HIT Standards Committee
Final Transcript
September 21, 2010

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director
Good morning, everybody, and welcome to the 17th meeting of the HIT Standards Committee. We're operating under the auspices of the Federal Advisory Committee Act, which means there will be opportunity at the close of the meeting for the public to make comment, and a transcript of the meeting will be available on the ONC Web site. Just a reminder for workgroup members to please identify yourselves when speaking and we'll go around the table now and introduce the members of the committee starting on my left.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Good morning, everyone. My name is Walter Suarez. I'm with Kaiser Permanente. I'm a member of the committee, and I don't have any conflict.

Natasha Bonhomme – Genetic Alliance – VP Strategic Development
Natasha Bonhomme for Sharon Terry at Genetic Alliance.

John Klimek – NCPDP – VP Industry Information Technology
Good morning. John Klimek from NCPDP.

Linda Fischetti – VHA – Chief Health Informatics Officer
Linda Fischetti from the Department of Veterans Affairs.

John Derr – Golden Living LLC – Chief Technology Strategic Officer
John Derr from Golden Living.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Stan Huff from Intermountain Healthcare and the University of Utah in Salt Lake City.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Dixie Baker from Science Applications International.

John Halamka – Harvard Medical School – Chief Information Officer
John Halamka, Harvard Medical School and Beth Israel Deaconess Medical Center.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Jon Perlin, Hospital Corporation of America and Vanderbilt Informatics.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Jamie Ferguson, Kaiser Permanente.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Liz Johnson, Tenent Healthcare.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
David McCallie, Cerner.

Judy Murphy – Aurora Healthcare – Vice President of Applications
Judy Murphy from Aurora Healthcare.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Wes Rishel, Gartner.

Cris Ross – LabHub – CIO
Cris Ross, LabHub Initiative.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Doug Fridsma, ONC.

Judy Sparrow – Office of the National Coordinator – Executive Director
We do have a number of members who are either on the phone or will be dialing in. Anne Castro, are you there?

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

Judy Sparrow – Office of the National Coordinator – Executive Director
And Martin Harris?

Martin Harris – Cleveland Clinic – Chief Information Officer
Martin Harris, Cleveland Clinic.

Judy Sparrow – Office of the National Coordinator – Executive Director
Any other members on the telephone?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Yes. It's Carol Diamond, Markle.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Jim Walker, Geisinger.

Judy Sparrow – Office of the National Coordinator – Executive Director
Jim, good morning. With that, I'll turn it over to Dr. Perlin.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Good morning, everybody. I've got admit, I was particularly excited about this meeting. The last meeting had felt as if we had closed a chapter collectively with ONC and the policy committee in terms of really getting the first stage of our collective activities running, and for those of us in our various roles outside of the committee, I know that we are living the dream, as these activities come to fruition. I think that's so important, along with quite importantly the input from members of the public, as we do operate as a federal advisory committee, because the committee's work has to be informed by those realities.

But what excited me about today's meeting was not only embarking on the next chapter, as with later when Doug offers some comments. We consider the implications of the standards to support stages two and three in the evolution. But that the work today in the agenda actually speaks to an emerging, or I should say, increasing internal coherence that is increasingly available for the operation of electronic health records independently. For those of us who witnessed the evolution from the emergence of personal computers to the large networking that became possible with the Internet, really the internal and external coherence that allows that interoperability to take form, which indeed is the basis for supporting higher value, higher performance healthcare, and that's really exciting.

I appreciate everyone who is here in person, those who have called in. We have actually lost a couple of members along this hallway. Next store is the National Priorities Partnership meeting. Janet Corrigan and Steve Findlay will be popping in and out between that meeting and this one. But it gives also an idea of the coherence not only in a policy context, but in terms of the focus on shared activities towards achieving that higher value or higher performance healthcare.

Toward really establishing the basis of my first point, the internal coherence, I look forward to the report from the hearing that was recently held on vocabulary. Providing that from the vocabulary taskforce will be not only Jamie Ferguson, but I want to welcome Betsy Humphreys to the National Library of Medicine, and thank you very much for being here to share your insights with the standards committee today. Also appreciate apropos to leaving the dream comment. Liz Johnson and Judy Murphy who, in the implementation workgroup, really are considering the implications of the standards, as well as the requirements for meaningful use and the sorts of guidance that would helpful so that these activities really do take roots in the way that is envisioned.

Now toward that broader interoperability is indeed a discussion at 10:30 from Doug Fridsma on the S&I, the standards and interoperability framework, the ability to achieve this sort of connectedness, not only that benefits one within one's office of institution or whatever the entity is, but across environments. That will lead into this afternoon's discussion about priority setting.

In that context, I again think it's a particularly exciting time because if indeed we have reached a certain milestone in terms of stage one, there's clearly a vision that we have to help support, as the meaningful use workgroup and the policy committee frame what stages three and two look like that will allow that real world implementation aspect. Those individuals who are really working quite diligently to achieve not only stage one, but working toward trying to achieve the continuity of health services delivery or whatever the particular aspect of their work in the health sector is with technology that meets, one, a set of business aspirations; two, a set of clinical aspirations; and, three, really supports or builds in the intentions of meaningful use and the broader policy framework in which everything is contextualized.

I want to take a chair's privilege to note that our co-chair, John Halamka, will be leaving a little bit early. Suffice it to say that, and more details later, that Safe Rx has identified Massachusetts as one of the named entities for advances in e-prescribing, and so pleased to hear about and know how terrific your leadership in that endeavor has been, so look forward to hearing more about that. We'll miss you here … the great state of Massachusetts, the commonwealth of Massachusetts will be well represented down on the Hill, so congratulations, John. Please join me in recognizing ….

With that, let me turn it to you for introductory comments.

John Halamka – Harvard Medical School – Chief Information Officer

As I'm living the dream, there are certain things that I run into, such as, just yesterday I was talking to the folks doing my quality measures on EHRs and hospital information systems. They said, as we go through all of these wonderful final rules, we see such things as, oh, here's a requirement. Use RxNorm for this particular numerator. We think RxNorm is great, but RxNorm subsumes 1,100 underlying vocabularies, and it happens to be that my hospital information systems use First Databank, which is a proprietary tool.

So I said, well, that's no problem. I'll just call up my buddy, Floyd Eisenberg at NQF, and say, so if you take the RxNorm concepts that you've identified for the numerator, how do you map those to all the underlying proprietary vocabularies in RxNorm? To which he responded, well, that is intellectual property only available to the licensee of the underlying vocabularies, purchasers. So, as we talk about today the importance of code sets and vocabularies, you will see a rich discussion of intellectual property and what can be released by whom and what circumstance. So NLM may do fabulous work, and it's all done, but there are these intellectual property issues about releasing it. So I ran right into your issue while living the dream, so I look for that discussion today.

On the implementation side, so again, another discussion John and I actually were on, we were talking about the realities of getting this done I'm doing a site certification for my 146 different disparate, home built, some bought, some legacy kinds of systems because there's no way, in a large, integrated delivery network, you could just buy an off-the-shelf product and achieve meaningful use for every department and everyone. So this discussion was getting a bit esoteric, such as if you build a wonderful system, and it's version 1.0, and then two weeks thereafter you add five new bells and whistles, do you need to recertify?

Now the answer is I don't think folks know the exact CMS interpretation of that question. Should I achieve meaningful use with the thing that I froze the day I certified? But if it's even better today, why isn't that good enough? So these are the kinds of issues that the implementation workgroup is going to be facing.

CCHIT had a 500-person call yesterday on introducing the certification process in all of the detail. Based on the questions you're seeing out there in the environment, you will have a lot of work to do, implementation workgroup, in just making sure people in the trenches living the dream can get this done.

The standards and interoperability framework discuss, and you'll see from Doug, it was a great kickoff yesterday with all of the contractors and all of the stakeholders figuring out how all this is going to work to create an open, transparent, coordinated, and integrated process without some of the waterfall problems that we had in the AHIC, HITSP, CCHIT days because it makes every member of the community responsible for a deliverable instead of here's a deliverable. It's yours. Bye. So you achieve a set of accountability and integration in doing this.

Of course, we'll hear from Doug how all of this will be knitted together across all the different functions and contractors. Certainly I hope we, as a standards committee, can have a governance role helping provide oversight, priority setting, and as you have your concept of operations document, provide any suggestions that you, as a collective set of implementers, might have to that. Then I will be dashing off to the heart building, but I am sure you will have a rich discussion on setting priorities.

Tomorrow, Paul Tang kicks off the policy committee's work on looking at stage two and three. I think a fascinating hypothesis: let's see how these guys go. If you don't bother with stage two, but in fact ask what do we aspire to in stage three, and then what must stage two be to get there might be an interesting concept. Then we, of course, will have to create the standards that support that activity, so I'm sure you'll have a great discussion after lunch of some of the things we may need, and then further guidance from Paul Tang and policy committee after tomorrow's meeting.

I believe, Judy, that we have scheduled October such that the policy committee actually meets on the 20th, and we meet on the 27th. So we should be able to have a discussion from the policy committee of everything they have done, which will guide our future work, so I look forward to the day.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thank you, John. Doug may be up a couple times. Any introductory comments you'd like to offer at this time?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
I'll have time to talk.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Terrific. Then let's move on to our first order of technical order of business, and that's the summary of the last meeting, the minutes. Please let me know if you have any amendments, revisions. I would note again the appreciation of the Office of the National Coordinator for, as always, incredibly thoughtful synthesis of the discussion.

Hearing none, we'll declare a consensus on the minutes and move to our first order of business, and invite Jamie Ferguson and Betsy Humphreys to report the vocabulary taskforce briefing and the recent hearing. John, did you want to offer some comments?

John Halamka – Harvard Medical School – Chief Information Officer
I think just the fact that this issue of providing vocabularies and code sets just turns out to be so critical in the reality of achieving interoperability and going beyond syntactic to semantic interoperability, as we all want to achieve decision support and these more advanced functions that will improve quality and efficiency. It's clear vocabularies and code sets are foundational, but we need someone to house them.

We need somebody to maintain them. We need somebody to version them. We need to make sure that every EHR can incorporate them. So the work of the taskforce is getting us to that nirvana.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I just want to emphasize this point. This is why I'm so enthusiastic about this meeting as a segue between what we've done and where we go because it's that transition from syntactic to semantic interoperability that really allows the coherence of these sorts of deliverables that both improved healthcare and improved informatics require.

With that, I invite Jamie Ferguson and Betsy Humphreys.

Betsy Humphreys – National Library of Medicine – Deputy Director
I just wanted to comment quickly on the living the dream. Didn't we all expect that when there was a rule that said that you had to use certain clinical terminologies that in fact this would wake up people? I'm here to tell you, it did and the world is beating a path to some doors. Really, the level of increase in the number of people licensing per month the UMLS, which of course they need to license in order to get SNOMED CT and certain parts of RxNorm, and the number of people who are using our APIs to get various vocabularies down has just jumped enormously. The first six months of this year higher than the annual volume for 2009, which was much higher than the years before because of the draft rules and so forth, so what we expected to happen has happened.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I'm going to start out refreshing our folks' memory. We have a list of the taskforce members and the materials. I'm not going to go through that. Most of us make most of the calls and participated in the hearing.

