

HIT Standards Committee Transcript September 18, 2013

Attendance

The following members attended the meeting:

- Dixie Baker
- Anne Castro
- John Derr
- Floyd Eisenberg
- James Ferguson
- Keith Figlioli
- Lisa Gallagher
- John Halamka
- C. Martin Harris
- Leslie Kelly Hall
- Stanley Huff
- Elizabeth Johnson
- Rebecca Kush
- Anne LeMaistre
- Arien Malec
- David McCallie, Jr.
- Kim Nolen
- Jonathan Perlin
- Wes Rishel
- Eric Rose
- Sharon Terry
- Andrew Wiesenthal
- Steve Brown
- Nancy Orvis
- Charles Romine

The following members were absent:

- Jeremy Delinsky
- Christopher Ross
- Lorraine Doo

Presentation

Michelle Consolazio – Office of the National Coordinator for Health Information Technology

Good morning, everyone, this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Standards Committee. This is a public call, and there will be time for public comment at the end of the call. As a reminder, please state your name before speaking, as the meeting is being transcribed and recorded. This is the 51st meeting of the Health IT Standards Committee and I will now take roll. John Perlin?

John Perlin, MD, Ph.D., Officer, Clinical and Physician Services, Hospital Corporation of America

Good morning.

Michelle Consolazio – Office of the National Coordinator for Health Information Technology

John Halamka?

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

I'm here.

Michelle Consolazio – Office of the National Coordinator for Health Information Technology

Andy Wiesenthal? Anne Castro?

Anne Castro – Chief Design Architect – BlueCross BlueShield of South Carolina

I'm here.

Michelle Consolazio – Office of the National Coordinator for Health Information Technology

Anne LeMaistre? I know she's here. Arien Malec? Martin Harris?

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

Here.

Michelle Consolazio – Office of the National Coordinator for Health Information Technology

Charles Romine?

Charles Romine – Director, Information Technology Laboratory – National Institutes of Standards and Technology

Here.

Michelle Consolazio – Office of the National Coordinator for Health Information Technology

Cris Ross? Dave McCallie?

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

Here.

Michelle Consolazio – Office of the National Coordinator for Health Information Technology

Dixie Baker?

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

I'm here.

Michelle Consolazio – Office of the National Coordinator for Health Information Technology

Liz Johnson?

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

I'm here.

Michelle Consolazio – Office of the National Coordinator for Health Information Technology

Eric Rose?

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

Here.

Michelle Consolazio – Office of the National Coordinator for Health Information Technology

Floyd Eisenberg?

Floyd Eisenberg, MD, MPH, FACP – Independent Consultant

Here.

Michelle Consolazio – Office of the National Coordinator for Health Information Technology

James Ferguson?

James Ferguson, Vice President of Health Information Technology Strategy and Policy – Kaiser Permanente

Here.

Andrew Wiesenthal, MD, SM – Director of Health Care Practice – Deloitte Consulting, LLP

Hello, this is Andy Wiesenthal. I was on mute when you called my name; I'm sorry.

Michelle Consolazio – Office of the National Coordinator for Health Information Technology

Okay, thank you.

Andrew Wiesenthal, MD, SM – Director of Health Care Practice – Deloitte Consulting, LLP

Uh huh.

Michelle Consolazio – Office of the National Coordinator for Health Information Technology

John Derr?

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

Here.

Michelle Consolazio – Office of the National Coordinator for Health Information Technology

Keith Figlioli?

Keith Figlioli – Senior Vice President – Healthcare Informatics Premier, Inc.

Here.

Michelle Consolazio – Office of the National Coordinator for Health Information Technology

Kim Nolen?

Kim Nolen – Medical Outcomes Specialist – Pfizer, Inc.

Hey, Michelle, I'm here. Good morning.

Michelle Consolazio – Office of the National Coordinator for Health Information Technology

Leslie Kelly Hall?

Leslie Kelly Hall – Senior Vice President for Policy – Healthwise

Here.

Michelle Consolazio – Office of the National Coordinator for Health Information Technology

Lisa Gallagher?

Lisa Gallagher – Senior Director of Privacy and Security – HIMSS

Here.

Michelle Consolazio – Office of the National Coordinator for Health Information Technology

Lorraine Doo? Nancy Orvis? Becky Kush?

Rebecca Kush, Ph.D. – Founder, CEO, President and Director – Clinical Data Interchange Standards Consortium

Here.

Michelle Consolazio – Office of the National Coordinator for Health Information Technology

Sharon Terry?

Sharon Terry, M.A. – President and CEO – Genetic Alliance

Here. Sharon Terry's here.

Michelle Consolazio – Office of the National Coordinator for Health Information Technology

Stan Huff?

Stanley Huff, MD – Chief Medical Informatics Officer – Intermountain Healthcare

Here. This is Stan, I'm here.

Nancy Orvis – Director – National Health IT Standards Participation and IM/IT Integration, Department of Defense

Yeah, Orvis is here.

Michelle Consolazio – Office of the National Coordinator for Health Information Technology

Thank you. Steve Brown?

Steve Brown – Department of Veterans Affairs

Present.

Michelle Consolazio – Office of the National Coordinator for Health Information Technology

Wes Rishel?

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

Here.

Michelle Consolazio – Office of the National Coordinator for Health Information Technology

Okay. Thank you, everyone. As a reminder, please mute your line, and I will now pass it to Farzad.

Farzad Mostashari – HHS/Office of the National Coordinator for Health Information Technology

Hi, everybody. Well, this is my last Standards Committee meeting, so I thought I'd leave you with some of my worries [*Laughter*]~~—~~passing along the worry beads, as it were. Before I do, I have to start off by acknowledging that none of what we have yet to do is necessarily gonna be any tougher than what we've already done and from how far we've come. Not only in terms of the specifics of the standards, but of the process of being able to establish priorities for us to work together as a community to resolve and then to get people focused on those priorities and to bring industry academic experts together and to do earlier implementations and pilots, and now the framework that we, I think, are getting much better at of having implementation and testing and validation before we get to the certification process, and then having that certification process be more rigorous.

My gosh, the progress made in all of those. By no means is our job done once the standards are endorsed, adopted, even put into regulation and certification. Where we stand now in the next 12 months, as important as the new development is gonna be in defining the next set of progress, making sure that the standards that we have already identified work and work in the detailed, *[Laughter]* nitty-gritty way that always ends up being the absolute key—kind of optimizing those implementation guides, working through problems as a community.

That is an immense challenge, but we need to get there. We need to move to the 2014 set of standards which, for the first time, identify the terminologies for some very critical issues, for the first time have the single standard for representing patient information in a summary, a template that is expandable and extensible there and universal implementation of protocols for catching and sending health information securely over the Internet. Those are key steps forward on interoperability, and I don't think that we can afford to delay interoperability. That is, that one of my worries is that, even while we have to balance the urgency with the _____ experiences of providers and some vendors who wish they had more time, the cost, let's be clear, the cost is towards interoperability. That's what we lose if we delay the progress on stage two.

I understand there's also concerns about, well, maybe we should have more time in stage two, and an extension of that. That, I think, we have time to discuss. The Policy Committee is gonna be discussing it. There may be some various ways of addressing that, but we have fought too hard to get to where we are with the interoperability advances and the 2014 certification criteria to not get there in 2014. This, I believe, is the time.

Looking ahead, sharing my *[Laughter]* worries with you as Dave McCallie put it, being always aware of making progress on what we know we have to do to solve today's problems with the standards that we have versus the future and potentially better ways of doing things in the future and the concern that urgency today may translate into concrete—I think Dave called it the last gasp of a dying standards set. *[Laughter]* Pretty dramatic, Dave. *[Laughter]*

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

I'm glad you remembered.

Farzad Mostashari – HHS/Office of the National Coordinator for Health Information Technology

[Laughter]

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

I had forgotten I said that.

Farzad Mostashari – HHS/Office of the National Coordinator for Health Information Technology

Yes, you did—so, balancing that, and taking actions to give implementers the specificity they want and demand to really get this plug and play interoperability and yet having, doing that only where we have some reasonable confidence it's not going to be a dead end or that it's gonna hinder us, that we're gonna regret this later. We don't want to be regretting what we do today, tomorrow. I think some of what Doug is gonna be talking about around the structured data capture and the data access framework and the APIs are very much in the spirit of saying, "Let's do something today that can be enduring," at least as enduring as technology permits us to be, even while we make progress on kind of the functional interoperability addressing the deeds of today getting more specific where we can.

Then, my final worry is around, are we meeting the needs of the situation? What are the needs of the situation now? If health information exchange organizations, if the priority for them for sustainability, if the priority for anyone providing exchange services is to sell what people want to buy—sell what people want to buy, we heard at our Joint Hearing back in January—what do people want to buy? What is there a business case for in information exchange today? Because all the standards in the world aren't going to cause data to flow where there's no reason for people to share that information, no incentive for people to share that information.

What are the business cases that we are pushing to create the environment for? The payment systems that are being modified, the readmission adjustments, single-handedly, I think, have created a business case for hospitals to want to share information better with the post acute care setting, with long term care, with home health, with primary care providers on discharge. Are we meeting the needs on the standards side for those transactions?

I think the voluntary certification for long term post acute care and behavioral health providers could be very interesting, but we also need to match that on the acute care side. Is the information that is really needed to ensure a safe transition of care, to reduce readmissions, are we focused like a laser beam on what information is going to reduce readmissions? I think it's tougher than it looks to reduce readmissions, but focusing on the needs of that situation.

Notifications, I think, both for the readmissions use case as well as the accountable care use case—just those simple notifications that say, “Patient has hit the emergency room, that you discharged or that you care for. You may want to know about that”—just that notification. There are many people doing it many different ways, some using the building blocks that we have provided for in the direct protocols, for example, but do we have sufficient guidance to ease those, the work needed to do those notifications?

When we're talking about population health management, the needs to manage the care, to identify care gaps and to transmit those care recommendations. Doug is gonna talk about the quality in decision support. That work is gonna be critically important to sharing not just information but insights and actions. This needs to happen. How do we communicate that today?

Finally, in terms of—a very important gap that often occurs is the gap between the prescription and the fill. If we are focused increasingly on quality, on blood pressure control, on lipid control, on sugar control, all of those require providers to become much more aware of medication adherence issues. Are we in a position to support that flow of information from pharmacies and benefits managers back to health care providers and in more than, at the time of prescribing only, which is, it's not the use case here.

Those are the needs of the situation and we hope that the market will respond, but the market can have failures, and whether it's around ensuring for portability of records to reduce switching costs, whether it's enabling providers, customers to choose what applications they use, having edge protocols for health information exchange, having APIs for third party applications—enabling tracking of cross vendor exchange so that we can monitor and hold accountable in Meaningful Use for cross vendor exchange in a way we couldn't do for Meaningful Use stage two. Those are ways that our standards can help a more perfect market come into existence.

Finally, the totally, I think, amazing, disruptive possibility of patient mediated exchange, it is, the building blocks are there to enable any of us to be able to be the mediums of our own exchange—HIEs of one. There are a couple of technical pieces there around data integrity and provenance, for example, to tackle. This is daunting, but it is the needs of the situation, and I leave it in your hands. Thank you.

John Perlin, MD, Ph.D., Officer, Clinical and Physician Services, Hospital Corporation of America

Thank you very much, Farzad. It's really quite remarkable when Michelle introduced the call to recognize this is our 51st meeting to recognize that this is a meeting of the transition. Our last meeting with you, I think your comments prove again to all of us the terrific vision, the inspiration, the intellect, the passion, the commitment not to technology as an end, but really as an enabler to better care.

I think we all are inspired by a number of dimensions and those include not only really the fragility that all of us as individuals, as patients, as family members of patients, as advocates for patients, as friends of patients, as health professionals, as inevitably engaged in care and health as individuals and citizens, we know the tools are imperfect. Your leadership, the work of ONC, the work, frankly, of this Committee really enriches the environment with sets of tools that help us build a better ecosystem. You know, that we're an ecosystem, Farzad, has been a part of our shared vocabulary and reflects not only on the history of 51 meetings, but on the history of our work together during your tenure, that ecosystem of possibility has expanded.

It's not theoretical, it's not projecting on—again, referencing David McCallie—what might be hoping only for aspirational standards of the future, it's really exciting to realize that so much of the work is now in progress. Because that work highlights for us, when we reflect, not only what's possible that was not possible before, but it also highlights numbers of decisions that we have to make about what's next and how, also true to your appreciation for the cadence of activity of the real world implementation on the priorities and focus that you mentioned.

What's been built is something that's enduring. You can't unring the bell. There is an infrastructure, an ecosystem of possibility that simply didn't exist before and, on behalf of all of the Committee, we thank you. We thank the ONC. I say this not only in this role, but as that prospective patient and individual and family member and citizen. That's an absolutely extraordinary accomplishment.

This is an important agenda. It's an agenda because it's one that really looks to the aspirations, that broader ecosystem of broad possibility, but it also, as John Halamka has so eloquently said, really brings into focus the admonitions of, really, of our own self reflection, sometimes channeled through our implementation work group, which can at times serve as our own, if you will, superego and put in check some of the broadest aspirations in terms of really appreciating what's necessary for the more immediate use cases.

So, as the business case evolves in the broadest sense, there is a business case that is supported by Meaningful Use stage two and I really appreciate the focus that will be brought by the Office of the National Coordinator later in the discussion about how we prioritize and how we lend our voice to identifying what priorities were immediate business case as we solve two puzzles simultaneously. One, that we build solutions that assure support for success with the most immediate challenges, the uses cases made possible my Meaningful Use stage two, but that each of those solutions, as jigsaw puzzle pieces, build together a picture that emerges that really includes those aspirations that address broader improvements in health and care as you so eloquently articulated.

As we look down the agenda for today, in addition to the discussion of the prioritization that will occur through the lens of the S&I framework update. It's really interesting to watch so many of these pieces come together, a puzzle piece that we've worked together as a part of. In fact, it's really exciting. Some day we'll look back and realize that this was the inception, the FDASIA work really is the introduction of a risk based, regulatory framework. I very much appreciate the work that Jodi Daniel is leading in terms of informing that process to, just as with the standards, assure that there is a balance between specificity in terms of immediate needs, the absolute practicalities in this instance of risk and safety, and also the opportunity to support discovery and innovation. Striking that balance is critically important.

