedback to make sure that we're moving in the right direction. So when we talk about like what is it that we're going to talk about or how we're going to tee these things up in the summer and in the fall, the question really is what's the conversation? What's the kind of information that we need? And sometimes it's going to be early, does it make sense for us to even kind of go down this path? Sometimes it might be later to say in fact, we've done some things and we went to see if this is on the right track, so just realize that when we put something on the topic, it isn't you need to make a decision and establish a standard for X, Y or Z, it's really about the conversations that need to happen at that time.

And so there may be some times where we need to get things teed up more than once, we may need to have multiple conversations that allow us to sort of say, here's the direction, here's a check-in, here's what the final product looks like. So as you're looking through the work plan, identify or help me identify, those times when you say, gee, I see that in September you're going to present this. It would be really good if in July, we had a little update, so that we could start preparing or understanding what's going on. So think about that as we go through it.

The other thing that I think is important is that, it's important for us, we've had some conversations and I want to sort of dissuade people of using this language, which is, well what are the things we can do and what are the things we can't do, because that makes the decision seem binary. And the thing is that, and we were talking about this earlier, is that when the HITECH Act was passed, there was a series of programs that were set up that were funded with stimulus dollars and that were intended to, at some, point to sunset. However, as part of the HITECH Act, there was…Congress gave ONC authority to establish the standards, implementation guides and certification criteria. It established the HIT Policy Committee with very strict kind of rules of the road, in terms of who could appoint and what would the representation needed to be, and it established the HIT Standards Committee as well. So this group is not something that goes away when the "R" dollars go away.

And so we need to think not only about Meaningful Use Stage 3, but we also need to think about what we need to achieve as a community going forward with health information exchange and interoperability. And so when we think about this stuff it may be, and sometimes I feel this pressure as well, sometimes we work in 12 to 18 months sprints, because it's like, oh, well the next regulation is coming out and we've got to get this done. Sometimes we're going to have to take 24 months to get something done, and we may need to tee something up now that will get us ready in subsequent rounds of regulation or for other kinds of regulations that we might have. Finally, and John sort of alluded to this as well is, we need to triage the work into coordination and additional information from the HIT Policy Committee. So some of the work that needs to happen is that we need to tee up, because there were questions raised that we need to tee up a conversation with the HIT Policy Committee to say, we the Standards Committee have some questions and we need you to help us with that. Sometimes there are existing standards that can be recommended to ONC, and so you guys can say, listen, there are already some solutions out there that will fit this, and we think that this is a path forward. Or, there's work going on right now in HL7 and we expect that it will be completed in time to be balloted and we can then recommend that.

There may be existing standards that need to be modified because they're not quite fit for purpose or new standards that need to be constructed that we need to leverage. And we've also built-in some time to do what we call a pulse check, for activities that have a longer time frame, may require multiple steps to get there. And we need to keep visibility in those things so that we don't sort of say, we need to work on this and then disappear for two years and then something emerges. We really need to make sure that we have this ongoing conversation. So that, just by way of framing, is where we need to go. So Farzad just arrived. Farzad, I'm going to finish my presentation and then I'm going to turn it over to you. Okay?

Farzad Mostashari, MD, ScM – Office of the National Coordinator – National Coordinator
Okay.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
We just got started anyway. So, the first thing here is this is kind of the Q1 January to March work plan.

The first thing is there are additional standards to support transport data to and from patients. And there were a lot of questions about what does that mean? Do we need to create new standards, what's out there? So again, thinking about the conversation that this group needs to have, there's the NwHIN Power

Team, I think Privacy & Security teams are probably going to be really important to provide us input. And the conversation really is what we have so far? We should probably do a presentation, an update, on what's going on with our existing transport standards. So yeah.

Leslie Kelly Hall – Healthwise – Senior Vice President, Policy
We need to talk in the committee, too about the new consumer teams also be included in this, because at the time it was written, those consumer teams did not exist.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
Okay, thank you for that friendly amendment. So we need to present existing transport standards. We need to have the presentation of the RHEx pilot that we did that was a RESTful interface that we did with the FHA and some of the federal partners, just to give you a sense for what's going on with that and get some feedback. And then we need the presentation of the ABBI and the Blue Button, that's kind of Leslie, to your point, where the consumers would get engaged. And then have a discussion about, do we have adequate coverage in our transport standards and if we were going to proceed to do some additional work, what would that look like? Where are the gaps and the holes?

What we thought is that we could probably tee this up in May, if we wanted to have the conversation here in the HIT Standards Committee. Or, if what we wanted to do is to have the Power Team, Privacy & Security, Consumer Engagement look at this first, get their heads together and then present back to the bigger committee, we could probably do that in June. So, if people have a particular preference, we'll either tee this up in May for the larger group community or if we want to, and I'm kind of looking at Dixie and Leslie and who else – well the Privacy & Security Tiger Team, we can talk to Joy about that. Do you guys want to talk about it first in committee and then bring it to this group?

Dixie Baker, MS, PhD – Martin, Blanck and Associates – Senior Partner
This is Dixie Baker. What's the next step there, it says presentation May/June, that's what you're talking about, which you have three presentations listed on the left side, are you talking about presenting all three of those in May or June?

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
Yeah, I think that that needs to be a conversation. These don't have to be extensive, but it's like, what are we doing with Direct, what are some of the issues that we're doing with Direct as it relates to our federal partners, to our certificate policies and sort of our goals and aims. I think there's some work that probably work needs to be done about the web services and kind of how that kind of exchange is occurring. Perhaps an update on the RHEx Pilot and what we've learned from that and whether there's a pass forward there. And then have a discussion about the consumer media, not just provider to provider, but what the issues are with provider to consumer. And I thought what we'd do is, we'd give ourselves an adequate period of time, maybe give some very brief presentations about stuff and give you some reading material ahead of time and focus the attention on the discussion. If you think that there's some value in doing some predigesting within the workgroups, then what I'd do is push it off until June and we'd work on it for the next two months.

Dixie Baker, MS, PhD – Martin, Blanck and Associates – Senior Partner
The RHEx – is that how you pronounce it?

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
RHEx.

Dixie Baker, MS, PhD – Martin, Blanck and Associates – Senior Partner
RHEx. The RHEx pilot, we did receive a presentation about that and that's pretty complex. There's a lot there. There's less involved in presenting existing standards and the ABBI/blue button, I think. But even the ABBI is something that's ongoing. So it wouldn't – I don't think it would just be a presentation from the Nationwide Health Information Network Power Team, right, it would be also involving some of the S&I framework initiatives feedback.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
So the issue is, I think that's kind of the information that maybe will help us have the conversation that we need to have in this group. The question is, is would you like us to work directly with the working groups first and sort of predigest it, and then come to this committee with that kind of insight?

Dixie Baker, MS, PhD – Martin, Blanck and Associates – Senior Partner
Yes, it would. You can work with NwHIN Power Team and I also want to take this opportunity to introduce my new co-chair, David McCallie, and thank him you for agreeing to work with me on that. Do you agree David, that we should take time to digest this.

David McCallie, Jr., MD – Cerner Corporation – Vice President, Medical Informatics
Yeah I …

Dixie Baker, MS, PhD – Martin, Blanck and Associates – Senior Partner
And kind of work with ONC to organize it?

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
Okay. So what I would suggest then is, let's make sure that this happens in June and then we'll work with the Committee to make sure the happens in May.

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

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
And to that point, Doug, I mean because Dixie has had many thoughtful comments on our phone calls when you talk about use cases, what is it we are trying to achieve with this one? Is it a download? Is it the use of Direct? Is it RESTful, what is this? And so doing that predigestion so you can get the what and then then understand the landscape and then say depending on the problem to solve, here are the standards you could use would be wonderful so you …

Dixie Baker, MS, PhD – Martin, Blanck and Associates – Senior Partner
And what are the gaps brought up before.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
Okay. Good. So the first couple of ones we'll spend a little bit more time discussing, we'll probably go faster through the later part of this. But it's very helpful for me to sort of have this conversation, so that we can figure out the best way to lay out the work. Number two, standards to support image exchange. I think what – if I can summarize the discussions that we had in the chair. Image exchange has come up on multiple occasions, in Meaningful Use Stage 1 and Meaningful Use Stage 2. And I think part of the challenge that we've had is that are we talking image exchange where we need a JPEG of an image that can be seen on my retinal display on my iPad, because I was seen in the emergency room yesterday. Or is it that I need a DICOM image of the full voxels of the MRI because we're doing cancer staging for a consultant who needs to have that image and needs to be able to look at it?

And so what happens is, is we aren't clear about the problem we're trying to solve and we end up saying, well, JPEGs aren't right, we need to window it in a website. Are we going to be able to download it? Do we need to just be able to view it? And we end up not necessarily getting clarity about what the standard is that we're trying to support. So the suggestion here is that we should figure out – we should have a presentation back to the Policy Committee to say, what is the goal you're trying to achieve? And hopefully they can say, there are two use cases, we want you to support X and Y and that we need standards that will support X and Y. I think once we get clarity around that, then we can turn to the standards community and what's in DICOM and what we have available on the Internet with JPEG's and all the other sorts of basic standards that are out there. Trying not to reinvent something that is different and more complex, just for health, but take a look at all of those things and determine what the right use case is. It may be perfectly sufficient to have a lossless image that's available for a patient and to have some more complex structures, if we want to send that to a consultant.

So the thought here is let's tee up in May a presentation to the HIT Policy Committee and have that conversation. And then once we do, we'll be able to then take that back and establish a fairly clear work plan for getting the work done. Any questions about that?

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Answer to your point, oh, please go ahead David.

David McCallie, Jr., MD – Cerner Corporation – Vice President, Medical Informatics
David McCallie. Just to point out that a tightly coupled question is the authorization to be able to actually view the image, and that's what the RHEx project was about, so there may be some cross-correlation between those two groups.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
That's good.

David McCallie, Jr., MD – Cerner Corporation – Vice President, Medical Informatics
Because zero footprint image viewers are pretty commonplace, but getting permission to actually invoke and view the image is where the barrier is, in our experience.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
Yeah. So the question I have is, we in ONC can certainly tee up some of these presentations. I think it is much more powerful if we have some representation from one of the workgroups who we then can review that with and them they can be the ones that potentially do the presentation supported by ONC, or at least have that conversation. We had indicated clin ops here, the consumer patient engagement power team as well. Do you guys want to volunteer to at least review slides and make sure we are on the right track? Okay. Good.

Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Tenet Healthcare Corporation – Vice President, Applied Clinical Informatics
Doug, this is Liz Johnson.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Liz, go ahead.

Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Tenet Healthcare Corporation – Vice President, Applied Clinical Informatics
Thank you, John. One of the things I wanted to add here and rather than repeat this comment several times throughout, as the chairs met, we are – the Implementation Workgroup will be working closely with these, with Clinical Operations to ensure that the feasibility and usability of the standards is also represented here. So if you would include that in the work plan that would be terrific.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
That is great. Thank you.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Per Liz's comment and your comments Doug, imagine the use cases, we want to deliver a patient, an image. Well let's think, if we were going to send a, oh I don't know, a gigabit DICOM blob over Direct, that may not actually be the usable or efficient approach. As an example, last meeting, I had somebody who was demonstrating the image of my X-ray being sent to HealthVault, and what they did is, the cloud hosted service and they sent the URL to HealthVault and it was a deep zoom, as sort of you think about JPEG, but a JPEG you could zoom and highlight and window. Oh, and if that's the problem you're trying to solve, oh a URL over Direct to a cloud-hosted, scalable JPEG, what I'll call vendor-neutral viewer. Oh well, that's fine. And so we, I think as a Committee, Clinical Ops would love to hear the problem you're trying to solve and then we will think the scope of standards, both content and transport to solve it.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
Yeah. No, I think that's exactly right. I think we need to bite off a chunk that is significant in its impact, but manageable in its scope. So we just have to figure out what that is, and I think having that conversation with the HIT Policy Committee is going to be important. Let's move on here. The standards, which address current content gaps. So I had a sidebar with Jamie just before this. This is really to say, we've got a bunch of stuff that is in the S&I framework, work that's gone on with the – within HL7. There are a whole series of additional kinds of transactions that the HIT Policy Committee has sort of teed up, this notion of canceled transactions needed and formulary downloads and version 2 lab orders and things like that. So what, and I teed Jaime up with this as well is that what we need to do is ONC needs to work very closely with the Clinical Operations Group and establish really what their work plan is going to be. Such that we can say, we've got two months of work and in June, we'll come back with these things that we are going to make recommendations for or we want to have a broader conversation about. And it may be a couple of meetings that we need through the summer as they bite off these chunks. So Jamie came up with a plan, so I'm going to just turn it over to him.

Jamie Ferguson – Kaiser Permanente, Institute for Health Policy – Vice President, Health Information Technology Strategy and Planning, Fellow
Well, thank you, Doug. But, I think it's premature to say that we have the plan.

M
A plan for a plan.

Jamie Ferguson – Kaiser Permanente, Institute for Health Policy – Vice President, Health Information Technology Strategy and Planning, Fellow
We have a plan for plan, that's right. So we will take our next Clinical Operations Workgroup meeting to go through this revised "to do" list and to chunk it up, so that roughly we'll come back to the Committee every other month with a presentation and/or recommendations on an appropriate chunk of work. And I wanted to thank you Doug, for mentioning the fact that some of the main feedback that we had was on the need for greater specificity of the use cases. Because a number of the things, the way they were listed, we just couldn't decipher what it is that's being asked for, so standards for images? Well what's the…I mean, there are a number of very different use cases that that could be about potentially, but we really need to understand what the Policy Committee has in mind for specific use cases, in order to really work on it at all.

So I think in that, just to take that particular case, if we are going to have an interaction with the Policy Committee, what we might do is outline two or three possible use cases and say, this is the range of use cases, what is it that you have in mind? And if it's all of them, then obviously, that will take longer to do.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
Yeah. So great. What we'll do then is probably on an every other month basis, take a chunk of the work that's being done there and just sort of tick those off the list. As issues come up too, we'll then modify the schedule as we go forward. Number 4 here, standards to secure data at rest, especially genomic data and consumer downloads. This is one that I really defer to the Privacy & Security Tiger Team and working with Joy Pritts and her office. We anticipate, given that we've got some things that already going to happen in May and June, probably in June and July we'll start teeing up some of those things. I actually frankly believe that this is going to be similar to clinical ops in the sense that there are a number of privacy and security issues that we probably just need to tee up on a continuing basis and maybe every other month or so have an update on where we're going. Dixie Baker will clearly be involved in those things as well, but that's kind of – I think we need too, again, in this situation we really need to think about what the use case is and what it is that we're trying to achieve. And there may be some easy wins if we basically say, here are the NIST recommended ways to secure things at rest, is this appropriate for the work that we have. Under HIPPA, and this is where we turn to the privacy and security, what are the responsibilities and requirements for data that leaves the enterprise and goes to the consumer and the like, so.

Dixie Baker, MS, PhD – Martin, Blanck and Associates – Senior Partner
Doug, I have a comment about that, if you don't mind. The HIPAA Omnibus Bill explicitly included text in its preamble that said that information that a consumer downloads to themselves, that the provider has no responsibility for and nor should standards be developed to address securing that, it's totally the consumer's responsibility to secure it. So we did provide that feedback and I'm kind of surprised to see it still on there actually. But – and by the way, I did coordinate that with Deven McGraw, who chairs the Privacy & Security Tiger Team, for those of you who may not be aware – and, from both sides, we agree that there really should not be standards in that area.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
And I think getting clarity on that from this group is going to probably be very helpful. Because I'm not sure everybody – there are some who feel like, if I'm going to use Direct or if I'm going to use something that provides that secure information exchange, that the endpoint receiving that, if you're sending information, there is, I think, some confusion about what the requirements are and whether it has to be secure.

Dixie Baker, MS, PhD – Martin, Blanck and Associates – Senior Partner
Well we can – I can just send you the text from the law.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
So the thing is that I – the reason I had this coordination with Joy and the Privacy & Security and Tiger Team as you, and I didn't put down something that said, here's the conversation that we need to have is because I want to go back and say, in June or July, let's put this to bed. Let's figure out a way that either we say here are our recommendations and this is how we need to do things, or we say there's additional work that needs to be done. So in large part, this is not proposing a particular standard, but the conversation needs to happen about, that may say, as you've indicated, that the preamble suggests we don't have to secure – the consumers are the ones who are responsible once they have that data.

Farzad Mostashari, MD, ScM – Office of the National Coordinator – National Coordinator
The question that I've heard asked Dixie, from providers is, when does their obligation end? At what point, in the – somewhere in between I hold it and you hold it, and where is that line drawn? So there may be …

Dixie Baker, MS, PhD – Martin, Blanck and Associates – Senior Partner
And I'm just saying, that's been answered. I think it hasn't been adequately exposed.

Farzad Mostashari, MD, ScM – Office of the National Coordinator – National Coordinator
Right.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
(Indiscernible)

Dixie Baker, MS, PhD – Martin, Blanck and Associates – Senior Partner
And I think we need to do something …

(Multiple speakers)

David McCallie, Jr., MD – Cerner Corporation – Vice President, Medical Informatics
That gives us an easy meeting.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
So let me give you an actual case example of what everybody's talking about. So it turns out that in Massachusetts we have this thing that's called an appliance or edge server that we use for interoperability. Now we know that not every vendor yet supports Direct, and will soon, but so we've said things like, "Oh, you know what we're going to do Dixie, we're going to use the appliance to receive a completely encrypted direct message. We will unencrypt the payload and sit it in the directory where it can be then FTP'd to a destination system." Well, wait a minute; I haven't yet delivered it and it is sitting unencrypted in a directory, is that okay? And I think what we need to be seeking is exactly the guidance that's been described. When in the handoff from a provider to another provider or a provider to a patient, might the payload be unencrypted? What are our responsibilities once it's handed to the patient, oh, none. Those are the sort of things that you, in a statement, could clarify.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
So, we'll work to get something in June and July to present back to this committee and work with Privacy & Security and Clinical and NwHIN teams as well. Going on to number 5, standards to support digital signatures. So this was one that we had teed up kind of later in the year, but the discussion in the chairs meetings said this is an urgent and important thing. And so we've moved this forward in our schedule, based on the feedback that we got from the various chairs. And I think there's been significant work that's happened within the esMD Project with CMS to establish some standards for digital signatures.

And they talk about digital signatures in sort of three levels. There's a digital signature that you can put on a folder or a collection of documents that you might have. So if you've got a series of different reports, you can sign that whole thing. That's considered sort of level 1. Level 2 is when you sign each of the individual documents. So you've got a document and you sign that. And then sort of that level 3 is being able to sign elements within a document. So you can imagine that for a – if you're in an academic medical center and you have a resident who signs it and then the doctor can add their – the attending physician can add their notes and then sign it again and you'll have two signatures within the same document. There's been a significant amount of work that's gone on with the esMD Project. And they are really moving forward, because from CMS's perspective, what they need to do is they – for them to move to a digital world that involves Direct and web services and to be able to exchange information electronically. They need to have that what's called non-repudiation and they need to be able to have a digital signature so that they can get away from the wet signatures. And so they've been doing a tremendous amount of work and I think what we'd like to do is tee that up in May or June, so that we can get an update on the esMD project, as well as Direct and the certificates there, to try get some distinction between the transport certificates that are signed and the documents that may have a different kind of signature attached to them. So Dixie, is this something that we should work with your group as well on?

Dixie Baker, MS, PhD – Martin, Blanck and Associates – Senior Partner
Absolutely. And I thank you for moving that up in the schedule. We – the Privacy & Security Workgroup – considers that a very, very urgent need.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
And I think CMS and the work that Melanie Combs-Dyer has been doing and Bob Dieterle and others within the esMD S&I framework Project, has really been very, very good at moving forward. And I think it would be great to have this group take a look at that work, evaluate kind of where they are with things and provide some feedback and input and recommendations and the like. So we'll try to tee that up sooner rather than later.

Arien Malec – RelayHealth Clinical Solutions – Vice President
Okay, sorry, this is Arien. Just as a request in that work, if we can tee over either to somewhere in the Policy Committee, because perhaps the Privacy & Security Tiger Team, the issue of proxy roles in healthcare. Because a lot of times the digital signature work assumes that the physician, him or herself is doing the actual signing. And in a world where there's an organizational team that's working under the direction of an individual, sometimes the work that's been done in digital signatures outside of healthcare, doesn't apply one-to-one. So if I could request that issue be teed up for consideration, because I think we sometimes get into unworkable workflows.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
Okay. No, that's a great idea. Go ahead David.

David McCallie, Jr., MD – Cerner Corporation – Vice President, Medical Informatics
And I'd like also, this is David McCallie, to question you Doug, if you think the use case of something shy of full non-repudiation of signature, but proof of tamper-resistance, proof that the message hasn't been altered at organizational level. So that, for example, things cross the firewall could be signed such that it hadn't been tampered with, even if it's not a formal digital signature for the author of the document. Because many of these documents aren't authored by humans, anyway, they're machine generated.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
Right. So if you take a look at the topics that needed to be discussed, it's the reason that I teed up not only the esMD work, which is really the digital signature, the replacement of the wet signature that you'd have on a document, and also discussion about Direct and certificates there. Because those, as you indicate, provide some degree – it encrypts between end-points and there's both an encryption and a signing piece to that. But I think having that conversation would be helpful because I think sometimes people mix those two things together and making that distinction will make it, I hope, clearer.

David McCallie, Jr., MD – Cerner Corporation – Vice President, Medical Informatics
Yeah, because the esMD stuff is going to be complicated to implement, but the proof that it hasn't been tampered with after it left the firewall is not as complicated to implement. So there may incremental steps that we should take.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
Sure. Yes Leslie?