Also just to review, the subject of the hearing was really a followup to questions that came out of our previous hearings that we ended up making recommendations out of this committee to the National Coordinator from. One of the central things that came out of our previous set of hearings and discussions was the need for one-stop-shopping, and basically make it easy for implementers to get the required vocabulary components, including both the content and cross maps and value sets and derivative works. So we wanted to have this hearing to figure out what should the requirements be for this one stop shop.

In the first place, how do you define one-stop-shopping? What does that mean from different stakeholder perspectives? What are the different kinds of requirements that would attach to this concept? Then, given that everybody has a different view of the end state, maybe there could still be some commonality in terms of what's most urgent? What has to happen first? Given the realities of stage one of meaningful use, of this program that we're living the dream on, what has to happen first, and what's needed most immediately, and so we wanted to get input on that.

We also had a set of 15 very detailed questions that really got to—so the written testimony is all available, and those answers described both the experience and the learnings and the desires of all the different participants. We ended up with four panels. Two dozen panelists participated. We really had a very good mix of public and private sector participants representing a full range of different stakeholders from the small office physician providers to hospitals, integrated delivery systems, academic medical centers on the implementer side.

We also heard from a range of electronic health record vendors and developers. We also heard Canadian perspectives. We heard research perspectives. We heard from a number of terminology services providers and terminological specialists. And so we heard a very broad range of input.

So I want to cover here some of the major themes, and then we'll drill into one particular issue on intellectual property. One thing that we started out thinking, well, everybody is going to want simplicity and harmony in these vocabularies and taxonomies and the mappings. That's true, so we certainly did hear that, but we also heard that clarity of requirements and clarity of what to do is actually more important than it being simple. So what the government can and should and must do is to make it clear to

people who are applying for meaningful use funds and who are implementing and using these technologies that what is required of them, how they have to do things has to be clear, and it being clear is more important than it being simple. That was a major theme, I would say.

The other thing is that in providing that clarity, there's an overriding desire for stability and predictability in terms of those requirements, so letting people know not only what's required in a very clear way, but what's the roadmap. Where are we going? What's going to be required tomorrow, not just today, and don't change it every five minutes.

Then we also had a good discussion with several of the panels on what simplicity means and the need for having exception mechanisms because any time you simplify something to make it easy, especially if you make it easy for the little guy that doesn't handle all the exceptions the different kinds of little guys may have. So the need for having mechanisms for handling exceptions and, for example, extensions to vocabularies that are needed, so if you have a core set of terms or concepts that are used for a particular purpose, different implementers may need different extensions, and so you need mechanisms for handling those kinds of exceptions.

Another theme had to do with having a comprehensive plan, and certainly along with the desire to have the government lay out a roadmap and a future direction and have clarity, having that roadmap doesn't mean that it all has to be done at once. So we really got an answer to the second major question that we had on what has to be done first. There should be a process to prioritize what's needed most immediately, and several of the cross-maps were mentioned multiple times, so SNOMED CT to the ICD-9 CM and the ICD-10 CM being the most frequently mentioned.

Also, I think RxNorm was pretty frequently mentioned in terms of cross-map requirements. So there should be a process that should define exactly which content sets being subsets or value sets or cross-maps, which things are needed most urgently. We didn't get to that specific list, but the fact that there needs to be prioritization, and not everything that everyone needs for all of stage one should be done right up front.

Another part of this overall plan is that we want to get to a stage where information about value sets is readily disseminated and easily downloaded from the one-stop-shop, so that was clear and consistent. But information about value sets can be very complex, and can extend into many different areas, and not everything is needed all upfront. At the same time, you don't need or, rather, you need more than just a list of codes, so value set is more than just a list of codes. It also has to include, at a minimum, a context, a description of how and why the value set exists, what's the intended purpose of it, and what are limitations on the use of that value set. So this is a minimum for value sets.

In other words, there's more than the list of codes. The minimum also has to include some context. The thing about adding additional information about these value sets to the one-stop-shop or the distribution mechanism is that attributes can be added over time, so again, a process should exist for having fuller, richer information about the value sets added over time, and it doesn't all have to be available upfront.

One of the other things, I think, that came out loud and clear is the importance of making a U.S. version of SNOMED CT with the U.S. specific extensions readily available and usable immediately. So this would lead to prioritizing the establishment of a U.S. extension to SNOMED CT to the international version, particularly where there are extensions that are going to be used in the U.S. that may not be in SNOMED CORE or the international release that are needed for value set extensions. So value set developers in the U.S. have found a need to add concepts. So in order to be able to do that rapidly, we need to have a U.S. extension that's a national extension to SNOMED that can accommodate the need of those value set developers. So these would be the measure developers for quality and process measures.

The third major theme was a whole set of things about intellectual property. I'm going to get back to that later. We have a couple of additional separate slides on intellectual property issues, and I do want to tease out some discussion on that. But let me pause for a minute in terms of the first two major themes of the government needing to provide stability, predictability, and overall clarity of what's required of

implementers being very important, and that being an important component of requirements for the one-stop-shop, and then also both having a comprehensive plan, but prioritizing what needs to be done first. So I'd love to get comments from the committee on those themes.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Dave McCallie.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Does the presence of Betsy at the table mean that NLM is going to take on this responsibility?

Betsy Humphreys – National Library of Medicine – Deputy Director
No.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
What is the strategy in terms of the timing around meaningful use stage one well underway? These are terrific goals.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Let me say that in our previous recommendations that came from the committee to the National Coordinator, we recommended that there should be a single federal office or agency put in charge of this coordination and that that should be done out of ONC. I don't think that's happened yet.

Betsy Humphreys – National Library of Medicine – Deputy Director
Let me just add to Jamie's excellent summary. One of the things that came through at the hearing was in terms of the government providing clarity, stability, and predictability. I think one of the aspects of this is not only clarifying requirements where that needs to happen, but also whatever the government chooses to do in terms of the one-stop-shop to set things up that will continue over a period of time, and so that people will be able to understand the level of service that the government is going to provide. We heard from many vendors and other people in the room that then other segments can develop services around what they know is coming. So I think there's not only the predictability of the requirements, but whatever the government chooses to do in terms of providing services or one-stop-shop that they pick something and then stick with it long enough for the people to be able to rely on it and continue going. So I just add that point.

I think that Doug and others at ONC can clarify. They're at a point now where I think there will be more clarity about who is going to be doing what in this space going forward.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Doug Fridsma, thanks.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
So we'll have an opportunity to talk when we talk about the standards and interoperability framework. I think there are a number of organizations that are doing very good work on establishing vocabularies and value sets and those resources. I think it is important for us to not reinvent the wheel, but to figure out how we can best leverage those resources. I think the further you move it towards the folks that care about making sure that those value sets are correct, the higher quality you're going to have in terms of the actual use and the ability of them to sort of solve some of those problems. So getting a mechanism in which the subject matter experts and the people that care about, say, the quality measures or the other things, determining those value sets, I think, is going to be important. We're just in the process, I think, of trying to figure out how best to create that one-stop-shop that allows us to access through services or a federated approach, the kinds of vocabulary services that might be out there.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Let's go to Wes Rishel.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

Correct me if I'm wrong, but value sets are purpose specific subsets of the total number of concepts that are enumerated for code type.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Right, and value sets may include more than one code set as well.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Then they link code sets together.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Right.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Right. Sure. That's a point where we really are bumping up against the creation of medical knowledge, right? I mean, that is how medical knowledge is encoded to a great extent, so it strikes me that the consensus processes around establishing value sets have to extend well beyond the sort of technical and informatical context that we understand, so I'll be interested to see how that goes on. Do all of the code sets that we deal with, excluding ICD-9, of course, support most of the desiderata for code sets? Do they not reuse the same code over time and so forth, all except for ICD-9? Basically ICD-9 reuses codes, right, so it's not?

Betsy Humphreys – National Library of Medicine – Deputy Director
I'm not even sure ICD-9 does anymore, but yes. I think that, in general, the code sets that are mentioned in the regulations are the same ones that were previously mentioned in HITSP and CHI processes, and the people who were selecting them in those previous processes obviously were paying attention to desiderata and also to access and a variety of other issues when recommendations were made. Again, I think, when they were made this time around as well.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
The notion of developing extensions to SNOMED CT undoubtedly critical to our success leads to an issue of some sort of international harmonization of extensions that are developed, which I assume we would count on … to take care of.

Betsy Humphreys – National Library of Medicine – Deputy Director
Let me just comment on that. There are two reasons for the extension. One is speed in the sense that if we have quality measures, value sets, or value sets for a particular message, and people are trying to zip ahead here to achieve meaningful use, that you want to be able to get something established quickly and have a code assigned to it that will persist going forward, and the SNOMED extensions would allow us to do that in that area, so that's one thing. These things, in some cases, a U.S. extension, as it is in other countries, may be kind of a like a staging area on the way into the international release.

In other cases, there may be U.S. requirements, but the IHTSDO is on a path for truly international distributed development of SNOMED CT where in fact people who are working or think they have a requirement that they need to model, in the U.S. for example, would actually be able to see and be in an environment where they would already have access to the Australian extension or the British extension or the Canadian extension if such things exist. So this is a real goal for the IHTSDO, and they are taking concrete steps towards that goal, so it can't happen overnight for a variety of reasons, but they're on the path to that. I suspect actually the U.S. people who would be involved in U.S. extension or editing right into SNOMED CT, the U.S. model that we're going to try to do for, will be a distributed model in the sense that we would expect there to be fully vetted and certified SNOMED editors in multiple organizations, but federal agencies and private organizations across the United States. That's the way we want to proceed, so the issue is figuring out how we can set that up as quickly as possible and then migrate to the truly international distributed approach.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

That's great. I think that you were obviously answering my next question that I hadn't asked yet, which was what to do about the fact when you change the consensus group, you change the consensus so that when standards are developed at the national level, there's almost certainly some change to go when it goes to a different consensus group. What I hear is you are suggesting that there is a measure expense that could be had now that would minimize that re-coordination effort, as we go forward.

Betsy Humphreys – National Library of Medicine – Deputy Director
That is certainly the goal, and I think that we will get there, and we will gradually improve on that. I think many in the room know about the IHTSDO vocabulary workbench and the process it's undergoing now to get that extended to more easily accommodate some of the international collaboration aspects of this. It's not instantaneous, so I think we're probably going to be in a very good environment for the international collaboration, probably by 2012. I hope that we will be able to get ourselves in a very good place for distributed development of U.S. input before then, so then we'll be able to play into that larger thing.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
That's great. I look forward to hearing how that well conceived process works appropriately with the NIEM process, as we go forward, because I think there's some of the same requirements beyond vocabulary there.

Jonathan Perlin – Hospital Corporation of America – CMO & President
We'll go to Judy Murphy.