As mentioned, the scenarios based testing update also strikes that balance between future aspirations for the interoperability that we seek and need in improved health and care, but also helps us advance with greater specificity the testing that supports the specific use case. Whatever standards might be produced helps align within the standards for successful fulfillment of the use cases in terms of transfer of information into very, very practical scenarios involving things that one easily understands as core to patient care and core to health improvement, and so I appreciate those efforts as well.

Before I turn to John Halamka, and I'll ask him please to introduce the clinical operations work group activities, let me just stop there and ask for official business action during this point in the meeting, which is the review of the minutes. I just note that the minutes are not only, again, done with exceptional sensitivity, but also leave, really, a track record not only of our discussions, but also a documentary history that allows one to understand the trajectory of these activities, both in terms of the specificity for the near term, support of the immediate objectives of Meaningful Use two, but also to get a sense of what we are all thinking about as we look forward toward building that broader ecosystem.

Anyone want to weigh in with any amendments, edits, corrections to the minutes?

Hearing none, let us assume consensus on that. Thanks to Michelle and team for very thoughtful documentation of that. Farzad will have some additional comments at the end, but thank you for the inspiration. I think it's really up to the rest of us to assure that we collectively deliver on both meeting the urgent and pressing needs in a way that solves real world opportunities today, but also that creates a path for discovery, innovation, and even greater success in an ecosystem of possibility tomorrow.

With that, we turn to Dr. Halamka.

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

Well, thanks very much, John, and certainly, Farzad, I want to offer my thanks and gratitude for your energy and your passion in driving the agenda as robustly as you have. I've been asked to key note the HL7 meeting on Monday, and I will share with them many of the worries you articulated, with a central theme of, "We better select standards that are fit for purpose, easy to implement, have little optionality, and are what the market wants." *[Laughter]*

We want to produce standards that as you, in your words, in effect, people want to buy because they meet the need, they're straightforward to implement, and they certainly, as we look at the use cases ahead, will meet all of our needs. If you wouldn't have had the energy and the passion that is you, we would have never have gotten as far and fast. David Blumenthal, he always told me, "Ask for 150 percent of what you want, because that way, when you compromise, you'll get what you really need." Well, I think you've done a remarkable job in creating harmony.

So, if we look at the agenda today, our Clinical Operations Work Group will present a framework for looking at the image transmission use cases. Jamie and I have had three meetings of the Work Group, and we've heard testimony from a variety of stakeholders, and what you'll see is, like so many other aspects of standard selection, it has to be requirements driven. As we look at use cases and specific architectures, view, download and transmit actually have different characteristics and may need different standards. When we're asked, "Well, pick the standards that you need for image management," you'll see that there may be multiple opportunities, depending upon the nature of the actors and the actions and the events. It may not be one size fits all. Our intent is to try to bring back solid recommendations in various use cases and architectures by October.

The scenario based testing, John, as you said, this is really important. Because, as a self certifier, I'm going through the certification process, and I see a danger in a certification process that separates the application into individual scripts with individual functionality because, sometimes, you could pass a section and demonstrate the functionality within that script, but it may not be part of a larger clinical workflow that actually achieves the goals that we want for safe, quality, efficient care. So the idea that you could thread a clinical scenario from patient arrival to patient departure and continuous care at home and show how each script leads one into the other is absolutely key, and I certainly look forward to that maturing and that being a preferred way of doing certification.

John, as you said, as we look at Meaningful Use stage two in future stages—ICD-10, ACA, HIPAA Omnibus Rule—there is a vast amount of work that is hitting simultaneously. Asking, given scope, resources, and time, “What are the standards that are real enablers? What are the barriers that we can take down?”—I think it does, as you'll hear from Doug, require reflection on what it is we've articulated as our standards goals, what the S&I framework is developing today, what is the pace of change that we believe is sustainable, and how do we set the scope right? How do we set the priorities and phasing correctly? We're not gonna answer that question today, but Doug will give us some framework so that, as our next meeting in October is face to face, we can spend several hours reflecting on how to prioritize our future work using objective criteria.

With that, why don't we dive into the Clinical Operations Work Group update. Jamie, do you want to go through the slides?

James Ferguson, Vice President of Health Information Technology Strategy and Policy – Kaiser Permanente

Yes, I'd be happy to. Thank you, John. If we could switch to the clinical operations slides, what I'd like to do is, we have half an hour allocated for this—

Leslie Kelly Hall – Senior Vice President for Policy – Healthwise

Excuse me, Jamie and John—this is Les. Is Farzad still with us?

Farzad Mostashari – HHS/Office of the National Coordinator for Health Information Technology

I am.

Leslie Kelly Hall – Senior Vice President for Policy – Healthwise

Can we just take—I didn't know whether you were planning to stay the entire time, so I just wanted to say thank you, Farzad. Your leadership and your commitment to patient engagement has driven a sea change in this nation, and I am so proud to be part of it and thank you very much.

Female

Hear, hear.

Farzad Mostashari – HHS/Office of the National Coordinator for Health Information Technology

Thanks, all.

James Ferguson, Vice President of Health Information Technology Strategy and Policy – Kaiser Permanente

Thank you, Leslie. Back to just the Work Group update here. What I'd like to do is to divide this section into three parts. First, I'll just go through our basic framing of the different considerations that have to be outlined for each use case that we want to solve for. Then I'm gonna go through some of the slides that were presented to us as Work Group testimony just as an example. This is not a complete set, this is about a quarter of our considerations, or maybe less, but this is an example of the considerations that we have for defining standards for the different image sharing use cases that comes from the testimony that we received.

Then the third part of this section of the meeting, what I'd like to do is to go back to a Committee discussion on the use case objectives. Really, I think that our question to the Committee is, what are the minimum set of use cases for image sharing for which standards are needed? I want to then have that discussion in the context of what I'm about to go through. If we could go to the next slide, please.

For each use case scenario, of course, typically, going back to other use cases that have been defined, we need to define the actors, but also, what do you want to do with the images? What are the actions? For example, reporting or audit or review actions are very different from diagnostic decision making. Then there's a range of content that could be decided based on the different types of images so you have time series, you could have a full set, you could have just key images, you could have a report with text and then there are many variations on the content requirements for the different actions. Then it's important, with image sharing, to understand how it's gonna be initiated, whether this is a manual pull or push, whether it's triggered by various conditions, whether it's automatic. Then, obviously, we have to look at the system actors as well as the human actors.

Then, from defining all of those things for each of the use case scenarios, then we can look at recommendations for the minimum required set of payload packages, what protocols and modalities fit. As John said, there may be different standards for different use cases and so the image quality and speed, there is a diagnostically acceptable, irreversible compression. There are standards for that and yet there are other times when that may not be indicated. We really need to go through and define a core set of use cases, frankly, better than we had done at the outset in order to come back and recommend standards. That's our basic framework, and we would like to keep it in the framing of you download and transmit where—transmit means transmitting to a third party, not downloading to a local or remote machine.

Next slide, please. Now, this is where I'm switching into some of the testimony that we received. This is from David Clunie, who's a radiologist who's been involved in DICOM, I think, since the beginning. Here he's going through some of the different specific purposes of image sharing for viewing, downloading, and transmitting the different parties and considerations involved.

Next slide, please. Now we're looking at—so what does zero footprint mean? That's something that had come up earlier. Of course, then there are a number of different nuances in terms of zero footprint that can have a profound impact on the utility or fitness for purpose of images in the different use cases, so just a set of technical considerations here that we would have to go through.

Next slide, please. Other protocol considerations for the **poll** scenario as to who performs which actions—here, we've heard a lot about the installed base and the fact that there is an existing, robust commercial market and infrastructure for image sharing, commonly by proprietary means, with which there are some issues; links go stale, companies go out of business, et cetera.

Next slide, please. Then we heard a variety of considerations about the different architectures that, for example, with a simple push architecture, of course, as we know, is relatively easier, but at the same time, you end up with large image sets, duplicated and stored in many places, and then you have management issues having to do with that and identity, of course, is a persistent problem in all of this. With the pull architectures, there are multiple modalities, really, within what we would call a pull architecture, and again, as different sets of issues with that. Then we've heard, also, a testimony about hybrid or brokered solutions, of which there are, again, multiple versions.

Next slide, please. One of the recommendations that we heard consistently, I think, from multiple points of testimony is that there is a lot of global experience, both in but also outside the U.S. in terms of image sharing and that we would be well served by considering both the successes and the failures and the maturing of standards and methodologies that have been used elsewhere. A couple of things that were pointed out here in particular were the Canadian regional repository solutions and the transition of U.K. programs from point to point push to brokered solutions to more centralized solutions. Then, some of the other considerations on the slide here have to do with whether the report is in scope or not. If it's images, does it have to be sent jointly? If the report text is sent separately, is that another redundant architecture? Is it just another document to be sent by means that other electronic documents are sent, and then how do you link those things up? We've heard, I think, a variety of experience on this as well. Then, from the user perspective, the transition from a local to remote image experience has to be considered in standards determination as well.

Next slide, please. To our next steps, what we really would like to do, and I did kind of rush through that on purpose so that we can get to Committee discussion on the minimum set of use cases for image sharing. Because previously, we had thought, relatively simplistically, that consumers needed to be able to download images to somewhere, whether it's a PHR, remote or local device for managing their own health, but we weren't very specific about whether those images must be able to be subsequently used for clinical decision making or not; the source and target systems were not well defined, for example.

After we are able to better narrow down the minimum set of use case scenarios, then I think we can move into the phase of analysis and identification of bundles of recommended standards for those use cases. There are a lot of mature standards. There may be improvements or constraints on the use of existing standards. I think we think that it's unlikely that any fundamentally new standards will be required, but there may need to be improvements or implementation guidance and specifications written for the existing sets of standards. Then, of course, whatever we come up with, we bring back to the Committee.

That's generally where we are. I'll ask at this point, John, do you want to add anything to that, or do other members of the work group want to add anything?

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

Sure. Just to add a couple of standard comments, I mean, as we had testimony from multiple parties, we heard from vendors and we had from informaticists—I was introduced to some standards I didn't even know about. STORS, which stands for Store Over the web RESTful Services, a mechanism of pushing DICOM objects from place to place using pure Internet firewall friendly approaches. WADO RS—Web Access to DICOM Objects, being able to do cross organizational pull of DICOM objects through firewalls across multiple organizations.

When we think of DICOM traditionally, we think of TCP/IP and inside an enterprise, but you know, there are multiple standards—now, I can't tell you yet as to their maturity, fitness for purpose, because we are gonna discuss some use cases, but I think we heard from Davie Clunie, you know, there actually may be a variety of standards we can select from that are pretty good if our constraints are cross organizational, web friendly, zero footprint, et cetera.

We also heard that there may be some ecosystem enablers, and I thought, Jamie, that it was an interesting discussion from the one vendor that, why is it the banking system of the United States does billions and billions of transactions? Oh, it's because it has the ACH and you've got not just standards so that you can go through a clearinghouse—in effect, one bank can push to a clearinghouse, another can pull from the clearinghouse. It's the fact that you've got this sort of nationally enabled, highly robust organization that facilitates cross organizational exchange. Is it the role of government, or is it the role of industry to create such a clearinghouse that facilitates an architecture or an ecosystem that leverages existent institutional DICOM systems, but then opens up a completely different set of possibilities for providers, patients, and other stakeholders by using some of the emerging standards.

These are interesting questions to ask, and as Jamie said, it all starts with requirements. I'm certainly happy to hear thoughts from other members of the Committee who heard testimony.

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

Hello, this is Eric Rose. I had one question and one brief comment. The question is whether images of waveform tracings like ECGs in particular are in scope for image sharing use cases.

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

Sure. Farzad specifically asked us, even though an EKG is an image, it's a time series, it might be represented in a .pdf or other binary blob, so yes, in scope for our discussion is, how does one enable the transport in a push and a pull or view architecture, view download transmit, a binary object that isn't free text—so yes.

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

Right. Well, I think it becomes relevant when one starts to consider use cases. Being less of a technical expert and more of a just familiar with practicing physician workloads, I think that the speaker's suggestion of giving more attention to use cases and clarification of use cases is extremely important.

From the perspective of—I think there are three buckets, really, regarding transmission of image related data from the perspective of actual patient care. One is, being able to transmit diagnostic quality images from one repository to another. The patient's moving and the image needs to be available should somebody subsequently do a follow up study and needs to compare the legacy study to the current study. The second is, for certain subspecialists, they want to be able to receive not just a radiologist's report but the actual image for planning surgery, that sort of thing, orthopedists, neurosurgeons, et cetera. The third is, for most, at least primary care providers, what they really need to receive regarding imaging studies is simply the text report from the radiologist, and the images themselves may be a matter of curiosity, may help with explaining to the patient if they can point out a specific abnormality, but really, the primary care doc is generally not going to perform an expert diagnostic evaluation of the image, and just getting a report is often enough.

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

Right, and one of the things, as you saw, in Jamie's discussion is, and Clem McDonald is quite passionate about, "Hey, reports! We better think about those, too!" *[Laughter]* It isn't just a binary blob. I think, as we discuss this today—I mean, we're hearing scope like binary blob, include non-DICOM format, also include reports because certain of these cases could benefit from that.

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

That might increase the images needed, I guess is what I'm saying for the real clinical, there.

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

Are you up for a discussion yet, Jamie, or are you still—

James Ferguson, Vice President of Health Information Technology Strategy and Policy – Kaiser Permanente

Yeah, please. Please, David.

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

First, that was a great overview of the complexity of the space. I want to add to the complexity, *[Laughter]* only to the suggestion that we not limit our discussion to the view/download/transmit case, but also consider a future directed query or a nontargeted—targeted query, nontargeted query. You know, if we're gonna think broadly about it, we need to think about what's next as well as the immediate view/download/transmit use cases. I'll just toss that out there. I'm sure that's informed your thinking already, but just make that more of a specific recommendation.

Then second, I would certainly endorse Eric's point about the value of the report. I think that we've got some emerging experience with HIE where we're focusing so heavily on the CEA summary documents, and that would be, we would be remiss if we didn't also make sure that we could exchange reports that have really valuable diagnostic information in them, and they're pretty easy to exchange, because we already have technical standards to do that.

The third point is, I'd like the description of the zero footprint, definition of how close to zero do you have to get—I would endorse that being one of the early questions for increased clarity. Those choices you gave look like a good set of chances. It'd be great if we could sort of hone in on that, maybe, as an early deliverable.