Leslie Kelly Hall – Healthwise – Senior Vice President, Policy
I agree that the whole idea of non-tamperproof is going to be a key component for moving data between consumers and patients. So, I think as a first step, if we look at that more holistically as just that seal of approval or non-tamper, would be something that would crossover the whole ecosystem. And then also as we'd look at that work, the next logical evolution beyond the provider is then how too we consider the patient and their signature for their directions for their consents and so forth. So I think that's a natural offshoot and we could be somewhat counter-populated or cross populated in that work. But I agree with

David that tamperproof seal can solve a whole host of issues for us.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
So, and the thing is, that that's exactly the kind of conversation I think that we need to tee up by these things. And so, it's the reason we moved it forward and we can already see that there's a lot of pent-up energy about trying to figure out this particular problem, that's a good thing. We moved it up, we'll try to then work to get both the esMD Project, in some sense give you a sense of what we've been working on so far and what various agencies are doing. And then provide some direction about how's – where's the low hanging fruit and what are the things we want to do as we move forward? Obviously, the bar that CMS has when they're talking about billing and they're talking about fraud and audit, and they're talking about some of those other things, they may have a different requirement than just that it hasn't been altered. They need somebody who says yes, this is a document that I vouch for. No, exactly, exactly. So, we're not going to solve it in this meeting, even though I think we would like to. We'll tee it up and try to get that on the schedule as soon as we can.

I just have a couple more that we want to get through here. We'll go a little bit faster here. So improvements to standards to facilitate unambiguous parsing, longitudinal record sharing and bulk record sharing, there was a lot of discussion about what is the scope? How does this fit in terms of our priorities and things like that. So this is another one Jamie that we're going to work, I think, with clin ops to try to get a sense for what's feasible. I think that there's probably some value in us talking about some of the work we're trying to do to open up electronic health record data, so we can create ways to easily access that information. And so we'll follow-up with you, maybe in July or August depending on how busy your schedule is, to tee up some of those things as well.

Standards to record advanced directive and care preferences. Again, this is a scope and priority issue. This may be one of the things that we can work with you and if there – if what you say is, we'd like to have this conversation in August around advanced directives, we need to have some guidance about what's out there, who's doing what, that sort of thing. We then can then work with the Committee to sort of tee those things up. This is not one of those we think necessarily needs a standards and interoperability initiative right now, because I think we first have to figure out what the scope is and what's out there, but we can try to with that. Leslie?

Leslie Kelly Hall – Healthwise – Senior Vice President, Policy
Doug, but also, there's a huge amount of interest in the consumer groups on this particular issue.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
Hey, what do you say, Jamie, what do we say we put Consumer in charge of this and then we coordinate with them, because you've got a lot of stuff on your plate. You want to do it?

Leslie Kelly Hall – Healthwise – Senior Vice President, Policy
Okay, no problem.

Jamie Ferguson – Kaiser Permanente, Institute for Health Policy – Vice President, Health Information Technology Strategy and Planning, Fellow
Great.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
Okay.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Yeah, because …

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
Leslie, you're going to keep – if you keep putting up your card.

Leslie Kelly Hall – Healthwise – Senior Vice President, Policy
I just learned about that, okay.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
I'm just saying, okay. You're going to get the work.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
I mean the comments that were made on the call with the death of my father last month, the critical importance of communicating end-of-life preferences, in some sort of interoperable fashion. Even if it's a blob of text, even if it's a checkbox and says an advance directive exists, is really key to consumers and families.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
So what I would propose, and I'm going to modify this, is that the Consumer Team take the lead but coordinate with the Ops team and we'll help support some of that work as well. Okay? Number 3, standards for application programming interfaces supporting modular application development. This was something that I think the committee felt was very aspirational and that there's a lot of work that needs to be done to get there. However, it would be useful for us to take a look at a couple of initiatives that are just putting their toe in the water around trying to figure out ways to standardize interactions between computer systems and other systems, if you will. So not so much the static data that gets exchanged, but what are the functional things that need to happen to be able to enhance or enable the kind of information exchange we'd like to see.

So, within the Structured Data Capture Initiative, there is the desire to create a standard that allows you to access, view, populate, and save information that can be supplemental, that can supplement the information that's already in an electronic health record. So, an electronic case report form, for example, as part of clinical research would be an example of such a document. Within the HeD activities, they're trying to figure out ways that there can be a service that's provided, that provides clinical decision support. So you send the data to this service and it comes back with the recommendation. And certainly, we've heard conversations about immunization registries doing the same sorts of things. Sent the current set of immunizations and age of the patient, and then come back with a recommendation for how to do things.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
On the Sharp Grant Smart Activities, too.

David McCallie, Jr., MD – Cerner Corporation – Vice President, Medical Informatics
Yeah, why wouldn't the SMART platform be on that list? I mean that's far and away the most advanced effort.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
I – on the list that was an oversight on my part. So…but, the idea here is that this is, in some sense, aspirational. But I think it would be really good to get a conversation in this group that would say, here are some things that people are trying to standardize in terms of interactions with other systems, that's really what an API is, and can we learn from the SMART platform? Can we learn from what's happening with HeD and Structured Data Capture and some of the other things here as well? Farzad.

Farzad Mostashari, MD, ScM – Office of the National Coordinator – National Coordinator
And, I don't know if our VA colleagues are here, we should make sure that they're as engaged as possible on this, because of the future work around the iEHR could really be a government as platform boost to this activity.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
Yeah. So again, kind of going back to the framing, what's the conversation that we want to have around this? I think we need to understand a bit about what's out there and what is the incremental path that we need to take. Is it first that we just need to make sure that APIs are transparent? Then, we go from there to things in which we try to standardize certain kinds of functions? And how do we navigate this landscape to get to that future that we'd like to see? And I think this group can help us. What we'll do is try to tee up some of those conversations and I think it's going to involve work with the Clinical Quality and probably with operations to help us frame that work. David?

David McCallie, Jr., MD – Cerner Corporation – Vice President, Medical Informatics
I think you've said it, but I'll just reiterate it, that, like everything else, this is incredibly use case specific. I mean, if you were to say, how do I write an application that can run on a Macintosh device? I mean there are probably seven or eight different answers, depending upon exactly what you mean by that, iPhone, iPad, computer itself, web browser. So, everything I've heard on this so far has been so vague that it doesn't preclude lots and lots of different incompatible choices, so maybe specific use cases.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
But David, the conversation that we want to have is not about picking a standard for the API. So you're absolute right, when we start to get to that point, we're going to have to start talking about very specific use cases. This conversation that I'm trying to tee up is a broader conversation that says, if we wanted to start standardizing those functions, what's the path to get there? So your original, your feedback right now is to say, we've got to get specific about use cases and we have to pick the targets. So that's why getting the SMART folks and HeD and the work on immunization may be helpful in us honing things down. But this is not intended to sort of say, here is the thing that needs to be standardized. We have to have a broader conversation, and that was the feedback that I got from the chairs, that this is really about a broader conversation that we need to have and then begin to kind of figure out if this is the right path for us.

David McCallie, Jr., MD – Cerner Corporation – Vice President, Medical Informatics
I think there's, hopefully there's more than one use case, we just need to be clear about which use cases and which standards or which approaches for which use cases. And it's a lot more subtle, I think, than many people who haven't tried to actually to do it expect. So an API into an EHR that takes a service oriented architecture approach that's not really focused on user interaction would be completely different than the API that might be a pluggable container that's designed to be in the middle of the workflow and inherits user authorizations and the like. Those are completely different use cases and different API standards. We wrestle with this all the time with people who ask us to extend our product in that way. And sometimes the questions are well-meaning, but they're naïve, because they don't understand the space of choices. And so maybe part of this work is to clarify what those choices are.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
Precisely.

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

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
Precisely and in keeping in my theme here, that Leslie said something and she got work, David and Dixie, we're going to have you guys help us sort of frame this, because I think that will be helpful as we go forward.

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

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
Yes, Wes?

Wes Rishel – Gartner, Incorporated – Vice President & Distinguished Analyst
So I, personally and professionally and everything else, I get all kinds of warm feelings hearing about this, my propeller starts to spin. But I get the chills every time you say aspirational and the…it would be interesting to ask, how does something go from aspirational to and a use of standards that improves healthcare in the United States? We have said, almost forever, that the right standard to adopt is the one that's already in use, and we have never lived by that, because we've always found very little actually in use and very serious issues with what was in use. Maybe the answer is it's aspirational until it becomes opportunistic. The first time we reuse one of these APIs for a different case, then we have demonstrated the strength of that API. And then there's a whole bunch of analysis about what's the space of use case as it applies to anything. But I think it would be important in our analysis to be driving towards the actual use and experience and I think it would be important not to limit ourselves to the United States in this regard. I think there's some interesting work going on in Australia now, that's worth looking at.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
Great, thank you.

Farzad Mostashari, MD, ScM – Office of the National Coordinator – National Coordinator
Wes, I wonder if it would be helpful to do kind of the survey or get some sort of situational awareness of whether, you mentioning it being opportunistic, whether there are indeed a number of vendors who are moving in this direction. I hear about it, in terms of open platforms and we want to be the one that other people build on and so forth, and to really get at well how are you developing this? Are you all – is there an opportunity here, as a number of vendors appear to be moving in the direction of having at least some open exposure of some of their services. Whether there's again an opportunity to be opportunistic, to bring those together and say okay, if four of you are working on kind of the same kind of APIs, would you be willing to work towards having a shared approach to this API? I don't know, it may be that folks are seeing those as yet other competitive advantages and would be unwilling to – it's more secret sauce in terms of how you're APIs constructed or you want to bind applications to you rather than others. But Wes, in terms of your industry analyst hat, what would you say in terms of what's happening?

Wes Rishel – Gartner, Incorporated – Vice President & Distinguished Analyst
Well I think – first, it's not a choice of, yeah we'd love to collaborate or it's the secret sauce. The middle ground and the more common ground is, we wouldn't love to collaborate not because we think it's the secret sauce, but because it's a complex situation and we're already collaborating with a bunch of people to try to create a broader field to collaborate on is going to slow down the process. That having been said,

I would agree that there are a number of vendors that are promoting particular APIs and it certainly would make sense to create situational awareness around that and then look at some common consensus. It may be that it's – we have the usual talk about the connection level, the security level, the content level and so forth. It may be it's in some area in there, but I think that would be an excellent.

Keith Figlioi, MBA – Premier, Inc – Senior Vice President, Healthcare Informatics
One thing I'm going to add …

Wes Rishel – Gartner, Incorporated – Vice President & Distinguished Analyst
Report back to us in a few months.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Sorry, Arien, was that you?

Keith Figlioi, MBA – Premier, Inc – Senior Vice President, Healthcare Informatics
No, it's Keith Figlioli from Premier.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Oh, please go ahead.

Keith Figlioi, MBA – Premier, Inc – Senior Vice President, Healthcare Informatics
The one thing I'd add to what Wes is saying is, and just to pile on a little bit on to this, but maybe add a little bit, is I also think it's not just the EHR vendors that are going to be going down this path. And so if you look at the general tech industry, pretty much every layer of the infrastructure stack is being opened up. And so I think it's a very strong suggestion to think about how this is actually going to take place, but I would not limit it to just the classical and established EHR vendors.

Wes Rishel – Gartner, Incorporated – Vice President & Distinguished Analyst
Strongly agree.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
This is good. We'll hold all those thoughts and expand on them. This summer we'll try to tee up some of the folks that we mentioned, some of the initiatives that are ongoing, make sure that we involve some of the folks that are at the VA and the DoD and again. And try to get a sense not only from sort of the current set of vendors, but also to think about the entrepreneurs and the innovation community and those that are not here typically seen in the healthcare space and to see if we can learn from them as well.

I'm going to move quickly on to the next tier around clinical quality. So there was this sort of broad topic about standards to support flexible platforms for measuring and reporting on quality. So this is one of those that again, it's a scope and priority issue and coming from the HIT Policy Committee, it was kind of hard to know exactly what all of this meant. I sort of say that Jacob Reider and the work that he's been doing around quality measures really needs to lead this effort. And I think what we – what I would like to do is, this summer to give you an update on kind of what's going on in the quality space. So we've got a whole series of standards that are being worked on, so there's HQMF and I understand there are some interesting papers that are going to be coming out soon about quality measures and the implementation of those. There is work on QRDA, which is a reporting standard and that within a quality measure you might be able to describe say a numerator and a nominator. But in many of the models that are out there, we sometimes mix the kind of structure of the quality measure with the expression language for how to kind of compute what the quality measure is.

I'm looking at Floyd right now because he knows this intimately, I'm sure. But I think what we want to do is, I think we need to tee up what our current portfolio of standards to support quality measurement are and have a conversation about where there are gaps, where there are things that need to be improved and how we can move forward on that? And so, we'll work with Jacob and his team and then tee this up so that we have an opportunity to have that conversation about what's out there, what's being supported and how we can again, continue to make incremental progress to support this. Okay.

Last page, okay, so standards for clinical decision support, both knowledge representation, application program interfaces, for query/response to knowledge resources. Again, huge set of topics and we've touched on some of them already. This notion of APIs and what does that look like. Clinical decision support, I think that number 4 and number 5, the one that we talked about to support quality and this one, which is all about kind of clinical decision support, need to be presented together as a unit. Because part of why we measured things is so we can improve those things. And one of the ways to do that is to create mechanisms that computers can help support the improvement of care using clinical decision support and other things like that. So again this, number 4 and number 5 really, I think, be combined and we'll have a presentation in August where we will talk about quality and care improvement and quality improvement. Jacob doesn't like just quality measurement, he likes quality improvement and once you say quality improvement, it's about both measurement as well as making sure that you can make some changes in differences as well. Okay?

Six, standards to support defect reporting to patient safety organizations. Now this is one that I think is probably going to be teed up later this fall. One of the use cases that we're looking at within the Structured Data Capture Initiative is coordinating with AHRQ around their common data format and figuring out ways that we can create a mechanism supporting reporting of this information as well. And so what we'll do is, we'll get the AHRQ and the clinical research activities an update later at the end of the summer, on what we're doing within the Structured Data Capture Initiative. I think we will have made some progress, at least I'm hopeful that we will have made some progress and that we'll get some folks to be able to say, how we're working with AHRQ around the common data format and ways to integrate that reporting into the electronic health record in a more, in a simpler way, if you will.

And then finally, standards needed for registry support including structured data capture, transmission to third-party repositories and the like. Again, this is one of those things where we've got work from the CDC on immunization registries, there's the cancer registry, there are a series of other things in Meaningful Use Stage 2. I think what will be useful for us is to kind of review that as well. Andrew?

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

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
Andy, I'm sorry, Andy.

Andrew M. Wiesenthal, MD, SM – Deloitte Consulting, LLP – Director, International Health Terminology Standards Development (SNOMED)
With regard to the latter, my European connection through the IHTSDO exposes the fact that the EU is developing standards for all clinical registries for the entire EU, we would be very well advised. It's called the epSOS Project.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
I know it well.

Andrew M. Wiesenthal, MD, SM – Deloitte Consulting, LLP – Director, International Health Terminology Standards Development (SNOMED)
Well, you know, so if they're doing it, why don't we just take a look.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
Yeah, absolutely. And I think one of the things, and it's not reflected on this work plan, but there are, if you've been watching the international press, about two weeks ago, there was a roadmap published in response to the HHS EU between the EU and the U.S., memorandum of understanding to collaborate around standards and work across that. One of the groups we've been working very closely with is the epSOS Group with regard to that. And in fact, I'll probably be – the ONC will be meeting with some of the

IHTSDO folks next week, at their meeting that they're having. And so, I think there's absolutely opportunities for that and if this group can identify where there's already low-hanging fruit that we don't have to reinvent, that is always useful information. So I'll take a note with this as well and it may be that as we report on some of those, the memorandum of understanding and some of the roadmap activities there, whether this might serve as an important use case for us to take a look at.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
And just for my info, how do you spell at epSOS?

Andrew M. Wiesenthal, MD, SM – Deloitte Consulting, LLP – Director, International Health Terminology Standards Development (SNOMED)
epSOS, European Program blah, blah, blah, I don't know what …

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
So it's "ep" small, SOS big.

M
It's European Patient Smart Open Services.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Of course, thank you very much.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
Yeah. Okay. Floyd.

Floyd Eisenberg, MD, MPH, FACP – Independent Consultant
Doug, I appreciate everything you have on here and as far as the realm of quality improvement, I actually see items 4, 5, 6, and 7 related to similar issues. So is there is some way that the Clinical Quality Workgroup, which has not met for a while, could be pulled together to actually discuss common standards and common issues related to these, because they're all based on data requirements, some of them on provenance. So I think some update to that group on provenance so we could present to the larger group would be very helpful.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
Okay, great.

Farzad Mostashari, MD, ScM – Office of the National Coordinator – National Coordinator
The thought I would echo, that there are important connections between the standards, around HQMF, QRDA 1, 2 and 3, as well as some of the VDR and others, and the CDS as well is quality measure side, but also on the tools, the MAT, measure authoring tool and the Cypress, the pop health, that make use of those. And I think that there is a risk that changes in one part, either on the tool side or the standards side, may have implications for the other pieces of this machinery, that if we don't really work hard to integrate and to be very planful in how we approach particular version changes. And when you have different organizations that are leading the work on different things, they may have unintended consequences if they update one part of this. I mean we saw this with Stage 2 quality measures, they update one part of this and then the balloted standard was not what matched the other parts of the ecosystem. So I think pointing out and highlighting the connections between the standards and the tools is going to be an important job.

Floyd Eisenberg, MD, MPH, FACP – Independent Consultant
So, I fully agree and I think one of the challenges is, we don't really have a map of what is the workflow a) of quality measure development, what are all the pieces involved in the implementation, but also what is the workflow of the actual reporting with the standards. So when do you actually use QRDA 1, 2 or 3? When do you actually incorporate all these and how they relate to each other, to address a lot of what you're talking about. I don't think that's been clearly done yet.

Farzad Mostashari, MD, ScM – Office of the National Coordinator – National Coordinator
It wouldn't be hard to do.

M
No.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
So one of the things that may be important is, as we think about 4 and 5, both in terms of our ability to do quality measurement and quality improvement, let's combine those two together. Let's reinvigorate the Clinical Quality Workgroup. Let's pick some scope and focus within that group and then target for late summer to kind of give an update on what's out there. And I've just made notes about making sure that when we talk about this, that we include not only the standards, but also the tools to support them. And I think one of the things that we've tried to do with tools like Cypress is that if you can create a set of standards in and out, it gives you flexibility to update the tool or have others develop new tools, because you've got kind of those standard ins and outs that we would have. So let's focus on that and maybe get that reinvigorated as we go forward as well.

So, we've had questions and discussions all the way through, and that was sort of my intent. I want to thank everybody for the feedback. Are there things on this that need to be discussed, but aren't on the list?

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Hopefully what you've heard is that Doug has incorporated most of the suggestions of the workgroup chairs in terms of constraining scope, seeking clarity, developing go-forward processes, trying to stagger the work in a way that can be done. You'll notice the first half of the slides say January through March and of course, we recognize that in the detail, he says actually, ignore the headings. These are things that we're going to work on over the next couple of months and then you've got some summertime. Also, he did use the word aspirational and I think we have to be a little bit careful, what are those things that we can truly deliver on versus what should we just hear about and do a pulse check? And if we hear that there are great things going on in the EU, I mean that's wonderful. There's a lot of learning we can do together on these things that are bit more forward thinking, so, I like the way that you have set up the agenda. Some work to be done, identifying existing standards, some learning together and then recommending going forward paths. But other comments? Oh, so your card is always at the side to me, I can't quite see it there.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
It's safe now because there's nothing up there that has to be done.

Leslie Kelly Hall – Healthwise – Senior Vice President, Policy
Except you asked for other work. So, this is Leslie. And so on the fear of probably taking this on, I do think that there's an opportunity to be very deliberate about harmonization and existing standards around patient…to support patient engagement, for fear that five years from now, we are in the situation where we have competing standards. This is largely green field right now and I'd like to take on making sure that across all of the groups, getting an inventory or a gap analysis, but understanding that the goal is significant harmonization across standards bodies to support patient engagement and nip it in the bud.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
Okay.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
And I also have an e-mail here from Liz Johnson who wants to remind us all that remember the Implementation Workgroup is, just as you have spoken up and gotten work, she is volunteering the Implementation Workgroup to tag-team along with just about all these initiatives.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
And on other thing, just to that point, I think one of the things that's really critical for us, is that the Implementation group has been very helpful in us trying to figure out how to best test and certify, when it comes to the standards that we'd like to see. So, getting a reality check about what's feasible and what's not, what is an appropriate use case and not, I think getting that group involved early is helpful. And I think that one of the things that we need to think about is, that when we think about an implementation guide, a complete implementation guide not only tells you how to implement the standard, it tells us how to test the standard. And I don't think that we've always been good about doing that, there's sort of a waterfall methodology and I think the more discussion upfront we can have about, here's the – one would hope that the use case is going to look an awful lot like the test, right? And if the use case doesn't look like the test, then we've lost something in the process.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
And Liz, Doug and I talked about that particular point yesterday. As I hear feedback from vendors on the Meaningful Use Stage 2 certification processes, what they feel, for certain use cases, there seems to be a disconnect to what the Standards Committee said, oh we thought – you know, it's generally a good idea to try info button. But then the actual certification process is so burdensome and so lengthy, it seems out of proportion to what we said, it might be a good idea. Right, it should be this big, not this big. And so I think that advice of couple standards with implementation guidance that includes certification testing, scripts and ensure that the scope is as intended, would be important.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
Does it make sense for us to get a pulse check on Meaningful Use Stage 2 certification progress?

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
So Liz, I know Cris is not on the phone with us today, but I presume your group has both heard from vendors and has plans for such hearings on Stage 2 meaningful use certification progress?

Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Tenet Healthcare Corporation – Vice President, Applied Clinical Informatics
Hi John, this is Liz, and yes, we did. Because that is – I think Doug, you and John both are exactly right. It's time now that we have gone through enough testing and had enough certification activities to really determine, where did we miss and where can we improve for the future. So yes, we've heard and yes, we do have hearings, we're working with MacKenzie now, we just need to get the definition and place.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
So I'll work with MacKenzie and to make sure that we tee things up and give time for that to happen in this group as well. Right MacKenzie?

Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Tenet Healthcare Corporation – Vice President, Applied Clinical Informatics
Okay.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
Lisa.

Lisa Gallagher, BSEE, CISM, CPHIMS – Healthcare Information & Management Systems Society (HIMSS) – Senior Director, Privacy and Security
I just want to thank Doug for the presentation. As a new member of the Standards Committee who hasn't attended all of the previous meetings, this really helps put our work in perspective. And also as a member of the Privacy & Security Workgroup with Dixie, helps me put that work in perspective. So, this is a good place for us to start, not speaking on behalf of all of the new members, but very helpful. Thank you.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
Great. Thank you.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
And of course again, welcome our new members. We're very happy to have you. John.

John Derr, RPh – Golden Living, LLC – Health Information Technology Strategy Consultant
John Derr. The last Standards Committee meeting, we had a very good presentation on long-term post-acute care, and they had one at the Policy Committee I think two weeks ago. When are we going to…I know we worked a lot on the S&I framework and we had the Longitudinal Care Committee, but I am on the Implementation, the Quality and also on the Patient Engagement. And I speak up every once in a while like on Liz's committee, when we do the test cases, I say, well what about if it's a skilled nursing facility or for home care? Could we put an appendage on it, everyone I – the meetings are all geared to hospitals and private physicians, because that's what we're tasked with. But when you get into ACOs and medical homes and HIEs, it always includes nursing homes and home care agencies and the rest of long-term post-acute care.

I know – I've been told what, I'm on my fifth year now, I've been told for five years that because we're not in the legislation, but I think the awareness of our value is here and now, and I don't know when we're going to incorporate that into all of the workgroups. Not to add more work to Leslie or Liz or to Jim Walker, but I think we've got to start thinking about that and add an appendage. And again, I volunteer the people that I represent, that could be part of it and say there's an appendage on here for nursing homes added on, because we have to harmonize. I mean, if we don't – when I go out and give talks, I have a very difficult time telling them what to do. And I know one day it's going to be an awakening. Anyway.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
Yeah, no, that's good. David, but then I wanted to comment.

David McCallie, Jr., MD – Cerner Corporation – Vice President, Medical Informatics
Well in my – this is David. It's a follow-on to John's comment, which is at the last Standards Committee meeting, we heard a pretty elaborate presentation, as he mentioned, that listed hundreds of new data elements that made sense in certain kinds of transitions of care. And I thought the – and I had some questions about the complexity and how this was going to stage in and everything, and I thought that we were going to follow that up, but I look here at our summer's plans and don't see that anywhere on the summer plans. Is that something that we should add, not that we have a lot of time…

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
We should, we should add that. And I am wondering if it's – if you take a look at kind of the standards to address current content gaps. If we think about a long-term care facility as a kind of transition of care, whether there's something that we could do in the clin ops, looking at our existing consolidated CDA work, and see that if there's a way that, if this is recognized as a potential gap, whether that could be teed up as part of these every two-month sessions. So, Jamie, can I add that to the list for clin ops?

Jamie Ferguson – Kaiser Permanente, Institute for Health Policy – Vice President, Health Information Technology Strategy and Planning, Fellow
Reluctantly, yes.

David McCallie, Jr., MD – Cerner Corporation – Vice President, Medical Informatics
It struck me that there may be new constructs that sort of, here's a template that you can send an observation in, but there's a separate list somewhere of the observations that you should be expected to be sending, if it's certain use cases. And to me, that's a new artifact that we don't have yet, so it's a nontrivial question.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
So John, I have added that to number 3, so that we'll work with Jamie on these kind of – these gap analysis of existing standards, because that's probably the most efficient way to sort of move forward.

John Derr, RPh – Golden Living, LLC – Health Information Technology Strategy Consultant
Yeah, we – this is John Derr. We have looked at gaps in the quality measures because on the NQF side. And I hope that we're beyond recognizing it as a gap. I mean, we should be getting it to solutions, I think now. Even though we're not part of the program.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Good. And of course, to David's point, just real quick, I'm going to follow-up on David's point. The question of course, is the scope of this particular work is really quite important. Because as we look at, oh, are we going to for every use case, modify the CCDA, you're going to get 389 new fields. Or is it that we can reduce it too, here's a couple of templates, and they are more generalizable and if your use case is long-term care transitions, use templates 1, 7 and 19, you know, that would certainly be a much more desirable and scalable approach.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
And that clearly was where the group that developed and has worked on the Consolidated CDA, trying to create a series of templates that may be an appropriate approach.

David McCallie, Jr., MD – Cerner Corporation – Vice President, Medical Informatics
Or, again, not to do design on-the-fly, but why not one template with the specification of what's expected in that template rather than just these incredibly complicated CDA templates that differ only in certain content elements. Just orthogonalize the problem.

Dixie Baker, MS, PhD – Martin, Blanck and Associates – Senior Partner
I just wanted to suggest that you add it to number 1 instead of number 3. Number 1 really addresses longitudinal record sharing and bulk record sharing, which I think is more appropriate than the API issue that's addressed by number 3.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
Oh no, no. What – the number 3 that I was talking about was actually standards, which address current content gaps. So it's actually back on Q1 number 3. I'm sorry, my numbering system is completely messed up, so, they don't number numerically, they start over.

Dixie Baker, MS, PhD – Martin, Blanck and Associates – Senior Partner
Oh, I see.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
It's like the worst standard out there, because we're reusing things right. But to your – so the idea was …

Dixie Baker, MS, PhD – Martin, Blanck and Associates – Senior Partner
It could be either of those actually. Yeah,

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
Yeah. Okay. Good.

Dixie Baker, MS, PhD – Martin, Blanck and Associates – Senior Partner
Thank you.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
Okay.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Other comments, discussion points? Wes?

Wes Rishel – Gartner, Incorporated – Vice President & Distinguished Analyst
So I have a question, and I really – two questions. One is, have the other basic studies that show us the cost of not coordinating with long-term care? And I don't even need the answer to the question. The bigger question is, where is the policy committee on this? I mean, if it's not an emphasis of the Policy Committee, I don't see how we will ever make any progress on it.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
I'll answer your question. Mickey, after lunch, will actually give us a presentation, which includes the answers to every one of the things you just asked, and specifically enumerates the importance of doing transition of care interoperability with LTAC as a goal of the Policy Committee.

Wes Rishel – Gartner, Incorporated – Vice President & Distinguished Analyst
All right.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
Did you guys talk before the meeting?

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Nah.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
Okay. I just …

Farzad Mostashari, MD, ScM – Office of the National Coordinator – National Coordinator
So I just want to, and I'm a little puzzled by the conversation, but I just want to make clear, from the policy perspective, it is obvious that transitions of care between acute and long-term care, are going to be a priority for reducing readmissions, for improving patient safety and reducing cost. And it is a priority, I mean, there's just no question about it. And I was under the impression that we've actually been doing a fair amount of work, including the work that was presented at the Policy Committee last time about the longitudinal care coordination, of which a major component is long-term care. So if there's something more pointed that we need to do about the long-term care handoff in particular, and bring in some of the experience that we've had with the Beacon Communities, that we've had with leveraging OASIS and the MDS and so forth. Then maybe we can do that as a smaller sub-focus, but there's just – there should be no question in anyone's mind that this is an important policy issue of huge relevance.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
And to just sort of bring it full circle to how we sort of framed the beginning discussions, which is, although long-term care providers are not eligible for the meaningful use incentives, this committee and our charge goes well beyond that and I think that's an important thing for us to consider with this. We include consumers, who are not eligible for incentives, and I think we need to make sure that our work sets the stage for what we see coming down the road that we need to be able to support, so …

John Derr, RPh – Golden Living, LLC – Health Information Technology Strategy Consultant
John Derr again. And I don't mean to be, that we aren't, I know we are, very much so. And it's harmonization that bothers me at times. So, I really respect, Farzad, everything that you guys are doing, because it's tremendous considering what, a few years ago or months ago, there was not that much emphasis on this. But I think we've found out that we have to be part of the solution. And I really thank everybody for that.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
Great. Thank you. So with that, I will say thank you to the committee for all of the great feedback and the like. We'll take all of these things in consideration and hopefully do yet another iteration. Again, this will be a living document, and as issues come up, or as things become more salient, we will then work with the committees to make sure that we've got things teed up and we can present them back. So, I just want to thank everybody for the work that they're engaged in and all the great feedback here. And now, I think we're almost on schedule, because I'll turn things over to Farzad.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
… for your opening comments.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
… for your opening comments.

Farzad Mostashari, MD, ScM – Office of the National Coordinator – National Coordinator
Yeah. One of the things that happened since our last meeting was the release of the President's budget and I just want to talk a little bit about this. I have the dual role as National Coordinator for Health IT, but also as the Director of a small staff division within the Department of Health and Human Services with about 170 dedicated civil servants and an annual appropriations budget. So it's in this latter role that I want to talk to you about, not just, not to overly amplify the significance of the role that ONC plays in the national health IT movement, which is a much, much broader, larger, deeper, than just the activities that ONC does. But I want to put our request into perspective.

The ONC was founded in 2006, had its first budget in 2006, established in 2004, and that first budget, under President Bush, was $61 million. And in those early days, under David Brailer's leadership and then Rob Kolodner, there was some really good work that was done. But the scope of use of Health IT, the issues that we faced, the complexity, the interplays, and simply how much of American healthcare was digital. Just to give perspective, in that first year, fewer than 1% of US physicians used an electronic health record to send an electronic prescription. And we're now approaching half or more. And our annual appropriations stayed, not even adjusted for inflation, stayed at $61 million. And the last year we actually had a budget passed, 2010, you can understand how having just given $2 billion to ONC, Congress understandably said, we'll keep your appropriations at 61 million. You have $2 billion to do the grants, the contracts, whatever else you need to do, and that is what we've done. And there has been great progress over the last few years. I believe we've made very good use of those one-time funds, and those funds expire in September of 2013.

In addition to support for the grant programs, those funds were used, through contracts, to help with, for example, the standards and interoperability framework. I'll give one example from Doug, about the work that was done, which has to do, and many of you are veterans of this and have the scars to show this. Of, how do we get a single national consensus standard around how we represent a patient summary of care record? In 2009, there were two standards, one with one standards development organization, ASTM E-31, the other the standards development organization HL-7. And we could not have, I believe, responsibly picked any one of those in 2009 and said, this is what the standard's going to be. And indeed, the harmonization of those standards identified how many issues Doug?

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
You mean, negative ballots?

Farzad Mostashari, MD, ScM – Office of the National Coordinator – National Coordinator
As judged by negative ballots, 2000. Two thousand separate issues were identified as challenges to adopting the draft standards. And we worked through those issues one by one over a compressed period taking the standards development process and harmonization and balloting from years to months. And we were able to have, in Stage 2 rules, finally a single standard. That took a few million dollars, but that has to be viewed in the context of $30 trillion that we're going to spend on healthcare in the next 10 years, $30 billion that we're going to spend on Health IT incentive payments. And we are at a critical time, in terms of whether those trillions and billions are matched with millions to help achieve the interoperability that really underlies the usability of that information, for us to learn from, to protect patient safety.

So for our 2014 budget request, there are two things I want to point out. One, we as a statement of priority for the administration, which is what the president's budget proposal is, a statement of priorities, we have an increase in our proposed budget to $78 million. For many of you around the table, that's – it's not a very impressive absolute number $78 million, but I think we really use that money well. We leverage the community participation to an unbelievable extent. And the total amount of time from outside participants in our processes really it helps – all we're doing is we're creating a convening context and some tools to help people work together. But without that, as Wes pointed out early on when we were talking about people actually successfully achieving the true meaning behind the Stage 2 standards, we've set the standards, now what? How do we implement successfully? Do we have the testing tools? Do we have the data sets? Do we have an ability to come together and identify problems and solve problems? Those are the critical things that we really believe that we need to continue to do, and we've asked the bulk of the increased budget request, would be to replace HITECH funding as the source for continuing those standards activities. And we are very hopeful that the Congress will understand this and will act.

The second piece is a user fee proposal for $1 million. Not $1 million per vendor, $1 million total that would be associated with – directly with the certification process. And the idea here is, that even though we are hopeful about our budget process, there remain significant uncertainties in the annual appropriations process, such as it is. And having an assured funding base, for the certification program, would reduce uncertainty for the industry. We're also aware that if we get certification wrong, if we don't have the resources to hold up our end of the bargain, that translates into, for every vendor, for the 1000 vendors who have had certified products, that translates into extra time, money and developer resources which they can scant afford.

So what we are proposing, and we can only do this with industry support, is that there be a $1 million total that is directly tied to the maintenance and improvement of the certification program, that would be generated through user fees. It would obviously have to be approved by Congress, and I believe that the only way this is going to work is if the vendors receive much more benefit from this, direct specific benefit from this, derive more value from this than whatever it would cost them in increased certification fees. So those are the two parts to this and I think we're going to have, clearly on the first, more conversations with Congress, and on the second, more conversations with industry, to help folks understand the context within which we make these proposals. Thank you.

John Houston, JD – Vice President – University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics
Comments, questions? Wes.

Wes Rishel – Gartner, Incorporated – Vice President & Distinguished Analyst
In talking about the user fee, you – it seems – I thought I had the draft that the million dollars was going to replace HITECH funding to maintain the work for certification. And then you talked about a new…an increased value proposition for the vendors. I didn't know – did – is that value, the extra value, just continuing what's been done or is there a new value, what's the ...?

Farzad Mostashari, MD, ScM – Office of the National Coordinator – National Coordinator
I think there's value in reducing uncertainty about and making sure that we can maintain the permanent certification program. But I actually do hope that this can be an opportunity where the vendors and the software developers who are seeking certification, can have a more – by having a stake in the certification process, and contributing resources, can help us improve it. And this can be an opportunity for them to express what, how they wish to see the program improved, and for us to be able to have the resources to act to improve the certification process as well as maintain it.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
A selfish question, which is, does this proposal for increased fees apply to self-certified hospitals and providers?

Farzad Mostashari, MD, ScM – Office of the National Coordinator – National Coordinator
This is just the authority to have a user fee, any final regulations would have to go through our usual proposal, comment and so forth. But, and I'm sure those issues would be taken into account.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
No, we're more than happy to find a wonderful streamline certification program, however, we amortize that investment at a single institution as opposed to an industry. Other comments, questions. Okay, well let us hope your budget gets approved, you're doing God's work. So we next hear from Jodi and Doug with further ONC updates.

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning - Office of the National Coordinator for Health Information Technology
Good morning everyone. It looks like I made it just in time, had some challenges this morning as well. As we have started doing this year, giving some updates from ONC's policy and programs, at each meeting, so this is really going to be a quick run through of a couple of things that have come up in the last month. I'm not going in depth on any particular issues, but wanted just to give you a flavor of some of the activities that you may have missed since last month. So, I'm going to keep it short and sweet, turn over time to Doug and take any questions after that.

So this is just an agenda of the different items that we will briefly talk about. So first, the 2014 editions of the test procedures. We've done an update to these test procedures and they are aligned with the Cypress tools. The goal was really just to address some of the problems folks were having and realign the program with the needs of the vendors that we are hearing about. So this is just an update and wanted to let folks know that it's out. Here is a link of where you can find the updates to these test procedures and we have a mailbox for any questions that folks have. So if you do have specific questions about the test procedures, you can submit them to that website and get any answers or information that you have, that you need.

Next, we've talked about this before but I just want to remind folks about the CMS/ONC request for information to advance interoperability and health information exchange. We do have a request for information out, the deadline is coming up quickly, it's April 22 by 5:00 p.m., so get your comments in if you have them. We have held a couple of public listening sessions and we do have one more listening session that is coming up. It is focused on behavioral health issues and it's scheduled for April 18, so tomorrow at 2:00 p.m., wanted to let folks know about that. We have had two general listening sessions that happened on April 3 and April 8, and we had one focused on the LTPAC, long-term post-acute care community issues, and that was on April 10. So we've been getting lots of input and we hope to hear from a broad array of folks, and then we will take all of that input into consideration as we think about how we can leverage all the different programs that we have to advance interoperability and health information exchange. Again, there's a link to the RFI as well for folks who need that.

I wanted to let folks know that we did put out an LTPAC issue brief, ONC put it out on March 15th. It overviews the opportunities for long-term and post-acute care providers to use Health IT to improve care delivery and outcomes while reducing cost. It was sort of a long time in the making and I think it really is a helpful brief of all of the issues and some of the opportunities that are there as well. And so we look to that as – we encourage folks to look to that in seeking through where we can make headway with respect to long-term post-acute care and Health IT and working with folks in those communities to do that. Again, I've given a link for folks on where you can find that issue brief. A couple things that are in there are some of the background on the communities, highlights on how LTPAC providers are using Health IT, financial incentives and new payment mechanisms that are available today and links to additional resources for LTPAC providers. This is up on our website, HealthIT.gov.

So this is an interesting one. With regard to our strategic planning efforts, we're trying a new approach to get public input using social media and more creative tools for reaching out beyond our normal scope and our normal stakeholder. We have launched, in collaboration with Cornell University, PlanningRoom.org on March 25th. We're collaborating with them to get public input into updating our Consumer eHealth strategies. So we are looking at updating our Federal Health IT strategy in the near future. The Consumer eHealth space was one where there's been significant change since we put out our strategy. We actually didn't even have – I think we had just hired a Consumer eHealth lead at that time that we put out the draft strategic plan. And there's obviously been a lot of movement within the industry as well in this space, so we wanted to get some input, particularly on this one, and so we thought it would be a great place to start in testing out some new tools that we can use to get public input.

We're asking for input on several emerging issues relating to Consumer eHealth, identifying useful health information, patient generated data, supporting shared decision-making through health IT, decreasing health disparities through health IT, supporting personalized healthcare, supporting new healthcare delivery models and using health IT to enable research and informed practice. The public comment period closes May 9th, so we encourage folks to go on the site. It is sort of an ongoing dialogue, so you can come early and often and give us your input, and we will use this as we are thinking about revising our Consumer eHealth strategy. And we may do other – use this tool, if it is successful, for getting input on other areas of strategy as well. This – we already have found out that we have reached people, we've asked people if they've ever commented on our material before, and there is a number of folks that are going to the site that we've never heard from before, at least based on their own self-identification. So, we are reaching a broader audience with this and looking at how we can leverage technology to get broader public input into our work.

There's also – we're also scheduling a Google hang-out, Google-Plus hangout…

Farzad Mostashari, MD, ScM – Office of the National Coordinator – National Coordinator
Jodi, could I – if I could just add, Jodi's team has really been great in helping us navigate all the different bureaucracies to be able to do this and it's something new for government. As a rule, we have a very static gated approaches to getting comment, where we develop a plan, we put it out, we get comment, and then we kind of go radio-silent for two years and then we come out with another plan. And the idea behind this is to have much more of a new approach for open government to have strategic plans be more living documents that we can almost – inline people can see other people's comments about something and have a community dialogue about very specific parts of the text. Rather than more of a spoke and hub model where everyone talks to us and we're in charge of integrating that, let's connect the different points of those spokes. So it really falls…there is…there's a specific content around Consumer eHealth, but it's really about a new way for open participatory government.

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology
Yeah and if you go to the site, I do encourage folks to check it out even if you don't want to make specific comments, but to look at it. We have some context about our current plans, our – some of what we're thinking about and we have specific questions we are asking folks. They aren't, that we're asking folks to consider as we're thinking ahead, you know, five years out for a revised plan. It's really interesting to see some of the comments that people are making and we aren't hearing necessarily from the folks who know this place inside out and backwards, which is really exciting. The reason we picked Consumer eHealth as a place to start was because we thought it was an area may be more accessible to a broader array of folks and to a broader public, because it affects every individual. And we are hearing from some of those people, so take a look at it and if you have any feedback also on how we can do this better, we'll probably do another round at PlanningRoom.org with a different topic area. If you look at it and think there's a way we could really solicit a better dialogue or discussion or feedback, let us know, because this is our first – as Farzad said, our first time out of the gate in doing this and we're both looking for feedback on the content, as well as on the process. So we'd love to hear from you on that.

So this is a new thing that Judy Murphy had announced at the last Standards Committee meeting in March. She announced the launch of the ONC's inoperability training modules. I – these modules are focused on Stage 2 Meaningful Use rules, to train eligible professionals and critical access hospitals on how to implement the new standards for transitions of care, lab exchange, patient engagement and public health measures. They're web-based training and there's a five-part series providing real-world examples and story-based approach to highlight interoperability of the HR standards in these areas. Specifically, last month we only had the first training course up and available, the interoperability basics training. We now have number 2 and 3, interoperability in transitions of care and interoperability in lab exchange available. And I believe 4 and 5 are coming very soon, it says soon, but I think they're kind of imminent. I hadn't heard that they were posted yet, but please, I think these are great resources for folks and can help some of the folks who are trying to understand how they can implement these requirements. And again, those are all on HealthIT.gov.

Next, we launched a series of webpages to meet health IT needs of access in small rural hospitals. This is again on HealthIT.gov. Our goal is that 1000 critical access hospitals and small rural hospitals will obtain meaningful use by the end of 2014, and so we're providing resources to help support that goal. These resources include information about existing federal funding opportunities for health IT infrastructure as well as resources, lessons learned from the field, and HIT implementation support tools. It can be found – I don't have the link there, but it's HealthIT.gov/rural health. So it's easy to remember.

Next on the Consumer eHealth side, this is just a quick note. There is a video for PBS, my health counts series that talks about how patients can leverage technology to track their health and wellness. This was Lygeia Ricciardi, from, our Consumer eHealth lead, our Consumer eHealth Director, and ePatient Dave, for those folks who know him, that were interviewed for this series. So, please take a look at that; it's fun viewing.

And last but not least, I just wanted to make sure people are aware of the Fourth Health Datapalooza that is coming up on June 3rd and 4th, so coming up soon. Registration is open now, so folks should go to HealthDatapalooza.org if you're interested. It will be here in DC and they'll be policy updates, training sessions as well as challenges announced during Health Datapalooza. I'm sure many of you have been there before and it is a great even for folks to attend, and we will be there as well. Some of the keynote speakers Farzad is one of them, but also I think Secretary Sebelius and Marilyn Tavenner are expected to attend as well. So, that is all I have, and I will, I can either take questions now or turn it over to Doug, whatever you prefer?