Judy Murphy – Aurora Healthcare – Vice President of Applications
Pulling this to my dream part, which is actually trying to implement the stage one and measure the stage one criteria, you're probably well aware, not so much from a standards development side, but from an actual specification standpoint, that the stage one meaningful use criteria have standards in some places and not in others. For example, it was very prescriptive in the smoking status. The CDC standard was used there to specify the value set. But then there are many others. One that bothers me a lot, preliminary cause of death, where there was no specification related to the value set. So I'm kind of curious if your workgroup thinks that that might be in your purview and if you were looking at those kinds of things because very specifically we have to worry about that, like today, not so much tomorrow, but today.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I have to say, we did not consider that particular issue in terms of the need for a subset or value set. But I think that we are hoping that the agency or office that's going to perform this coordination would get established by ONC quickly so that those things could be resolved appropriately. We don't think that that is so much in the purview of the workgroup as it is in the officer agency that's going to get the designation from ONC.

Judy Murphy – Aurora Healthcare – Vice President of Applications
Again, you guys are really focusing much more on the standards development codification part of it, and not so much on the specificity of the ….

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Well, on the process and governance aspects and the requirements, but not on actually implementing the particular value sets, if you will.

Betsy Humphreys – National Library of Medicine – Deputy Director
Or defining them.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Or defining them, exactly.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Let's go to Stan Huff.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
This is just a comment more than a question. I think the model that we espoused in the hearings and talked about was one where the expertise stays where it already is, that we're not creating a new group to try and become a new expert. So if we're talking about statuses for orders, it would be HL-7 and NCPDP who are the experts, and those experts would stay, and you would use the same consensus process within those organizations to create the groups. Then that value set would come, and you would have the technical part of maintaining that value set in a common store, but there wasn't this idea that we're going to create a new consensus body at a national level. The power would stay with the people who had the authority and responsibility for that particular transaction or for that particular meaningful use scenario.

You can think of—at least this is the way I have it in my head—that you can think of the national work being essentially a librarian where they're taking the work that has been done by others and indexing it and making it available, persisting it, versioning it, but the people, the experts, the subject matter experts that are doing that remain where they are, and use the consensus process within the organization that they have to generate the content. You guys disagree if I'm misrepresenting that, but we're not trying to create a new body of experts to be the know-it-all for the nation. It is to bring together the knowledge and allow the processes that are already in place to establish the content.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I think Stan is exactly right. At the same time, when we're talking about the one-stop-shop under a single office or agency, we're talking about having a coordinator with some authority to say that the authoritative place for that particular set is here, and here's the pointer, and how to contact them and where to get it and how to download it.

W
…your general question, that was your first question, so what worries me is that there's this big lag, and I don't know if the people who actually own that understand that they own it and are planning to work on doing that. Again, Stan, what you said, it definitely makes sense, but so who is working on this?

Betsy Humphreys – National Library of Medicine – Deputy Director
We had a panel of people work on value sets in a variety of areas. I think that their notion of clarity also had, okay, who is responsible for what. Then again, the priorities for whatever it is they're responsible for, what is sort of the view of where is the shoe really pinching in terms of the first, second, and third set they should be working on.

Jonathan Perlin – Hospital Corporation of America – CMO & President
John Halamka.

John Halamka – Harvard Medical School – Chief Information Officer
Three general follow-up comments: A perfect intersection between the implementation working group and the vocabulary taskforce, for example, smoking. So we have a vocabulary that's now been specified. Well, I've been building things for 20 years, and it turns out that I've recorded smoking status, but in a totally different way. I bet Kaiser has had the same issue. So we all want to do the right thing, but where the rubber meets the road, how do we take what we've got and then represent it in these vocabularies that we're now being given? It's the right direction. It's just getting us the maps from here to there that's going to be an implementation challenge.

If you do have this curation, as you've described—and I think it's a very reasonable thing to do, leveraging the subject matter experts we've had in the past—then how does one release the intellectual property once the curator has decided what is the right value set and code set to use? Of course, you're going to talk about this in a moment. I would just urge you, from all the experience I had at HITSP, doing redirection of Web site to Web site to pointer to pointer is ultimately not very satisfying or productive. So hence, if there is a mechanism by which, as has happened in the past, the governments can license or make available this intellectual property or that the authors of intellectual property agree to what I'll call

partial releases of intellectual property for the purpose of mapping and put that in a one-stop-shop, that will make life so much easier.

In fact, I'd ask Doug. I know in your standards and interoperability framework there is a contract to Stanley for tools, which I thought was quite ironic. Is …?

W
....

John Halamka – Harvard Medical School – Chief Information Officer
Yes. That's right. Now is the tools contract for NHIN to include conceivably a virtual repository or physical repository in the cloud of these value sets and code sets to support NHIN and other activities?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
That particular contract was specifically designed to provide that kind of infrastructure to help all of the users that you might have, so you might have tools that would be necessary to help with subject matter experts coming up with the use cases and identifying some of the value sets. There's going to be the need, I think, for tools and browsers that allow people to see what's there and what can be reused. The primary objective of that particular contract is to sort of figure out how to set up that infrastructure.

One of the charges, and to all of the contractors was, if you come to me with a blank sheet of paper and say you're going to start from scratch, then I'm going to send you back until you've figured out what else is out there in best of breed and make justifications as to what you're going to use. That, I think, includes the vocabulary services as well. I think we do better in creating an ecosystem that's sustainable, even if it is a one-stop-shop, to define how people can kind of interface with that repository and that store, if you will, of information.

I don't include in my slides this time, but we are trying to think through if you were going to implement something, you might need this vocabulary. You might need this value set. You might need this transport standard. You might need this content standard. How do you assemble those pieces, almost putting it in your shopping cart and have it generate what you need to do to implement those pieces if you had all of those things selected? That's maybe a little bit more future than where we are now.

I think even just having a place where people could go to say what are the value sets that support meaningful use? What are the standards? Is there an explanation about the definitions and how they work together? I think that would be valuable?

John Halamka – Harvard Medical School – Chief Information Officer
So just thinking about architectures we've had in the past, there's USHIC, which has been a repository of some of this information, PHIN VAD at the CDC that has some of this information. The Social Security Administration did the mega hit pilot of how do disability adjudication using a continuity of care document, and what they did was really quite interesting, which is they took those pieces of the C32 specification. They took those vocabularies and code sets that are necessary, and published in one PDF everything that an implementer would need.

Now maybe because they're the Social Security Administration, they can do that, but I would challenge us. If we're going to build these tools for the real world, having one place I can go with everything that I need would be wonderful. We could certainly leverage your contracts. That'd be great.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
I like this notion around clarity because I think that provides clarity to what we're trying to do. Some of the problems that we're trying to solve are complex, and if you have a complex problem, and you try to provide a simple solution to that, sometimes you're going to have a mismatch with that. So I think we have to recognize what the target is. The target isn't to make it simple in the sense that it is not meeting the needs of what it is, the problem you're trying to solve. But it needs to be clear, and part of clarity is simplicity. It isn't as if those two are disconnected, but we really do need to try to strive for that because I

think the more that we can make it clear, the more that we can make it simple, the more we're going to be able to drive towards adoption and use of these things.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I think it's important that … capture a couple of themes, Jamie and Betsy, in response to this line of dialog. One was in operationalizing simplicity. Where do you get these resources? … greatest fans would agree with you that the pointer to pointer to pointer is challenging. So I think you give a very inspiring example of something that synthesizes the social security example of all of the necessary information in one place.

The second line of discussion had to do with the pragmatism, and Judy maybe gave the example of the smoking cessation, recording those quality measures. Doug, you described the need to really cultivate an ecosystem. In one sense, an ecosystem might evolve through natural selection. What we need to do is decidedly goal direct it. I was going to say unnatural, but that sounded a little strange. But it is a very goal directed, and goal directed toward meaningful use one, two, and three. I hear that pragmatism as well, so I think we need to capture those two aspects in terms of the ongoing work.

Let's take three more comments on this topic: Dixie, David, and Wes, in that order, and then go back to the second set of themes from the hearing. Dixie?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
The hearing is great too. First, to just observe that code sets are inherently unstable because they're always updating, always new versioning, releasing new concepts, etc. On the other hand, or equivalent to that, value sets seem to be established by kind of context specific stakeholders. I had two questions giving those two facts. One is do you expect through this versioning or this governance that you anticipate, do you expect that concept versioning will be maintained stable across value sets? Secondly, do you also anticipate replacing concept extensions, the concepts that are in the extension with a code set concept if one is released that's equivalent with an equivalent code that's released?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I think that it seems that the answer to both of those is probably up to the value set developers, which would be in meaningful use initially, the measure developers. I don't have an easy answer for that at this point.

Betsy Humphreys – National Library of Medicine – Deputy Director
In terms of what happens to the primary codes that are vocabulary when something migrates from a produced extension into there, my view is that clearly what we have to do going forward is deal with the fact that whatever the original identifier was assigned is still an active alias for whatever. If another one has to be assigned, well, okay. But we have to have that as an active alias going forward. We can't really be expecting everyone in the world to go back and back maintain their electronic health data.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I really was talking about moving forward.

Betsy Humphreys – National Library of Medicine – Deputy Director
Yes.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
It really is. Both of my questions have to do with the evolution of value sets, and it sounds like there will be, within an EHR system, multiple concepts used by different value sets, right?

Betsy Humphreys – National Library of Medicine – Deputy Director
We'll have to see how this evolves over time. At the moment, I cannot imagine that every value set for every measure that makes use of the same concept and vocabulary is going to be updated on the same day because, in fact, these things relate to exactly how those concepts are recorded in health records

and whether this is going to be a meaningful denominator or numerator or whatever. It seems to me it's kind of impossible to imagine that in any near term, that all would be happening simultaneously.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Right. I would also just comment that the use of or the need for a U.S. extension to accommodate a new need that's found for a particular value set, that's the exception. So I think that the vast majority of these value sets do and will continue to use, for example, SNOMED CORE, the international release of the underlying taxonomies. And so this is not something that it's not present, and it's not a problem that's going to be found in every value set. But there will be somewhere this applies.

Betsy Humphreys – National Library of Medicine – Deputy Director
Of course, value sets that rely on searching for a set of test results or dealing with a class of drugs may have more rapid updating requirements as new tests come in to use for testing for the same thing or the set of drugs used in U.S. healthcare or elsewhere for a particular thing changes.

Jonathan Perlin – Hospital Corporation of America – CMO & President
David McCallie?

David McCallie – Cerner Corporation – Vice President of Medical Informatics
This question may be too technical, or it may be something that's addressed as your theme two, but I'll queue it up anyway if it is, or you can push it forward. But what I was pondering is the approach to creation of value sets, particularly with trying to deal with the complexity of the underlying vocabulary. So if something like SNOMED, which allows for post-coordinated complexity, one use of a value set is to pre-coordinate the common combinations so that you don't have to deal with the post coordination complexity, which isn't really terribly standardized at this point.

A similar complexity issue might be crosswalks where it's not a one-to-one mapping between the two vocabularies, and you have to either define rules or constraints to decide how to automate that mapping. Is there some thought given to how to wrapper some of those complexities in the output of this work to create a one-stop-shop? I know that's a really broad question, but those are the things you stumble on in implementation.