Anyway—that's what I wanted to say. Thanks.

James Ferguson, Vice President of Health Information Technology Strategy and Policy – Kaiser Permanente

Great. Thank you.

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

Arien Malec has also requested a comment.

James Ferguson, Vice President of Health Information Technology Strategy and Policy – Kaiser Permanente

Okay. Arien; please.

Arien Malec – RelayHealth Clinical Solutions – Vice President

Thank you. Just a couple of points. If you look at the 95 percent, 5 percent use cases that aren't currently covered, the 95 percent is just repeat textual reporting. There's actually a lot of really good experience about transmitting textual form radiology reports. As David notes, there's existing standards. MDM is pretty universally used here.

The 5 percent unmet need case—there's a lot of cases that are met, where the need is met with remote imaging centers or imaging stations that are just networked into the PACS. The 5 percent case that is unmet is horrible, and anybody who's been here—John, I know you've been here, I've been there—it is a complex referral, requiring multiple specialists to coordinate around an image intensive care. You've got Oncology, you've got Neurology as probably the biggest needs here. The state of the art in the U.S. health care system is atrocious. It is the worst patient experience possible. It is hand carried DVDs that aren't interoperable from one setting of care to another. It's hand carried films where you're relying on patients who are going through traumatic situations to coordinate their own care.

My plea would be, let's look at the 95 percent use case, although it's—the 95 percent unmet need, which probably can be solved by textual reporting, but let's do a laser like focus on the 5 percent with a suggested use case of complex image intensive referrals.

James Ferguson, Vice President of Health Information Technology Strategy and Policy – Kaiser Permanente

Great. Thank you, that was excellent input. I wonder, Leslie, if I can call on you for your thoughts from the consumer perspective, because we did start out this conversation a few months ago thinking about the needs for consumers to be able to download and use images as well.

Leslie Kelly Hall – Senior Vice President for Policy – Healthwise

Well, there is a huge demand, and I think Arien touched on it, just that we, as patients, are the data transport of one. An area that brings the most value is the ability to expedite image results to all of our team members in care. It is just a huge stumbling block that prohibits us from getting a referral on time, getting the next event on time, and it creates huge angst for patients that they can't get that data easily and can't move it.

I think that lab results and imaging for the consumer to be able to easily get to will help them to take better control of their care. We hear this over and over again, mostly from patients that are in a chronic situation or an acute situation, smooth movement of that image is really a life saving opportunity.

In addition, we've heard from consumer groups about a concern around unnecessary exposure to radiation and encouraged that we have the ability to pass the level of that exposure inside whatever's able to be viewed, downloaded and transmitted to the patient so that they have an ability to monitor their own exposure and to have that information as well passed on to the next provider.

I think this is just really terrific and important work, and very well thought out. As a former, I integrated PACS in 1998 across seven health systems, and it is just profound what the movement of imaging can do to expedite care and get appropriate care for the patient and make it understandable. Even though a patient might not be able to read and understand the entire radiology report, when someone circles something and says, "This is the problem," it's an opportunity for conversation. Thanks, Jamie.

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

Jamie, if I could add just a few comments from my experience with my family as patients, I think to build upon Eric and Arien's comments, there are use cases, absolutely, where the report is sufficient, and that is, if you go to an emergency department and say, "I've had these chronic headaches and I have a report that has a negative MRI showing no tumor growth," then that's, of course, very salient in a workup.

In the case of my wife's diagnosis of breast cancer, her need was to bring the actual diagnostic mammography images in a clinical quality form to multiple providers of care in Hem/Onc, in Radiation Therapy, and Surgery. As Arien said, what she ended up doing was shuttling around all these DVDs that were Windows version specific and didn't necessarily load on a work station—it was really nightmarish. You could imagine a use case where she had the capacity to push such images to multiple providers of care, and even if that was a cloud and they could retrieve it from the cloud, I mean, all kinds of architectures—but her having the capacity to get rid of the DVD or the CD was a critical issue.

Certainly then there are other cases where I can imagine that, in my ER work, we have trauma patients and if you're going to take a trauma patient from a suburban hospital into an urban setting, it's really, really helpful to mobilize the surgical teams ahead of the patient's arrival by viewing all the images from the outside facility. In fact, it's been such an important use case that we've purchased a variety of proprietary products to enable that kind of ahead of time transfer. Our trauma teams were saying that they actually were constrained by the lack of interoperability in that particular setting.

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

John?

James Ferguson, Vice President of Health Information Technology Strategy and Policy – Kaiser Permanente

Yeah. Go ahead. Sorry, David.

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

This is just David. I had one clarifying question on the problems that you had, that you described in your own personal experience with the DVD. Was it more of a problem around the management of that means of transport, or were there issues with the DICOM images themselves?

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

Sure. Well, the DICOM wasn't the problem, it was the fact that every DVD comes with proprietary readers. *[Laughter]* David, you'll find this interesting, and Dixie, it's a point for you—we typically don't offer system administrator rights to the generic public work station that a doctor might use in a public clinic setting. So wait, I take a random DVD with a random executable, put it in a public work station—oh, I don't have rights to execute the proprietary code. *[Laughter]* That was the issue.

Steve Brown – Department of Veterans Affairs

This is Steve Brown from the VA, and I might also say that you might not have the rights to execute anything on that DVD. All of our DVDs are turned off in the VA.

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

John?

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

Yeah. Dixie, please, go ahead.

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

Yeah, I have a different comment, but I want to make sure you finished discussing that one before I make it. Okay, let me make it—Jamie, I expected to see resolution represented somewhere here, because, say, a radiologist for example needs a much higher resolution than does a general practitioner or a consumer or the trauma team that John just mentioned. The resolution of the image has huge impact on the architecture and the standards that might be prescribed. I'm wondering whether—and in fact, the resolution also has security impact, because the higher the resolution, the more information it's conveying.

I was wondering how resolution factors into this.

James Ferguson, Vice President of Health Information Technology Strategy and Policy – Kaiser Permanente

Yeah. Thank you, Dixie. I think that's what we really mean by, when we say image quality which, I think, is very much in here. I think that, again, that depends on what specific action steps need to be taken in the use case scenario. Whether there need to be measurements and analysis by specialists based on the images as we've heard about for surgical planning or for other purposes, that clearly comes into play. I think that one of the things that we heard from the Radiology community is that, with regard to what's considered to be diagnostically acceptable image quality, that there are in fact existing standards for diagnostically acceptable, irreversible compression that also would come into play in the selection of standards so that the result that you get out the end could meet the needs of the measurement or analysis that has to be done on the image set.

Arien Malec – RelayHealth Clinical Solutions – Vice President

This is Arien. I just want to note that the use case that John and I are pointing to, the image intensive referral that requires significant coordination, often requires the full diagnostic quality image, because you've got clinicians either making diagnoses on the basis of the image or making surgical decisions on the basis of the image. In both those cases, you want the full diagnostic quality image.

James Ferguson, Vice President of Health Information Technology Strategy and Policy – Kaiser Permanente

Right.

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

If I can just sort of recap what I'm hearing in the discussion thus far is, I think I'm really hearing four use cases that we would need to detail out. Let me raise a trial balloon on these four uses cases.

One is really primary care physician use of reports, which may or may not have images associated or attached with them but that are not images on which, for example, surgical measurements or analysis would be expected to be conducted.

The second would be the, what I'll call the specialist referral use case, which could be clinician to clinician or care team sharing across facilities with specific requirements for measurement analysis on diagnostic images.

The third one is a consumer mediated exchange of diagnostic quality images and report. The fourth use case scenario really is consumer self tracking of radiation exposure. How do those resonate as a potential minimum set?

Anne LeMaistre, MD – Senior Director – Clinical Information Systems and CMIO, Seton Healthcare Family Ascension Health

This is Anne LeMaistre, if I could just comment on your first use case. I'd be very careful about assuming that a general practitioner has a lower requirement for quality than others. Here's why. If you're a family practitioner, you may be serving as an orthopedist needing to see the higher quality image in order to see fine stress fractures or other things, and so I think it's important for any provider to get the same diagnostic quality of image.

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

Before anybody answers, there's choice. That is, we did hear from the IHE pilot that there was capacity to look at high res and low res, sort of the way you would look at thumbnails and click on a thumbnail and get to the higher res image if you needed it.

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

Yeah. This is David. I would second that, that you need an escalating capability that doesn't punish the whole system because the hard stuff is hard. If all you can get is the report, at least start with that. If you can then get a summary view with a zero footprint browser in a few seconds to verify what the report says, enable that, and then if you absolutely have to have the full resolution, enable that, but don't wait until we can do all three before we do something.

Anne LeMaistre, MD – Senior Director – Clinical Information Systems and CMIO, Seton Healthcare Family Ascension Health

Yeah. This is Anne. I would agree with that. I just don't want to limit their options.

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

Yeah. *[Cross talk]*

James Ferguson, Vice President of Health Information Technology Strategy and Policy – Kaiser Permanente

Okay, so I really—I like, David, the way you characterize that as escalating capabilities for image quality.

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

Well, Jamie—this is Dixie again. I think in the four, that you said the four use cases, are you including the radiologist and the specialist? Because I think there's a level of quality in between that the consumer—or a couple—between the consumer and what a radiologist would get.

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

Yes, Dixie—oh, please, go ahead, James.

James Ferguson, Vice President of Health Information Technology Strategy and Policy – Kaiser Permanente

Sorry. Andy, go ahead—sorry.

Andrew Wiesenthal, MD, SM – Director of Health Care Practice – Deloitte Consulting, LLP

Oh, thanks. I didn't realize it was my turn. I actually have a comment which I think may sort of thread the needle here. I would hope that we have an expectation that radiologists would begin to do one additional activity beyond their interpretation or whoever the primary interpreter of an image is. That is, designating which slices or pieces of their data are the ones that are of greatest interest, that have the lesion and indicate something important. Then, the escalation that was just described can actually be very fruitful. The requester, who either wants to push it some place or pull it some place says, "I want it all," so it's high res, all slices; or "I want what's of interest" or some other way of framing the categorization. "Just show me the slice that has the tumor on it because I need to show someone else."

That's where, so the use case is, I get to choose, whether I'm a doctor or a patient, and I get to specify, but someone has to do the filtering for me up front and I hope that becomes part of radiologist's or gastroenterologist's or cardiologist's workflow. That's some of the substance of my comment. I think that the standards ought to allow for that kind of categorization.

James Ferguson, Vice President of Health Information Technology Strategy and Policy – Kaiser Permanente

Okay. Thank you, Andy. In fact, we have captured that in our framework. We called it either full set or key images versus the report. That's the way we've characterized that.

Andrew Wiesenthal, MD, SM – Director of Health Care Practice – Deloitte Consulting, LLP

Because then we get past arguments about resolution—do I want a full resolution slice or a low res—it doesn't really matter if you're passing one slice, because that's what's of interest.

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

Jamie, there's a corollary question to this, and maybe this is a Farzad question as a process issue. I'm now implementing these capabilities at Beth Israel Deaconess, and we're getting into some very interesting policy and legal issues. If you make a clinical decision based on the image subset that Andy just described, do you have to save a copy of every image that you viewed in your local PACS or EHR so that, should there be a request for medical records or litigation, that you guarantee you can produce it versus keep a pointer to it where you got it the first time, but to your point in the PowerPoint, what if the pointer expires or the company goes out of business? What do we do as we share more images? Replicate every image of interest, everywhere, for everyone? If so, buy stock in storage companies!

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

Can I add to that, John? This is Dixie.

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

Sure.

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

We need to also consider the accounting of disclosure coming down and how much of what you just mentioned do you have to include in that accounting of the disclosure? Do you also have to capture exactly what quality of image was viewed or downloaded or transmitted?

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

Right. Hey, Farzad or Jodi or Michelle, do we punt back to the Policy Committee to get advice on that one? *[Laughter]*

Farzad Mostashari – HHS/Office of the National Coordinator for Health Information Technology

I think—actually, Dixie, I think for when it goes to the patient, I don't think that there's an accounting for disclosure requirement for—

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

Right, right, but if you're sending an image between two providers—

Farzad Mostashari – HHS/Office of the National Coordinator for Health Information Technology

Right. That's why the focus on the view/download/transmit was a strategy to simplify some of the policy issues around this question.

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

How about the persistence question, Farzad, of do we need to incorporate everything viewed if used for clinical decision making in the viewer's EHR or PACS system?

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

This is Wes. Is there any controversy about that?

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

Our Radiology Department would much rather store a pointer if there was a guarantee that the cloud poster of the images would have them persistent for as long as the state government required them to be available.

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

But is your lawyer willing to trust another practice to—you could argue that there's a new business opportunity for a forensic medical databank that has sufficient governance and there's some certifying organization that says, well, they're not gonna go out of business, they're locating their data in a ROC and so forth, but it seems that, historically, forensic requirements for persistence have not been that easy to meet externally.

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

Yeah.

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

Okay, thank you.

James Ferguson, Vice President of Health Information Technology Strategy and Policy – Kaiser Permanente

Great. Well, this has been a really great discussion. I don't want to take up the whole meeting with it, however. I think we've gotten a lot of extremely valuable input that will help us to go off in the work group and to better define the use case scenarios and what the requirements are, and then we can bring that back to the Committee for further discussion.

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

Great. Well, hey—

Keith Figlioli – Senior Vice President – Healthcare Informatics Premier, Inc.

It's Keith Figlioli. Can I add one comment?

James Ferguson, Vice President of Health Information Technology Strategy and Policy – Kaiser Permanente

Yeah, please.

Keith Figlioli – Senior Vice President – Healthcare Informatics Premier, Inc.

Just something for the work group to consider, and I saw it in the slides, that there was a mention of the U.K. and the NHS system, and I know it's a bit different, but it's a bit nuanced, and I've spent a little bit of time there over the last couple of years. Specifically, NHS Scotland have done some incredible work on the image sharing. Obviously, it's different because there's a national ID there, there's a lot of different things out there, but I think on some of these more nuanced issues, mostly around provider to provider, day to day clinical work flow needs, it's probably worth that clinical work group at least reaching out to NHS Scotland and trying to find out exactly what they're doing and what they have, sort of the pitfalls and the good stuff that they've actually uncovered and some of the work that they've done over the last couple of years. Because it's a lot more telling in Scotland than it is in other parts of the NHS.