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
So questions or comments before we turn to Doug's presentation? John Derr.

John Derr, RPh – Golden Living, LLC – Health Information Technology Strategy Consultant
I just wanted to thank Jodi for all of the work that she has done and on the review of the LTPAC thing that went very well. I am on about four different groups that are doing comments on that, and the paper was very good and has gotten wide dissemination as well, so I think your people are really supporting us greatly and we really appreciate it.

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology
Thank you for that.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
What, it's so quiet.

Wes Rishel – Gartner, Incorporated – Vice President & Distinguished Analyst
Hey, I shot my wad on LTPAC already.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Very good. Well thanks so much, Jodi. Great work. And Doug.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
So we'll go very quickly through these slides. Some of these slides are just included as reference and I won't spend a tremendous amount of time on them. So, just a quick update on what's going on in the community that's supporting many of the standards and have been participating in the S&I framework activity. We now have 2,000, over 2,200 people that are registered on the Wiki. Of those, there's about 700 people now that are participating in regular calls. We continue, and it's been 27 months at this pace, a meeting every 3-1/2 hours. There's been over 1,400 sessions that have been done as well and we're in the processes that we've done with HL-7, we've resolved about 3,000, about 3,100 different ballot issues that we've received. We've gotten about 2,500 that we're currently working through at this point.

I think it's important to highlight where a lot of the pilots are going on. So, what happens in these communities, people come together, they kind of – we facilitate their conversations coming to consensus on a particular approach. And then many times that community then goes back and pilots and tests and sees what is going on. We've got a number of pilots that are all over the country right now, and I think it's a testament to the groups and the enthusiasm that they have within the standards and interoperability framework, in terms of where these pilots are and kind of the work that's going on. We have gone through a whole series of initiatives, and this is my sort of common slide that I've got which describes all of the things that are going on. I'm not going to go through all of those, in fact, I think what I want to do is I want to do is talk about this slide here, which kind of summarizes a lot of that stuff.

And I think what we're doing right now is we're taking a look at our portfolio, and remember, when we think about standards, we really are thinking about a portfolio of activities to support standards and then a portfolio of standards that are out there that we hope people will be able to use and leverage as they try to solve problems. And so we've got a number of things that are highlighted in blue that are active initiatives that are ongoing. We've got the longitudinal care coordination committee, the group that's doing laboratory order interfaces, Health eDecisions, structured data capture, a whole series of things. We've got some others that are in, you know, it says maintenance here, it's really kind of a the transition. We're trying to figure out how we can sustain these things over time. And our job is to accelerate the standards, to help provide consensus, to serve as a coordinator. But really these are things that by bringing the community together, the community owns this, this is something that the community has a vested interest in.

And so we're working with HL7 and others to try to figure out a way to support the ongoing maintenance of our standards through the transitions of care and the like. The data segmentation for privacy, we're figuring out how we can create ballots or other things that will allow us to have a relationship with some of the standards development organizations. And then we've got some that I wouldn't say are closed necessarily, but we're not at this point having these things on an ongoing basis. So we had work early on with provider directories. We've got some activities with certificate interoperability that we did early, but much of that work actually has continued in some of the discussions around Direct. And although the prescription drug management program, or the PDMP Project, just recently ended, we are now taking that information, learning from it and trying to decide what the next steps should be and supporting programs like that.

The thing, and I sort of alluded to this before is that, one of the things that we've tried to do, and I've got…you've all seen the diagram where I talk about, use cases, harmonization, implementation, and then we kind of work through the process that we've got within standards and interoperability framework. What we've tried to do though is we've tried to separate or create two kind of distinct functional areas within the standards and interoperability framework. The first sort of gets us from use case to implementation specifications. But we realize that in fact what's happening in Meaningful Use Stage 2 and what's happening with Meaningful Use Stage 1 is that, our initial pilots certainly helped us refine our standards, but now what's happening is we've got, we've gone from in vitro testing to in vivo testing of these things. And these things are now out there in the community and people are now creating, implementing these things and we're finding that there are things that we need to refine, that we need to fix.

And so for example, if we are not achieving interoperability through an implementation specification, theoretically there could be a whole host of different reasons that that could occur. It could be because our testing is not testing the right things, you know, that we're not testing asymmetrically, that the send and receive are happening correctly. And so the fix to achieving interoperability is to work with NIST and others to make sure that we've got better testing scripts and better ways of testing things. It could be that we're not getting to interoperability because our implementation guides are underspecified, and we have to have a more constrained way of describing how to apply the standard in a particular setting and our implementation guides have to be updated. It may be that it's our standards that we need to take a look at and that there's an attribute that's missing or there's something about the standard that needs to be updated as well. And so one of the things that we've done is, we've now developed what we call our standards implementation and testing platform that takes a look at the work that's going on in the community and tries to provide ways for us to understand what's happening and then direct and triage the work appropriately.

So, I'm going to skip over this right now. So the standards implementation and testing platform is really – our first thing that we did is we set up an issue tracker, because if somebody has an issue with regards to implementation, we need to be able to track that, so that we can, if it's a quality measure -problem, we need to engage CMS. Maybe we need to involve our standards organization, so we're using, for those technical geeks out there, GR-Tickets. So if you've ever put a request into the help desk, and they give you a number, it's a way of tracking internally that you resolve all the issues that come up. And so we've put it into an issue tracking system that we're currently using with the quality measure folks, to try to make sure that we can track issues and resolve things that come up in the communities. We've extended the standards and interoperability framework to include a forum. So we've got moderated discussion boards that we hope will drive some of the community collaboration, and we're working with some of the Beacon Communities, for example, to bring their communities into these forms and help moderate those as well. We hope that as we understand what's going on in the community, we track the issues and resolve them, we can develop an ongoing knowledge base.

So if any of you have ever gone to the Microsoft or the Apple website and you've typed in a question in the search, sometimes you'll get an answer, but sometimes it will direct you to a forum that will have a whole series of discussions that will then resolve those issues. And so we believe that this is a way that we can help support the community as they're implementing, and provide examples and best practice and other things that we will be able to do. And we're thinking, although we have not implemented this, we're thinking, is there an opportunity for us to begin including other resources? So for example, if you need to test against the scripts or the testing infrastructure that NIST has, that may be helpful for certification, but if you're trying to debug your code and trying to make sure that you kind of break it up into pieces, sometimes you need a different kind of environment to interact with that allows you to sort of turn certain things on and certain things off and interact with that more directly. And so we're looking at that and trying to figure out how we can help support content and secure transport in some of the testing environments, that will be helpful, not so much directed at the implementer – at the vendors getting certified, but at the implementers that are trying to make sure that all their systems work.

So just to show that it's not vaporware and we've done a soft launch of this, we've been taking a look at working with HL7 to help support the consolidated CDA. And so we've created issue trackers and we've created links to the forums that you can then use this as a way of saying, here are some of the things we've found and we then can help triage that. Is a testing issue? Is it an implementation guide? Is it a standards issue? We've got some forums here that are just kind of getting rolling, and we've got some moderated discussion boards there. Issues that are tracked, all of this is transparent so that if there's something that's being tracked, others can take a look at that as well. And then we've got sort of a testing environment to test transport and content, that allows us to upload files and to do sort of a checkbox to see if you're compliant with not only the structure of a consolidated CDA perhaps, but also some of the vocabulary issues that might be relevant and important as well.

So I just wanted to very, very quickly go through that and just give you a heads up because one of the things that we wanted to provide, and a lot of this was based on discussions that Wes Rishel, whose card is up, I see in my peripheral vision, said, we really need to move beyond just developing those standards. We have to find a coordinated strategy, if you will, for how we're going to implement that. And so we've been kind of working to try to find a way that we can provide the support people need, so that they can be successful in implementing the Meaningful Use Stage 2 requirements. So with that, I'm going to end and turn it back over to John.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Thank you very much. Wes.

Wes Rishel – Gartner, Incorporated – Vice President & Distinguished Analyst
So, I'm going to pick on a specific point, and I hate to do that because I really strongly thank you for the work you've done and think it's very necessary and well-balanced between what the SDO can and should do and what needs to be done among all SDOs to keep the industry on track towards a given phase. And I really I think I'm going to be talking about an oversight on what you said, rather than in the process. Can you go back one or two slides? One more. One more, like I said, two slides, you talked about the forum as where, in essence, the issue would be reconciled or resolved. It's been my experience that many issues can float in forums for years and never get resolved. Is there – in this process, is there a way to recognize when a definitive consensus process is needed and schedule that process to happen with an SDO?

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
So, I think at this point we've recognized that part of this is that there has to be engagement from ONC, there needs to be engagement from the SDOs or the NIST and others that might help provide some of those solutions. Part of the reason that these are moderated is that we want to be able to essentially identify when an issue needs to be, as you say, sort of brought to a definitive conclusion. Clearly, it's certainly possible and in fact I think to be expected, that there may be different approaches. Approach A an approach B, both of which have very strong supporters in terms of resolving that, and that the community itself doesn't come to a consensus and that we have to create some other mechanism to do that. In large part, having the forums and having the discussions is intended for us to get feedback from the community about what's working and what's not, so that we can then engage in those more definitive things.

So, for example if, let me just use a quality example, if suppose there is a quality measure that comes out of CMS that turns out there's a logical inconsistency or there's something that needs to be done. Using

the issue trackers, hopefully we can then say, CMS this is a problem, this is kind of – this isn't about a standard, it's not about testing, it's about kind of how this has been described and you folks are the ones who are going to have to help us resolve it. But I think that's the intention, to bring these things that are important to resolution and get decision makers, whether that's the community or whether it's groups like CMS that can help us resolve that.

Farzad Mostashari, MD, ScM – Office of the National Coordinator – National Coordinator
In addition to that Wes, can I maybe turn your question into a statement, that there should be a mechanism, in those cases where the moderator feels that it could be kicked over to a SDO process to do that?

Wes Rishel – Gartner, Incorporated – Vice President & Distinguished Analyst
Well, I – yes. I'd like to elaborate if I might. My remarks can be extended for the record, is that right. I think there – the thing about forums, fora, is that it's often difficult to look at a series of entries and decide what the issue was. You have people talking at cross-purposes, you have people who have more time and typing facility than others and last longer, and it's often hard to know whether the consensus was, let's do it this way, or it's not worth the trouble. And I think what we need is a responsibility for the moderator of the forum to be actively identifying those issues that have the appearance of being critical towards ongoing implementations, pulling them out of the muck if you will, and moving them forward.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Thank you for that. And Eric.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects
Yeah, so I want to actually thank you for setting up the issue tracker website. I had occasion to use it yesterday, with my vendor hat on, when I had a question about a nuance of certification requirements around CMS – CQM calculation and it's absolutely phenomenal to be able to see questions that others have asked, to be able to search. Wes' comments notwithstanding, and I agree with them, it's such a step forward from what most people expect to be an opaque bureaucracy that at best you'll get an answer, but no one else will be able to see your answer. And I think that this is an example of why ONC needs to be funded, although I'm not sure how much of it is funded by ONC versus CMS. I mean, if we're at a point where it's kind of like a couple years after passage of the Clean Air Act or the Clean Water Act, if industry were not able to be able access the bureaucracy and get clarification on what's required of them, then that would have been – due to underfunding of that bureaucracy, that would be a serious problem. So, it's already working very well.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Other comments? Well, just one comment from me that's similar to, I think, Wes' theme, which is deciding when consensus has been achieved and issues have been resolved. I know you're going to really not like my bringing this up, but, in Massachusetts of course, we needed a provider directory that could be used across all stakeholders and there was no standard that we felt was mature and appropriate. You concluded that as well. So we had to invent a set of RESTful interfaces to do, add, change, delete, modify, to provider directories for a whole Commonwealth. And we'll have experience over the next few months on how that works in production and certainly would love the opportunity to Doug, hand that off that back to you and say, our consensus on provider directories was, there was no standard that was mature, everybody go do what you will and we'll learn. Well, there should be a loop closing that takes place after that hand-off, if there, Wes to your point, hasn't been a positive achieved consensus, a negative achieved consensus is fine, as long as there's a follow on. And I can tell you, RESTful, simple XML works great. Okay, well, yes, David.

David McCallie, Jr., MD – Cerner Corporation – Vice President, Medical Informatics
This is David McCallie. Just one more comment, not much different from what John just said. But first, to preface with, this looks really good Doug, and I think that proof-case around the CCDA and getting those issues resolved, this'll be a great test case to see if this is the right way to do it. And it looks like a great start, so thanks for responding and creating this, because I know we discussed it a number of meetings ago and this looks really good. You listed, though, to make the broader point, you listed a number of reasons why interoperability could fail, all of which were good reasons, and this tool and context is good to address them. But, the other reason is that there just isn't an appropriate standard available or applied, you may have picked the wrong standard or there isn't a standard there. So to John's point, it would be nice to see a way, maybe it's the S&I framework in general, but a way for alternate solutions or different approaches to get cycled through without the overhead of going through the laborious SDO process, which can take years for something new to emerge. So maybe there's something that can be leveraged where feedback from experience in the community of a different way to solve a problem, gets into the loop for refinement. And pushing to the SDO with a priority attached to it that says, hey, this is going to go to the real world or is already in the real world, you better pay attention and do it a little faster than the normal cycle.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
If I can just – we talked about aspirational, can I tell you what my aspiration is here? By separating out the kind of standards development pieces, use case harmonization and implementation from the support for implementation and testing, I hope that we reverse those arrows. So that what happens is, just as you've suggested, there's an issue that is raised in the forum, you realize in fact, that there's a gap. And then we take that and say, we have heard in the community there's a problem and we don't have adequate

Standard, and we use that to help us drive the use case and harmonization and development of those standards. Because I think right now, we tend to sort of say, what's the problem we're trying to solve, almost in the abstract around a use case, and we drive that to an implementation. What would be great, is as people are trying to solve problems like provider directories, realizing that there's not a good solution out there, coming up with rough…working code and rough consensus, and then feeding that back in, I think is going to be a really important step. And I think it depends a little bit on how the communities come together and how they help organize. Our job is to sort of support that, but I would clearly – it would clearly be a great outcome to see the issues discussed in the forum and have the conclusion of that be, we need something that does X, Y and Z. We've got a pilot that's doing that, how to we create a national approach that is scalable and easy and all those other sorts of things? So, it's exactly, I think, aligned with both what you were saying, as well as what Wes had said, that we need to make sure that we've got a way of creating a definitive answer. Sometimes that definitive answer is the negative, we don't have something and that the definitive answer is, we've got to work to actually fill in that gap. I think that would be a tremendous outcome.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
A corollary to this is what if this body achieves by consensus an answer that turns out to be wrong? And that, as Jamie was talking about, an issue on eMeasures and HQMF, and when you tested in the field, even though the best minds thought it was a reasonable idea, it turns out to be very flawed and filled with gaps and non-implementable and Liz, this is another one for you. How do we make sure that gets back and we revise decisions we might make.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
And I think, to that point, and I've got Jodi sitting next to me so if I say anything wrong, she will correct me. But the issue here is that our job is to support that implementation. It is not, it's not as if the forum comes up with a recommendation, we aren't going to take direct recommendations from that particular forum. I think this group here is the ones that are going to say, we had this discussion, there were a lot of people that achieved this particular approach. We can say, we've been monitoring this and we've been looking at the community and bring that to this group to say, help us resolve this, because they came up with a consensus decision, but I'm not sure it is aligned with the HIT Standards Committee priorities, the way in which we've approached things. So I think it's important to realize that as we have this implementation and testing framework, there will be interactions with what gets discussed there, that will come to this group that I think will be again, one of those ways of making some resolution about discussion items.

Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Tenet Healthcare Corporation – Vice President, Applied Clinical Informatics
Yeah and Doug, this is Liz. As I'm listening to this conversation, and I'd already dropped MacKenzie a note, to say the correlation with the Implementation Workgroup and this group could be very helpful. Did I understand you to say that the issue tracker is currently only looking at quality measures? Was that a misread on my part?

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
We started with the GR-Ticket tracking to support the quality measures, and we've been doing – this has been, I think a soft launch, we haven't made a big deal about it. We just sort of got it out there and got it running, and the goal is that that will be one of the foundational building blocks, that as we have additional discussions and as we're supporting consolidated CDA and some of the other MU2 standards, we'll be able to expand that as well. But, the principal focus, when we first started with the trackers was around quality measurement.

Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Tenet Healthcare Corporation – Vice President, Applied Clinical Informatics
Well you can obviously see where I am going in terms of the value. I think it's a terrific idea and I think the value that can be gained from using that to track implementation issues overall, and then play those back into both standards certification and testing is that the power of that opportunity is pretty phenomenal.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
To Liz, again, as people make good suggestions then I assign them work, you hear where I'm going. I think actually we should get our team that's been working on the implementation and testing platform, perhaps they need to get queued up in the Implementation Workgroup, just to give them a sense about what's going on and to get the feedback from that committee, to see if there are other things that we might consider.

Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Tenet Healthcare Corporation – Vice President, Applied Clinical Informatics
Yeah that's a great idea. In fact, that's exactly what I just e-mailed MacKenzie to say, how can we bring that group to the Implementation Workgroup for presentation and collaboration? Thank you, Doug.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
Thank you.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Dixie and then Wes.

Dixie Baker, MS, PhD – Martin, Blanck and Associates – Senior Partner
Yeah, thank you. This is Dixie Baker. As the Recovery Act HITECH acknowledged, there's a close interdependency between policy and technology. And I can certainly foresee that in these issues, both in the issue of tracking and in the forums, there will be policy issues that are raised as well. And so I would like to make sure that there's some thought to that because as we know, everybody who is on well either of the groups I lead, that policy issues frequently come up. And we're talking technology, but we realize it's really a policy issue and there needs to be a way to really elevate that out of a technical forum as well.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
And in fact when I was saying the reasons you don't get to interoperability, I cited three. Dixie, you remind us that a really important fourth, is that sometimes it doesn't occur because there's a policy issue that needs to be resolved ahead of time. So I think, it is another case in point as to why, to get this, we're going to have to have the ability to sort of understand what's going on in the community, identify the issues, and then properly triage and route so that we get those definitive answers. Thank you.

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

Wes Rishel – Gartner, Incorporated – Vice President & Distinguished Analyst
In the context of this process, I think it's important to recognize the difference between implementers and everyone else in the entire chain, which is that implementers are expected to get it done whether or not they get it right. And they therefore always make do at the end, in order to get the project done, if it means being nonstandard, we'll be nonstandard. If it means somehow finessing a policy issue, we'll somehow finesse a policy issue. As you look at the working of this process that you're going on, I think it's important to keep in mind that there are two values that can come out of the clarifications that come through the system. One is, queuing up the issue to get it right. And the other is coming up with a provisional solution to get it done. And in the context of Meaningful Use Stage "N," is coming to fruition now, getting an interim solution is as important as anything else.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Thank you, Wes. Other comments? Okay, well we are right on time. And so in the interest of getting to a lunch break that isn't as late as MacKenzie originally scheduled it, why don't we go ahead and move on to, it's more Doug. It's time for structured data capture.

Dixie Baker, MS, PhD – Martin, Blanck and Associates – Senior Partner
Meaningful Doug.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Yeah, I was going to say, MacKenzie, did you do this purposefully?

MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator for Health Information Technology
Do what?

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Poor guy.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Office & Director, Office of Science & Technology
So I am going to be joined by Evelyn, because all the hard questions go to her. Okay, I just want to tee that up with this. So what I wanted to do is just give a brief update, because we're what 6, 8 weeks.

Evelyn Gallego-Haag, MBA, CPHIMS – Office of the National Coordinator
Since January.

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science& Technology – Office of the National Coordinator
since January. End of January we started this initiative called the Structured Data Capture Initiative. To just give you an overview of what's going on, this is one of those kind of pulse check, give you a sense of what's happening, get some early feedback and things, and then, there'll be other opportunities and check-ins that we'll have later in the year. So, background and overview, kind of what our timeline is, what we've done so far. There's a big list of candidate standards and what we've been doing with the National Library of Medicine and the NIH, and what we hope to accomplish with this activity.

So currently the Structured Data Capture Initiative is one of 10 active initiatives that are under the S&I framework. We launched it in January 23rd. This has been a partnership with the NIH, NLM and AHRQ, although I will say we've had conversations, very productive engagements with variety of other agencies as well. I mean we've talked with FDA, we've talked with CDC. There's a number of folks that have been interested in this. And the issue is this, is that right now we are focused on sort of two different kinds of activities. The challenge that we have, and I – when we think about the learning healthcare system and we think about kind of getting to this point where we can use the electronic health record to help support clinical research activities, and to be able to support kind of that learning. A lot of folks came to us and said, gee, we need our 600 data elements in the EHR, and we need our 80 elements in the EHR. And as you begin to expand and grow, you realize that what people are saying is that we need, and all of their use cases are important, they're all important things that we need to capture. But it simply becomes really hard if the only way to capture something in a structured way is to have that particular way of collecting that information certified as part of an electronic health record. And for clinical research, often times you're collecting novel information, it's because there's new information and new knowledge that you want to gather.

And so we said, how do we get away from this notion of taking electronic health record data as secondary use? We're going to take it and we're going to use it a secondary purpose, but begin thinking about a partnership, if you will, between the clinical care and the research community, that says, how do we supplement the data, collect it in the EHR, with other data that would be relevant for clinical research purposes and the like? And so we've been working with the Patient-Centered Outcomes Research Group as well as with the National Library of Medicine to say, how can we enable electronic health records to participate in clinical research activities without requiring them to be certified to all possible data elements that are out there. But we can supplement research data with things that are already part of the electronic health record.