Betsy Humphreys – National Library of Medicine – Deputy Director
I think that certainly there are people who, in addition, obviously to you, who understand these complexities. I think that my own view is that this is where Doug's focus on iterative and going forward is, I think that from my way of thinking, there is a very long and profitable, in some ways, R&D agenda around how we can really make this as efficient and useful over time. Yes.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Wes, go ahead, please.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
In the last round, we had an interesting dialog between John Halamka and Albert Einstein. John held up an imaginary PDF document and said, it's got to be this simple, one document. Albert Einstein is known for saying things should be simple, but not too simple. I want to emphasize that in this one Einstein is wrong, John is right.

If there's one thing we've learned, what I learned early in programming is that my expertise is limited by the number of fingers I have because I had to have each one in a different page in a book and try to flip them all together in order to make a decision about something. The funny thing, URLs don't do much more than fingers in terms of count. If we cannot reduce our specifications to something that is accessible to someone who is not an expert in informatics, just a working guy trying to get some programs written, then we will fail. So I just want to make sure that we don't accept complexity as a compromise rather than hold to that ….

Jonathan Perlin – Hospital Corporation of America – CMO & President
Well said.

Betsy Humphreys – National Library of Medicine – Deputy Director
When we were discussing simplicity and clarity and clarity being even more important than simplicity, I think we were looking at it, or the comment was made. Maybe I even made it. Clarity actually has to precede simplicity. It's very difficult to simplify something you don't understand.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
If I could add to that without getting too philosophical, creating simplicity actually feeds back into creating clarity. That is, as you try to make it simple, you realize by leaving decisions to the last implementer, you were leaving things undecided. The fact is that there actually has to be a feedback process that goes all the way through and back.

John Halamka – Harvard Medical School – Chief Information Officer
So the SSA's mega hit implementation guide is not simple, but it's extremely clear. That's why it was very easy. I mean, Jamie, I think you probably implement it. We implemented it. It was just, okay, you're on page three. It says you have three choices: A, B, or C. Okay. We just write the code.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Nancy, quick, and on this point.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
I'd like to figure out how we could also help the industry understand how important this clarity of content knowledge is before you go and say, "Well, gosh, let's go implement something about discharge summaries," because it's a long education battle to tell technologists and engineers and systems engineers that you can't build this yet if you don't understand what you're going to be sending. I think it's a hard thing to do where people are used to iPhone apps and stuff like that they can just—"Well, can't you just make it happen and we can view it?"

I'm not sure how we can put this discussion in so that—and I sometimes—it's the information management concepts that have to be defined before the technology can work in this industry. If we can just use this process to help say that basically healthcare organizations don't fully understand how to communicate well with each other yet, and we've got to figure that out before we try and apply all go hell bent for the other to go for this technology solution.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Terrific point.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Let me just summarize perhaps quickly some of the other major themes, and then I do want to drill back down into the intellectual property issue. We heard very consistently that version management is absolutely critical, and this is for all the implementers. They have to know exactly what version. One of the things that was also discussed is the possibility of having expiration dates on different content sets to essentially force updates to maintain the level of currency in terms of a version management scheme. Whatever the version management mechanisms are, that was a key set of requirements for the one-stop-shop to facilitate access and use of the vocabulary content.

We also had a theme of what you would expect, I think, sort of, I call it, technology infrastructure, but this was a focus on system performance characteristics, availability, uptime, making sure that there was appropriate security around the actual technology that was used for the one-stop-shop so that folks could have a sense of confidence and reliability there. There was some discussion. Some of our panelists suggested using particular aspects of cloud technology, some distributed solutions. It sounded to me as though that was getting into the solution space, and our hearing was really trying to get to what are some of the requirements, and so the requirements were to have good and published uptime to have

appropriate system performance, which may involve load balancing or other kinds of solutions. But whatever the solutions are, they have to meet that set of requirements to have a stable, available system.

We also heard—and this is back to some of the previous discussion that we've had here today—we heard a very important and repeated theme around value set context. This is where we're getting into Wes' comment about medical knowledge that the intended use of a value set really does establish a particular purpose and suitability of the value set to be used really only for that one intended purpose. So one set of requirements that we have for the one-stop-shop is to be able to document and make available an understanding, a consistent understanding of that intent and of the context for the use of the value set.

We also had a very interesting discussion about what was termed off label use of the value sets, so if you're using a value set for something other than its intended purpose in a particular measure, we had some examples of cases where that could cause some serious problems. But in other cases, it may be fine, and so information about permissible off label uses of the value set could also be helpful. So, we had a very rich discussion on the need for that kind of context information. I think this goes back to the previous statement about just an enumerated list of codes being insufficient for implementers of particular value sets. There needs to be some method of consistently documenting the intent of the use of the value set and its context, and that needs to be essentially part of the initial information that's made available for implementers.

There was also some discussion in multiple panels and actually some variety of views about the ownership of value sets. But I think, regardless of who should own the value set, there was a very consistent theme of the need for multi-stakeholder, cross-functional involvement, not just in the development of value sets, but also in a review process and refinement of the value sets and of the description of their intent and their context before their publication. So the idea is that the one-stop-shop should facilitate by making that information available during the development process, facilitate that cross-functional review of the value sets.

What I'd like to do now is drill down into some of the intellectual property issues. We did hear from every panel that IP can be a significant barrier to implementation. We heard some examples here from the living the dream comments earlier about particular aspects of mapping to proprietary taxonomies or even IP being contained within particular value sets. So every panel said that IP restrictions and licensing is an issue. I want to pause for a minute to just describe what the scope of that issue is.

The issue is not just about the vocabulary standards themselves. In other words, we're not just talking about the proprietary medication or procedure vocabularies. We're also talking about extensions. We're talking about derivative work such as the cross-maps that include the proprietary IP on one side of the cross-map and value sets that contain the IP. But we also heard, and unexpectedly for me, but very interesting, the same issue coming up in terms of both the use of HL-7, as well as X12 messaging standards that contain particular value sets that have IP, the exact same IP issues related to the messaging standards that use this vocabulary content. So this focus of our hearing was clearly on the vocabularies, not on the messaging or infrastructure standards, but the same vocabulary issues in terms of intellectual property, licensing and restrictions comes up in the context of the messaging standards as well.

So everybody said this was a major problem, and all of the panelists who said it was a problem had different potential solutions. The solutions, as I say here on the slide, were all over the map. So we had folks who said, "Well, just make monopolies illegal, and don't allow monopolies for any code sets that charge fees." Another solution that we heard several times was that the government should pay national licensing fees, so basically make all of this free to everyone who is implementing this intellectual property in the U.S. So basically if it's used or referred to in a regulation or in the meaningful use incentives program, then the government should license it. So those are sort of two opposite ends of the spectrum.

Then, in between, we heard the Canadian model essentially, which is that there is a national license, but that providers pay a user fee essentially for the use of that IP that defrays a part of that licensing cost. So, whatever that percentage is—in Canada, it may be a small percentage. Here, there was discussion

about it by some of our panelists being a higher percentage. But these are just different potential models for dealing with that issue.

But we also heard from the actual implementers, from the hospitals, academic medical centers, from the small office physicians. You just have to make this simple for us, and so this is one case where simplicity in fact may be more important than clarity. So I've got a few quotes here from my notes of the hearing, and I'll just read these out. So one fellow said, "I understand the need to pay for the standards I use in my EHR, but I'm not in the business of tracking intellectual property in my practice." This was a small office physician.

We had other folks who said, "Of course, I'd like it to be free. Free is better, but we don't really mind paying a reasonable fee," and, "We're used to that model. We're used to paying for intellectual property, but you have to make this simple for us." We had another panelist who said, "Just tell me how much it costs and where to send the check," basically.

So in fact, considering these comments and the plea for simplicity in this area really suggests potentially a different model rather than national licensing or making it illegal. But in fact, the idea is that the government or its agent could centrally administer licensing payments and for the intellectual property that's used in meaningful use. So this is really separate from the question of whether things are licensed nationally or not. So some of these are licensed nationally. Others may not be.

But the idea is that to make it simple for the implementer, there should be essentially one-stop-shop for IP. So you can imagine a variety of different potential ways that this would be used. One might be essentially a checklist. You fill out the checklist and say, which are the value sets, and which are the taxonomies that you're using, and at the bottom it tells you what your check is and where to send it. But the idea is that somebody else—other than the providers who are implementing EHR technology for meaningful use—should be administering the intellectual property and processing the payments, and potentially even negotiating what the license fees are.

This is an idea that came out of the testimony that we heard from our panelists. We did not discuss this idea specifically in the hearings. But after we sat back and reviewed what we heard, this came out of the testimony pretty clearly as an alternative. So I'd love to get discussion on this concept from the committee.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Why don't you go ahead to your conclusion slide, and take that ….

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
In terms of next steps, we are hoping for full committee discussion on this, and then we have additional taskforce meetings scheduled to develop recommendations, which we'll bring back to the committee. But I really did want to get back and get input from the committee on this idea of centralized administration of intellectual property, so not just make it free, but have somebody administer it.

John Halamka – Harvard Medical School – Chief Information Officer
Let me start, and that is that being a very practical person, when you look at the alternatives, I know we won't allow any one organization to develop vocabularies. It's very challenging to implement such a rule. I know we'll find government funding forever, and that'll be the solution to the problem. I mean, maybe, but it may take a while. So what you proposed is intensely practical, which is a government as a platform, in a sense, to facilitate a process that could conceivably be near cost neutral because I would completely concur from an intellectual property perspective. If I could write a check to the National Library of Medicine for $5,000 a year and then be able to download all the IP that I would need, I mean, wonderful. I would be very happy to do that.

Betsy Humphreys – National Library of Medicine – Deputy Director
I think that we can't accept your check, but no doubt somebody could. But I think that just to bring up a couple of the other issues that came up in this, if you were doing something like that, and you would

actually imagine that what might be an accompaniment to such a thing is that certain government agencies or other groups would actually pay the fees for certain groups. We were commenting, and we heard this. Even the cost of paying for an HL-7 standard or being a member of HL-7, which is really not that big depending on where you are in the food chain, is more than many county public health departments in the United States can afford because, if you've got $20,000 or $15,000 is the entire public health budget for your county, and somebody says a $300 fee or a $5,000 check. I think there's that.

As someone who spent a great deal of time thinking of every possible way to get out of doing certain things that I ended up doing, the notion of who has paid and who has not, and who are they covering, and how do you keep track of it and whatever, you would just have to come up with a very simple system for that. When you do, I'm going to be very, very delighted to see it. I mean that truly because one of the issues that you have is how you figure out who's covered by what I've paid, and if I'm covered, and I contract with Dixie to do something for me, is she covered. Then when I get rid of that contract and go to somebody else, are they covered?

It is something that is, in a way, very attractive and probably can be done. I'd just say that there are a lot of details to be worked out. Then you have to divide by the number of people who would actually pay the fees and would not get out of it because they were employed by someone else who paid them and say, "Okay, can all the rest of them who are going to pay actually afford it, or have we raised the bar too high?" I just point those out as issues that would have to be pursued, but that doesn't mean that somebody shouldn't really think about it and potentially pursue them.