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

Jamie, I have many contacts in Scotland. I will contact them and find an appropriate person.

James Ferguson, Vice President of Health Information Technology Strategy and Policy – Kaiser Permanente

That sounds wonderful. Thank you very much.

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

So John Perlin, let us turn the agenda back to you for our scenario based testing update.

John Perlin, MD, Ph.D., Officer, Clinical and Physician Services, Hospital Corporation of America

Well, first, just an absolutely terrific, engaging discussion. The Committee thanks Jamie and John for terrific work, there. I think both of us have actually introduced the utility of scenario based testing. It really brings together a number of threads, most importantly, the ability to support increased operability of standards in the intended use cases.

With that, let us turn over—and I don't know if Scott Purnell-Saunders is on the line.

Scott Purnell-Saunders – Office of the National Coordinator

Good morning; I'm here.

John Perlin, MD, Ph.D., Officer, Clinical and Physician Services, Hospital Corporation of America

Terrific. I understand you'll be leading this presentation, so let me turn it to you, and I don't know if Carol Bean will be there as well.

Carol Bean – Office of the National Coordinator – Director, Certification and Testing

I'm on, but will not be doing the presentation.

John Perlin, MD, Ph.D., Officer, Clinical and Physician Services, Hospital Corporation of America

Great. We look forward to your presentation.

Scott Purnell-Saunders – Office of the National Coordinator

Great. Thanks everybody for joining this morning. I'll be going through just a brief scenario based testing update with kind of some of the events that have happened since our last meeting in August, and then we'll kind of describe where things are currently and where we are moving forward with the rest of the development and piloting, as we've talked about thus far.

Next slide, please. This is the scenario based testing development timeline or kind of the activities that have been conducted surrounding scenario based testing to date. As we discussed earlier, the proof of concept, including the draft test scenario, was published and released on our website earlier this spring. With that developed scenario, we piloted—we developed a pilot with two vendor ETL pairs, which was extremely successful, earlier this summer.

The results of that were extremely positive in that there was a significant amount of time reduced in testing and a significant amount of burden reduced, to the tune of approximately half the amount of time needed for testing conducted in a unit based testing scenario was used to do the scenario based testing as was described. We understand that, certainly, it was kind of done in a vacuum, so it's a little bit different than can be done or will be done with the fully developed scenarios as we finish them, but we were significantly pleased with the results of that pilot. It enabled us to leverage the development of the additional testing scenarios a lot faster and with a bit more improvement.

After that, we developed the planning and completed development of the other testing scenarios. There are two groupings that we'll go into in the next slide and delineate how they were done and the timing, completing the first set along with the second set. Then we, last week, just released the complete set of the first five draft scenarios for feedback on our website. That information is included in a couple slides from now as well.

At the bottom of the slide, you'll see kind of our brief timeline showing where we've been since January with the development of proof of concept, the pilot that occurred in June, the scenario planning that occurred since June and the development and refinement that we're currently engaged in now.

Next slide. Our approach in developing the current crop of the scenario based testing procedures is a split between two specific groups. Group one follows a patient through their contact with an EP or EH through care and follow up; that's notated in blue and is currently available. We published the draft versions of that on our website for feedback currently. Group two follows an EP or EH patient through public health and clinical quality measure reporting. We're targeting that to be available in early 2014.

Certainly, once we can get through the development and the completion of the first group along with the other necessary pieces including, once ONC has approved this process, as an option for testing because, as we talked about before, unit based testing is the requirement for the 2014 edition test method, but the scenario based testing is gonna be provided as an option once we can get this approved. We have to instruct our testing labs and certification bodies in how this will be done exactly, which includes going through our other regulatory bodies, ensuring that they have the appropriate training to do this testing effectively. That will happen hopefully once the group one is approved later this fall, prior to 2014 availability for group one. Group two will follow that same process once we can get group one completed.

It does include—both of these sets will encompass the entirety of the 2014 Edition Certification Criteria set, and the future development will include trying to build out this library of testing scenarios. The goal is to not just have these scenarios be self developed by ONC, but to open it up to development from all sources. For example, if a small developer vendor decides they want to contribute to this testing effort, they certainly can. If research want to get involved, as well, they'll be able to. The idea is to open this up, in a sense like crowd sourcing, to get the best possible scenarios developed and included in this option to try to get this as comprehensive as we can make it in the time allowed. Once those are developed, ONC will, of course, review those, vet them, and ensure that they're functional and operational before we can approve them and include them in the future development for the testing scenario program.

Next slide. The grouping of the developed testing scenarios for group one include these five different groupings. First, the encounter intake; second, the encounter interoperability intake; third was the encounter care ordering; fourth was the encounter care results; and five was the encounter post care. As I indicated before, this basically follows the standard where a typical path that a patient will go through in receiving care in a particular environment. Scenario two, which is highlighted in red, was the one that was conducted during the pilot early this summer, which was extremely successful. We chose this approach due to the availability of the unit tests and how they would connect, understanding that we could get this done in a pretty rapid time frame and be able to get this out prior to 2014.

Next slide. The three scenarios that are on track to be developed for 2014 are the reporting, the privacy and security, and the system, as we've kind of described them currently. They do encompass the clinical quality reporting as we talked about, and those are included and detailed in the criteria list below, and the privacy and security and overall system operations that are needed to kind of pull everything together. With the understanding that these three groupings were pretty comprehensive and intensive, we decided to try to focus on the ones that we knew we could get done in a rapid time frame first, with the target of getting these other three groups done in 2014.

Next slide. I wanted to give you guys the direct address to where we stored the current draft set of the testing scenarios as we put them out currently. On our website, so it's healthit.gov/policy-researchers-implementers, and you can follow the rest of the address. The short way to get there would be healthit.gov/certification, which is directly linked to our site, and you would click on the 2014 test method, and then there's a sublink on there directing you to the testing scenarios area. It provides not only the developed scenarios, but some background information including a narrative explaining how you would walk through a scenario, the specific test data that's required to conduct these scenarios along with the slide deck. Some of these slides have been presented here along with some other ones, giving all of it more background on where we come from and developing the testing scenario process and it provides, also, a method for communicating back to us as far as receiving feedback.

The one change we want to point out as well—we are moving away from our direct on-certification@hhs.gov e-mail address to a GRUB based entry management system. We're asking for or seeking feedback on this through the, on the concept of structured usability and clinical plausibility of scenarios through this management system. Once you click on the link that's below with project tracking certification link, it'll be required that you submit your registration information, which is typically your name and e-mail address and in the subject when you submit a request or inquiry to us, just include that you're notating a response to the testing scenarios that have been posted and we will certainly receive that feedback and categorize it as we move forward in refining these in the next 30 days or so. Because these were posted on September 12th, we're seeking feedback by October 12th to give us enough time to make any required refinements as we move forward with this the rest of this fall.

John Perlin, MD, Ph.D., Officer, Clinical and Physician Services, Hospital Corporation of America

Well, Scott, thank you for a very succinct presentation, and I'm sure we will, as will others, follow your invitation for rapid feedback. Let me just note that a lot of this work was really done with a great deal of reference to a lot of the observations and hearing input that the Implementation Work Group received. As we go to generally discussion, let me invite, in particular, Liz Johnson or Cris Ross to make any comments on their perspective.

Let us then open the floor for any other comments.

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

I have a question. This is Dixie.

John Perlin, MD, Ph.D., Officer, Clinical and Physician Services, Hospital Corporation of America

Please go ahead, Dixie.

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

Walter and I recently have had some conversations about the testing that will be done for the 2014 Edition. I'll remind everybody that the 2014 Edition no longer requires that modules submitted for certification be tested against all of the security requirements or any of the security requirements. We've been trying to figure out exactly what might trigger a module having to be tested against any requirements, but as you present this today, Scott, it does occur to me—obviously, if a product is submitted as a complete EHR, it would have to be tested against the security requirements. If it, as a module, it requests to be tested against the security requirements, that would be tested as well.

I'd be interested in hearing what really would trigger, other than being a full EHR or saying on the security module, what would trigger a module being tested against the security scenario that you have there.

Scott Purnell-Saunders – Office of the National Coordinator

Because we're opening the scenarios up as just an alternate means, it's really up to the developer vendor to choose which way they'd like to go. Certainly, we understand that, and as we talked about it with the pilot, there's a significant savings in time of testing which we can hopefully correlate that to a savings and cost of testing as well. While we haven't done any specific studies of how cost effective the scenario based testing would be as opposed to the unit based testing, we're sure that that would engage some developer vendors to choose that option as opposed to going with the standard unit based.

Also, because there is, the necessity to enter the same information repeatedly is reduced, we get the, we've gotten the opinion from the developer vendor and the ETL pair that participated in the pilot, and that was a significant savings for them as well. While it may not be directly correlated in cost, if they're able to simply pre-load a certain set of unit based criteria that are gonna be connected in a scenario and do that one time with the data that's needed or necessary, it cuts down in their preparation time needed for the test. Certainly, because this is a little bit more flexible and provides more efficiency in testing and processing, we think that it's gonna be a very favorable choice moving forward.

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

Yeah, I'm sure it will be, I absolutely am sure of that—but a lot of the security requirements are not evident in a scenario. One example we brought up recently is encrypting data that are persisted on an end user device. The scenario is not likely to bring up, "Well, this is being persisted on the *[Laughter]* end user device." It's not clear to when it would really—when a module would have to be tested against either the scenarios or just standard testing unless the vendor actually requests that.

I think the scenarios makes it even harder to identify whether it needs to be tested against the security requirements.

Scott Purnell-Saunders – Office of the National Coordinator

Okay. I mean, we'll take that back and certainly, as we're developing that, try to keep all that in mind.

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

Yeah, and of course, we're certainly willing to talk to you about it if you like.

Scott Purnell-Saunders – Office of the National Coordinator

Certainly we'll engage you guys.

John Perlin, MD, Ph.D., Officer, Clinical and Physician Services, Hospital Corporation of America

Okay. Any other comments on this topic that haven't been covered?

We did receive a note from Liz Johnson. Some of you had heard that she is expecting a new great grandchild today, she stopped away, but she notes, "Scott, the implementation work group stands ready to assist in any of the scenario testing and questions that need to be vetted in the future." Many thanks for your work there, and let us proceed on with the continuing agenda.

In fact, let me turn back to John Halamka. There is, obviously, a lot of work that we'll hear in this next set of presentations on FDASIA. As I mentioned, we're really at the inception of building a risk based commenting or providing input to FDA's building of risk based regulatory framework. I look forward to Jodi's terrific synthesis of this work, but then we segue into Doug's activities and it really interdigitates with the comments that Farzad offered at the very beginning about focus and priority, and we'll be seeking a good bit of our input. It also coalesces with our own work plan, which everyone I know has put in a huge amount of effort in supporting, no more so than John Halamka, who's really been helping us keep that work plan front and center for the Committee, so with that, let me turn back to John.

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

Great, and Jodi, we of course want to reduce risk while at the same time fostering innovation, so tell us how we're gonna do that.

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

Great. I would be happy to. Thank you all for inviting me. Last week, folks were interested in hearing more about FDASIA and what we heard from the Policy Committee on the risk based regulatory framework recommendations that they came up with. I'm gonna spend the bulk of my time talking about what came out of the last Policy Committee meeting and the process and where we go from here, but I will also talk a little bit about the Meaningful Use conversation and then some upcoming activities that are going on through the Policy Committee, just to make sure folks are kept up to date. With that, I'll get started.

Next slide, please. Okay, so starting with FDASIA—next slide. There we go. Just to catch everybody up, the FDA Safety and Innovation Act, there was a section that required the three agencies—FDA, ONC, and FCC—to provide a report within 18 months, so January of 2014, which is, as we are very much aware, coming up very soon. It asked the agencies to develop a report with the proposed strategy and recommendations on a risk based regulatory framework pertaining to health IT, including mobile applications, that promotes innovation, protects patient safety, and avoids regulatory duplication.

That is a tall order to try to do all of those things and, in doing that, it authorized, permitted the Secretary to convene a working group of external stakeholders to provide input on the strategy and recommendations to be included in this report. The FDA, ONC, and FCC all agree that we should leverage the fabulous committees we already have and we set up a FDASIA work group under the Health IT Policy Committee to very quickly deliberate on recommendations for us to consider with respect to this report.

The statute also provides a lot of guidance on the composition of the work group to make sure that there is geographic diversity, stakeholder diversity, and a way to include folks from all different kinds of organizations in our Committee. It was in fact the largest work group I think we have pulled together so far or maybe the second largest one, but it was over 30 folks. We had a lot of representatives that we had to get to come to some agreement on talking points for us to consider in a very short period of time. They did a fabulous job.

Next slide. This is the charge to the work group, it was to provide input on the issues and concepts identified by FDA, ONC, and FCC to inform the development of a report for the appropriate risk based regulatory framework.

Next slide. Let me tell you about the process and what's gonna happen from here. We had three months of deliberation, one in-person meeting. They decided, because of the short time frame, to divide it into three subgroups so that they can take on more discussions in a short period of time. One is on taxonomy, the second was on risk and innovation, and the third was on regulation. They did consider much of the prior work that was done in this area, including the IOM report that we received on health IT and patient safety, and they included input from all three agencies; each of the agencies are actually represented on the work group; the public—we did have an open commentary, which I'll mention in a minute—as well as the Policy Committee. They presented a draft input and got some feedback from the Policy Committee, went back and provided their final input at the September meeting.

Next slide, please. We did, in fact, want to make sure that we got very broad public input. While we do, of course, always have an opportunity for public comment at the end of any of our work group meetings, and in this case our subgroup meetings as well, we put out a Federal Register Notice in May to get further public comment, and we did. We told folks that if they got us comments by June 30th, we would be able to forward them to the FDASIA workgroup for consideration, but we left the commentary open 'til the end of August. All of that input will be considered by the there agencies as we develop our report.

Next slide, please. The workgroup final product, just highlighting what the categories and the types of things that they provided to us—they provided a taxonomy for considering the parameters of health IT and what health IT might be considered for a regulatory framework; not how it should be used, but what's in and out. They described current regulatory frameworks, and I have to admit, I learned a lot in hearing about some of the other regulatory frameworks that were discussed, including perceived ambiguities, deficiencies, or duplications. They did also highlight some of the things they really liked about regulatory frameworks that existed and what we should make sure to keep. They provided suggestions to promote innovation in both short and long term and to maintain patient safety. They provided recommendations for the new risk framework, including stratification of health IT by risk and assessment, and they provided us with some use cases.