When we started talking about this, AHRQ says, listen we've got – they were one of those people in the conversation that said, we have all of these data elements as part of our common data format for reporting on patient safety events, and we'd love to have all those certified as part of the electronic health record as well. But as we talked, we realized that the use case was very similar. This notion of having a whole series of data needed to be recorded for patient safety events, some of which is going to be captured in the electronic health record, but some of it may not be routinely captured. And that if we could supplement that information and find a way to do that, we could also support patient safety reporting events. And so we launched this back in January. We had over 280 individuals who participated in our individual launch, it was fairly well-attended. And now we've got about 200 registered community members, 50 or more that are participating regularly.

And we've got, in addition to the NIH and AHRQ, FDA is interested in it, because they work very closely with organizations like CDISC and the clinical research communities and PhRMA. CMS is saying, gee, we'd like to be able to do pre-authorization of high-cost of care, mobility devices, those things you see at night on late-night television. I don't know if you guys are up at that time, but I am. And if there's a way that we could capture some of those data elements and preauthorize some of that work. CDC is looking at, how do we do case report forms and how do we collect that information? And so those folks are engaged and also participating in this. If you take a look at the community participation, what's remarkable is that there's such a broad swath of different groups; we have HIT and EHR vendors. We've got provider organizations. There are folks that are commercial payers. We've got folks from standards development organizations, federal agencies, and there's really a very good cross-section of people that are participating in this activity.

So the question is, why focus on this? I've alluded to some of this as well. There's an exponential growth in the volume and detail of clinical information that is captured. And some of it may just need a header and free text, some of it may need to be structured. But, we have to provide flexibility in electronic health records, such that we can have an interaction with things outside of the EHR that allow you to sort of improve this. So, if what we can do is begin to standardize more granular data and create a way for EHR's to interact with that more granular data in the electronic case report form or something like that, we provide tremendous additional flexibility in interacting with that research community or the patient safety reporting as well.

So the utility of EHR data for supplemental purposes has been limited because we have – one of the things about common data elements and I wish Betsy Humphreys was because she could probably articulate this better than I could. Everybody has a common data element, the only thing common about the data elements is that they don't share a lot in common, and you can just parse that through. And so everybody recognizes the importance of having common data elements, but they don't share a lot of things in common, per se, in terms of the syntax with that. And so, if there is a way that we could create more uniformity in the terminology, then the elements that you have in the data elements, when an EHR wants to interact or be able to capture this stuff, there might be a way that, if we have a common syntax, we can certify electronic health records to that common syntax, and provide flexibility to the domain experts to say, here's the research study that I want to do. Here are the data elements that fit into that Syntax and that an electronic health record certified to that syntax, should be able to interact with those.

So a whole bunch of other things that we think that this is going to be helpful for the learning healthcare system. We think that rather than requiring an electronic health record to be certified to all of those data elements, we can be very focused, and if you want to do clinical research as part of your practice, there's a way to do that without having your EHR have all of that functionality. We think that by having a common syntax we can start to compare different data elements and also can be able to aggregate them more effectively as we get increasing consensus around the definitions. We don't need site-specific EHR enhancements. Chuck Jaffe has a classic picture in which he shows people participating in clinical research activities that have six computers sitting in their back office, each computer, for an individual clinical trial that they might involve in. And also, if what we want to do is do public health reporting or we want to do adverse event reporting, having that be captured in an interface that is supplemented by the EHR data, rather than stored directly within the EHR data, is something that may improve people's comfort level with reporting information around adverse events or patient safety issues. Developing a valid standards-based data architecture, so that this can be looked at, we've looked at other kinds of things. So, electronic case report, the incident report forms that they've got, surveillance case report forms for public health, collection of patient information for the determination of coverage. And we've sort of talked about those as different ways of doing essentially the same thing, which is to take highly granular data, put it into a form that allows you to capture that and have a way of interacting with it.

So, in some sense, and this is kind of how I try to describe things, there are four things that we want to get out of the Structured Data Capture Initiative. The first thing as a standard structure or a syntax, for describing common data elements. The second is a container, you can call it a form or a template or whatever, but a container that those common data elements can fit in. And standards about how an EHR can access, view, populate and save that information. So those are the kinds of transactions that you'd like to take a look at. So, it's an ambitious project, there's a lot of stuff that's going on with this and there are existing standards that are out there. CDISC has a standard for retrieve form for data capture, which is an IAG profile that we can look at. And so we've been starting now with going through a concert series of different activities to take a look at this.

Here is sort of the conceptual flow of things. A provider might select a particular form or template or find stats. The, that form or template is then accessed remotely. It's then displayed in the setting of the electronic health record. There is data that has been pre-populated, maybe it's the patient's name or some demographic information. Additional data might actually be provided as well and then that's stored some place, either as part of the electronic health record or as an external repository. So if you think about the standards that we want, we want to be able to have a CDA structure that allows us to create a common way of describing these common data elements. A former template structure for how we would assemble those together, definitions of how an EHR would interact with these forms and CDEs and then a way to auto populate that from the electronic health record, where it makes sense.

So, we are here in our project, we just got started. We are looking at some of these use cases and we've identified these two. Now what we're going to start doing, and we're actually working right now at sort of doing our – what we call our concert series, where we bring different people in and we have them tell us about how their approaches might solve some of these problems. And we're ready to I think begin moving into creating sort of what the CDE structure should look like, what the forms and templates should look like and what the APIs or the interaction standards might look like as well. And so it's an aggressive timeframe. We're going to be working very, very hard over the summer to try to bring these things forward. But given that there's a set of existing things that are out there, we think that we can help.

So, we've achieved, those of you have been involved in standards and interoperability frameworks know that the first thing is, that we put out a draft standard or draft charter, and then we ask everybody to achieve consensus and to essentially modify it, as need be. Everybody's cards are going up, but I am going to get through this presentation at the end, and if you're going to ask questions, it's going to take away from public input, okay. So I gave you all sorts of flexibility in the previous one, but I'm going to drive to the end with this one. We've kicked off the use case and the development phase and we've got interactions with HIMSS and the public health organizations, learning healthcare systems, some of the SDOs and the EHR and other vendors.

The use case scope right now is, we're just trying to take a look at how we can look at these initial things, we're not so much talking about the external repositories at this point. We're doing our concert series, which is to get together – there are the folks from NINDS, the traumatic brain injury research folks, AHRQ. We've had some of the PhenX people from the National Human Genome Research Institute, the purple button, another color button out there, about patient event reporting, FDA, there are some other standards that we've taken a look at with regard to candidates that we've got. NIH and PROMIS, USHIK, Duke and some of the work they've been doing in the Research Institute and the clinical information modeling activities with CIMI, have all had an opportunity to sort of present.

Obviously there are a lot of different things that we could choose from, and I think part of what we want to do is get a lay of the land and then we want to sort of begin to refine as we look at the use cases. And I've included those sort of as standards. One of the things we're looking at is CIMI, there's a lot of work that's going on there. And CIMI has a whole series of different modeling efforts, Stan certainly can speak to this as well. But we're taking a look at the work of RFD, we're taking a look at the IHE profiles. What we really want to so is kind of leverage what's out there and achieve consensus on those four things that are going to be important.

In January as well, the National Institute of Health has launched a common data element portal and I think one of the things that's really important to get clarity on is, that what's going to come out of this initiative is all about syntax. And if you think about interoperability, there are two pieces of it, right, there's kind of a syntactic interoperability and there's a semantic interoperability. We want to get the

syntax first, but one of the reasons that we're working so closely with the NIH and the National Library of Medicine is that to achieve consensus around semantics is going to require governance. And it's going to require domain experts to come to the table and say, this is what we believe the definition of closed head injury is, and the data elements that we would want for that. So we've been working very closely with the National Library of Medicine and the NIH to help us understand how, if we can get consensus around syntax, we can then work with other organizations to come to consensus around the semantics of the critical elements that we want to capture. So the National Library of Medicine is working on a repository and they're working across the various institutes to come up with some consensus. There are some governance boards that have come up that are trying to at least identify what is present in the 22-odd institutes that are the NIH and to try figure out who's doing what work and we will continue to work very closely with them as well.

So what we hope to get it is, we are working on the use cases and the functional requirements. In some sense this is sort of, the best analogy that I've come up with is, it's like if you go to a website and you pull back a form that has a whole series of elements that need to be filled in, some of which are automatically populated because you have cookies on the desktop and it knows to populate that stuff. And that once you fill it out, you click the button and then it submits it someplace. And that's kind of the interaction that one might like to see. Now, I don't know, I think it's the community's job to try to reach consensus on where we're going to go with these various standards, but we've got to – we want to get implementation guidance, we want to be able to get those standards together. We hope to develop some pilots and to test these out there in the real world and make sure that we've got alignment of these things across the various activities that we've got.

So these are the folks that are sort of leading a lot of the efforts. We've got a number of people that are engaged. And so there, I've have gotten through all of this, got a lot of cards that are up and I'm going to turn it over to John who now can differentiate who needs to go next.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
I'm keeping notes as to when the cards went up …

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
Excellent.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
So Andy, go ahead.

Andrew M. Wiesenthal, MD, SM – Deloitte Consulting, LLP – Director, International Health Terminology Standards Development (SNOMED)
So, well wow, I was first. To quote Mark Twain, and probably many of you have heard this, you can keep your mouth shut and have people wonder if you are a fool or you can open it and remove all doubt. So at the risk of removing all doubt – at the risk of removing all doubt about myself, I really applaud this. I think it's great, but I'm reminded of 10 years ago or more when we were actually, in the absence of any model, which didn't exist then, trying to create the data model for an electronic health record for a big system and having enormous arguments about things like, how many genders are there and what are they? How many races and ethnicities are there and what are they? And somebody piped up, well, there is the Census Bureau, and I think there are something like 130 recognized races and ethnicities if you're the US Census Bureau, and when somebody told me there were six different varieties of Ashkenazi Jews and I didn't even know which one I was, it creates this sort of garbage in, garbage out problem.

So what I'm worried about is, in the absence of the stuff that Stan is working on, and he hasn't raised his card, so I raised mine. In the absence of a defined data model that's extensible, I'm not sure how far you can get past some very general agreements around syntax, right. Because – and the EHR implementation forces lots of changes on the work practices and how people conduct their business in all sorts of health care institutions and I would submit the people who are designing forms for research and for other public health purposes and reporting purposes and safety purposes, need to be mindful of the fact that they can't just do it the way they used to. You can't ask for everything and have your own definitions anymore. But if you don't know what the data model is, you don't know what to design your form to. So if we can say we've got a gross structure for a form, but hang on, wait a little while longer, or a lot longer, because we don't actually know what the names of all the genders are, and if you want gender, you're going to have to wait. I am sort of troubled by that, because if we put this out and we can't tell people what else to do, how are they going to proceed? Even the simplest things need a basic data model.

Farzad Mostashari, MD, ScM – Office of the National Coordinator – National Coordinator
I open my mouth and remove all doubt. I think this is a release valve, for all the people who want, and maybe for their purposes, need the very specific question about occupation and whether the person was working with asbestos or not. And I don't think the – right, one approach is to say, listen, we're going to hard code the key information model, the data model, on every data element and you know what, you may want smoking history somewhere, in some other way, but what you get is, five categories. That's what's in meaningful use, that's what you get, get over it. That's one approach and say, you should be able to do just fine with the five former, current former, never, heavy smoker or light smoker or every day, some day smoker. And we have the LOINC codes for those, the SNOMED codes for those. The other approach is to say, well really for your study, you actually need to know pack/years, and maybe there are a whole lot of other people who need to know pack/years, too. It's not in meaningful use and maybe we don't necessarily put it in meaningful use in a way that you can collect all the things you want to know, but let's represent – in fact, I just went to the NIHs CD thing and it's awesome, they actually have already all these different data elements. So there's measurement of respondents, thirty day quantity and frequency of consumption of alcohol.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Right, so everybody, you've got to check this out, because when you say I have one drink a day that could vary from the shot glass size to the venti or three-gallon size. And we need a standard for that.

Farzad Mostashari, MD, ScM – Office of the National Coordinator – National Coordinator
And so alcohol …

M
Little line on the tankard, right?

Farzad Mostashari, MD, ScM – Office of the National Coordinator – National Coordinator
Alcohol past month consumption frequency has a ID, 282-8779, and a precise definition and quantity number has a precise definition. So if anybody else wants to create that question, right, I that know in your system, the likelihood that you would have done is, you would have just created a new variable, right, that's what you have to do. But your systems new variable has no way of connecting to Stan's variable that he created. So I think the idea behind here is, you don't try to constrain everything to one…everyone has to agree, you're only going to collect – you only get to collect smoking status this way, and yet have that escape valve so you can all collect it in ways that can match to each other.

Andrew M. Wiesenthal, MD, SM – Deloitte Consulting, LLP – Director, International Health Terminology Standards Development (SNOMED)
So I know other people have their cards up, I don't disagree, and yet at the end of the day, it's still secondary use and there are still doctors and nurses doing regular work that are generating this and they're not going to do, unless in very, very isolated circumstances where they're paid extra and motivated highly ….

Farzad Mostashari, MD, ScM – Office of the National Coordinator – National Coordinator
That's right, and that's the whole point. The way I see this is, instead of asking, my – and I do this sometimes, it's the community I know best, right, my public health peeps, and yours, right.

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

Farzad Mostashari, MD, ScM – Office of the National Coordinator – National Coordinator
Would say occupation, you've got to collect the NAICS, 400 categories of occupation whatever, or another group might say, you have to collect whether the person is a food handler. Another person says, you've got to collect whether they're a day care worker, you gotta, right? Because all those matter for very specific things. And so I would say, if the person has hepatitis A, then you are motivated to collect whether they're a food handler; for everybody else in the world, you don't need to document whether they're a food handler or not. So I think you're exactly right, there's a difference between things that you collect in the routine clinical care on every patient that becomes the exhaustive healthcare and there are things that are not for secondary use, but supplementary use, where you collect on a smaller number of people but still according to specific standards.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
And Andrew, we have actually solved the gender problem for the world.

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

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
There are only four, male, female, other, and unknown. So we got that. So Stan, is this related…

(Indiscernible)

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Well, there are 27, but we actually reduced it to four for purposes of …

M
Your purposes.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Yeah, yeah.

Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare
Yeah, it probably fits best just as a response to this. I mean it's – I agree with the discussion and I agree with the challenges Andy's pointing out, and it's one of the things where, a couple of thoughts. One is, there's some simple – things that we thing are simple that are actually the hard cases, and gender and marital status, and some of those are extremely hard. Not – mostly because of sort of the social impact and the other social implications of what's going on. But, it is complicated, I don't think we should let the hard cases keep us from trying this because I think there, in fact, are simple cases where I could see, for instance, where we could get some useful information about weights. I mean, there are just things that we can get and until we start doing it and get some experience, I don't know that I would know how to solve all the cases, but I think we can. Because there are hard cases, I don't want to give up trying to get anything. And so, we might not get to poetry, but we might, could get to where we could do two plus two.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Jaime.

Jamie Ferguson – Kaiser Permanente, Institute for Health Policy – Vice President, Health Information Technology Strategy and Planning, Fellow
Thank you. Doug, thanks for the presentation. I wanted to suggest that, in order to address some of the issues that have just been raised and discussed, there may be, in fact, a process step that's missing from the program or maybe it's a process step that needs some governance. And I'll call it requirements management. And I know the example that you and I have discussed previously is one research agency has a question and things are always structured as questions with answers, so they absolutely have to know is the patient over 59, yes/no. And another research agency has a requirement and their requirement is, is the patient over 65, yes/no and so – and they both absolutely require the yes/no answer. And the current program that you've outlined, I think, would just take those as requirements and say, so what's the right data model and what's the right syntax and procedure for us to answer that question in a standard spaced way, is the patient over 59 yes/no and have a separate requirement for is the patient over 65 yes/no. But in fact, if you had a requirements management process with some governance it could take the different requirements that are coming in and could say well, all right we actually have a date of birth and a current date and so, in fact, the requirement isn't 59 yes/no, the requirement is something different.

So, but that would, I think change the structure of the program slightly. And then obviously, there are going to be a lot of cases where something else with new specificity is required that's new and different, but the things that can common, with truly common underlying data could be managed as…so that's why I call it requirements management.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Leslie.

Leslie Kelly Hall – Healthwise – Senior Vice President, Policy
I would just like to add that an important source of this information is the patient themselves and that instead of adding so much burden assumption that the provider gathers all of this, let's think outside the box and think how a patient can also participate. CDISC has done some great work identifying roles and family members and actors all involved and I think that should be included from the get-go and I would encourage that role or actor being added to this mix. Otherwise, we can get in data collection hell at the provider's side. And I would also offer caution, in a patient's point of view at an appointment or provider setting, I want the doctor to name my tune in two notes. And if he can name it in two notes and say this is what you have and the rest of the 7.5 minutes is question and answers with me, that's what I want. So just be mindful that the collection burden isn't just the providers, it's also the patient and if we can take that off-line and use these great new technologies to provide the question gathering independently and get to the actual research and clinical diligence, I would encourage that, so, just add it.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Thank you. Wes?

Wes Rishel – Gartner, Incorporated – Vice President & Distinguished Analyst
Yeah, I think it's important to separate this effort into standards for the process and I guess you could throw syntax in there, and never assume that the semantic problems are solved. I think that one of the confusions we just dealt with here is, there are four genders for administrative purposes. For clinical purposes, the number of genders has varied over the years and will continue to vary, I assume. The – I think there's a lot of good to be had, simply by recognizing two new roles associated with viewing EHRs in the process of research. One of them is the researcher and the other is the consumer, as Leslie mentioned, just wanted to save you having to put your card up again. But there is a transition, there is a transition from data collected for the purpose of care and data collected for the purpose of research. And the way I see this, this is all about first leveraging the data that has been collected for care. And then later on, improving the process by making the data collected for care sometimes more compatible with the needs for research. But whether we talk about adverse event reporting, whether you talk about clinical research studies, there's a whole lot of opportunity right now to simply smooth the process of grabbing existing data and supplementing it and getting in the into the research stream that could benefit very much by just fairly simple standards for Meaningful Use Stage 3. And then we can then go on begin to approach the semantics the way Stan described.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Thank you. Floyd?

M
So you're saying you agree with the approach?

Wes Rishel – Gartner, Incorporated – Vice President & Distinguished Analyst
I didn't quite hear the separate – well, I didn't quite hear the – yeah, I guess, I do. All right, all right, all right.

M
It is tough to tell that.

Wes Rishel – Gartner, Incorporated – Vice President & Distinguished Analyst
Well no, I guess my concern is, he talked about semantics first. I mean, I'm sorry, syntax first and then semantics, and I certainly agree with that. What I didn't hear was the ability to, at that intermediate step, call out actual meaningful use measures and begin to use them, even though the semantics aren't nailed down. And that's the point I was trying to make.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Well, let the record show that Wes agrees with approach. Floyd.

Floyd Eisenberg, MD, MPH, FACP – Independent Consultant
I didn't know I was next, but thank you, I'll take it. So first of all, I wanted to comment on having had the experience of seeing everything asked for and the difficulties implied with that in some of the Clinical Quality Measures. But what I wanted to address was in working on the quality measures and working in IHE and HITSP prior to that, thinking of retrieve form for data capture, there was real significant importance placed on what is the syntax and what is the data model. And so I want to go back to Andy and Stan's comment. I think the data model and the syntax are important, the semantics coming later, but, I think that for EHR vendors and EHR implementers to participate in this, this same model needs to be used. And I'm not saying which model, but the same model and syntax needs to be used to capture the data from quality measures, as it does for all of this reporting that might come directly from the EHR, so there's a standard way to manage that. That was the approach we were trying to take at NQF with the quality data model. It may not be the model you want to go forward with, but that was the intended approach. It also tried to apply, although EHRs do not have it yet, the provenance to know the source is the patient, so you could include the patient as a source, you could include it came from a device and I need to know that for the research, and not that it came from someone manually entering it. So I think trying to pay attention to that will be really important for this approach.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Thanks. Becky?

Rebecca Kush – Clinical Data Interchange Standards Consortium – Founding President and CEO
I think David was first, but if you want me to go first, I'll be glad to…

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
David, but we can go Becky, David and …

Farzad Mostashari, MD, ScM – Office of the National Coordinator – National Coordinator
Don't challenge the chair, yeah, don't challenge the chair.

Rebecca Kush – Clinical Data Interchange Standards Consortium – Founding President and CEO
Okay, okay. He lost his over the edge is the problem…

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
The edge thing, sorry David.

Rebecca Kush – Clinical Data Interchange Standards Consortium – Founding President and CEO
I just want to commend this work, because I've been waiting for this since I joined this committee and so I think it's a great opportunity and I'd like to try to address a few of the things people have said by saying, there's a huge body of requirements that have been gathered around this. There's a lot of work that was done on it. It can be informed by things like the interoperability specification number 158, which was actually done differently than a lot of the ISs that came out of HITSP. This one in particular was the last one, it was funded and managed and done by a group that came together, 37 organizations funded it. There were many, many people involved in it, it was a very good process and I think it can inform this work.

There's also some testing that has been done and by using an approach like this one. At Harvard they have shown that when patients were discontinued from a drug, rather than digging out a form and sending it by fax to the FDA, which took 35 minutes and didn't happen, that an adverse event could be reported in less than a minute, so the ROI is there. And also, there is an international standard for a minimum core data set for research that has been done through the FDA's Critical Path Initiative in 2006, it was posted in 2008. It is used around the world. Some of the NIH centers are using it, others haven't figured out how to use it yet, but it doesn't approach the, what we would call efficacy or the therapeutic area type standards. It's a core data set that is used to satisfy regulatory requirements by all the regulators in all the ICH countries, Europe, Japan, the U.S., and other countries. So, it's available and I think EHR vendors who have been wanting to support research have been looking for something like that to which they can map. And so, there are also reasons behind the way that this standard, which is called C-DASH was developed. Because when you collect those data elements, they put the data in a form that can be used in analysis and reporting. And we've had some discussions in a meeting with several of the NIH centers recently on taking some of the common data elements and then using them downstream for analysis and submissions. And they're seeing how some of the CDEs need to be formed appropriately to pave the way for that downstream analysis. So I think this is a huge opportunity and I think there's a lot of work that can be built upon to take this forward.