John Halamka – Harvard Medical School – Chief Information Officer
So you're right. The devil will be in the details. Let me give you an example of intellectual property I license. So there are many publishers of electronic journals. And those electronic journals have a fee. Of course, they license them to me, Beth Israel Deaconess Medical Center, and then the affiliates of Beth Israel Deaconess Medical Center, well, we're on staff. We get access to those journals too. My brother works in the office on Tuesdays, and he gets access to the journals. Now his wife also. Suddenly defining what is the scope of access to intellectual property does get challenging. I agree.

Betsy Humphreys – National Library of Medicine – Deputy Director
It gets extremely challenging. Of course, I guess I know a little bit about that problem as well. The other issue is then you get into equity issues, which can be very interesting where you have people who work in the hospital, and some of them are affiliated with somebody who has a license, and in fact they're covered by the license. But they're working with people on a healthcare team in a hospital, and the other people in the healthcare team don't have that same affiliation, so you can end up with very strange things of where the access falls off and then how you handle it. As I say, it's an interesting idea.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Let me just comment as a counterpoint to this discussion that the scope of this recommendation that we're proposing is for meaningful use. Meaningful use has a known list of eligible professionals and hospitals and other specific kinds of organizations that would be the licensees. So there's a very specific list of who would be covered.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Even granted that limited scope—and particularly in view of the fact that the scope is going to have to expand dramatically to meet the country's needs—I think it would be worth doing a very careful economic analysis. I believe that analysis would show that the cost of accounting for this was greater than the cost of the government just licensing the various rights and providing them to anyone who wants to use them basically, perhaps commercial, well, even commercial entities probably. But I think we're assuming the results of an economic analysis that we haven't done.

I think we also need to recognize that it is almost certainly the second economic analysis, almost certainly in HHS's and the government's financial interest to encourage the widest possible use of these things, and that that would be another reason why not just the cost of the accounting, but any possible. It's hard to believe there wouldn't be some retarding effects of such accounting on the use of these things widely,

whether that retarding effect wouldn't be greater than any amount of money that might be raised by such a system.

Betsy Humphreys – National Library of Medicine – Deputy Director
Jim's point is well taken and, as far as I'm concerned, as one who used to have to charge for med line searches, I've got to tell you that it costs a lot of money to collect money.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Let's go to Linda Fischetti.

Linda Fischetti – VHA – Chief Health Informatics Officer
I couldn't agree with Jim any more, and certainly, Betsy, I can write you a check. We don't call it a check, but I could send money to you, and that would be easy for me to do from the Department of Veterans Affairs platform.

But the one thing that I wanted to point out to emphasize Jim's comments were when I read slide eight last night, I was absolutely stunned at how gracious the providers were within the context of meaningful use, within the context of the incentives, within the context of how invasive we are being to not only going to use health IT, but this is how you're going to use this, and this is what you're going to do, that we would even come along and ask them, "Oh, and by the way, how are you going to pay for the intellectual property that we are telling you that you must use in your organization?" They were so gracious in their response, and I'm surprised they didn't sort of come across the table and say, "That's an easier thing for you guys to fix. Fix it."

Jonathan Perlin – Hospital Corporation of America – CMO & President
Let's go to David McCallie.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
I would also like to second the comment Jim made. The cost of managing a system just has to be pretty darn close to the cost of just buying the licenses. The second thought is, from our experience with SNOMED, when the license went from something that you had to go worry about, whether your users had it or not, to something that was covered for everyone.

It radically increased our interest in imbedding SNOMED in our products in a way where we didn't have to worry about that. So innovation in all sorts of ways was released or generated by the fact that that licensing hassle was taken away. So marginal use cases for something as powerful as SNOMED all of a sudden became no brainers where they had been complex argument before the national licensing. So I think there are just a huge number of benefits downstream to removing those issues from the table, and keeping track of who qualifies.

John's point is a great point. I mean, we run into that every single day with re-licensing products. Who is covered by a particular license? It's just a nightmare. I don't think we can afford to do that. That's a comment, not a question.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I do hear a theme, and looking at Wes' face, I'm wondering if we're getting ….

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I'll think of something different. The first thing I need to say is that just so everybody is aware, HL-7 has never charged a user fee for its standards. You'd have to be a member or pay for the book, but just because you buy an EHR system that uses HL-7 standards, including the codes that are in HL-7 standards, your practice doesn't have to pay for HL-7. That's different than some of the code standards where if your IT system uses it, you have to pay for it.

I think that if I was seconding what's been going around, I'd be the fourth second or something. The real issue we have is a pragmatic one, which is that you don't ever get to stop this jet plane to change the

engine. We, as advisors to the government, can suggest that future activities move towards standards, the development of which is funded in some way that it doesn't have to be recovered by a user fee directly or that is available on a national license or something like that. We can point to some history like SNOMED that says that when that happens, adoption goes up.

We can do things like RxNorm, which were effectively an attempt to break a deadlock of content providers, but by creating an interface vocabulary, which works pretty good. I understand Metformin is still a problem, but other than that, it works pretty good. But the one thing I think we can't do is create a situation where we go to the developers and say, we have to buy what you have to offer no matter what the price. Therefore, an attempt to get to national licensing, to get to pave the development as opposed to licensing for use, will continue to be an influence and a direction we head in as opposed to a clear and simple, all applicable policy.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Let's take the last comment on this discussion from Cris Ross.

Cris Ross – LabHub – CIO
Actually, my question is not around IP, but around your recommendation themes number two. I figure there's no other cards up, so maybe it's fair game. This question around version management, there's this task of two organizations that might properly encode everything they do, but wish to communicate with each other, and their versions are not identical. I'm curious whether your hearings address that issue, and if you talked about whether you expected that task to be delegated to each individual organization, whether you saw a role for intermediaries to do translation tasks? How might that be handled because it feels to me as though that could be a significant overhead burden on organizations if they need to be aware of what's the language that my receiver needs to speak for me to be able to speak to them.

Betsy Humphreys – National Library of Medicine – Deputy Director
I'm not sure that I entirely understand the comment. I know that in forward development of measures and retooling of measures that are related to quality measure value sets, they are in effect working on, in some sense, because of the transitions they know that they're happening going forward of having the value set or the denominators and numerators defined in terms of multiple vocabularies. So for example, you have the SNOMED CT definition of the numerator or, say, the denominator. You have the ICD-9 CM definition of the denominator, and they're also working on the ICD-10 definition of it.

Cris Ross – LabHub – CIO
I guess the example I'm thinking, let me give you a trivial example maybe would be NCPDP version. For example, someone is operating on 8.1, and someone is on 8.2 or 10.6. There's role for intermediaries, for example, in that situation to translate between the two so that you don't need to know what the receiving entity is capable of receiving. That may not work in every situation, and I'm wondering if that. Perhaps it isn't an issue at all, but it seems to me as though two organizations who may have value sets that are perfectly codified, but they're not the perfectly up to date version, they're not working on the current release, have some task and some difficulty in communicating, especially the case of where someone is using an older version and wants to communicate with someone who is using a newer version.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I guess, in the first place, the primary use of the value sets today is for the measures that relate to meaningful use, and there's only one recipient, which is CMS. I guess that mitigates that issue to some degree now. I think that the comments on versioning also to a large extent would apply to the different subsets, the convenient subsets that would be changed and updated, as well as to extensions that would be downloaded at different points in time.

Betsy Humphreys – National Library of Medicine – Deputy Director
Jamie, I think there are a lot of value sets in the messaging standards already that people have to use, and they all obviously go through versioning. The whole issue of how the versioning of code sets and

value sets are going to map onto the absolute requirements for meaningful use and for certification of products—I think that this is one of the issues that is going to have to be iteratively improved over time because, when you're dealing with rulemaking, and you're dealing with a test—I have to pass this test in order to have a certified EHR product—then it's actually, there's actually language about this in the rules because, on the one hand, we would like the product to be able to handle the most recent version of whatever it is.

On the other hand, I've developed my product, and I've worked on all of it. I'm sending it in to be certified, and the day before I send it in to be certified on a schedule that I have no control over, the ABC value set gets updated. So the actual certification process and testing and whatever has to address this issue.

Others in the room probably are clearer on the details of it than I am, although I certainly read these rules many times. But I think they actually are handling it with sort of a minimum requirement, and then if you come in with something that is more recent that you would probably also be certified. So what you're describing is going to happen, and I think that the rules, I mean, and I think that there are going to be issues and problems around it. How significant they're going to be, I guess we'll all find out. I could imagine there being services or approaches where people would focus on this problem where it really matters and provide a service that solved it for a group that was exchanging data. I would sort of expect that those services might emerge.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I hate to draw this session to a close because it's so much at the heart of the concept of interoperability, but just a terrific discussion. I take away a couple points. First, I commend the taskforce and the synthesis of the hearing. I think you have just provided a very eloquent and usable definition of clarity in terms of your statements. But I think you heard from the group that we need to together operationalize simplicity.

Some specific guidance we heard was the one-stop-shop phenomenon. Second, heard a priority for those things that support meaningful use; third, clarity of the underlying information concept if we're moving on to the broader architectural implementation concepts; fourth that the vocabulary be accessible such that it can be used broadly by an array of potential users. Then that we have to—and I think this latter discussion about … really falls into the operationalization and simplicity that we have to manage the IP efficiently—I think one pragmatic or very practical piece of guidance on top of that is that limiting to the universe around meaningful use helps to scope that.

I heard two themes about the management of the IP. First to make it overly complex in terms of managing the IP, as … Jim Walker's point that those costs could be formidable, and that the general consensus that when SNOMED became accessible, its implementation, not surprisingly increased dramatically. But we can't—to the point that was also made—create it at any price situation, which would also create its own set of challenges. This leaves many unanswered questions, questions that both the vocabulary taskforce, as well as the overall standards committee, will have to grapple with.

I think Wes has always brought us to the philosophical grounding. Einstein did say make it simple, but no simpler than it need be. I also heard from the discussion that the devil is in the details. It's interesting. One of the architects known for really a reductionistic approach to simple elegance … Vanderow, and he charged that God was in the details. It's going to take that sort of masterful synthesis of what we hope to achieve to reduce it to a simplicity that reflects the desired utility, which I think was the upshot of our collective discussions. Thank you. Great presentation. Great discussion and obviously a good bit of work ahead.

It also serves as a terrific transition into then the next topic, the update from the implementation workgroup. We have Judy Murphy and Liz Johnson, and I'll turn to John Halamka to moderate this session.

John Halamka – Harvard Medical School – Chief Information Officer

As that one transition sentence, and that is, one of the great themes of the implementation workgroup is reducing barriers and accelerating enablers. Based on the discussion that we just heard from Jamie and Betsy, I would suggest that solving this intellectual property issue is one of the great enablers. I can think of no better way than to get meaningful use and standards interoperability accelerated than to just make it simple and easy to access and reduce the administrative and the intellectual property barriers that everyone discussed. Whatever I know, Judy Sparrow, that is probably not in our purview to recommend funding models to ONC or HHS. But I think we heard loud and clear that the licensure of SNOMED intellectual property was a real accelerator and enabler for the country, and if we want to get this done, we should certainly consider how we might use that in other contexts.