That's a broad overview. I'm gonna tease this all out in a little more detail.

Next slide, please. The taxonomy workgroup was basically trying to do the scope—what's in and what's out? What are some of the things that we should just not even consider? They're not health IT, or they don't belong in a risk based regulatory framework for us to even consider. Then those that were subject to the risk based regulatory framework and some guiding principles. They weren't so much saying that anything that's in should be regulated, but just should be considered as part of a framework that the government will be putting forward in a report. It may be that there is a particular thing that is health IT, which would be considered by the agencies with respect to this framework, but that in fact there will be _____ discretion and there will be no oversight of that product because the risk is low. This was really a scoping question as opposed to what should happen if it's in scope. The taxonomy was just, "What are we actually talking about, here?"

Next slide. They identified that there were eight dimensions that they were considering in thinking about what was in and out of scope, that there was no single characteristic that determined whether health IT would be subject or eligible for evaluation under a proposed risk based regulatory framework or not, and I just wanted to highlight that to show kind of how they were thinking about the scope.

Next slide. Then they identified certain things that would likely not be subject to a risk based regulatory framework, and I just want to highlight a couple of these—claims processing software, health benefit eligibility software, scheduling and inventory management software, communications applications like e-mail, software using historical claims data that predicts future utilization or cost of care, disease registries, et cetera. They identified certain things that they thought weren't even on the table for discussion, and those things that were _____. I didn't go through—they did a whole lot of these, but I just wanted to give you a flavor of what was in and out.

Next slide. Then the risk group came up with their framework for assessing risk. The patient risk framework that they put forward enumerates various important factors influencing the risk of software systems and devices. It doesn't weight or calculate any specific risk for a given product, but it really serves as a framework to assess the factors to consider when evaluating the potential risks of patient harm arising out of the use of a system. The matrix _____ the relative risk, is it low, medium, or high, of certain conditions, and this they intended to serve as directional guidance only.

Some examples, they walked through a couple of examples and just so you can kind of get a flavor for their conversation, one example, they talked about an mHealth nutrition app or an mHealth blood pressure display app. They said, they went through the calculation, went through the matrix and determined, for instance, that that was a lower risk category whereby a closed loop insulin pump with implanted continuous glucose monitor was mostly medium and high risk and the "more attention" category. Again, it was just a way of thinking about risk and the types of dimensions that went into assessing risk.

The workgroup had an easier time classifying lower risk applications and they had a harder time with some of the more complex software, but they passed this onto us as consideration, since we are putting forward a report on a risk based approach.

Okay, next slide, please. Then I went to the Regulations workgroup, and here are some of the questions they asked. They asked, as I mentioned, “Are the regulatory schemes deficient in any way with regard to how health IT is regulated?” They weren’t evaluating the regulations in their entirety, just about how they applied to health IT and whether or not the construct made sense or not. Whether there were ambiguities in the three systems that need to be clarified so health IT vendors can more easily innovate, because they’ll understand how the rules may apply to them or may not apply to them. Do any of the three regulatory systems duplicate one another? Whose is the duplication question? Is there a better way, setting aside the existing approaches, they talk about, is there a better way to assure that innovation is permitted while safety is assured. They went through what is and then talked about whether or not there were other opportunities.

Next slide, please. These are some overall recommendations that we received from them, and they did a whole lot of recommendations in the slide. It was quite an extensive body of work. David Bates led the group and did a phenomenal job of putting all of this together and getting so much agreement and discussion in such a short period of time. Overall, the recommendation was, there were recommendations about what it is—that the definition of what is included in health IT should be broad, but have some decided solutions, and this is the taxonomy conversation. The patient safety risk framework and example that we’re provided should be used as a building block to develop a more robust and transparent framework which would allow application of oversight by level of risk; that the agency should address the identified perceived ambiguities, deficiencies, and duplications that they identified; and that new framework with some of the characteristics aimed at stimulating innovation could be helpful in thinking about a proposed framework.

The next slide, please. Again, I’m walking through—this is Policy Committee recommendations to the agencies. This is, even though I’m saying this, this is not agency policy, this is just the recommendations that came to us. Next, they talk about that there was not a need for substantial additional regulation of health IT beyond what is currently in place, with some exceptions, and that a new risk framework should support re-evaluation of what’s currently regulated as well as new health IT.

Next slide, please. They went back to the IOM recommendations as well and highlighted a couple of things that the IOM recommended, and these were more on what, not who, the actor should be. They talked for instance about having vendors list products which represent at least some risk, and that there is a non-burdensome approach developed for this. This isn’t who should be doing the listing, whether it’s ONC or FDA or the private sector, but that there should be a way of capturing and listing the product that may pose some risk. Better post-market surveillance of health IT—again, this was called for in the IOM report. They’re not saying who should do this, but that we need to do a better job of it. There needs to be an approach at the national level for aggregating safety issues. Again, similar to what we heard from the IOM, but they thought that there was some federal leadership here that needed to be exerted.

Okay, next slide, please. Hold on a second. My computer just went to sleep, so let me just get back on so I’m with you all.

All right, I’m back. Just to highlight a couple of these, they talked about national accountability, and I’m not gonna walk through everything here, but they talked about using standards a lot, and they talk about international and national standards for quality processes. They talked about interoperability standards to lower the entry costs—again, focusing on innovation—as well as reducing safety by having standards for devices just to be able to talk to one another or for devices to be able to talk to EHRs. They also talked about—and this is interesting—supporting the ability to experiment or early develop products so that somebody who is very intimately familiar with the FDA process mentioned that there is currently, in FDA regulations, provisions to enable sort of beta testing or small tests of a particular product without going through the full FDA approval process. So having sort of safe places for experimentation and sort of development.

Next slide. They also talked about local accountability and leveraging the—talked a lot about implementation process and how we can make sure that software is implemented in a safe way and mentioned Joint Commission as one potential entity that can support that. We do in fact—ONC does, in fact, have a contract with the Joint Commission right now with respect to safety investigations and analysis of safety events in health IT, so that probably played into this recommendation.

Next slide. There were some ONC specific recommendations and some FDA specific recommendations. With ONC, they talked about increasing the flexibility of compliance, making sure that we didn't depend effectively on a single source for information that may be required under our rules or under Meaningful Use, and the increase of predictability, talking about staging requirements and a road map. A lot of things we've heard before, but it was good to hear again.

Next. There were some FDA specific recommendations, and I'll just highlight a couple of these. That FDA should actively establish a policy enforcement discretion for lowest risk health IT where enforcement of regulations is inappropriate, in their view, that the FDA should assess the manufacturing practices for lower risk health IT, expediting guidance on health IT software including mobile medical apps, et cetera. Lots of recommendations that were specific to the FDA as well based on the review of their regulations.

Let me get into next steps here and just let you know where we stand with this. Next slide, please. The Policy Committee accepted the recommendations from the workgroup, and ONC, FDA, and FCC are working collaboratively to review all of these recommendations as well as all the public comment we received so far. _____ consider this work as we are drafting a report for a proposed risk based regulatory approach to promote safety, to promote innovation, and reduce regulatory duplications. We will—I will assure you that we are working very hard internally to hit that January deadline. We'll see how things go in government land, but that is our target. The report will be something that we put out for public comment, so for folks who didn't get a chance to comment during our deliberations with the FDASIA work group, we will put out a draft report and we will get feedback, we will solicit feedback on that report so that once there's something that the agencies put forward, we can have something more robust for folks to react to, respond to, comment on, and help us to understand the implications of what's in the report, and then we will finalize that report.

It is not—and I want to highlight this—we are not taking these recommendations and going and making changes and coming out with new regulations tomorrow. We are taking the recommendations to think through a framework that we will put forward in the report for comment, so stay tuned. Obviously, there are activities—the FDA continues with their activities, the ONC continues with our activities, the FCC continues with their activities as we're proceeding on this. I think this is really exciting and interesting work that can help shape how we think about safety and innovation as a pair and how we think about health IT and kind of reducing risk, but in a way that makes sense and where the government can add value, or where the private sector can add value or whomever, so thinking about this in a really comprehensive way.

Let me quickly move on.

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

Yeah, I wonder, we have two questions on FDASIA. Would it be okay—

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

Do you want to do that first? I know we have a couple more slides, but if you want to do that and then we can go on, that's fine; either way.

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

For just FDASIA questions, we have Arien Malec and Eric Rose.

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

Let me just say one thing, that these, again, are recommendations to us, so these are not endorsed by the federal government at this point, they're just recommendations like your recommendations are to us. I may not be able to kind of go into detail about what they were thinking or what each word meant, but we're taking this as a package. That said, I would be happy to take questions.

Arien Malec – RelayHealth Clinical Solutions – Vice President

Thanks, Jodi. Understood. As I think some people know and maybe others don't, what kicked off this was some language that Congress inserted, as you noted, into the FDASIA reauthorization that was based on FDA draft guidance on mobile medical apps and the draft guidance, rather than looking at a 510(k) approach, does it look like a thing that's been traditionally regulated? Does it act like a thing that's been traditionally regulated? Okay, then it goes in the 510(k) category—created a new class of devices, and it also pointed to some language in the Food, Drug, and Cosmetic Act that took what I thought was a little bit of a stretch about contrivances to diagnose disease, and using that as authorization for having oversight for clinical decision support as a category. Because most EHRs these days are deployed or are deployable in formats that can be viewed on tablets, viewed on other mobile medical devices, based on that draft guidance, EHRs that supply clinical decision support—which, per ONC regulations, is all of them—would fall under FDA draft guidance and be classified as medical devices.

I'm wondering if the—just a couple of things on that, just from a technology perspective, looking at whether something is renderable on a medical device, and just to note the draft guidance had an explicit trigger condition that if you had html that was specifically renderable on a medical device, it would be classified as a medical device. From a technology perspective, the line between a mobile medical device and an EHR is pretty much nonexistent these days, so I'm wondering whether the FDASIA workgroup looked at that issue specifically and then secondly, whether the FDASIA workgroup looked at the issue about whether clinical decision support should be regulated under FDA or whether it should be regulated instead by other means and what the appropriate agency is for regulating particular classes of health information technology software.

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

On the first question, this is sort of in process now, as far as the guidance. I don't recall specific conversation about your first issue, although there were like 35 meetings in the course of three months, so I did not hear every conversation. I don't have an answer. I don't know if Steve might be on the phone, feel free to jump in, Steve, if you are aware of that conversation.

With respect to the second on CDS, there was conversation in the context that yes, it's in scope, the consideration on how you deal with CDS, and they did talk about how it's hard to classify a particular CDS does one thing, because there's all different kinds of clinical decision support, and you have to look at the framework, the risk framework, for figuring out if it's low, medium, or high risk. There might be some CDS that's low risk, some that's medium, some that's high, and so they were looking more at use cases and how certain use cases may fall in the risk paradigm as opposed to a class like CDS. This is my view of how they talked about it.

Again, they sort of stayed away from the “who” question, like, “FDA should do this,” or “ONC should do that,” but more of, “If something is risky, you need a greater level of oversight or consideration than something that's less risky.” They didn't categorize all of CDS as one thing and say, “FDA should regulate,” “FDA should not regulate,” but more looked at it based on those criteria that are in the risk matrix and suggested that we think more of those building blocks as opposed to categorizing a particular product. Does that make sense?

Arien Malec – RelayHealth Clinical Solutions – Vice President

It does. I think there's, depending on how this plays out, there's kind of a looming issue in that some of the feedback that we've been hearing from Congress is that Congress never intended to regulate EHR software under FDA oversight and so at some point, that issue needs to get—and I think it doesn't meet the plausibility tests, the clinical decision support that's offered through, for example, a website that's renderable on an iPad is ipso facto a medical device. There's a looming issue there that does need to get resolved at some point.

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

Thanks. Eric?

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

Hi. Eric Rose here. I think the FDASIA workgroup deserves a lot of credit for tackling head on something that's been a hugely controversial and, at times, acrimonious issue, one of the most, I think in the field of health care informatics for years, and obviously a huge amount of thought and care was taken.

There's one thing that I don't, it doesn't sound like really has been addressed, though, and I'm wondering if this has been discussed or how it's been discussed. What I hear most from in the trenches physicians as far as frustration that relates to things that FDASIA might deal with are the issue of software defects. Things like data, when you're looking at data on one patient, the software displaying data on another patient, or miscalculation of calculate values like the weight or height percentage for tracking the growth of a pediatric patient. What I hear from vendors, on the other side, is that often—there are some things that are absolutely, uncontroversially software defects that could affect patient safety, and then there are other things that, from the perspective of the end users, might be perceived as a defect but may actually be a design issue.

I'm wondering, how does that—and if you talk to people who feel that health IT needs to be regulated, that's the reason why they feel it needs to be regulated; at least, that's what I hear most often. Was there any discussion of how to address that within current or new frameworks?

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

I mean, I think that, again, there wasn't a, "This particular thing needs to be regulated in this particular way," kind of. We didn't ask them to focus on that, we asked them to give us the things that we should be considering in developing a risk based regulatory framework that—recommendations that would kind of run the gamut of different kinds of health IT products that they defined as within scope.

They did talk a lot, though, about the technology versus the implementation and part of the reason that they wanted, I think, the device listing was to have a better sense of what's out there that people are marketing. They have the recommendations on implementation, they have recommendations on surveillance so that we can better understand what the problems are, and whether there are implementation problems or design problems. There was—I think it underlined a lot of what their conversations were, but they didn't specifically come out and say, "This thing should be regulated by FDA, by ONC for these reasons." It just—that wasn't sort of what we had asked them to do or what they really focused their conversation on.

We heard all of that, though, in the discussions about, “What are the things people are concerned about? What are the complicating factors? Why—because we’re talking about design versus implementation, because we’re talking about the sociotechnical environment, that sometimes, that one approach, like an FDA approach may not work because it’s really an implementation issue, and an implementation over a _____ approach may not work, it’s really a design issue. It’s complicated, and they actually have a hard time with some of that, teasing that out, honestly. That’s how they ended up with that risk matrix to identify those things where, if there is a problem with the product or the implementation posed the most risk and therefore should be considered differently than things that pose less risk. That’s how they thought about it rather than specific, “This agency or this organization should do X for these specific products.” Does that help?