One last comment, AHRQ is doing their adverse event reporting form and I have talked to Evelyn and Doug about seeing if we could harmonize that with five other adverse event standards that were around the federal agencies that have already been harmonizes. So that if we can do that, it can be leveraged by all those agencies and I think it's an opportunity there.

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

David McCallie, Jr., MD – Cerner Corporation – Vice President, Medical Informatics
So Rebecca and I are going to do the good cop bad cop duo. She is going to push mine off again. So I think that to the degree that – which this enables the creation of sort of remotely defined forms that can be invoked in a workflow that's appropriate to a clinical setting and capture data in a structured fashion consistent with a clean form definition, that's really good. We've got some attempts to do that in the past, they haven't may be worked as well as they should. So that part I like.

The thing that concerns me is the side effects of Clay Shirky's famous dictum about what killed the semantic web, which is the semantic granularity mismatch, which is, that it's impossible in practice to define granularity for the data that you want to capture that makes everybody happy. Somebody wants really fine-grained data, somebody wants it lumped, somebody wants it split one way, somebody wants it split another, Jamie's point exactly. And I spent a decade in my time at Cerner building structured clinical documentation tools where we worked incredibly hard to try to solve that problem and develop thousands of structured trees that allowed for incremental granularity. The deeper you went into the tree, hundreds if not thousands of clinical encounter pathways that leverage those deeply structured trees, so that a clinician who wanted to document lightly could go through quickly and somebody who wanted to dive deep could dive deep.

And despite the fact that we've used this with a lot of clients, we're moving away from it because it's just too constraining for providers. And no matter how clever you are about the structure of those what we've called canonical forms, which was our definition of a tree that you can dive into to go as deep as you wanted in structure. And in fact, alcohol consumption was one of the ones we built, because it kind of naturally fits, you know, drinks yes/no, drinks a lot yes/no, drinks a lot this much, drinks a lot this much for how long. I mean, you can kind of drill in as deep as you want. You still couldn't keep people happy that you are capturing the data that they wanted.

So I guess what I worry about is absent what Rebecca was describing, which is very thoughtfully pre-curated data sets that a large number of people agree are the right questions to ask, you're going to get into trouble with people wanting answers to literally hundreds of thousands of different questions. And if the EHR is expected to be able to pre-populate the form, no matter which one of those hundreds of thousands of elements, that it just won't work.

Farzad Mostashari, MD, ScM – Office of the National Coordinator – National Coordinator
I think there's a fundamental misunderstanding there. The idea isn't that the EHR pre-populates all those elements …

David McCallie, Jr., MD – Cerner Corporation – Vice President, Medical Informatics
Well that's what Doug said.

Farzad Mostashari, MD, ScM – Office of the National Coordinator – National Coordinator
No. What he said was that where…like there is something to pre-populate, like the address, where there is a match, then it pre-populates. If not, then it presents…

David McCallie, Jr., MD – Cerner Corporation – Vice President, Medical Informatics
But I think will frustrate people is they will say, you wanted a smoking history, I've got that smoking history. I just won't have it in exactly the form that was defined for this form, because of the way our doctors defined smoking history doesn't line up exactly with what the author of the form. So the form would rightfully say, I can't pre-populate that and somebody's going to get pissed because it should've been able to pre-populate it if you had semantic interoperability of the likes that we've all probably will long retire before we ever see achieved. Because it's so darned hard to reason that this thing which is almost the same as that thing, it's good enough for this use case but it's not good enough for that use case. So it's the degree to which the pre-population fails, because the predefined set of granular questions don't match the predefined set of granular questions in the EHR vendor. And that could be mitigated in Rebecca's world where everyone agrees on a common set of data elements. And to the degree that we can get there, I'm all for it, but my experience is, that's incredibly hard.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
So David, let's not let impossible get in the way of good enough.

David McCallie, Jr., MD – Cerner Corporation – Vice President, Medical Informatics
I didn't say stop, I just was warning.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
So the issue, and I think it's really…to paraphrase on the perfect, I suppose. We, and I'll say this twice, just so that we get it. This is focused on syntax, it's not focused on semantics. What we're trying to do is get consistency around syntax and not around semantics. What has been raised are incredibly valid points, but we have got to, in an incremental process, tolerate heterogeneity around the definitions of common data elements. That people are going to define them differently, but frankly right now, because we tie, because they're not comparable, because someone describes it in this syntax and another person describes it in this syntax and we can't even compare the underlying semantics, because they all do it differently.

So we – the first step on the incremental path is, we've got to figure out, is there a common way that we can describe the syntax of these things? And once we've done that, then we can open up the Pandora 's Box that you described which is, yeah, there's going to be a whole host of things. But frankly, if I'm a clinician and I'm involved in a clinical research activity and I've just collected smoking status because of meaningful use and now I've got a patient in front of me because they're on a cancer trial. I know that it's going to have to be different, because I've already agreed to do that. And so we have to understand that right now, we have heterogeneity in both syntax and semantics, and we're not going to get the interoperability unless we're able to get that first one taken care of. And so if everybody's describing them differently, but the all have the same definition, they all agree on the semantics, we've got the semantics right, but everybody represents those in syntax that are different, we're still not going to be able to get to the functionality they want.

So what we've got to do is separate the problems. And that's what this initiative is intended to do, is to separate out the discussion that fruitful and important around semantics, until we get something consistent around the syntax, we aren't going to be able to develop tools. We're not going to be able to do comparisons. If people use a common syntax and say, I'm going to name my common data elements with structured vocabularies like SNOMED, for example, we suddenly get clustering of related things that are somewhat different. So the thing is, we've got to make an incremental progress and we cannot say, because it is impossible for everybody to agree on definitions that this is simply not good work to do. We've got to get the syntax first and then we can start working on governance and clustering and all those other things that will help us get to more semantic consistency.

David McCallie, Jr., MD – Cerner Corporation – Vice President, Medical Informatics
So I want – I should clarify, despite that I introduced this bad cop. I'm not opposed to the work, and I think like I said, to the degree you create a well-formed and well-workable forms capability that can bring in an external definition and instantiate it in a process and flow of care and capture data reliably and securely and send it back. I like that. I mean there are techniques out there that you're looking at to see if they're the right ones RDC and others, some vendors have invested in those already, so it would be nice to reuse what we've done. But if there's a better way to do it that's new, then I am in favor. And the syntax I understand. My issue was on the pre-population point, because no matter how well defined your syntax is, if it's asking for a data element, I have to have some way of knowing what that is in the data model of the underlying HER, and that's a semantic question.

So to the degree that – I mean, once you get past the trivial things like date of birth and gender, which we've discovered is maybe not so trivial, but once you get has the semi-trivial things, then that's where it gets hard. So you won't get too far down the pre-population benefit until you address some of the either pre-agreement, so that the matching is one-to-one and you just say your EHR should capture these fields and if you don't you won't pass certification or whatever stick you have. Or, you get into…you're in the semantics space of having to say, this is close enough to what we call that and we'll let this pre-populate, because that's where it will get hard.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Doug, I think of the work that we've done on I2B2 up in query health, which is that we recognize there are an infinite number of questions that could be asked. But if you have problems, meds, demographics, labs, you know you could actually get pretty far, and we agreed on a syntax for query response and then worked on an ontology that gave us the semantics and what we ended up with is actually pretty useful, not perfect, but pretty useful. So I hope we follow that same kind of trajectory. And Becky, I think you had one follow on and then we'll go to Eric.

Rebecca Kush – Clinical Data Interchange Standards Consortium – Founding President and CEO
I wanted to say that the CCDA was mapped through a clinical research document to C-DASH. So that's already been done.

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

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects
So, I think my comments are in general consistent with others, which are have caution but don't stop. This is certainly – I think everybody wants to support good research and good understanding of patient safety events. If you talk to practicing health care providers, which I do a lot, the two frustrations that I hear most often that they have with EHRs is, a) the data entry process to the degree that it involves structured data entry is extremely burdensome. And it's burdensome from a time perspective and also from a cognitive workload perspective. And particularly, in the context of a face-to-face patient interaction, both of those are extremely important and scarce resources. And the other, which is kind of getting recognized more and more as a problem, is that the output, in terms of the record of a patient encounter that gets generated from an EHR when the input is highly structured, is often almost unusable. It's extremely difficult to figure out these days when you get a note from the ER or a chart note generated from an EHR to figure out what the heck actually was wrong with the patient, what happened at this encounter.

And so one thing that I would like to see on your stakeholders list is practicing clinicians. I know that the American Academy of Family Physicians, of which I'm a member, would be very happy to give you input from a stakeholder perspective here. And I think in general, part of the plan ought to be to understand the potential burden on the actual practice of healthcare, from collecting the extra structured data elements.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
So, if I can respond can respond to the personal anecdote. Many of the professional societies, for recertification purposes, require you to do something like a quality improvement initiative or take a look at your patient data and figure out a way that you can improve the care, and you run a little mini-study. And so, wouldn't it be great if my EHR could help me, help support those kinds of activities and allow me to create a little form that I could populate with information that collected some additional information that would help me improve my practice? That's a tremendously challenging thing to do and I tried to do this when I was back, years ago, and I couldn't do it, I had to go to paper. Because there was no way that I could, as sort of routine care, do that recertification study using the electronic health record, because it was both cost prohibitive and there was no way that I could kind of with 6-months to get a change and I couldn't afford it.

So, in some sense one would hope, and maybe by engaging the providers we can find those uses that would really resonate with them, but I know as a physician that was a frustration to me. That I saw this tool that I wanted to use to help me with some of those recertification requirements, but there was no good way for me to kind of create a little pop-up that would allow me to populate stuff and randomize patients or whatever. There was just simply no way to do that. So one would hope that this functionality is not something that just the researchers would benefit from, but having the ability to collect things that you want to do as a physician, in a way that allows it to integrate into your electronic health record, that isn't necessarily directly part of that. You know, common data element doesn't have to be entirely structured, it could be just a label and free text, I mean, that's still a reasonable approach. So, I think it's important to realize, and maybe Evelyn's making notes here, so I'm just double checking, but to make sure that we address those things as well, as an important part of the value proposition, if you will, for these kinds of functionalities.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects
Yeah, there's maybe some room for some coupling, some flexibility in the coupling between the required data element and what's in the EHR. So if the EHRs collecting data say on tobacco use at a more granular level than what the extract expects, not having to also collect data on just tobacco use when you're already collecting do you smoke, do you chew, do you smoke the pipe …?

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Dixie, last comment.

Dixie Baker, MS, PhD – Martin, Blanck and Associates – Senior Partner
I think this is really important work as well. And as you know Doug, several years ago I did similar work for CDC on outbreak management and how to generate forms quickly, etcetera, etcetera. And one of the most important things that we did was to make, we didn't make complete forms. We made modular forms, where the sections of the form were reusable and so that you could put together outbreak instruments quickly and you could also plug in the value sets that you wanted for that particular, based on that characteristics of that outbreak. I didn't hear that you're doing this at a level below form and I think that it's really important that you reach to that level.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
Yeah, I've always been, I've tried to be careful to use the word container, because forms and templates, everybody has their own sort of terms that they would use. But I think what you're suggesting is that whatever the container is, it be compositional in the sense that you can compose a new container from existing ones.

Dixie Baker, MS, PhD – Martin, Blanck and Associates – Senior Partner
Yeah and plug in your own value sets based on what you are using it for. Right.

Doug Fridsma, MD, PhD, FACP, FACMI – Office of the National Coordinator – Chief Science Officer & Director, Office of Science & Technology
Right. Exactly.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Well, a lot of thoughtful comments. I think Doug and Evelyn, you have basically the affirmation of the committee that this is important work and it should move forward, but with vigilance. And so I thank everybody for their comments. And we of course now have our public comment period and so MacKenzie, turning it back to you.

Public Comment

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Operator can you please open the line for public comment and while we're waiting, I'll just remind everyone that public comments will be limited to three minutes and if there's anyone in the room that would like to give a public comment, if you could please come up to the table.

Alan Merritt – Web Communication Specialist - Altarum Institute
And also, if you'd like to make it public comment and you're listening via your computer speakers, please dial 1-(877)-705-6006 and press *1. Or if you're listening via your telephone, you may press *1 at this time to be entered into the queue.

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
And we do have a public comment in the room, so if you could please identify yourself.

Thomas R. Bizzaro – First Databank, Inc. – Vice President, Health Policy and Industry Relations
My name is Tom Bizzarro, I'm Vice President of Health Policy and Industry Relations for First Databank and a pharmacist. As you discussed the necessity of including long-term post-acute care and home health care in the transition of care, pharmacy should also be included in these discussions. Pharmacy providers including community pharmacy, play a key role in providing pharmaceutical care in long-term care facilities and in the home. The point of transition of care as well as providing pharmacy services in acute and in chronic care situations, not so for the patient that is managing their own care. And I thank the committee for the opportunity to comment. These comments I have made in the past, I've made them at the Policy Committee also and hearing John Derr and the work that he is done with getting long-term care as a focal point for inclusion in the transition of care and other areas of the transfer of health information, I think it also points to the fact that pharmacy needs to be part of that, also. Thank you.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Other comments, do we have comments on the phone?

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Are there any comment on the phone?

Alan Merritt – Altarum Institute
We have no comments at this time.

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
And are there any more comments in the room? Okay, with that I would say we can break for lunch.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay. So we are actually a few minutes ahead of schedule. This is a miracle. So thanks everybody for your comments and the timeliness today. We have a lunch break until 1:30 p.m. where Micky will be joining us by phone and the mechanics of lunch Mackenzie, did you get a big table for us or what are we doing?

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
There should be a big table in the restaurant here in the hotel and your food should be ready.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay, well folks, I will see you all at 1:30 p.m. Thank you.

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
If everyone can please take their seats, we'll get started. Operator, can you please open the lines back up.

Operator
All lines are now bridged.

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thank you. Welcome back from lunch everybody. I will turn the agenda back over to John Halamka.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Well thanks everybody for being so punctual today, we are remarkably on time. So the next agenda item, we're going to hear from Micky and he's going to give us an overview of the Policy Committee Interoperability Workgroup's feedback on interoperability and exchange. Recall that I said this was informational for us, I think you'll find a very interesting restatement, as Wes discussed this morning, of some of the Policy Committee imperatives, goals for interoperability and how we can actually reduce some of the barriers. So Micky, are you on the phone with us?

Micky Tripathi, PhD – Massachusetts eHealth Collaborative – President and Chief Executive Officer
I am. Good afternoon.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Well good afternoon. And sorry that we couldn't meet at Logan at 6:00 a.m., our home away from home.

Micky Tripathi, PhD – Massachusetts eHealth Collaborative – President and Chief Executive Officer
Next time.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Well, so I'll turn it over to you.

Micky Tripathi, PhD – Massachusetts eHealth Collaborative – President and Chief Executive Officer

Okay, great. Thank you and thanks for the opportunity for sharing some of our deliberations on the Policy Committee side related to the CMS/ONC RFI on health information exchange. So I'm the chair of the Information Exchange Workgroup. I have the pleasure of presenting what are really workgroup findings, these are certainly not my own, but they are the hard work of a number of members of the Information Exchange Workgroup. They were presented to the Policy Committee last week or the week before, there were a couple of additions that the Policy Committee suggested and I've incorporated those into the presentation that you're going to see here. So, why don't we just dive right in.

So if you could move to the next slide please. So, high-level summary of the findings here are one, we noted as a workgroup and as the Policy Committee that HIE is advancing rapidly. However, also noted

that it is being held back by some – by sort of a number of points of friction on the demand and the supply side that are created in many ways by variation in federal and state programs and policies, that give unequal and sometimes conflicting emphasis to interoperability. And I should say, for the record here, that there are lots of other things that sort of are both enablers as well as barriers to health information exchange that don't have to do with federal and state programs. I just want to remind the committee that the context of this is a response to the RFI, which specifically asks about government levers that can be pulled. So I certainly don't want to suggest that the only barriers to greater interoperability are the variation in federal and state programs, because that's obviously not true. However, that being said, we did note that there are a lot of programs and policies that are sometimes at odds with the broader agenda of wanting to aggressively move forward on health information exchange across the country. And the recommendation from the Policy Committee is that an HHS slide review of the main areas of with such friction, and the most effective combination of levers for eliminating it could do much to advance HIE across the country. So, next slide please.

The overall framework that we used to consider this question was, first off we had relatively limited time to develop the recommendations. And we have a number of members who spent a bunch of focused time over a couple weeks, and even some members, like I don't know if Arien Malec is there in person, but we managed to use the power the East Coast has over the West Coast to have him get up at 5:30 and 6:00 a.m. for a number of calls, which we really appreciate. And what we did is we decided to focus in on 4 topic areas. Again, not to suggest that there aren't other topic areas, but we needed the framework for it, given the limited amount of time we had. And we thought that the 4 priority topic areas would be payment policy, providers who are ineligible for meaningful use, state-level program and policy variation, and then opportunities for leveraging existing or planned HHS infrastructure. So those are kind of the four domains, as it were. And then we also, just as a matter of going through this and coming up with recommendations and thoughts, we thought of a number of different levers that one could apply in any of those domains. And each domain doesn't mean you pull every lever, but it was sort of a consideration of what types of levers would be most appropriate in each domain. And you can see there the different types of levers that we considered.

Next slide please. And I should add that I'm not going to be going through, in the presentation that you received, there are some detailed slides that cover each of these domain areas. So what I'll do is go through, for each domain, one slide on background and then one or two slides that give a high-level view of the recommendations. And then accompanying the summary slides, in an appendix or at the back of the presentation, are detailed slides for all of you to look at. But I won't be covering those in detail.

So first off, thinking about payment policy. We did note by way of background, that the diffusion of advanced payment models does seem to have successfully spurred a lot of provider demand for information exchange, which is a very good thing and something that we should all feel very positive about. And is doing that through great combination of carrots, such as shared savings, gain-sharing, what have you. As well as sticks, and as we know, things like hospital readmission penalties are starting to get some traction in the market and are making organizations start to think hard about how to enable interoperability and avoid getting those penalties. We also know, however, that these models are very nascent and there are a number of areas, perhaps where they could be improved. Albeit that they will of their own course, I think, start to get some traction but be that as it may, there are still some areas where there could be improved, just even from what we're able to observe right now.

One area is the complexity of the requirements. The second is that there's a lot of – there's sort of a lack of alignment across payer programs, both across public programs as well as when you think about public versus private. And then, want to also recognize that even though these are moving forward, advanced payment models, there is still relatively slow diffusion, and it's a very complex part of the economy, as we know. And so there's going to be a long tail of fee-for-service for a long time. So that's something that I think we all need to take into account as well. So moving now to the recommendations in this domain. Next slide please.

First off, it was – an appropriate focus area would be to simplify and harmonize requirements across advanced payment models for public and private payers. Now obviously the public…alignment across public and private would be more of a facilitation kind of exercise, I think, than necessarily something that's regulatory or statutory in nature. But certainly, across the different public programs, there seem to be a lot of opportunity to think about how to simplify and harmonize requirements, whether it's related to alignment of clinical quality measures or clinical decision support types of activities and requirements. Then starting to think how those really could be a line to cross these programs could do much to move us forward. And in particular, I think it would help providers focus more on the desired outcomes than on the often complex and sometimes bewildering mechanics of the current programs. And so what a number of workgroup members had observed in their experiences out in the market is that, there is a lot of attention being played to the very detailed complex mechanics and requirements of each of these advanced payment programs. And perhaps, a little bit less attention to what they're – the spirit of what we're trying to accomplish rather than sort of thinking about the detailed requirements. So that's one set of recommendations is simplifying and harmonizing those and would allow people to sort of step above that as it were and start to think a little bit more about where we want to head, rather than on these complex requirements.

The second is that, just noting that, as they said, there is a lag of adoption through the advanced payment models and there could be a possibility let's say, for highly focused supplemental payments to capitated and fee-for-service models to motivate HIE-enabled activities. So what does that mean. In the advanced payment side, it may be that there are still certain things that though we are focused on outcomes, that we may not see some traction in specific HIE areas. And there might, therefore, it might be reasonable to consider some supplemental payments to enable certain types of things with the more of a focus toward using HIE infrastructure or processes rather than assuming that an outcomes focus is going to pull all that through as aggressively and quickly and sort of as rationally as we'd like it to. So that's on the advanced payment side, there may be some specific focus areas to think about there.

Perhaps the biggest opportunity right now though, and perhaps the biggest concern, is more about the fee-for-service tail. And one of the things that we talked a lot about in the workgroup is, perhaps giving some recognition in the fee-for-service model to what we might think of as cognitive activities that use HIE. And perhaps a lever that could be pulled right now within the fee-for-service model would be for example, giving higher E&M coding for cognitive activities using HIE. And a cognitive activity would be information reconciliation, allergy reconciliation, med reconciliation, that I think as everyone knows, right now are not things that are directly compensated in a fee-for-service model. But to the extent that providers use HIE technology to perform such activities, maybe there's an opportunity there to – both to give an incentive to performing those activities and performing them through health information exchange.

And then finally, the opportunity to have voluntary certification programs for HIE functions that enhance enablement of value-based purchasing activities. So the idea here is that, to the extent that there are things that it would be beneficial to have certification of technologies, that go beyond what Meaningful Use Stage 2 and where we think Stage 3 may head, but that would sort of go beyond that, but we think are important for value-based purchasing activities. We may want to consider having such a voluntary certification program. And we come back to the question of whether\ – it's not clear right now what would be statutorily allowed in the way of certifications, so, some of it may be levers that could be pulled of asking – formally requiring private certification bodies to have these types of certification programs. Or, more likely, helping facilitate a model where they could launch such programs on their own.