I'll turn it over to Judy and to Liz.

Judy Murphy – Aurora Healthcare – Vice President of Applications
Well, I'll get us started. The implementation workgroup member list, at the last meeting we talked about that the committee was in transition, and that we were adding new members. As you can see on the list here, we added a significant number of new members, and we've still got a few to go from VA and from ONC, but otherwise have assembled quite a cast of characters. I'm going to use your quote, Jonathan. God is in the details. This is definitely the group that's working on the details where there's a fair amount of rubber hitting the road.

Our broad charge, again, was to bring forward real world implementation experience into the HIT Standards Committee recommendations with special emphasis on strategies to accelerate the adoption of proposed standards or mitigate barriers if any. That is proving to be quite interesting and, I think, again, pragmatic, which is a word that's been said several times this morning, is the bent that this group is really trying to take in terms of going forward and understanding what it's really going to take to achieve and document and measure meaningful use.

We had one meeting between our last standards committee meeting and today, and then we do have monthly future meetings set up. But let me talk about the discussion that we had at the September 15th meeting. There are four slides that are going to talk about some of our list of potential activities. What we did at the committee or the workgroup meeting was really brainstorm ideas of what would be most helpful going forward in terms of implementation, and how could we give the best guidance, and how could we help the constituency in terms of those folks that are really trying to go after stage one meaningful use criteria?

The first recommendation, and Doug actually was on the call, was to recommend that ONC create a publicly accessible, online report, and/or dashboard to track implementation progress. The idea here was not just meaningful use qualification, but also progress for the regional extension centers, the state programs, the beacon communities, and the national health information network. The ideas were not to duplicate any of the existing reporting that's currently taking place for these initiatives, but rather to again harmonize, and that's a word I think we've been using a lot, but post in one place. Yes, not links to links to links, but posting in one place what is already being done through the various programs, and create a simplistic way of making sure that folks can stay aware of the progress of the different initiatives.

Then we spent a bit of time actually talking about meaningful use and the ability to provide access to the public, lists of vendors who have completed certification, providers in hospitals who have registered with CMS. I think you all know the registration starts January 1st, so the idea is those folks that are going after this are going to be registering, and the ability to have that publicly accessible so that if Peter wants to find Paul, to dovetail onto some activities or to understand what other folks are doing that there'd be that capability of doing that.

Then, furthermore, providers and hospitals who have attested to meaningful use with CMS, and that again is going to be as of April 1st, that those lists are publicly available. Then providers or hospitals who have successfully achieved meaningful use qualification and who are cited to be receiving the incentive payments. Again, the idea is the networking that that would provide, as well as the public availability of

this information. The goal here is to provide situational awareness and transparency, as well as, again, access to potential resources between different organizations.

I think I'd like to pause and see if there are any comments or questions, and to give Liz a chance, if there was something I missed from the ….

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
I don't think you missed anything. I think what we really heard though very clearly is that today when you go out to the CMS Web site, and we go out to ONC Web site, you get into this sort of circuit where you go from link to link to link, and then to huge documents that are almost uninterpretable by our public and are saying, can you simplify. Can you bring us places where we can find very crisp information that's useful in moving forward? That's a challenge for us, no question, but it's one that we're going to undertake so that we can stop that process as much as possible, which is part of what Judy was saying about not duplicating the work of others, but instead getting to more concise and more navigable Web site presence for us.

We'll entertain questions regarding to this first round of brainstorming.

John Halamka – Harvard Medical School – Chief Information Officer
Comments? I think everyone agrees with you.

Judy Murphy – Aurora Healthcare – Vice President of Applications
We'll move on quickly.

John Halamka – Harvard Medical School – Chief Information Officer
I think we all agree with you, as we all, 5,000 hospitals in the United States are going out individually to try to find this information on this own. So I had this funny conversation with somebody saying, "How do you get the answers?" I said, "I just e-mail Tony Trenkle. Don't you?" The answer is no.

Judy Murphy – Aurora Healthcare – Vice President of Applications
That's an interesting one because when you suggested that you were going to go after site-based certification, and that just popped into my head. Oh, my gosh. That journey or that experience, I don't know how many other folks are planning to do that, especially early on, but that's another experience that would be particularly helpful, I think, to be able to let people know how that goes.

There are a lot of folks in particular, I think, that we had talked about that are going to have to certify just components like a data warehouse. If they could understand how simple or complex it is, and how much it costs because that seems to be buried right now as well. It might be particularly helpful and less scary to individuals who are deciding they need to do that.

John Halamka – Harvard Medical School – Chief Information Officer
… start that process tomorrow, and I've chosen CCHIT as our certification entity, our ATCB. They have given me permission to document the process, the cost, the steps because I'll be doing a site certification of 146 different systems, as well as a quality data center that is provided as a third party service separate from our organization and the HIE services, which are separate from our organization, all at one time.

Judy Murphy – Aurora Healthcare – Vice President of Applications
How long—if I can get this in the public record—how long does that expect to take?

John Halamka – Harvard Medical School – Chief Information Officer
I don't know.

Judy Murphy – Aurora Healthcare – Vice President of Applications
You don't know. Yes. They probably don't either.

John Halamka – Harvard Medical School – Chief Information Officer

Every step of the way will be documented publicly, so the journey will be shared.

Judy Murphy – Aurora Healthcare – Vice President of Applications
So our second slide, list of potential activities, and maybe when we get to the end, I will ask for some feedback in terms of prioritization because, again, we can't go after all of this stuff, although we do realize that we definitely need to partner specifically with ONC to really get this stuff done. Provide feedback or reality tests. It's the HIT Policy Committee and HIT Standards Committee recommendations. Does this make sense from an implementation standpoint?

There was a fair amount of discussion about kind of the voice of reason, the feet on the street, realizing that a lot of the committee structures and the work and the workgroups that go on are positioning us for the future and worrying and thinking about the future. There's still that rooting in the reality, and I know that we had a brief foray into that this morning during the vocabulary workgroup report that although we do need to be worrying about the future, we also have some realities of exactly what's taking place today. Looking at, again, synergies and then, of course, areas of concern.

The next activity, encourage or advertise use of existing resources. I think those of you who are going to the health IT Web site certainly noticed the redesign a couple of weeks ago. But more importantly, there seems to be an underutilization of a fair number of the resources that are actually available on that Web site, so the health IT buzz blog, the federal advisory committee blog, several of those have postings that are quite old, almost ancient by IT times.

The health IT journey, stories from the road, and here we were talking about actually in all three of those areas of using some of the committee membership to try to reinfuse some ground swell of activities where we and our friends would get people posting to hopefully get some activity going, which would then show the value of it, which would hopefully then get other people posting for the purposes, again, of sharing those stories from the road, if you will. Calling out another quote from today, those who are living the dream or not so much.

Then the ONC FAQs and the CMS FAQs: There was some discussion there about getting good answers in some cases and, in other cases, I used my vendor experience for this one where you post a question, and you get back the—we always called them NAPWADs (not a problem; works as designed) and questions getting close without actually being answered like solved. It's like, "Well, could you tell me what the answer is?" So a little bit of not dissatisfaction as much as needing some additional clarity in some of those FAQs.

We did understand that in many cases there were difficulties in doing that because the folks who were actually posting the answers, it's not in their purview to give the answer. We had a fair amount of discussion actually with Lisa from NIST specifically related to what they can comment on and what they can't comment on. Then can we create a venue for comments or questions that are outside the purview, if you will, of some of those organizations? If so, who would answer those questions?

Let's go to the next slide and do the comments at the end. Evaluate and consider use of social networking tools to connect people and learn from each other's implementation efforts. That was met by an interesting set of comments. We don't necessarily want to create yet a different venue for incorporating comments and experiences, and yet, we did feel like there was some untapped potential there to connect people with other people who are doing some of the same things. So there was a bit of a discussion about that.

Providing clarity on the meaningful use specification and resolving any confusion on available resources, everybody has been experiencing, I think, the same thing. Many of the vendors, many of the different organizations are weighing in and posting comments and documents on the meaningful use specifications, and there have been some concerns about what exactly is the source of truth.

If an organization posts something that's maybe not exactly perfectly correct, what kind of concern is that going to hold long-term? Really looking at the health IT Web site and the ONC Web site, CMS Web site,

as a source of truth and creating the playbook for meaningful use, providing the guidance on the National Health Information Network, and NHIN Direct, as well as helping providers and hospitals determine how to bridge efforts regarding the meaningful use performance, the quality measures, and the National Health Information Network, and again, some confusion about how to harmonize really all of those different activities.

Last on this slide, to clarify consumer expectations of EHR vendor certification. What can they actually expect from a certified EHR vendor product? We had a fair amount of discussion that if I implement a certified product, than am I done, and I can walk away? Of course, nothing could be farther from the truth. Several of the meaningful use criteria actually have adoption measures. It's not just that the software is capable of doing a particular feature function, but rather than the users are using it in a particular way.

Similarly around the quality measures, exactly getting that data entered into the EHR and then reporting it, can I just assume that that's just going to be magic. Again, those of you who have been working on the quality measures understand that one. Those are particularly, let's say, troublesome or more difficult because it's not information that we have typically documented across the board in codified format.

Our last slide on activities consider a home for the questions that NIST is not able to answer, and a place to public lessons learned. I alluded to this one on the previous slide, but really a place where we could go and have more of a free format ability to post things and create reaction and answer questions. Ascertain, if it would make sense, to create a version of the NIST test scenarios for consumers to use in evaluating their implementation and adoption of the electronic health record. It was noted that not just our sites using the NIST test cases or the test scenarios for looking at if they're attempting to achieve certification on their own, but even if they're using a vendor product that there's a level of specification in those test scenarios that puts additional clarity around some of the standards and the measures. Should we maybe just make that more clear that that is a resource that is available, and then look at those not just from the standpoint of using them for certification, but also to actually use them for specification.

Then there was some discussion about really determine what drives our workgroup agenda. Certainly, as these slides have inferred, we had our understanding of what we thought we wanted to do, and we did some brainstorming around that. But getting some additional input from others, and again, we thought that we might use some of the more publicly available venues like the blogs to get some input from the feet on the street, if you will, in terms of what their feeling they need for implementation, and then certainly getting the policy committee and the standards committee's feedback.

With that, I'll go through our next steps, and then we will open it up. We want to find out what ONC and CMS already have planned, and what they need our input or feedback on. We want to prioritize our activities, create a roadmap to begin work on the highest priority items. We do want to add a member from public health and then determine metrics to measure our success as a workgroup. Of course, being feet on the street and having that pragmatic bent, if you will, we did think it was important to look at success criteria for the workgroup itself and measure ourselves against that criteria. Liz?

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
I would say that it's pretty clear that what happened was we spent about almost two hours, and the world is our oyster, as they say. Everything that you want and we want, they want now. So we really do need your help to prioritize where we can be the most effective. We're going to go back to the work team in October and set out the roadmap, and then we'll bring it back to you. But this is critical because the time is short and the needs list is expansive. And so we really did.