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

Yes, I think so. I think that it might be worth exploring a little bit what can be done in that area that’s fair and pushes us towards more just understanding the problems better.

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

Yeah.

Leslie Kelly Hall – Senior Vice President for Policy – Healthwise

Jodi, this is Les, and as I understand it, EHRs are under FDA regulatory oversight today, they just have not exercised that right. As to Arien’s point, it’s as important to know what will be ignored [*Laughter*] as it is what will be enforced.

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

Yeah, so there was a lot of conversation about clarity by FDA about how they are using their enforcement or their enforcement discretion, and that came out a lot in the mobile medical apps phase. You are correct that FDA has very broad authority and that health IT, that EHR could be considered a device within FDA’s authority. They have not been—they haven’t said much about EHR. [*Laughter*]

Again, it was—there was a lot of interest in, “Well, if we already have ONC as their certification program and we want to avoid regulatory duplication, so it will be confusing if we have two agencies try to look at the same thing”—again, in the regulatory duplication conversation. Yes, in fact, they have authority to do more than they are doing in the space. They do, in fact, have a risk based approach. They have their classes of devices, but they also have been very cognizant of avoiding regulatory duplication and of not—and of the concern about stifling innovation—and have been working very collaboratively with us, I have to admit, on thinking about this issue and these problems that are really challenging.

Based on my interaction with the FDA, they really are trying to figure out how to work well with us. I think that whatever comes out in this draft report, and it is something we’re actively working on, will be a true collaborative effort of the agencies and will represent kind of all of these issues and will be—it’s gonna be hard. The work that’s been done has been tough, but the work that’s to come is gonna be, I think, equally challenging on our part to try to pull this all together in a way that makes sense, but addresses the issues Eric was saying about safety, but also addresses the issues of encouraging products to be developed that really help improve health and health outcomes.

Arien Malec – RelayHealth Clinical Solutions – Vice President

Sorry to pile on—this Arien again. Just as an unsolicited point of opinion, the existing 510(k) registration process wasn't broken. In the advent of mobile medical devices, I think you could argue that the app that I have on my iPhone that measures my pulse would meet an existing 510(k) registration process, and maybe there's no need to fix it. Then I also want to follow Eric, I sometimes jump into these comments without the prior niceties, that the risk based framework that the FDASIA workgroup put together is a thing of beauty, and I do want to commend the FDASIA workgroup for that work.

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

Well, given that we are about 15 minutes behind schedule and we do want to give Doug Fridsma plenty of time to introduce his topic—Jodi, if you could just go through your last couple of slides and we'll get right to Doug.

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

You got it. Okay. Let's get back up here. All right. Meaningful Use—next slide.

I just want to give folks an update—you can go over to the next one—on our conversation in the policy committee meeting on Meaningful Use. The Meaningful Use workgroup—and this was approved by the Policy Committee—developed overarching principles and high level outcomes framework for guiding Meaningful Use stage three. This was presented on September 4th. The focus here is more on outcomes, less on the threshold for the objectives, more focused on the key principles and concepts that should be included in the MU3 and how those key concepts link to outcomes—so kind of taking it up a level and looking at the big picture and focusing on an outcomes perspective. This outcomes framework was approved by the Policy Committee, and it will guide further consideration for Meaningful Use three this fall. They're gonna start going a little more deep on this, but they just provided the framework for their next conversation.

The outcomes that they talked about in the outcomes framework were six—improving quality of care and safety, engaging patients and families in their care, improving care coordination, improving population public health, affordable care, and reducing disparities. If you go to the next slide, you'll see that this is, we actually did a cross walk with the National Quality Strategy priorities and identified how these are connected to those priorities. If you look, there is a lot of alignment between the Meaningful Use workgroup outcomes framework and the National Quality Strategy, which was intentional.

Next slide. They are planning to move forward with more detailed recommendations within this framework for a presentation in November. There were three key areas, the functional objectives, so they will be talking about and providing detailed recommendations on functional objectives that are expected to build on the outcomes framework. They'll be deeper than what's in the functional objectives, but they're gonna be focusing more on the concept than the specific percentages—so getting the concepts right as opposed to trying to figure out if it's 10 percent or 15 percent.

For example, for care coordination, they decided to focus more on the types of transitions in care where a summary of care document would be needed, and what that summary of care document must include to be effective as opposed to the percentage of EPs that have to implement—there's a percentage of times they have to make that summary of care document available. The second was deeming. The recommendations will be on the potential for an optional functional deeming pathway for Meaningful Use attestation. That will be—we'll be interested to hear what they come up with in November on that. Last but not least were the eCQMs. We have an Accountable Care Clinical Quality Measure Tiger Team that is conducting an analysis of current and pipeline eCQM measures that would be most important for stage three and for a deeming pathway. We expect those recommendations for November as well.

Next slide. Okay, next one. I think this is my last slide. Okay, so I just wanted to let folks now about some upcoming meetings, hearings. There's gonna be two upcoming hearings. One on advanced directives, it will be a virtual hearing, and that will be on the 23rd. That's the Meaningful Use workgroup. The second is on accounting for disclosure, this is our Privacy and Security Tiger Team, and that will also be a virtual hearing on the 30th. I wanted to let folks know in case you wanted to look into those. Finally, I wanted to let folks now that we have charged the Certification Adoption workgroup of the Policy Committee with recommending a process for prioritizing health IT capabilities for volunteer EHR certification that would improve interoperability across a greater number of care settings. This is really looking at those entities, those providers that are not eligible for Meaningful Use but who would benefit from having an EHR and having certification criteria and certified products to choose from.

We've asked the workgroup to look at this. We have two Standards Committee liaisons, John Derr and Stan Huff, so thank you both for volunteering. I also wanted to let folks know, in line with this, that we just published certification guidance for EHR technology developers that are surveying the ineligible health care providers. The goal there was similar, which was to focus on interoperability criteria that could be leveraged for products by non-eligible providers and that can help with exchange of information between those entities and entities that are adopting certified EHR technology today because of the Meaningful Use program. I wanted to draw people's attention to that, and I think that is it for me. Happy to pick up if there's a question or two; otherwise, turn it over to Doug, whichever you prefer.

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

Well, so hey, maybe one, two questions max, then over to Doug, because we need to give him time. Any comments on that last portion on Meaningful Use and the Policy Committee update?

Okay, well, hearing none—John Perlin, hey, I turn it back to you and we'll charge ahead with Doug's presentation.

John Perlin, MD, Ph.D., Officer, Clinical and Physician Services, Hospital Corporation of America

Well, I'd say, why don't we both turn it to Doug. I think the trajectory has really been a great segue and Farzad at the outset inspired us to think both about the evolution and big picture, but also prioritization value and the most compelling immediate business cases. I think, Doug, you'll tee up some provocative discussion around these questions.

Doug Fridsma, MD, Ph.D. – Chief Science Officer and Director – Office of Science and Technology

Sure, so thanks, John—and John. We had a really good call, I guess, last week in preparation for this particular meeting. We've included in the packet sort of two things that we hope people can take a look at. I'm gonna go through those as well, as we go through this presentation. We've shortened the presentation quite a bit, so that this isn't a didactic discussion or update but really an opportunity for teeing up some conversations among the committee.

Let's go to the next slide. What I'd like to do is talk about some of the current things that we're working on and describe a little bit about the Structured Data Capture and the data access framework, kind of give you an update on that, because that's one of the things for which we have a number of different use cases that it's supporting and so one of the ways that we can prioritize things is if I can develop one suite of building blocks, but use it in many, many different ways, that's something that I think really leverages the time and the effort effectively.

I want to talk a little bit about kind of this three bucket prioritization. We talked about this probably, I guess it was last summer as well, when we think about how to look at the work that we're doing as well. There's a lot of activity that's going on, and so rather than sort of diving into all of the activity, I'd like to provide an Excel spreadsheet and a brief presentation that will allow people to take a look at that activity and help us understand where the industry is at and where the vendors are at and where providers are at in terms of helping to guide the conversation about the work that we do.

Let's go on to the next slide. When we think about the things that are currently on the plate, the things that we have been focused on right now is to take a look at the Structured Data Capture, and it should, because it covers a number of different use cases, all the way from public health and preauthorization to safety reporting, and there's a whole host of things that we think that this is going to be helpful for. We talked a little bit about the data access framework and what we're trying to do there, particularly as it relates to making sure that patients can move their information from one EHR to another EHR and providing that basic functionality that will allow that to occur.

Looking at APIs, this is something that we heard from this committee about an important way to move forward and certainly some of the more recent recommendations looking at the HL7 FHIR resources, for example, are very much along the lines of APIs, and so we've been examining that as well. Then, of course, quality and clinical decision support, things that are gonna be really important for us as we look ahead towards being able to measure what we do and improve the work as well.

That's gonna continue, I think, for really the next 12 months or so, and then there are some other things that we're working on that I think are longer term. One is to sort of expand our data access framework, and we'll talk a bit more about that as well as some of the work that we're doing with the EU and the U.S. While we've targeted this for a plus 12 months, more recently there's been significant international engagement, particularly from the U.K. and, of all places, Slovenia. They are quite interested in helping move things forward, so we may actually have those countries do more of this work, accelerating the work that we're doing here domestically as well. I'll update you as things move along.

Let's go to the next slide. When it comes to the Structured Data Capture activity, remember, what we're trying to do is extend the functionality of an electronic health record so that it can capture additional information for which it wasn't sort of initially constructed to do, so new data that may need to be captured that wasn't built into the system to begin with. Providing a flexible framework that allows an EHR to go and access a former template, fill in that information or that form, and then make sure that that information has been accessed, displayed, populated, and then saved.

We've got a number of work streams that are going on with this. One of them I think that is critical is around Patient Centered Outcomes Research, or the PCOR activities. This is really an effort to sort of provide basic functionality in EHR so that if some provider, either in the community or in the larger practice, wants to be able to participate in clinical research activities or quality improvement initiatives within their organization, they have the ability to capture some additional information, either an electronic case report form or the like, and be able to then save that as part of their care delivery.

We're also working very closely with AHRQ and common formats, because that's an area in which patient safety reporting is really important, and if you wanted to do that as part of having that functionality within the EHR, we've constructed the possibility within the Structured Data Capture initiative that you can capture that supplemental information around a patient safety event and not worry that it would be stored within the electronic health record, it would really go directly to the patient safety organization and not be stored within EHR. We're also working with public health, because obviously things like epidemic outbreaks or new diseases that need to collect information as well as their ability to do case findings can be supplemented by using the kinds of functionality that Structured Data Capture is trying to achieve.

We've got the technical workstream that's working on trying to figure out what are the appropriate metadata or attributes of a common data element. It's important to understand that we are focusing primarily on syntax, not on semantics here. We just wanted to be able to say that if I wanted to collect a data element, what's the appropriate metadata that we would need to capture that would allow a system and a provider to be able to track that information. That all needs to fit into a form and a template structure, and then we need to figure out sort of the APIs or the interactions related to how the EHR would interact with that and how it might auto-populate.

Let's go to the next slide. The use case that we're looking at, and this has been presented before, is that one would hope that over time, it would be possible that we could construct common data element libraries that are based on a common syntax. That would include clinical research or AHRQ patient safety or other sorts of domains, and from that, you could generate form. Those forms then, through the electronic health record system, could go and access those forms. Those could exist on a URI some place or a URL. You could then display that form in a window within the EHR or in some fashion it would be displayed, and then you could capture that information either automatically, if it was information that the EHR already knew about, or that the provider or nurse or whoever could enter that information directly into that form.

Next slide. So, when we think about the deliverable that we want—number one, CDA structure, is about getting that meta-data, and that's gonna be the part that would populate this forms library or this CDA library. There's a template or container that then would be populated with these common data elements. The EHR interaction is really gonna be drawn from some IHE standards, and we've got good participation from both CDISC and IHE in terms of how that interaction should occur. Then the auto-populate is something that would say, if the data is already part of known data within the EHR, is there a way that we could simplify things by putting in demographics, for example, or date or visits or other things like that, that then could be populated within that particular standard.

Next slide. Currently, we're looking at two different implementations; one that's based on REST and OAuth, and this relates very much to the recent recommendations that we got from the HIT Standards Committee, as well as one that is looking at SOAP and SAML, since that was one of the actual criteria that we had in the past, Meaningful Use stage two. We've had very strong participation from the AHRQ and National Library of Medicine, and they are kind of kicking off and leading the Forms workgroup, and they're currently drafting kind of what the relevant implementation guide sections might be incorporated.

We're working—we're gonna be, we've also kicked off a Standards workgroup that's trying to select the standards both based on CDISC, IHE, and HL7 kinds of standards. They're planning to go through a consensus, and they're taking a look at the various IHE profiles, particularly one called RFD. They're now moving into some of the other use cases, particularly public health and some of the pilot outreach, including GE, Greenway, and QuadraMed. Some of these organizations and vendors have already piloted some of the RFC implementations, and so they are keen to be able to take a look at that.

Things are moving along quite productively. This is a very nice group that has a lot of interactions. There's a lot of moving parts to this, but we think if we can focus on the syntax and leverage existing standards that are out there, look at both restful approaches as well as web services, we think we might be able to help support a use case that would provide this additional functionality to an electronic health record.

Let's go to the next slide. The second initiative that I want to just update people on was what we call the Data Access Framework, and I think this brings together our notions of trying to make sure that patients have access to information if they were to change providers and the providers had different EHRs underlying it, make it possible for providers to get access to their information to do sort of small data analytics and understand how to improve their work process and manage their patients more effectively. It also incorporates this notion of targeted query, because if I can ask a question of EHR, like, "Give me this particular patient's most recent clinical summary document," if you add to an authentication and authorization framework and a way of transporting that question, you can actually start looking at—it starts to look an awful lot like this notion of targeted query that Farzad and others have talked about before.

I think that's our principal, our initial scope—we understand that when it comes to kind of the broader vision, there's also something around query health, and that if you can do this in a targeted and a distributed way, if you add consistency with information models or other things like that, you can actually have this ability to get both local enterprise and sort of de-identified access with questions around query health, all under the same rubric.

Our initial focus is primarily on the local data access to provide that mechanism of extracting information relevant to a patient and allowing them to bring it to a different provider or a different vendor, and this notion of targeted data access to provide, when a provider has access to a known individual, the EHR record that, at the time that the patient was seen, the CT results perhaps hadn't been read out. That's, I think, where we're initially starting with this Data Access Framework.