Next slide please. So the second domain that we looked at was providers ineligible for meaningful use. And I think as the committee is aware, there are many categories of providers that were not included in meaningful use. And some of these are relative, very significant sectors of the care continuum. And in particular, long-term care, post-acute providers, pharmacists, behavioral health, commercial labs, all of them are significant contributors to a whole list of care perspective, but as we know, were not including meaningful use. And that presents a number of barriers to everyone's collective ability to invest in and use health information exchange. If you have significant gaps among those trading partners that you may have, who for lack of having strong incentives from the meaningful use program, don't move as fast as those who did have direct incentives. So what we noted is that those gaps are in effect, structural impediments to progress and interoperability. We know they're moving, but they're moving much more slowly.

Next slide. So some of the recommendations to address this were, one, some levers that we think HHS can pull on its own, which would be to harmonize some of the required documentation and reporting across these programs and consistent with the meaningful use framework. So there are a number of requirements that are placed on different types of providers by CMS, and harmonizing those with the CCDA constructs that are now coming into place, we think would do a lot toward creating a common and uniform interoperability framework. So when you think about some of these documentation requirements, or MDS for long-term care providers and Oasis for home healthcare, and there are a variety of those types of requirements that come from HHS, different parts of HHS, but that right now are not fully aligned with CCDA types of constructs.

Another area would be incentives to part D providers, to motivate HIE enabled and therefore HIE enabling activities. So some of those may be thinking about the incentives that are built into the Stars Program, as well as for medication therapy management on the Part D side are both things that Medicare Advantage as well as pharmacies participate in that right now are not exactly aligned with some of the meaningful use HIE constructs. And we think alignment there could do a lot to pave the path for those types of providers to see an incentive to move more in alignment with where the rest of the market's headed.

And then finally we haven't done a whole lot in meaningful use related to administrative simplification. But certainly where it intersects with clinical standardization, it seems like there may be opportunities. In particular, the workgroup noted that there are, to the extent that we can start to think about a significant paying point among providers, which is prior authorization requirements. And perhaps trying to align some of the clinical elements for prior authorization documentation with the CCDA constructs and the meaningful use requirements that fill those CCDA constructs, that there may be an opportunity there to align some of the stuff in a way that would energize the market and help it move forward more quickly.

The second category is commercial labs. I think as everyone on the committee is aware, the commercial labs are not covered by meaningful use. And one particular opportunity that we noted was that, perhaps allowing some safe harbor from certain CLIA requirements, and in particular, we noted the visual inspection requirements that CLIA imposes on labs. And if we entertain having a safe harbor for the commercial labs from those requirements, for those providers who are compliant with meaningful use and using certified technology. That that might start to align the commercial labs with the Meaningful Use Program and give them more of a stake in the meaningful use process, which I think would be beneficial to all, given that they are something like 20 or 30 percent of the national market anyway.

Another point that we noted was that labs are a very significant gap in terms of our ability to move forward aggressively with health information exchange and hospitals are the large share of the results delivery market across the country. And so we just note that the Stage 2 requirements related to hospital lab results delivery, it would probably be beneficial to be more aggressive in Stage 3 by first moving that from a menu to a core requirement, which I assume would probably happen anyway, but just noting it. And also, perhaps moving much more aggressively in terms of the thresholds. So, disconnecting it from electronic orders, for example, would be one way to start to say that all results, or close to all results, should be delivered according to a set of standards.

And then finally, related to, in the previous domain, requiring if possible, or facilitating if not, voluntary certification of technology used by the providers who are ineligible for Meaningful Use. So again, would at least give them the sense, as it has among eligible providers and eligible hospitals, at least a base of technology that they know can perform certain functions, even if they don't have the incentives to actually embark in those activities. But at least providing a platform for that, we think could be a very good step forward for the ineligibles.

Next slide please. The third domain is state-level program and policy variation. We've noted that the state-level variation really impedes HIE adoption by really making it just much more difficult for multistate entities, whether they're providers or vendors or the federal government, to create scalable processes, services and products in the area of health information exchange. Some of this variation lies in differences in programs that have both federal and state components. So the federal government does have a participation in those and so that gives a set of levers that is different from what's noted in the third bullet, which is areas where states really have independent policy authority. So we sort of consider those as two different things, but just note that both of those affect health information exchange.

Next slide please. In terms of recommendations in this domain, the first thing was just a broad recommendation that CMS essentially, as it thinks about sort of the broad range of programs and policies they have in this area, which really encompasses quite a broad range of state waivers, advanced payment demonstrations, really quite a huge portfolio, starting to look at that more explicitly through the lens of health exchange information requirements, which we believe is not really done systematically or consistently today. And where appropriate perhaps, having coordination with state HIT coordinators when these programs are embarked upon or approved. It wouldn't necessarily be relevant in all cases, but the main point is to start to look at it through a consistent framework. And then perhaps, at the points of contact in each state, to make sure that you're at least having that coordination at the state level with the HIT activities that have already been funded through the ONC and CMS programs.

The second two recommendations relate to the CDC, which is really about trying to work to harmonize the variability that exists in states and the standards utilized for public health reporting. And in particular, establishing a single standard for the exchange of immunization information, which there's still a lot of variation around. A fourth recommendation there is perhaps to create some model language that could be available for inclusion in state-level programs. And really the reason we're talking about modeling…is that, we're now in the area of policy domains that really are state authority for the most part. And so the idea here is, what are the levers that can be pulled there? Well, perhaps just a provision of model language that might allow states to use that language to get some greater consistency in the way that they might think about health information exchange in state employee health plans for example, and how they think about the networks for state employee health plans. Where right now, even with the best of intentions, without any consistent kind of framework they would be doing it in a variety of ways at the state level.

And then finally, we just note that privacy and perhaps liability, but certainly privacy. I think, as we all know and the variation that we see across the country that was documented in the HSPIC Project earlier, which was done a couple years ago I think, which documented a lot of the variation in policies. But I think there isn't a clear answer to how to move forward on that, recognizing that there is a lot of state authority in the privacy area. But just wanted to a) recognize that that is still an issue a and still a barrier, and liability issues related to health information exchange may be an emerging issue as these mature. But wanted to note that to the extent that HHS was able to identify and encourage any opportunities for reducing this variation, that they should think hard about that. But we didn't have great answers for any concrete levers to pull in that area.

So, next slide please, and the final domain. In the way of infrastructure, we just noted that first off, HHS maintains a very large infrastructure to maintain the huge expanse of programs that they manage. Whether it's for healthcare payment, delivery, public health, regulation, and many other categories that I didn't list. And the recommendation here in general was to – that some of these infrastructure components and associated services, sort of in the spirit of open data, could be opened up for public use in ways that could catalyze and enhance development of market-based products and services to more innovatively and aggressively move forward on health information exchange capabilities.

Next slide. So one area would be just the ability to perhaps repurpose existing data and business infrastructure to facilitate such development. So for provider databases for example, there are a number of databases or directories that are maintained by CMS right now, NPES, Meaningful Use, NPI, for example, that if made available with – obviously there'd have to be given some thought to what are the terms of the availability and protection of privacy and all of that. But making such data available to the market could then be used by the market to perhaps feed certain provider directory capabilities. Certainly as we – the Information Exchange Workgroup on the Policy Committee side, as well as the Standards Committee did last year or the year before, consider provider directory standards and requirements. And noted that there's not a lot of maturity in the provider directory space right now industry wide. But that said, I think the idea here would be to not try to create something that's perfect, and recognizing that these databases are not perfectly aligned necessarily with what an operational provider directory for the purposes of health information exchange may require. But simply making them available with those caveats clearly articulated, could then perhaps allow the market to take that data and then massage it or tweak it as it needs to, to make it – to employ it for those provider directory purposes.

The second opportunity would be to build on the credentialing that occurs now for patients and providers, that can perhaps support validation needs for HIE activities. So for example, as a part of Medicare or Medicaid enrollment, provisioning patients with direct addresses could be one way to at least start to create the infrastructure. Both business processes and the identification and connection enrollment of individuals, whether they be providers and patients in programs, could go a long way towards health information exchange, if they are at least enabled to connect in some way. And a related point would be to build on the development of the health information exchanges in a similar way. So in Massachusetts, we are considering both for the Medicaid participants as well as HIX participants, perhaps making…using that business and credentialing infrastructure that's going to be used to enroll people in either of those programs, to also be able to provide them with direct addresses, let's say for them to then be able to take the technology of their choice and participate in HIE activities more directly.

The last couple points are related to – first is as feasible, perhaps enabling patient access to immunization information that's now contained in public health immunization registries. And it may seem peculiar to be pulling that one out, but again, as we looked across the public health portfolio, the immunization registries seemed to be an area where there's a lot of information that patients would, as a matter of convenience as well as safety, would very much like to have some access to. And there are a few states that in participation with some ONC programs, do enable that type of access today, so there are models out there. Still an open question of whether it makes more sense to have patients have direct access to immunization registries or to try to do everything we can to make that information as seamlessly available to providers…to their providers as possible, so that the providers in turn could make it available to patients. And we had discussion in the Policy Committee about that. But, be that as it may, trying to, without getting too specific about what the pathway is, it seems that making that data available just creates more of the substrate for what health information exchange can accomplish and therefore start to generate more demand for it.

And then finally, I'm sorry, my computer just went out here – the last category that we looked at was related to the FDA. And just noting that there are a number of areas where the FDA has authority related to device interoperability, as well as structured language requirements or structured product labeling, that are right now not fully aligned with the constructs that have been created for meaningful use. And whether it's for adverse event reporting or for some of the structured product labeling, it seems like there's a great opportunity to start to align that in a way that would more directly connect those programs and serve the interests of HIE more broadly.

So I apologize, I think that's my last slide. I apologize for a little bit of the fire hose, but wanted to get through the summary for all of you and very much look forward to your thoughts and questions.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Micky thanks very much. And one of the things we talked about with Doug this morning was, as we look at our work plan, trying to ensure that we're meeting the needs of the Policy Committee and the needs of Meaningful Use Stage 3. And of course one of the things we're going to ask the Policy Committee for is certain clarifications and specificity on some of the aspects of standards and interoperability. So for example, if we are given the goal from the Policy Committee, image exchange is good. We discussed this

morning, there are so many use cases and so many architectures and so many models, the problem to solve could be quite different depending upon the specificity. And I'm curious, I mean you've given us some really great recommendations. The word image does not, for example, appear in them. Was there any discussion in your group about image exchange?

Micky Tripathi, PhD – Massachusetts eHealth Collaborative – President and Chief Executive Officer
You know, there wasn't, but I don't think that that reflects a sense that there was a lack of importance, it probably was more just a reflection of time constraints that we had.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Got it. So let me open it up to the group here. See, we're in that post-prandial, everybody's just satisfied with what you said because it was so good. Oh, we've got David McCallie, go ahead.

David McCallie, Jr., MD – Cerner Corporation – Vice President, Medical Informatics
Hi Micky, it's David McCallie. Those were some great suggestions, I really liked them and I'm just going to offer a vague comment and ask for a vague response. It seemed to me that most of your suggestions were either about removing barriers or were about changing incentives such that HIE is a natural side effect of the new incentive rather than pushing HIE for HIE's sake. Would you agree with that? Did you feel that was the approach you took? Does that make sense?

Micky Tripathi, PhD – Massachusetts eHealth Collaborative – President and Chief Executive Officer
Yeah, it does make sense. Yeah, I mean I think that's fair. I don't think we explicitly took that approach. I think how – the reason it may sort of seem like that is that the idea is that for a lot of the other programs and the other domains that we were talking about, it isn't as if they're main purpose is HIE, to have another purpose in mind, whatever that is, and those are highly varied. But the idea was that HIE should be sort of a foundational element of whatever that other purpose is. Rather than trying to sort of create whole new areas of policy saying that there should be more explicit focus on HIE or perhaps creating other and different types of programs that already exist in the meaningful use umbrella, specifically related to HIE. So, I think that's a fair point, but I think that's why it reads the way it does.

David McCallie, Jr., MD – Cerner Corporation – Vice President, Medical Informatics
And I think that's the way it read positively to me as well, that you weren't merely saying, let's have more HIE because we think that's a good thing. You were saying, let's have these other good things that will demand HIE be deliverable?

Micky Tripathi, PhD – Massachusetts eHealth Collaborative – President and Chief Executive Officer
Yeah.

David McCallie, Jr., MD – Cerner Corporation – Vice President, Medical Informatics
So I commend that approach. I think you did that really well. Thanks.

Micky Tripathi, PhD – Massachusetts eHealth Collaborative – President and Chief Executive Officer
Thank you.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
David, to your comment, 65 percent of the patients in Boston are in a global capitated risk plans and basically what we've all said is, oh my God, unless we share data, we can't survive. So it's not that we're being incented, we are, in fact, being scared into sharing data.

David McCallie, Jr., MD – Cerner Corporation – Vice President, Medical Informatics
That'll make it happen.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Right. Other comments, questions …?

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

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Yes please, go ahead.

Nancy J. Orvis, MHA, CPHIMS – Department of Defense – Director, Business Architecture & Interoperability, TRICARE Management Activity
This is Nancy Orvis, I'm on phone today, from DoD. I wanted to make some general com…very good presentation. We as a federal agency have also been aware of these other gaps and we really commend the policy work on this. Because no matter what we say, they're still needs to be financial incentives or there need to be ways to make this viable for the other entities that you've gone over here to do this exchange. It does cost some kind of money and I think – we know that, for example, the DoD and our Tricare insurance policy, we know that we need many, many vendors and commercial labs and other sources in order to provide information for our patients. So I think we would – I'd just say we would like to facilitate some more cooperation on that market development of HIE capabilities. The commercial laboratory entities are a huge player that we are very interested in participating in thins.

We also know that the policies that the FDA is doing on device interoperability is huge for us and we've been helping – trying to help you all on the international front on those international device standards. I'm curious on whether – what priority – the other key thing that we are looking at is credentialing and access, you know, getting providers up as soon as possible and getting access to verification of credentialing of providers. Do you have particular activities that you see are going to promote that or that are actually working on that today in the provider credentialing area?

Micky Tripathi, PhD – Massachusetts eHealth Collaborative – President and Chief Executive Officer
Yeah, we didn't talk about that at all.

Nancy J. Orvis, MHA, CPHIMS – Department of Defense – Director, Business Architecture & Interoperability, TRICARE Management Activity
Okay. So maybe there should be some – there may be some more – do you think that will come – we need to bring that up again in the Policy Committee at some point in the next few months?

Micky Tripathi, PhD – Massachusetts eHealth Collaborative – President and Chief Executive Officer
Yeah, I mean certainly if there are some opportunities there, then yes, I think that that would make sense. And we're certainly happy to take it back and have a more focused conversation at the Information Exchange Workgroup and then bring that up, as appropriate, with the Policy Committee if there's something – talk to you offline about it

Nancy J. Orvis, MHA, CPHIMS – Department of Defense – Director, Business Architecture & Interoperability, TRICARE Management Activity
I think we should – good. I mean, I think as you've mentioned, there are many different kinds of insurance policy issues between the states and the federal policies and private insurers. And that does seem to be – there's more and more encouragement of being able to share that data for certain kinds of taxpayer constituents for whatever they are in and I think that's always been a big problem. So we would like to see more work on that, we'd be happy to talk with you on that.

Micky Tripathi, PhD – Massachusetts eHealth Collaborative – President and Chief Executive Officer
Okay. Thank you.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
And Nancy you mentioned labs and I'm curious, because Farzad is sitting next to me. I would guess that ONC's lovers with regard to incenting commercial labs to behave well, would basically be through doctors who have to have certain behaviors funded by Medicare. And the doctors, as customers of the labs, pull the labs into doing something. I don't know, does your office in any way really affect what a commercial laboratory can do or not do?

Nancy J. Orvis, MHA, CPHIMS – Department of Defense – Director, Business Architecture & Interoperability, TRICARE Management Activity
Well …

Farzad Mostashari, MD, ScM – Office of the National Coordinator – National Coordinator
We should clarify that the request for information is a joint request from ONC and CMS. And CMS certainly has many policy levers including payment levers, in terms of the behavior of laboratories type of payment.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Because I just recognizes that, Micky to your point, you can directly incent a hospital to deliver its labs electronically, and at least when I was thinking about some of our Stage 1 requirements for laboratory exchange, it seemed like we had less flexibility around saying …

Farzad Mostashari, MD, ScM – Office of the National Coordinator – National Coordinator
Yeah, that's right. And that's the whole point of this RFI is to say the levers that we have are not limited to meaningful use, that's the whole point of this. And there's one example actually, let's just take the labs. I'm not suggesting that this will become enacted, but one proposal that someone said to me was, well if CMS thinks they get more value out of labs that are delivered electronically with codes attached, why don't they pay more for those and less for labs that are delivered by fax.

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

Farzad Mostashari, MD, ScM – Office of the National Coordinator – National Coordinator
Think about the impact that would have on commercial laboratory standardization of and delivery of their laboratory results. It creates a business case for information exchange and interoperability of it. So I think that's the spirit of this RFI is to say, we are intent on using every policy lever at our disposal to increase data exchange and interoperability and make it profitable to share and unprofitable to hoard patient information.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Great. Very good. Wes.

Wes Rishel – Gartner, Incorporated – Vice President & Distinguished Analyst
Hi, Micky. Thanks for a very comprehensive report. One of the things that continues to puzzle me about health information exchange is the transition we see from the point of view of CIOs of private large hospital corporations and so forth in terms of their attitudes from a few years ago where it was, how do I appear to play ball without really getting involved with my HIE? To these days where it is, how do I get the health information exchange done that I need done, without being at the mercy of the board of the state HIE organization or the state sanctioned HIE organization? And that concern leads to a lot of what we see as privately funded HIEs and locally governed – or HIEs governed by the primary data source springing up. And at the same time, there are all kinds of issues that don't break down well along state lines. Everything from HIE's that happen to be located in a border city to national laboratories lacking ultimate plug-and-play interoperability with each state HIE, would rather make an alliance with each significant vendor of EHRs to deliver than go through a third-party, through the state HIEs. Did the Policy Committee consider at all whether there are, could be, should be or shouldn't be a trend towards a less specifically state-oriented approach to help information exchange?

Micky Tripathi, PhD – Massachusetts eHealth Collaborative – President and Chief Executive Officer
You know, I'm certainly – Farzad and anyone else who's there from the Policy Committee can weigh in as well. But I don't recall that specifically being part of the conversation. There was some conversation about the problems that you note about certain perhaps key large provider organizations not participating in HIE generally, for a variety of reasons and whether there were any good levers or appropriately focused levers that could deal with that. I don't think there were any real good answers to that. But in terms of the other question you had, we didn't really talk about that. I mean I think that in general, at least from what we are seeing in the market, the private HIEs are certainly starting to blossom from the

bottom-up and really being driven, as John notes, by the advanced payment models that are starting to get greater and greater penetration in the market. That doesn't mean there aren't still sort of silos being created now around the advanced payment models as opposed to just perhaps a particular hospital or what have you.

But, there are a lot of ways that people can do health information exchange, the verb as opposed to the noun, and it seems that in such a dynamic environment, both in terms of a business environment as well as technology environment, it's pretty hard to have sort of a broad brush ubiquitous approach that's going to work for everyone. And so, having an approach that creates the incentives for health information exchange but allows the flexibility for people to do it in whatever ways make sense locally seems like it's going to be the most durable answer. So in some places it may be that they have to go with the vendor network for connecting across advanced payment kind of silos, for example…there's a need, whereas in other places, you may have a statewide health information exchange or HISP that can perform that activity for them.

Wes Rishel – Gartner, Incorporated – Vice President & Distinguished Analyst
Thanks.

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

Leslie Kelly Hall – Healthwise – Senior Vice President, Policy
I just wanted to say thank you for including patients in the – in your ongoing recommendations of the pivotal part of making HIE successful. So thank you.

Micky Tripathi, PhD – Massachusetts eHealth Collaborative – President and Chief Executive Officer
Absolutely. The pivotal part.

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

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Other questions or comments? Okay. Well Micky, I think you have answered all queries. So thank you very much.

Micky Tripathi, PhD – Massachusetts eHealth Collaborative – President and Chief Executive Officer
Okay. Thank you.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
And I think we will then move on to our last agenda item, which is the HIE governance updates and a little information about some of the grants, the pilot grants that you gave out.

Mary Jo Deering, PhD – Office of the National Coordinator – Senior Policy Advisor, Office of Policy and Planning
Well good afternoon. We're the last between you and adjournment, so if you were postprand – what?

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
And second public comment.

Mary Jo Deering, PhD – Office of the National Coordinator – Senior Policy Advisor, Office of Policy and Planning

And second public comment, that's right. So, I think we can get through this very expeditiously because we are here, in fact, in response to your request. You asked to hear about an update on some of our governance activities, so Kory and I will be talking to you about two of them. Again, just for the broad context, remember that the HITECH Act mandated that ONC should establish a governance mechanism for the nationwide health information network. And, pretty powerful one-liner, but in fact, based on the RFI that we did, we listened and heard and decided that we would indeed not proceed with regulatory approach to governance at that time. But instead undertake a variety of efforts in the interim, that included some grants that Kory will talk about, a framework of principles that we hope to release shortly; the governance forum that I'm going to talk about, we're doing monitoring using the data that we have available and other sources, and other listening and learning opportunities. So all of that is part of what we think is a proactive stance to governance without being in a regulatory mode.

Now, that said, before I jump in, I want to do a little semantics exercise here. So people ask us, what is our definition of governance? And everyone has a different one and so ours is really pretty simple. It refers to the establishment and oversight of a common set of behaviors, policies and standards that enable trusted electronic exchange among a set of participants. I think it's important to note what's missing there, is that it doesn't say who does governance, that's not part of the definition. Another part of the semantic exercise is the fact that we are actually focusing on exchange at a national level, and between exchange organizations and across state boundaries. We're not trying to govern the internal operations of any organization, at any level, much less the single health exchange information organization.