We heard over and over, we need to be the ear to the street. We really need to be responsive in a very proactive and timely manner to get them the information they need. So as we went through and tried to synthesize all of the input, you can see the kind of priority list we have in front of us, and now we need your input from your perspective, are we on the right track? What do you look to us for, and certainly both from the workgroup, as well as the committee?

John Halamka – Harvard Medical School – Chief Information Officer
Comments or questions? I'll certainly suggest that everything you stated about coordination of communications is right on because the last thing we want to see is every practice and every hospital reinventing the wheel, having the same questions, going to Google to try to find the answers because, as you've suggested, the answers will be highly variable depending on the site you click on. Walter?

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
I think it's hard to disagree with any of the topics that you included. I think they're all very critical. Then the challenge in my mind was to try to define the scope, if you will, of the activities of the workgroup, and as I was looking at the various activities that you describe, it included education. It included outreach. It included monitoring and evaluating what's going on, how things are going, so in my mind, as a suggestion, I guess, as a recommendation of trying to scope out the priorities, I would say the implementation workgroup and, as I recall, the … charter and some of the discussion back then was to look at best practices of how implementation was taking place in the country, and highlighting those, perhaps, and then identifying issues of implementation.

Now implementation of what? Well, I think there are two answers to the what: the implementation of meaningful use, and the implementation of HIEs. I think those two seems to me important priorities to focus on. There is implementation with a lot of other things that are happening in the HIT realm in the ONC portfolio of activities, including the REC, the regional extension centers, the beacon community projects, so there are a lot of other things that are happening. But from my understanding, the interest was to try to focus on the implementation of meaningful use and HIEs from the standpoint of the standards and how the implementation of those standards was happening and, again, try to identify best practices to highlight perhaps pathways for others to follow.

I would suggest that that might be one way of trying to scope out the focus of the work coming up. I totally agree. I think that the first recommendation is part of maybe why you didn't get a lot of reaction was that's the great idea. I think it should be already on its way, or it should be done, or the work should have started already. I think probably ONC would argue that they already are starting to assemble that kind of information, maybe putting it in one single Web site, and it's one next step. So I think that first recommendation is terrific, but I think into moving forward, the recommendation I would make is to focus on HIE implementation and standard—and I have a visitor here—well, HIE and meaningful use. I think those two would be the ones that I would suggest get focus.

John Halamka – Harvard Medical School – Chief Information Officer
Dixie, David, Nancy, and Wes.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
The stage one meaningful use, it's only security requirement is risk assessment, and it assumes HIPAA compliance, but I suspect that these organizations will need more guidance in both how to conduct a risk assessment. Secondly, how to configure the security functions that are available in their EHR so that they will counter the risks that they've identified because it will not come all set up right out of the box, and there are places you can point. NIST certainly has some excellent documents on security. But I think that they'll need something very specific, especially the small practices.

John Halamka – Harvard Medical School – Chief Information Officer
Very good advice. David?

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Who do you think your primary consumers would be? Are they more likely to be the vendors who are implementing systems, or the customers of those vendors, the actual end users, or both? I think that the way you structure and the kind of content would differ depending upon who the primary audience is. We get a lot of questions that come to our internal Web site, many of which are answered fairly quickly and easily, some of which we bubble up and call Tony Trenkle or someone and get the right answer. But it's a different set of questions depending on where they're coming from, and who are you targeting?

Judy Murphy – Aurora Healthcare – Vice President of Applications
I would say we're targeting both. The reason I say that to you, David, is there's not a coordination between the two, the response is for both, then we end up on one side or the other of the world of implementation, uncoordinated and, therefore, not successful. That would be my response.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
But if I had to focus on one or the other, it would be the users, if you will, or the consumers of the electronic health record. I think, to kind of go back to Walter's comment, our first slide might have been confusing actually in that we listed out the beacons and we listed out the state designate entities and the HIT regional extension centers, but actually only to the extent that they're providing those best practices for the average consumer, if you will, or the average user of the electronic health record, and to make sure that what is being learned in those spaces can be adopted or adapted, if you will, by that provider or hospital organization who is trying to achieve meaningful use and quality for the incentive payments.

Judy Murphy – Aurora Healthcare – Vice President of Applications
I can tell you, David, the most significant cry for help though is coming from the smaller physician groups, the smaller providers. That's where if we can take the learnings of the larger organizations than what the vendors providing them, and translate it into those really significant need areas of the smaller doctor's office, the smaller hospitals, then the work will be very meaningful.

John Halamka – Harvard Medical School – Chief Information Officer
Nancy?

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Just a quick question about, there was one item about some questions about the NHIN or Nationwide Health Information Network and the Connect, and I was curious whether it might be a little early for some of these end users to think about it, but were they trying to say there was a connection on having an EHR certification and their ability to get onto the nationwide health network?

Judy Murphy – Aurora Healthcare – Vice President of Applications
I think the idea was understanding where it fit in stage one. In other words, you're right. You do not need to be connected. You have to do one test. By the way, it doesn't have to be with the NHIN. And somebody actually saying that because the comment on the call was actually that it was confusing to them because there's all this activity going on, and then they're over here, and all they really have to do is one test, and I think it's clear, but there was some discussion on the call that it was not as clear as maybe those of us who follow this closely.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
That's a good point. It is confusing to many people. That's for sure.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
I think that is probably your point is well taken is that that is part of the charge that we have is to begin to add clarity because what seems clear obviously is not. That was said over and over.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
I think the question I was driving to is were they anticipating that they needed to be a trading partner sooner than later. So it's very good that you're clarifying that they don't have to be right up there ready to trade information right at the beginning.

Judy Murphy – Aurora Healthcare – Vice President of Applications
Correct.

John Halamka – Harvard Medical School – Chief Information Officer
I was asked to give a lecture next week, and it says, make sure you tell me how the NHIN will impact my practice this year. Well, you should know what the acronym is about. I don't know.

Judy Murphy – Aurora Healthcare – Vice President of Applications
Send us those slides, okay?

John Halamka – Harvard Medical School – Chief Information Officer
Yes. Wes?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I hate to be the old guy who says isn't never going to work, but I hear a conflicting set of missions here. One is to provide a forum that is governed only to the extent that it keeps the forum productive for its users. In that forum, there is an exchange of opinions among the people in the forum about what it means to be certified rather than to get meaningful use or things like that. But it's absolutely clear that those answers are not official answers. Then there are mechanisms for gathering input that might be prioritized and answered officially, but it has to be a different venue.

I note that there are a few companies that run betas that have more users than most companies' fully implemented products. They don't want to commit a certain amount of money to tech support for free software. So what they do is they let the users help each other, and they quietly monitor. Occasionally they put in a definitive answer when the users are wondering through hyperspace. The users quickly get to know which of those people really work for the company, and which ones don't. But it's all done through the nuance of social networking. It's not done through service level agreements and all that sort of thing.

I think we really have to look at the value proposition for the user. If they go there, do they come back with something that helps them? So that means you either have to trust the community, or we have to have some way to, if you will, subtly add value to what the community does and not distinguish.

I think that we get so often the people who know that the way to get the most attention is to contrive the worst possible scenario out of words that they've heard rather than read the details. You accept that as part of the social contract around social networking. But you have to also have the value there to get people to come back. So I think that will be the art to getting this to work.

Judy Murphy – Aurora Healthcare – Vice President of Applications
That's a really good comment. I know we've flip-flopped back and forth from some of these suggestions being around the posting of anecdotes or personal experiences, as compared to official, not opinions, official comments, if you will, from places like ONC, and we'd have to be real clear in differentiating that.

John Halamka – Harvard Medical School – Chief Information Officer
A rich discussion, and thanks very, very much. I think we will have many, many more discussions of this topic, as we hear input from the field, and that small doctor's office especially.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Just briefly to drive Wes' point a little farther, do we have an example of an effort to provide this kind of support that has worked?

John Halamka – Harvard Medical School – Chief Information Officer
I think that in the HITSP days that our education and communications committee, which did Web sites, did Webinars, just did everything possible to aggregate information and share it out to the community was a very successful example.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
As a consumer myself, or potential consumer of this kind of resource, there had been a number of such resource centers created. My anecdotal impression is that very little is known about either the science or the art of creating an effective resource like this. We can't wait until we've done the research to try to do it. But I would suggest that we recommend funding to really test what we do so that the next time we try to do something like this, we know a little more about the science and the methods.

John Halamka – Harvard Medical School – Chief Information Officer
The NHIN Direct effort also maybe informative because there's been an attempt there to create a community … resources, one-stop-shopping in some ways, so probably want to leverage that too.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Again, tagging onto Jim Walker's comment, this past weekend I had an occasion to seek some clarification, and it's interesting. The work of the policy committee and the standards committee is not necessarily a synthesis of the definitive regulation. So I found myself having to go back to the primary source documentation, which is always good in science, but that is some tough sledding. Outside of the sort of semi-moderated community or moderated community that was described, I mean, I think one immediate resource—and I'd be interested in the group's response to this—would be a synthesis that is more accessible than the federal regulation doesn't introduce new information, but in fact realize there's always danger in simplification. I think we had a discussion a little while ago, but that makes, that synthesizes that fairly large document in a way that's accessible. Seeing a number of heads nodding on that.

Judy Murphy – Aurora Healthcare – Vice President of Applications
I would tell you that your experience is very much like my own, and I have a whole group of people that are using this, going back to the reg, going back to the source consistently. Then, unfortunately, there is not a singular place you go within the reg to get a complete answer. Until we're able to provide that to our communities, our public, we haven't finished our work yet.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Not to be oblique about it. For example, the issue that I was specifically interested in was the quality measure requirements, and I went to my usual sources, went to geek doctor, which of course had terrific information. I went to David Blumenthal's *New England Journal* article. I went to the federal register itself for the document. But just as an example. What was also notable was in the absence of a definitive source, there were some sources that were posted that one could search and find. It was notable to me that they were not consistent with actually what was in the federal register, and that that could be problematic as well. So I think what you identify, at least for me wearing a user hat, would be extraordinarily helpful.

John Halamka – Harvard Medical School – Chief Information Officer
Let me move on, Doug, to your standards and interoperability framework. As we've discussed previously in this forum, there are a set of RFPs. I think Doug today can tell us that every one of those RFPs has been assigned, except one that is going to be re-released, so we have names. We have duties. We have coordination plans being made, so look forward to your discussion.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
So what I want to cover today is three things, and we'll try to rush through a few of those because I'm the only thing standing between you and food. So the first thing I want to do is give you an update on the standards and interoperability kickoff that occurred yesterday. I'd also like to spend a little bit of time talking about some of the lessons learned that we've had in two of the initiatives that have used the standards and interoperability framework at this point, and that is the NHIN Direct project, as well as some of the work that we've done on the Section 1561 out of the Healthcare Reform Bill to come up with some administrative simplification.

But I think the thing that I'd like sort of get to and to make sure that we have adequate time is that there's a series of questions. Many of them are resonate with some of the discussion that we've had so far and try to tee up some questions that we need to think about with regard to the standards and interoperability framework.