Let's go to the next slide. This is sort of just a graphical representation of what I sort of first talked through. The first is about local access, the second is sort of targeted access, and then the third is sort of this distributed access or distributed query. We're really, what we realized is that all of those different initiatives—patients, targeted query, and our query health activities—really were all about access. If we looked at them as a collective unit, we might be able to provide reusable building blocks to make that happen.

Let's go to the next slide. Again, this is just for your review, this notion of having the ability to access that information, getting lab, radiology, pharmacy out of the electronic health record and having the provider get that kind of information. It may be that our low hanging fruit is to at least get those things that are structured, that are currently part of Meaningful Use stage two, and I think this community is just getting started to kind of look at those use cases as well.

The next slide. We launched, on 07/16, we've got consensus on the charter just at the end of August, and so we're starting the use case discussions now, the middle of August, launching the user stories at the end of August. We're really only a couple of weeks into this in terms of taking a look at things. As I said, patient portability, the ability to get data from one EHR and move it to another to empower them if they change providers to not have to go back to paper, and to see, from our innovation community, whether having that standard API or that standard access into the EHR might provide value to the providers to do small data analytics. They're not gonna have the ability to have a clinical data warehouse, but they may have the ability to actually ask some of those questions, because they have the ability to sort of put it, plug in an analytic tool on that as well. Currently we're drafting some short proposals to submit to IHE. We're trying to get those done by the end of this month, and then we're gonna continue to work, I think, on the targeted access query as we work through the use case development through October, November, and December.

Let's go to the next slide. Before I go onto this, if there's any just brief question about kind of where we are with Structured Data Capture and the Data Access Framework activity?

John Perlin, MD, Ph.D., Officer, Clinical and Physician Services, Hospital Corporation of America

The floor is open for any comments. John, I don't know if you want to start.

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

No specific comments. Of course, the meat of our discussion, I'm looking forward to the—these are great, and what, in the next year, in addition to these, should we focus on, given that these are foundational building blocks, and I'm all for building blocks?

Doug Fridsma, MD, Ph.D. – Chief Science Officer and Director – Office of Science and Technology

Okay. Let me then go on to the next section of this presentation. One of the things that we included in the packet that got sent out to the members of the HIT Standards Committee was an Excel spreadsheet that included a whole host of information that can be visualized in a variety of different ways, and I'm going to go through each of the tabs in that Excel spreadsheet as a way of sort of guiding the conversation that we might have.

The first tab that we wanted to take a look at was, we went back to the recommendations and sort of the priorities that we got from the HIT Policy Committee and that the HIT Standards Committee took a look at. What we did is, we included in the spreadsheet this notion of all the topics—so, lab orders, digital signature, image exchange—what that topic description was, what the current status of that was with regard to our HIT Standards Committee work plan.

Then we included a tab that said, “We need to hear from you, the HIT Standards Committee, about whether or not there are currently problems either with the standards or with the technology or with how our approaches that would require us to get some bug fixes in there.” Maybe this is something that is such an urgent priority we need to make sure that we include it in our ongoing work, and some of the other things that may be more aspirational. Maybe our eyes were bigger than we thought when we started and that we may need to think about deferring those. Now, it's really important to understand that there are certain things that have dependencies and other things like that, and just to get a sense of where we are out there. The first tab is about the HIT Standards Committee work plan, and the amount of work that we've got going on there, all the things that we set up at the beginning of the summer, some of which have lagged just because of the volume of work, and help us understand, reprioritize, if you will, where we need to focus our energies.

The other thing that we did, and I will go to the next slide now—the other thing that we did is, we took a look at the current Standards and Interoperability Framework activities and did a cross walk of the Meaningful Use recommendations or the Meaningful Use sort of activities that came from the HIT Policy Committee and the Standards Committee. What we did is, down in the column, we took a look at all the S&I framework initiatives, like Transitions of Care and LOI and Query Health. We then linked that to specific recommendations like how to manage summary of care and how to do referral reporting, or interdisciplinary problem lists with the numbers that are assigned to that particular discussion item, if you will, from the HIT Policy Committee and, again, provided an opportunity for people to be able to indicate whether there are big fix activities, this is an urgent priority, or whether it's aspirational. The first half talked about the HIT Standards Committee work plan. The second talks about our current S&I Framework activities mapped against some of those Meaningful Use topics that we had earlier in the year.

Let's go to the next slide. The third tab talks about potential new S&I framework activities or new Standards Development activities. When we did that cross walk in tab two, there were a number of things that were listed that did not have an existing Standards Development activity. For example, on clinical care and patient safety, one of them was, “Consume external; never drug-drug interaction.” So being able to provide that kind of support to EHR and being able to consume that stuff directly, or to be able to enable the EHR to implement alerts to newer event rules provided by external resources and to sort of bring those things in. There's some about consumer empowerment, care coordination, infrastructure of health IT, including stuff around medical devices that we just heard about some of the activities going on around medical devices as well. Again, prioritize this in terms of bug fix or do you prioritize in aspirational activities?

The final view into this stuff is that there's a number of things that are currently getting at varying levels of ballots. Next week is the HL7 fall meeting. We've got a number of ballot items that are currently in process, and so all of these things are being reviewed. Some of them are kind of bug fixes, some of them add new functionality, but just to give you a sense of what's currently in process and where people view these things in terms of their priorities. Now, if something is in a ballot, obviously, it's fairly mature in terms of the standards process, but I think it'd be important for us to understand from an industry perspective whether these are things that we really need to accelerate the ballot reconciliation activities, or whether these are things that we need to just sort of take a look at and maybe consider reballoting or taking a look at at the next meeting at HL7, which would be in January.

With that, we'll go to the next slide. I just have a slide—this slide, here, talked a bit about just recognizing all of the folks who have been working on this. As you can imagine—where are we, on three buckets? We have to go to—are the slides advancing properly? Or maybe mine's just not updating at this point.

Michelle Consolazio – Office of the National Coordinator for Health Information Technology

Which slide did you need to be on?

Doug Fridsma, MD, Ph.D. – Chief Science Officer and Director – Office of Science and Technology

We're on Current S&I Ballots. I want to go to the next slide after this one. There we go. This is just a reminder that I want to send a special shout out to Mera Choi, who has been leading a lot of our S&I Framework activities. Lauren Thompson, who has been working with the division; she leads the Standards Division in OST. Really, the team of the S&I Framework coordinators and contractors that are helping support this as well as the community that has been really just accelerating and doing all of this work.

It can sometimes be overwhelming, but our job is to sort of help support them and to step back and, in large part, that's my role as well, to allow Mera and Lauren and the team to be able to really do this work. This represents a really very thoughtful analysis of all of the activities viewed in four different ways, and I hope that this will provide the fodder for folks to take a look at, fill in, ask questions, and provide us some feedback about where your head is at and where the industry that you represent is thinking about this.

With that, I'm gonna turn it back over to the Johns.

John Perlin, MD, Ph.D., Officer, Clinical and Physician Services, Hospital Corporation of America

Well, let us open the floor for any comments.

Arien Malec – RelayHealth Clinical Solutions – Vice President

This is Arien, I've got one in the queue.

John Perlin, MD, Ph.D., Officer, Clinical and Physician Services, Hospital Corporation of America

I thought there'd be one. John Halamka, do you want to offer any framing and then we'll go to David McCallie next?

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

Exactly what I was going to frame, which is that we began this year, as Doug has suggested, looking at gaps and looking at, with Meaningful Use stage two and other regulatory activities, where we might need to do additional work on the Standards side; of course, thinking about stage three and the Policy Committee's request of us as well. I think what we can see now is, we created an omnibus list of all the things that we could work on, but now, when we would look at the actual reality of implementation, we look at the advances being made in Standards development like FHIR, the interest in adopting RESTful approaches. What is it that we should narrow our focus to, given our volunteer time, *[Laughter]* and given the environment around us? Doug has teed up nicely the activities of the S&I Framework and the ballots that are in process. I think it's important for us to reflect at our next meeting—how do we skinny down the list of all the things on the Standards Committee agenda so we can focus on a few things and get them done well?

Please, let's—comments, I'm happy to hear thoughts on the framework, how we prioritize, and the work in process.

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

Okay. Are you ready for David?

John Perlin, MD, Ph.D., Officer, Clinical and Physician Services, Hospital Corporation of America

Yes, please, David.

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

Okay. This may be a little too detailed, but there is a higher level question embedded in it. Doug, you covered a lot of material, as usual, and it went by pretty fast, but I was confused by references to data portability in your discussion of local use case for the Data Access Framework and when I'm looking at the slide, I see provider to provider, but you mentioned patient to their own record and then data portability which, to me, brings the question of, is this the case of somebody moving their EHR—their record from one EHR system to another EHR system? I got lost in what the focus of that use case was. Could you clarify that, or maybe just tell me it's too detailed and I need to go to the workgroup?

Doug Fridsma, MD, Ph.D. – Chief Science Officer and Director – Office of Science and Technology

So the initial use case that they're looking at is sort of twofold. One is, is that if a patient comes to a doctor and says, "My insurance has changed and I've got a new provider. I'd like to have a copy of my record in an electronic format that I can bring over to my new doctor." Oftentimes, a Transitions of Care summary or the copy of the most recent note may not be sufficient. There may be other kinds of information that would be relevant to be able to have that patient move their information from one system to another. Currently, there's no sort of consistent way of providing a patient—I wouldn't call it a longitudinal care record, but I would just sort of say sort of the collection of information in electronic format that another electronic health record could import.

I think that's one of the use cases. I think the other use cases is that, we discovered in the Query Health activities and certainly we've looked at it in the targeted queries that we've made it very easy for people to ask questions of the data who aren't the ones who answered the data in the first place. We've heard from some of the providers that oftentimes it's a challenge to ask sort of simple questions and get information out of the electronic health record in sort of a consistent way. This particular group within the community is just taking a look at those questions and trying to see if there's a need for other kinds of standards or other ways to sort of have that functionality.

It's sort of two. One is—and I think the one that's perhaps the most important—is that of a patient who changes health plans and changes doctors who may use a different system shouldn't be penalized because of that and have to lose all of the electronically captured information from the first EHR when they moved to their new provider. Then the second is really about trying to provide some value to the providers as well as we add some _____ more and more of this data.

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

This is David. Thanks. That's what I heard, and I just wanted to make sure I heard both of those very clear. Just my two bits of feedback on those particular use cases is the notion of an export/import format obviously would have to be standards based, otherwise it would be sort of pointless. On the second one, the ability to get the data back out of the EHR, I'm not so sure I see a clear—just for a provider to do something with it, a clear case for a standard, but that one I'm just a little bit less clear about. The export/import certainly would have to be Standards based, but I'm not sure I would call that a Data Access Framework. That's really export/import, which, this may be a good workgroup to deal with it, but that certainly has a more complicated, that's not a—that's a batch operation; in other words, a more complicated set of constraints.

Thanks for the clarification.

Nancy Orvis – Director – National Health IT Standards Participation and IM/IT Integration, Department of Defense

Nancy Orvis has a question and comment when you have the queue set up.

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

Wes Rishel is also in the queue.

John Perlin, MD, Ph.D., Officer, Clinical and Physician Services, Hospital Corporation of America

Okay. Please go ahead, Nancy, and then we'll go to Wes after that.

Nancy Orvis – Director – National Health IT Standards Participation and IM/IT Integration, Department of Defense

Okay.

John Perlin, MD, Ph.D., Officer, Clinical and Physician Services, Hospital Corporation of America

Sure, and Doug, any time you want to jump in, please do jump in.

Nancy Orvis – Director – National Health IT Standards Participation and IM/IT Integration, Department of Defense

Yeah. Doug, as a duty provider and payer or whatever, I really like this summary of your three buckets and what's going on. I think one of the questions, I wanted to follow up on Dave's issue of the import of transferring a record, I would hope—I mean, that's what the British National Health Service and Canada has been trying to do already. I would suggest, is there anything else we can leverage already, since they're trying to transfer records from province to province?

One reason I would like to focus on these last three slides is, it's—given all of the, how to engage for a provider organization or an insurer or any vendor, this is a very good look at what is the most bang for the buck that you need a particular kind of representative in, whether you need a government entity or a vendor or an other provider organization. I would welcome—I've noticed that we haven't had a lot of time in the Health IT Standards Committee meetings to talk about the best way for various members to engage. I would welcome your comments on where individual organizations or whether it would best be able to do that since everyone has limited resources and they can't involve, get involved in all of these projects in terms of helping set priorities.

Doug Fridsma, MD, Ph.D. – Chief Science Officer and Director – Office of Science and Technology

Sure. So, Nancy, part of what I—we probably won't finish the dialogue or the conversation today. This is really, I think, to kind of tee up that conversation, but the spreadsheet that we sent out includes the ability for people to sort of enter notes in their priorities levels across every single one of the different initiatives and different ways of viewing things. What I'm hopeful is that this can serve for a way for people to start focusing on just the things that you're talking about, like what are the things that we believe provide the biggest bang for the buck? What are the things that we should prioritize or think about? We can then use that to sort of help people understand where to target their energies, to be able to sort of come back and say, broadly speaking, we've got lots of feedback that said, "These are some things that are gonna be really important." Just sort of share that information and allow people then to say, "If you want to then engage in some of the things that people really, from the HIT Standards Committee feel is important work, here are the areas in which we might be able to do that."

That's why we provided both of you into the HIT Standards Committee work plan. Those are the things that we were gonna try to have in the committees to review. We took a look at it with regard to the S&I Framework and kind of a cross map there. We took a look at the things that aren't currently being covered but maybe could be, and then also to just take a look at the things that are out there in the ballots, because those are the furthest along, and just to give kind of situational awareness as to what's coming down the pike.

Nancy Orvis – Director – National Health IT Standards Participation and IM/IT Integration, Department of Defense

I think that's great. Let me give a use case that I see is coming up very high priority in the consumer area. A colleague of mine fractured their collarbone on Cape Hatteras, so they were hospitalized for three days at a hospital there, they went back to Philadelphia where the Penn University system has really nice online stuff, but her discharge summary from this other hospital on vacation was on paper. The question of, did that information get from the North Carolina providers back to her health care provider was all of a sudden a very interesting topic for a bunch of people who are getting health care in different states, or traveling around.