So these are the two activities that we're going to be talking to you about today. The National HIE Governance Forum was launched through our cooperative agreement partner, the National eHealth Collaborative. These were the criteria that were set up for the participants, and if you read those, you'll see that they harp back to the slide before, where I talk about the level of entities and the level of governance that we were looking for. Well, we have 37 participants including three from the Standards Committee. We have both David and Arien representing the Care Well Alliance. We have Jamie representing the Care Connectivity Consortium. We have a total of, as I said, of 37 including several states ranging from Arizona on one side to West Virginia and states and regions in between. We had DirectTrust and Healtheway, we have the Epic Care Everywhere coordinating body. We have Sure scripts, we have DOD, VA and SSA. As I say, 37 in total so it really is quite a wide variety. The participants, the materials about the Forum are all on the NHIC website, and at the very end of our presentation, there will be a URL where you can get all that information.

So the goals were to create a collaborative environment for the leaders, and in fact, one of the things that they told us, that this was indeed a high value for them, the first time that they could all actually get together and talk with each other. And to bring them to some kind of a common understanding of what is governance, what's going on out there right now and how can we prioritize the key issues and the emerging commonalities and best practices. But we recognize that there are variations in governance approaches that reflect different use cases and different needs. And so while we talk continually about trying to identify common approaches and common problems, why we certainly know that one size doesn't fit all, so in some instances, there is indeed more than one appropriate way to govern a particular need or interest.

So the kickoff was just last Friday, this is brand-new, brand newborn and we did a straw poll of the participants and this is what we asked them, and these are their responses. And while we will be certainly fine-tuning their prioritization exercise in the weeks ahead, why it was interesting to see how this came

out. And in fact I'll say on the trust side, that since consent is already – is being handled still very actively by the Privacy & Security Tiger Team and in some other venues, and the patient matching, Kory I think will mention it in the context of one of our grants. Why, the trust agreements, we certainly, I think all of us, hear about that in a lot of different context. We know that that's a high interest and we are in fact actively planning now to see if the next meeting could begin to surface approaches to trust agreements.

So, the next steps are actually to, in addition to sharing around trust agreements, we want to begin to develop a landscape of current and emerging governance practices and different models. Again, to identify common – the word common certainly appears a lot because that seems to be the high value for everyone. The next meeting date is May 3rd at 11:00 a.m. All meetings are public, they're all by teleconference, by the way. And the agendas, the slides, the dial-in information is all posted on NHICs website and again, you'll see that at the end of our presentation. So, over to Kory.

Kory Mertz – Challenge Grant Director – Office of the National Coordinator

Thanks Mary Jo. So I'm going to be touching on the Exemplar HIE Governance Cooperative Agreement Program that we recently made awards for. So back on December 20, 2012, ONC released the Exemplar HIE Cooperative Agreement funding opportunity announcement. And really the goal of this opportunity announcement was to work with existing governance organizations kind of out in the field, to really help strengthen and address some of the key national challenges we saw in the health information exchange governance. This program really came in directly out of the comments we heard on the RFI, people said hey. there are a lot of organizations out there working on governance in the community, ONC, you should work with them. So, we established a competitive process to really lay out where we saw some key priorities, and then to allow organizations to apply and go through the competitive process to work with us to address some of these areas.

And we set it up with a couple…with our framework was really on, we see some key priority challenges around directed push-based exchange and then query exchange, and said hey, here's where we see some key national priorities. We're hoping to be laying out other issues we haven't identified here. Because again, these are cooperative agreements, it's really about a partnership and working with these organizations to address these challenges. And so one of the other pieces is, we really want to figure out with these solutions, how we can incorporate them potentially into some of our national policy levers, be it certification, standards adoption, etcetera.

So, in the past couple of weeks, we've made two awards through this program to DirectTrust and that New York eHealth Collaborative on behalf of the EHR HIE interoperability workgroup that they have led, that is a combination of quite a few states, EHR vendors and HIE vendors across the country. So it's a really strong collaborative of folks there. So, we're going to be working with these awardees closely and their partners, to develop and adopt policies, interoperability requirements and business practices, that address some of the key national priority areas. We're going to be focused on overcoming interoperability challenges, reducing implementation costs and again, assuring privacy and security of health information. As you will see, these aren't huge awards, that was really on purpose. We wanted to be working with organizations that were already out there and existing and really provide some funding to focus in on some key target items. So, again, we're really at the early stages with this. We're working with the organizations over the next coming weeks to really finalize their work plans and the scope of work. And we're going to be posting additional information on HealthIT.gov when we have that finalized. It should be in the next couple of weeks here.

Just kind of at the high level, what we're hoping to focus on with both organizations. So with Direct Trust, we really see our work with then as working to continue to expand the work they've done around kind of setting the policy, framework for direct and also really making sure that we're going to be ready and vendors are going to be ready for Stage 2, to really make sure we have that vendor-to-vendor interoperability that we need. With the EHR HIE interoperability workgroup, we're focusing in on figuring out what else can we be doing around patient matching, to really improve that, hoping to be able to go out and do some pilots with organizations working in different ways that they're doing patient matching to see, hey, what are ways we can do this better.

And then the other piece they will be working on is around querying provider directories. I think we heard from Micky's presentation and various conversations the IE Workgroup's had, and Standards Committee has had, that this is really a space where there's a lot of demand and desire and they're going to help us figure out some of the issues there and work on some of the standards. So we're really excited to be partnering with these two organizations and their members to really drive things forward around governance. We're certainly encouraging our grantees and the rest of the health IT community to actively participate in the work of these awardees. So that, I think is …

Mary Jo Deering, PhD – Office of the National Coordinator – Senior Policy Advisor, Office of Policy and Planning
Leave that up there. There we go. We're happy to take questions.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
We have a couple of cards that have gone up. Lisa.

Lisa Gallagher, BSEE, CISM, CPHIMS – Healthcare Information & Management Systems Society (HIMSS) – Senior Director, Privacy and Security
Hi, Kory, great presentation, both of you. With regard to the two contractors, DirectTrust and the interoperability working group, how or are they going to facilitate input from other industry stakeholders? And who is going to do that, will they? Will you guys facilitate them? I'm just wondering, during the course of their contract.

Kory Mertz – Challenge Grant Director – Office of the National Coordinator
Yeah, so I would say both organizations already have their kind of existing infrastructure and organizations they're working with and ways to get feedback. So, I think we would certainly see those as being the ongoing way, but you could certainly reach out to us at ONC and we provide feedback into the process as well. But I think the key way would be working with the organizations kind of through their existing structures.

Lisa Gallagher, BSEE, CISM, CPHIMS – Healthcare Information & Management Systems Society (HIMSS) – Senior Director, Privacy and Security
Okay. Thank you.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Certainly we want to make sure that the loop is closed, DirectTrust, we've had many discussions about, NSTIC versus federal bridge versus DirectTrust, and many approaches to solve the same problem. And you'd like to get that free flow of information back to us because we don't know which of the horses in this race will win. Maybe all of them.

Lisa Gallagher, BSEE, CISM, CPHIMS – Healthcare Information & Management Systems Society (HIMSS) – Senior Director, Privacy and Security
HIMSS has been working on patient matching and we have a number of organizations that we know have solutions in the field that can be looked at, so we'd be happy to facilitate getting you that information or getting it to the interoperability workgroup. So, I'll reach out and chat with you about how we can help.

Kory Mertz – Challenge Grant Director – Office of the National Coordinator
That would be great. Thank you.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
This has been a bit like a Jeopardy buzzer, I actually think David buzzed in and then John and Anne. Go ahead.

David McCallie, Jr., MD – Cerner Corporation – Vice President, Medical Informatics
And my question is just a little bit more detail of Lisa's question, which is, what is the duration of these grants and what kind of report out do they – will they make? How will we be able to track what they're learning – I guess really the timetable?

Kory Mertz – Challenge Grant Director – Office of the National Coordinator
Yeah, yes, I'm sorry, I should have covered that. So the awards are initially funded for one year. We made it so it's possible for an additional year extension, but we only have funding for now, so we'll see based on performance and availability of funding after the one-year period runs out. And as far as following progress, I think we're certainly, as I mentioned, we're planning to post things on healthIT.gov and certainly plan to have webinars and other forums to kind of get the word out and allow people to plug in. We're at the early stages here, so this is one of kind of our first public opportunities to talk about it. Certainly we can bring back updates to the Standards Committee and Policy Committee … interest.

David McCallie, Jr., MD – Cerner Corporation – Vice President, Medical Informatics
And maybe through this, the forum, Mary Jo, would they be expected to report?

Mary Jo Deering, PhD – Office of the National Coordinator – Senior Policy Advisor, Office of Policy and Planning
Well obviously they're members of the forum and so that's one of the public venues as well.

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

Mary Jo Deering, PhD – Office of the National Coordinator – Senior Policy Advisor, Office of Policy and Planning
And it's a way for them to share and get input as well.

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

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

John Derr, RPh – Golden Living, LLC – Health Information Technology Strategy Consultant
It's John Derr. Mary Jo, thank you. The HIE is very important because there's a rumor out there at times, that there are not going to be in business after a while and a lot of people in LTPAC sometimes are a little hesitant because of the funding and that it goes there, so I think you forming this is an excellent idea, having guys talk about it. But mainly, is Kory, I wanted to thank Kory because he heads up the four challenges for LTPAC and does an excellent job at it, and I just wanted to recognize that. And also ask if we're going to get any more challenges for LTPAC, because there are other things we could be working on. Thanks.

Kory Mertz – Challenge Grant Director – Office of the National Coordinator
I don't think we have any plans at this point. But we're certainly always interested in looking for opportunities to work with the LTPAC community and drive things forward. I think you've seen some of the activities going on now. We've put a few papers out and the RFI, I think, is a key opportunity for the LTPAC community to get their voice out there.

John Derr, RPh – Golden Living, LLC – Health Information Technology Strategy Consultant
Results have been outstanding for the four guys working, tremendous cooperation and working on very, using the word meaningful, very meaningful projects that they're doing. Thanks.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Thanks. Anne.

Anne Castro – Chief Design Architect – BlueCross BlueShield of South Carolina
Hi, I have a question about the scope. It says governance is focused on health information at the national level, so I'll cut to the chase. My interest is at my state level and the interaction between me as a payer and my IDSs in my state or my hospital organizations, as I'm working on payment innovations with them. Does your scope covering that?

Mary Jo Deering, PhD – Senior Policy Advisor, Office of Policy and Planning – Office of the National Coordinator or Health Information Technology
Well maybe I'll let Farzad address that, but I mean, we made the decision not to try to govern the internal activities of a state governance structure per se.

Anne Castro – Chief Design Architect – BlueCross BlueShield of South Carolina
It's a little different than that, it's not really governed by the state now, so it's – it wouldn't – there's not a governance structure that I know of today. So I'm wondering, is this the governance structure that would govern those information exchange – health information exchange relationships? My understanding, the earlier version of governance was all-encompassing, all players. And we provided feedback that that was hard to put a governance in place when there are so many players and there are so many payment innovations that are being encouraged, but we're not sure what the governance is going to be. So I'm just asking, in this iteration of governance, does it cover what I just described as my relationship with the hospitals in my state, when I have to do health information exchange in order to support patient-centered medical home, accountable care, payment methods, blended payments whatever, that involves a lot of information exchange of health information. So my question is, does this governance that you're working on cover that?

Farzad Mostashari, MD, ScM – Office of the National Coordinator – National Coordinator
So, our initial concept behind the RFI was that we would, through regulations deal with all the issues and we would have a federal governance regulations that would cover that. And I characterize this as kind of swinging for the fences, trying to get a home run, you know, circle the bases. And what we're doing now is more a series of singles and maybe a bunt or two, where we're trying to advance the ball in discrete ways. One of them is for us to respond to what people have said, what do you think is the right thing to do? Right, you don't have to regulate it, but just say what the federal principles are, the federal framework is for governance. What do you think the rules should be? And we're going to do that, we're going to say, we think based on the recommendations from the Health IT Policy Committee, the Privacy & Security Tiger Teams, our federal partners, we believe these are commonsense good rules of the road. And we're going to express those, that's one. And that will include the behaviors of individual health information exchange entities in some cases, but in particular, how those health information exchange organizations relate to each other on interoperability, on trust and on business practices.

Anne Castro – Chief Design Architect – BlueCross BlueShield of South Carolina
I hear you.

Farzad Mostashari, MD, ScM – Office of the National Coordinator – National Coordinator
The second thing, the second base hit is then to say, okay, but there's a lot of that happening out here that may not fit into this mold neatly. There's a lot of activities that are going on and in the forums, we're going to learn about all the variations on the themes and what people are doing, and get kind of the who's who of health information exchange and governance experiences together and maybe focus the conversation on a few things that we need to resolve. Like for example, what do you do if your health information exchange has different rules, I called it impedance mismatch, with someone else's health information exchange? Can no information flow? Can some information flow? Are there certain situations where you can agree that information can flow, and so forth.

The third part of that, rounding the bases, is okay, let's have an explicit ONC association with one or more emerging public/private or private sector governance activities that are being stood up that are attracting different health information exchange entities to say, let's have some umbrella trust agreements between health information exchanges. And that's the deeming, kind of the, not deeming, but the relationship that we're able to establish with these exemplar governance entities that are setting rules and regulations and requirements for the participants. And saying, we think you should do whatever, authentication of users to this level. And that has a flow down for what those entities would need to do. And in other cases it's saying, this is what you should do in terms of having a trust umbrella between different health information exchanges. So, it's a pretty comprehensive set of different activities that are moving the ball. And many of those would, I believe, have implications for participants in health information exchanges at the local level, like a health plan who's exchanging information and so forth, but none of them are binding.

Anne Castro – Chief Design Architect – BlueCross BlueShield of South Carolina
Right, not regulatory.

Farzad Mostashari, MD, ScM – Office of the National Coordinator – National Coordinator
So it's providing, not regulatory. It's guidance, it's information, it's conversation.

Anne Castro – Chief Design Architect – BlueCross BlueShield of South Carolina
But it is nucleus.

Farzad Mostashari, MD, ScM – Office of the National Coordinator – National Coordinator
It's nucleating.

Anne Castro – Chief Design Architect – BlueCross BlueShield of South Carolina
Right. And it'll radiate out, and so my question is, the team that's in the forum, I looked through the names real quick and it's hard to tell whether there are any payers in there. It's just hard to tell from the link. So my interest would be that you have adequate flavors of payers to provide input at this nucleus level. Because I don't have any issue with – I think it's good work and I think it needs to start somewhere, I just need the constituents represented that would be impacted as it moves out.

Mary Jo Deering, PhD – Office of the National Coordinator – Senior Policy Advisor, Office of Policy and Planning
To get those voices heard.

Anne Castro – Chief Design Architect – BlueCross BlueShield of South Carolina
And it radiates out. Payment innovation, as you know, is one of the key ingredients that has to take place, along with digitizing everything as an electronic health record. And making consumer satisfaction with healthcare increase, but it's also that cost has to come down. So we need to be able to have fast ability to create that and it would be a shame if that is what we're – one of our big third leg of the three-legged stool, would being contained without representation early. And that's really what I wanted to get to. So, I would like to know more about signing up for this one. I'm just not having the visibility in that forum, who gets to beyond that and …

Mary Jo Deering, PhD – Office of the National Coordinator – Senior Policy Advisor, Office of Policy and Planning
Why don't I follow-up with you separately afterwards.

Anne Castro – Chief Design Architect – BlueCross BlueShield of South Carolina
That would be great. Thanks.

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

Dixie Baker, MS, PhD – Martin, Blanck and Associates – Senior Partner
Yeah, the two that – the two exemplars that you've awarded use totally different architectures, the Direct uses direct and the New York uses more of an exchange model. Have they been asked to address how to make governance compatible between those two exchange models?

Kory Mertz – Challenge Grant Director – Office of the National Coordinator
So, the New York folks are doing actually query and directed, just to put that out there. But, I think a key part of what we included in the program was explicit requirements around coordination and collaboration between the two awardees. So it's definitely an area that we'll have conversations with and explore as part of the work.

Dixie Baker, MS, PhD – Martin, Blanck and Associates – Senior Partner
Okay, good. Thank you.

Mary Jo Deering, PhD – Office of the National Coordinator – Senior Policy Advisor, Office of Policy and Planning
Well, and for example, in the forum I mentioned that what we're working on possibly for the May 3rd meeting would be to look at the trust agreement component of governance and to compare and contrast and identify commonalities. And certainly, the direct model, the DURSA model and the DURSA-like model, which many people are cannibalizing the DURSA and just using its elements and certainly New York is one of those that's doing that, so they're coming up with their own hybrid models. Now one of the things we want to make sure is that in our quest to surface these different approaches that we avoid two mistakes. We avoid the one-size-fits-all mistake, but we also want to avoid the inadvertent blessing of too many different innovative models, to putting the elements together. So our goal would be to say, where are the truly common elements and where are the truly unique elements depending on the model?

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay. Other comments? Well, very good. Thank you very much for that presentation and certainly look forward to hearing back from the experiences of your two grantees. I know that, I keep harping on provider directory and other missing standards, and hearing more examples of what works and doesn't work is going to help us all. So MacKenzie, I believe we have a second public comment period?

Public Comment

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
We do. Operator, can you please open the lines for public comment? And if there's anyone in the room that would like to provide public comment, if you could please come to the table. And again, as a reminder, they will be limited to three minutes.

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

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
And we do have a public comment in the room, so please go ahead. Thanks.

Darryl W. Roberts, RN, MS, PhD – American Nurses Association – Senior Policy Fellow
Hello. This is Dr. Darryl Roberts with the American nurses Association. I'm always looking for opportunities to look back at my lovely Master's thesis on HIPAA and find confluences in it. And the proposal for the health information exchange national governance could really benefit from learning a great deal from the successes and pitfalls experienced by HIPAA. HIPPA set a national floor, it didn't set a ceiling. The national floor just said, if you're at the state level and you are meeting the floor, great, you don't have anything else you have to do. If you're not at this floor, you have to at least come up to this level. And these were things around privacy, security, portability, many other areas that HIPAA covered. And it was essentially really a fairly weak law. It did, however, start a national conversation on issues of security, privacy, confidentiality, portability and that national conversation got the states thinking about, what could we do, or should we do, to exceed this national floor?

Some chose to stay right there, it worked just fine for them. Others said, we need to identify what our state needs, but we can't go below this level, which kind of worked as well. Another thing that really worked very well was engaging an accreditation bodies, such as the Joint Commission, who said, well in order to get accredited as a hospital, you have to meet national floor at your hospital for HIPAA requirements. That worked and it actually gave an enforcement arm that the Office of Civil Rights really didn't have. When they first launched HIPAA, they had 7 people in that office and I'm sorry, 7 people are not going to regulate an entire country's confidentiality and privacy. And these successes really made a big difference. And now HIPAA kind of works, kind of doesn't. The pitfalls and why it kind of doesn't are that HIPAA became overly prescriptive in a lot of areas, and those areas that it was overly prescriptive, were the elements that still are not implemented. So in identifying how the governance for health information exchange is going to go forward, think about what can be done, what can't be done, what shouldn't be done, and what the floor ought to be. Let the states identify what their state needs above that floor. Thank you very much for the time.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Thank you very much.

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thank you. And I'm showing we do have one public comment on the phone. If you can please identify yourself.

Gary Dickinson – CentriHealth – Director, Healthcare Standards
This is Gary Dickinson.

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks, go ahead please.

Gary Dickinson – CentriHealth – Director, Healthcare Standards
Back to a comment that Farzad made this morning, I think, regarding the vendors seeing value in certification. One of the things that would recommend, I'm Gary Dickinson, the Director of Healthcare Standards at CentriHealth. I'm also the co-chair of the HL7 EHR workgroup. One of the things would be to tie meaningful use to the international standard, ISO-10781 EHR system functional model. And one of the ways we do that is to develop a functional profile, which we actually have underway, which would link then the Meaningful Use Stage 1 and 2 system certification criteria to the conformance criteria of the functional model, ISO-10781. So that when a system is certified for US Meaningful Use Stage 1 or 2, it could be simultaneously certified against ISO-10781 and therefore have an entry into the international market from that standpoint. So that's something that I would recommend. Thank you.

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thank you.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Thank you very much Gary. We missed you here. I hope all is well in California. Other …?

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Are there any more public comments on the phone?

Alan Merritt – Altarum Institute – Web Communication Specialist
We have no more comments at this time.

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Okay. No more public comments in the room either.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Well very good. And so we have no closing benediction from anyone here. I do want to thank you for a really good discussion today. I think important take home today is the work plan ahead is going to evolve over the next couple of weeks. And well a lot of us still working together and of course with the Policy Committee and close with our ONC colleagues, so that you can get a sense of what is accomplishable and how we will leverage, not only our Committee but other committees and other ONC activities to get the work done. So, I did have an interesting pre-discussion before the meeting today about the fact that we are actually the result of legislation, as opposed to say HITSP or other organizations that were contracts that could evaporate as administrations change. So one of the things we don't actually have to plan for, I don't think Farzad, is in end to our work. Yee haw. So that's the 47th meeting and I will see you at the 48th.

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
So before we close, I just do want to update for record that we had a few members who were not present during roll call, who were in attendance today. On the phone, we had Jeremy Delinsky, Keith Figlioli, um, let's see, Nancy Orvis. And in the room, I believe Stanley Huff, you missed roll, so Stanley is present, as well as Andy Wiesenthal and Kamie Roberts for Charles Romine. So with that, we're adjourned.

John Halamka, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Great. Thank you everybody.

Public Comment Received During the Meeting

1. Is it possible to define triage levels for tickets that are raised so the moderator is able to present those issues that comply with triage guidelines --e.g., Level 1, 2, 3?

2. It could be cumbersome for the moderator to tease out high quality content versus less important content or issue reporting --showstoppers versus speed bumps.

3. This has been valuable information shared. One item to correct Retrieve Form for Data Capture is an IHE (Integrating the Healthcare Enterprise) standard - not a CDISC standard. As one of the co-chairs of this Quality, Research and Publich Health domain I am happy to hear of the upcomng tcons.

4. Mickey: Excellent job summarizing a lot of detail.

5. Lab codes should be in LOINC. The payment for LOINC codes labs should be more. Thus, there should be a policy and payment lever for using advocated lab codes. The premise is that lab codes in LOINC afford easier and more accurate sharing of data and information.