I think they were all excited about, well, each provider is supposed to give you an electronic copy of what they have—but they're finding that they aren't getting electronic copies; only from their home care provider are they getting it. I guess that's one thing I would say. I think consumers are gonna start saying, "Well, if you have an EHR, why aren't you able to do that, and why can't you send it to my other provider?" I think that's something that maybe we could help address in the next year or so.

Doug Fridsma, MD, Ph.D. – Chief Science Officer and Director – Office of Science and Technology

I'll just say one brief comment there. Obviously, if that's something that is not covered on some of the current initiatives as you reviewed the Excel spreadsheet, I think people should feel free to add to, I think it's tab three where we've got new initiatives, to say, "Here's something that the HIT Policy Committee and the Standards Committee and the current work in the S&I framework are currently not addressing. It may be something new, or something that we hadn't really thought about, and to add that in and create a priority around that as well.

John Perlin, MD, Ph.D., Officer, Clinical and Physician Services, Hospital Corporation of America

Let's go to Wes. Wes, you had your card up electronically.

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

Thank you. I am at risk of being a little out of order here, because I'm just looking for a place to stick in some related comments, but they aren't laser like focused on narrowing the channel for next year. In my, one of my volunteer jobs is to serve on the board of a Health Information Exchange in a rural county in California. One of the things that we're constantly battling is the issues other than the technology standard in actually getting data from certified EHR vendors or into certified EHR vendors. I don't know if there is any lever to avoid some vendors charging substantial amounts for these interfaces or not, but at least I think we have a need somewhere in the Policy or Standards Committee to have awareness of the actual results of getting lab data interfaces running, to take one, for example, and certainly the newer data types that we're contemplating in stage two. There needs to be some sort of a spotlight shown on who's actually doing it as opposed to who's certified. This is definitely out of line for Doug's presentation, but I wanted to get it.

The other thing that's a little closer to the overall S&I Framework process is, I think it's worth putting some expert into documenting trial use. I had the occasion to read a paper as a referee for a journal recently that was documenting trial use of a certain standard and found, at the end of it, that it didn't answer the important questions that one would ask about whether this standard was sufficiently proven in practice to carry forward. I'm wondering if, somewhere in the process—and maybe this is an Implementation Workgroup Committee thin, but somewhere there isn't a need for a standard set of questions that are asked when reporting out the trial use of the standard that helps the various working groups and subcommittees to evaluate the experience in the industry. Thanks.

John Perlin, MD, Ph.D., Officer, Clinical and Physician Services, Hospital Corporation of America

Okay, Doug. We can parking lot the first issue, as Wes recommended, but any comments you want to make, jump in.

Doug Fridsma, MD, Ph.D. – Chief Science Officer and Director – Office of Science and Technology

I think that's a really, I'm writing down a note to that to see what would be a useful way to do that kind of documentation and collect that information, so thanks, Wes.

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

John Perlin, Dixie Baker has a comment.

John Perlin, MD, Ph.D., Officer, Clinical and Physician Services, Hospital Corporation of America

Okay, good. Please go ahead, Dixie.

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

Thank you, I appreciate it. I would like to first agree with Wes that there are a number of issues that are barriers to broad interoperability that don't exactly fit into policy or standards but they're barriers anyway, and I do think there's go to be some way to get those addressed.

I wanted to talk about, make a couple comments, Doug, about your, the first tab in your spreadsheet about the work plan activities. There are a couple activities that the Privacy and Security workgroup has completed that would number one, change the status, but also I have questions about them. The first is that ESMD, here, it says that CMS presented it to the Standards Committee. Subsequently, the CMS presented that same work to the Privacy and Security workgroup and to the clinical operations workgroup, but the question that is the current status is, a question was raised as to what does ONC need from us with respect to the ESMD digital signature, especially since it's a CMS standard, so if you could clarify what you need, we would really appreciate that.

Similarly, the Privacy and Security workgroup also was briefed on the Data Segmentation for Privacy, but we never were asked for any feedback, it was more of an FYI, and now the work is over with HL7 and I understand, is there an expectation for anything more from the Privacy and Security workgroup, on both of those?

The third thing I wanted to point out is, on that same spreadsheet, the transport standards that were overviewed in June, we presented the final at the last meeting, the August meeting, and this was the NSTIC Work Power Team, presented the final recommendations in our last meeting. Subsequently, we made a couple of tweaks to the presentation and the formal transmittal of that recommendation has gone to the ONC. In my view, the NSTIC Power Team has completed that action.

Doug Fridsma, MD, Ph.D. – Chief Science Officer and Director – Office of Science and Technology

Right. Thank you.

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

So, about—do you expect any more from us on ESMD or Data Segmentation for Privacy?

Doug Fridsma, MD, Ph.D. – Chief Science Officer and Director – Office of Science and Technology

Well, both of those are—Data Segmentation for Privacy is something that Joy Pritts's office has been deeply engaged in. I just made a note here that I need to double check with her about that. I think, with regard to ESMD, there's a lot of questions out there in terms of how that fits into the entire portfolio of ways that we need to secure and provide that nonrepudiation, if you will. Lots of ways to do that—I mean, obviously, you can do that with digital signatures, you can do it as part of a transport if you're using something like direct between organizations. I don't know if I can give you an answer right now that there is no additional work, but what I will do is, I will take it as an action item to talk with Joy about that and to see if we can get some clarity about if there's anything else that might be needed from the Privacy and Security working group.

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

Okay, and I do have one more comment, a quick one, is that consumer downloads that you have—by the way, we did, the Privacy and Security workgroup did provide ONC written feedback on this list. The consumer downloads was directly addressed by the HIPAA omnibus rule, which clearly stated that a provider is not responsible for securing data that has been downloaded to a consumer environment, so that should be taken off your spreadsheet.

Doug Fridsma, MD, Ph.D. – Chief Science Officer and Director – Office of Science and Technology

Sure. Just put that in there. I mean, we—this is why I wanted to share this, so that if there are things that are already resolved, we can just check the box.

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

Okay. Thank you.

Doug Fridsma, MD, Ph.D. – Chief Science Officer and Director – Office of Science and Technology

Thank you.

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

This is David. One comment about Dixie's question.

Doug Fridsma, MD, Ph.D. – Chief Science Officer and Director – Office of Science and Technology

Jump in.

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

Just on the Data Segmentation for Privacy and on the ESMD, I was struck by reviewing those that this is a case where the standards may be technically correct and complete and adequate, but the implications on provider workflow are so profound that it's not really a standards question any more, it's a, "Do we really want to force this on provider?" question. I don't know where those kind of questions get addressed, whether that goes back all the way to policy or if it's in the clinical operation work group or something else. We may have signed off on the adequacy of the privacy and security issues, but that doesn't mean it's a good thing to impose on the users of our systems.

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

We haven't signed off on them, anyway, David, just to be clear.

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

Okay, well, even if we do, there are really—the broader implication is really the workflow question, whether it's feasible to do it.

John Perlin, MD, Ph.D., Officer, Clinical and Physician Services, Hospital Corporation of America

Okay. The floor remains open for any further discussion.

Well, John and Doug, I'm actually stunned. Doug, I think that must be testament to the uptake of the prioritization and the very thoughtful model. I look forward to continuing discussion. Let me turn to John for any particular comments in terms of your perspective on what Doug has just presented and our work plan.

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

Well, Dixie in the past has created a framework for us to look to standards maturity, applicability for purpose and these sorts of things. I have a feeling that as we have our next meeting and we look at the body of work in progress at S&I and the body of work that we had suggested a year ago that together we'll try to come up with some criteria that does separate the urgent and important from things that might be aspirational.

Just as Dixie has done with her work, it certainly would be nice to have objective, reproducible criteria so that as new projects are introduced in our queue, we can say, "Ah, well, here's where it fits, or here's something we might want to take out of our queue," because we know that our scope and time and resources at this point, they're relatively constrained and maybe scope exceeds our time and resources. Hence, we will need to skinny down the list. I think as Doug has done today, he's given us a sense of what's in process, what we have as existence deliverables and future deliverables and we'll use that together—comments, develop criteria, and hopefully come back to ONC with a suggested work plan for the next year.

Doug Fridsma, MD, Ph.D. – Chief Science Officer and Director – Office of Science and Technology

John?

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

Yes, Doug.

Doug Fridsma, MD, Ph.D. – Chief Science Officer and Director – Office of Science and Technology

I just wanted to say, one of my suggestions—and I think this is one of the things that would be very helpful, I think, from our perspective, is that now, equipped with this spreadsheet, without overthinking it, trying to get members of the committee to sort of go through that spreadsheet and indicate as quickly as they can notes or jot down things and then to send that back to either me or to yourself, John or John. I think it would be very helpful between now and the next meeting. Because I think part of the reason there's not a lot of questions is, I just presented a ton of material, and it's really kind of complicated and interlinked, but I think if people between now and the next meeting use the spreadsheet to help organize their thoughts, perhaps we can have some time at the next meeting, which will be face to face, to really start to tease apart things. Maybe there's not a lot of controversy out there and everybody will agree, but I think we won't know until people do that exercise.

John Perlin, MD, Ph.D., Officer, Clinical and Physician Services, Hospital Corporation of America

Well, thank you. I think you've given us a task, but hopefully all are motivated by the intended outcome of that task, which has really helped for clarity, focus, and prioritization. With that, speaking of constraint and time constraints, we're actually just about on time. Before I come back for some final, final comments, with the critical portion of our agenda where we ask for public comment, so at this juncture, let us turn back to Michelle for a moment to ask if there are any public comments on the line.

Public Comment

Michelle Consolazio – Office of the National Coordinator for Health Information Technology

Thanks, John. Operator, can you please open the lines for public comment?

Operator

If you are on the phone and would like to make a public comment, please press *1 at this time. If you are listening via your computer speakers, you may dial 1-877-705-6006.

We have one public comment. Shelly, go ahead.

Shelly Spiro - Pharmacy e-Health Information Technology Collaborative - Director

My name is Shelly Spiro. I'm the Executive Director of the Pharmacy e-HIT Collaborative, representing over 250,000 members of the majority National Pharmacy Association and key pharmacy organizations involved in health IT. Pharmacists play an integral role in the interprofessional health care team in providing medication related services outside and in conjunction with prescription dispensing functions.

Pharmacists are in a unique position to engage patients and caregivers more often than others receiving meaningful use incentives. Providing patients with accurate and meaningful medication lists is a high priority for pharmacists. Pharmacists are highly trained as medication management experts. Over several years, the Collaborative and its members have been working with NCPDP and HL7 on standards that will assist pharmacists in Standard Structure Documentation of these patient care services such as medication therapy management as required by the Medicare Part D program, also some Medicaid and private insurers.

One such standard is a joint project between NCPDP and HL7 for structured documents using the consolidated CDA to meet a CMS required Part D patient takeaway document after an annual comprehensive medication review. This structured document contains pharmacist provided reconciled active med list, allergy list, indications for active medication, and special instructions for the patients in easily understandable language. This structured document supports our _____ SNOMED CT. This CMS regulatory requirement went into effect January 1st, 2013. For 2014, CMS recognized the electronic version of the Structured Document in their 2014 call letter by encouraging Part D plans to adopt the use of the electronic version of this takeaway structured document and the use of medication therapy management defined SNOMED codes in addition. CMS asked for comments related to coordination of comprehensive medication review and the physician's annual wellness visit. Pilot testing of the use of this CMR electronic Structured Document should begin before the end of this year.

The Pharmacy e-HIT Collaborative is a committed member of several of the S&I Framework workgroups in hopes of driving industry adoption of the comprehensive med review consolidated CDA containing pharmacist reconciled active med lists for Meaningful Use to ensure our patients have the ability to electronically receive pharmacist provided reconciled med lists, and an easy, understandable instruction list.

Relating to Dr. Fridsma's presentation this afternoon, the Pharmacy e-HIT Collaborative is interested in the Standards Committee recommending a high priority rating given to the new potential S&I Framework Initiative Medication Management and Reconciliation by considering the use of the CMR Consolidated CDA Structured Document as a use case. We applaud ONC's engagement initiatives, and speaking on behalf of our nation's pharmacists, we have developed a valid medication reconciliation solution for Meaningful Use in all practice settings. Thank you.

Male

Thank you.

John Perlin, MD, Ph.D., Officer, Clinical and Physician Services, Hospital Corporation of America

Michelle, are there any other calls on the line?

Michelle Consolazio – Office of the National Coordinator for Health Information Technology

It doesn't look like there—go ahead, Ashley.

Operator

Sorry. There are no further comments.

John Perlin, MD, Ph.D., Officer, Clinical and Physician Services, Hospital Corporation of America

Okay. With that, let me ask John Halamka, any last words that you'd like to offer?

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

I just think it's an exciting time. I think Dave McCallie said that we are on the cusp of a whole new generation of standards and thinking. I just look forward to getting Meaningful Use stage two fully implemented as Farzad has advised us, making progress with the standards that we have while putting our attentions into the next generation of standards that will be simpler, we hope, and appropriate for purpose.

I think the work of the Standards Committee will never be done. Congratulations on our 51st meeting. We will continue to make good progress.

John Perlin, MD, Ph.D., Officer, Clinical and Physician Services, Hospital Corporation of America

I appreciate those words. It was at the last meeting that Farzad shared with the Committee his departure. We had a lot of discussion, but I hope that, Farzad, you feel, viscerally, the esteem and admiration that all of the members of the Standards Committee feel for you personally and professionally. I note the resolution of our last meeting and recognition of your terrific leadership and public service that was adopted unanimously and, on behalf of the Committee, as you mentioned you're doing a walkabout, the first four lines of the old Irish blessing seem apropos: May the road rise up to meet you, may the wind always be at your back, may the sun shine warm upon your face and rains fall soft upon your fields until we meet again.

We look forward not only to continuing work in the remaining time ahead, but also to our paths crossing, intersecting in so many positive ways in the future. Thanks so much for your leadership, Farzad. Anything you'd like to say before we close?

No? Well, with that, we will stand adjourned. We need—

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

He must be tearful, John.

John Perlin, MD, Ph.D., Officer, Clinical and Physician Services, Hospital Corporation of America

[Laughter] Okay. We stand adjourned until our meeting in Washington on October 16th. Thanks to everybody on the call for all of your work and our ONC colleagues and importantly, members of the public who participate and engage with this process. We're adjourned.

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

Adieu.