One of the things that we came to is that we really were trying to think about the mission. What is it that we're trying to accomplish within the Office of Interoperability and Standards? We came up with really three things that are trying to be guiding principles for all of the work that's going on within the standards and interoperability framework. I think one thing is that we want to be able to promote a sustainable

ecosystem that drives increased interoperability and standards adoption, so we begin to change the value proposition that says I'm not going to compete on having unique ways of communicating, but in fact there is value in being able to have interoperability and using standards.

We want to create a collaborative, coordinated, and incremental standards process that's led by the industry in solving real world problems. I think one of the things that we've gotten from the implementation team and others is that we don't want to let perfect be the enemy of good. Sometimes, if you feel like if you get it wrong, you don't have any way to fix it. If we have a process that is forgiving of that, that allows us to sort of say, here's the beginning of the solution, and then we can build from that. We hope that that would lead us more quickly to getting some things out there.

Finally, to leverage government as a platform, so the idea here is that the government isn't in the business of sort of creating new standards. In fact, OMB circular A119 would tell us that we shouldn't be developing standards within the federal government, but instead I think we need to provide tools, coordination, and harmonization that helps support people who are trying to develop solutions. I've been focused primarily within the standards and interoperability framework in getting to the point where we have implementation specification because that's something that I think we do need to provide as a resource.

If we take a look at the framework, I've now listed here all of the different contractors that we've got. The standards development contract is one that we will be rewriting and reissuing. This is really to help us engage with the standards development organizations, fill in some of the gaps, perhaps provide resources for vocabulary value sets and other things like that. Again, targeted to some of the work that's going on with meaningful use.

The use case development and functional requirement was awarded to Accenture on Saturday. The harmonization and core concepts, as well as the implementation specification, has gone to Deloitte. Lockheed Martin is working on the pilot demonstration projects and the reference implementation. The Stanley team is working on tools and services that will help us with testing, as well as with the certification processes.

If we think about that, we've mapped that into the organizational structure that we have within the Office of the National Coordinator. Within the Office of Interoperability and Standards, we have a division that focuses on standards, one that works on the Nationwide Health Information Network, one that helps with certification and testing, and then we also have connections to the FHA as well. So each one of those contracts sort of has a home within our organization to try to help us distribute the work and make sure that we've got good coordination across the various teams.

One of the things that I want to just sort of dive a little bit deeper in just to give the committee some awareness is that I know that the last time that I talked with you folks about a month ago, we talked about the NIEM process. One of the things about that is something called an information exchange package document or an IEPD. This is sort of a technical collection of artifacts that describes the construct and the content of an information exchange. It's really the package that one would take a look at that would help us define what those implementation details might be.

It provides business, functional, and technical details of how that exchange would occur. It creates a core set of artifacts that sort of all work together and, again, use prescribed formats and structures to allow for some consistency. It's meant to be shared and reused. It's sort of modular in its construct so that we can take different pieces and use them in different kinds of exchange. It doesn't contain design specifications necessarily, but it contains design specifications for information exchange, but it may not include all the supplementary information such as implementation decisions. One of the things that we're doing is working very closely with the team that has coordinated NIEM in the past to see if we can't extend some of the things that are found in the information exchange package and use that to help support the work that we're doing.

The kind of artifacts, I just wanted to put this up there so that people had some awareness of the kinds of things that we include. So the main things are listed in bold, which include sort of an XML schema for the exchange. There are some additional things that are optional, things like a constraint schema or extensions that can be made to a particular IEPD. We have some metadata around the data that's in there. There's the ability to put in sample instances and style sheets.

We also have a lot of optional requirements around business rules and business requirements that may give us some notion of the services that need to be described. We know that that's an area that the IEPD has not really captured in the past. If we think about the Nationwide Health Information Network, and we think about some of the work that we're doing with regard to interoperability, we want to be able to provide descriptions of the standards, the services, and the policies. So this will provide sort of the envelope, if you will, for us to be able to provide that kind of description. So the teams right now are trying to figure out exactly how we can provide valuable descriptions of business rules and some of the services that might be required as part of this package. But I wanted you to get some sense for how we're putting together those packages and what that artifact might look like.

We're working right now to sort of develop that kind of common core. It's important to note that we are sort of setting our own, I guess, I call it the mutant flower, if you will. But it's the one that is really focused on health information exchange. We're calling that NIEM health to differentiate it from some of the NIEM core concepts. It isn't that we wouldn't necessarily draw when there are things relevant, but the goal here is really to focus on the health first and to make sure that we've got that as well.

We recognize that within health and human services, we've got both the health side of the organization and the human services, and the human services group with John Teeter and others have already begun developing IEPDs that use the NIEM core right now. We are going to focus, I guess, on really the NIEM health aspects of things. We will, at some point, need to figure out how to bridge those, but that's an exercise for the future, I think, as we move forward.

Again, we've got sort of this notion. We've mapped what we do within the NIEM process to both the standards and interoperability framework, so you've got sort of the use case development harmonization specification development down one column, and then we've mapped it in sort of this rational and unified process or sort of model driven approach, and basically have mapped things like scenario planning, analysis requirements, how we do the mapping, and where that would fit across the project timeline, if you will. Just as an example, certification and testing is involved throughout the entire process, so there are activities that need to happen when we're analyzing requirements, and we're doing our mapping and modeling. But certainly when we get to the point where we're doing specification development, there's an increase in those activities around that so that we can make sure that we validate and we assemble these things in ways that are going to be testable and useful for certification.

We've got a number of challenges that we're addressing already, and we're taking a look at. Some of these things are not new, but I wanted to sort of put them out there so that we have them for discussion, particularly when we're talk about some of the questions. We are blessed with having a lot of different standards and specifications out there, different approaches. So part of our challenge is going to be to take existing exchange requirements and figure out where there are gaps, duplications, and overlaps, and how we can get those things to fit together. That's going to take some time and resources, and we're going to have to figure out where in the priorities and what's the best way to approach, kind of taking those different kinds of exchanges and harmonizing them together.

There are a lot of well-established, large vocabularies that will help with semantic interoperability, and I think our approach here is to leverage existing vocabulary repositories. PHIN VADs, there's coordination with UMLS and the National Library of Medicine. USHIC is another that has been mentioned as well. We need to figure out how to manage the existing repositories for vocabularies and other things to help support this effort and not reinvent the wheel.

There's the need to have sort of usability of existing exchange protocols and specifications. So we're really focused on trying to create these computable and usable implementation specifications. I've talked

with the implementation specification team, and I've really asked them to think about getting tech writers, and to get people who can really kind of create clarity in the implementation specifications so that we can provide that as a resource.

We are addressing some of the shortcomings that we have of IEPDs and altering its structure and content so that we can include both transport and behavioral activities, as well as the security aspects of exchange, which currently aren't as well addressed in the way in which an IEPD is described. We want to make sure that we have some compatibility and leverage what we can of existing tools within the NIEM infrastructure. But as we make modifications to the IEPD that's going to require us to develop some additional tools that will help support browsing and taking a look at some of those new artifacts that we've got.

We know that we need to provide traceability all the way from use cases through to the implementations and have both semantic and syntactic modeling constructs that will support defining that. I think we are going to have to come up with conventions for how we do that modeling. We need to make sure that we can both do the harmonization, make this possible to be adopted by different organizations, and to integrate it into sort of the NIEM processes. I think it's become clear that we will be doing a fair amount of extensions and collaboration with the NIEM teams because we have a lot of really sort of tight timeframes and new kinds of constructs that we need to accomplish.

I am going to skip through these next couple of slides because I think they're highly detailed. They're in the packet that you've received. But basically what we're trying to say here is to demonstrate. We want to be able to take what people have in their head in terms of a problem they want to solve, and they write it down in a paragraph, and we need to take that description and drive it all the way to ones and zeros that a computer can understand. As we do that, we have to make choices.

We have to constrain and become increasingly specific with the information that we have. So, as we do that, we have some things that are going to be independent of a computational approach that should be suitable for both a sort of non-computerized approach, as well as a computerized approach. Then we've got ones that are independent of a particular platform, and then we've got ones that are very specific to a platform. So, as we do that, we make additional choices as we constrain it because, to be able to do the implementation, we need to get to that point where we can actually have ones and zeros represented in computers, and we know how those things work.

This diagram just illustrates that even though I've got that standards and interoperability framework and the very neat arrows between how people might be doing their work, in fact, there's a lot of overlap. The red lines kind of describe how we have to have input from all of the different standards and interoperability activities into the various artifacts and how those things will map into the various models that we might have, both from kind of our use case models and domain models into more specific ones, and then into really detailed platform specific approaches as well.

We've got a bunch of things that are on our list with regard to this, and this is not a complete list. In fact, there are probably things that need to be added in here, but I know that our teams are working on developing sort of the processes for how we're going to harmonize and coordinate, figure out what the roadmap looks like and what our milestones are. All of our contractors are going to be working very, very diligently on coming up with milestones, metrics, and risks that they see so that we can manage these things effectively. We want to make sure that this is iterative. We want to be able to have appropriate tooling and guidelines for how we do our modeling. We want to make sure that we've got sort of that traceability all the way through, and that we can use to promote transparency and collaboration across a broad range of stakeholders.

That was a very, very quick introduction. I just want the committee to know that we're continuing to drill down a bit further on sort of the standards and interoperability framework. We had probably about 80 or 90 contractors and other folks that came to our kickoff meeting. The thing that was most refreshing for me was not only did we have the contractors get together, but then we reserved a whole series of meeting rooms that afternoon, after our meeting. The instructions to the contractors were, each of you

are charged with one of the boxes, but what I care about is the arrows between. You guys have to figure out what those arrows are going to look like and how you're going to work together to make sure that you can coordinate.

So there was a tremendous amount of discussion. In fact, I had to sort of cut off some of the discussions to stay on track. Between the contractors, to basically say even though you're responsible for one of these tasks, your success depends on your ability to coordinate with others in this. Also, to make sure that it's not just about kind of the work that you guys are doing, but that success will require you to reach out throughout the whole process to people who can help you because we have more work to do than what we have money to support with regard to these various contracts.

So we need to reach out to our community not only in the use cases, but we need to find experts that can help us with getting good implementation specifications with reference implementations, testing tools at every point. Each of the teams sort of said, that needs to be part of what they do is to try to figure out how they can reach out to the communities as well. We will likely have these kinds of meetings over the course of the next couple of quarters because I think it's going to be good to keep our contractors on track and meeting the needs that we have here.

John Halamka – Harvard Medical School – Chief Information Officer
Doug, I have to just take off to Capital Hill in just a moment, and one of the things before we move on, the bottom of page five, your slide on addressing challenges for the Health Information Exchange Model, you highlight compatibility of the S&I, IEPDs, and existing NIEM infrastructure and tools, as well as existing healthcare information exchange protocols. I think the committee may want just a couple of words recognizing that NIEM has been used quite successfully in the Department of Justice, but it creates global XML models that were a greenfield. It doesn't really incorporate HL-7, NCPDP, or any other protocols for transport content or vocabulary we've discussed here. Any thoughts on that challenge?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
I think there are two things. One is that that was one of the reasons that we decided that rather than reuse, as our initial starting point, the data type specifications for example within NIEM, that we wanted to be able to leverage some of the existing standards that were out there, and then try to make sure that we work closely with the NIEM team so that they recognize that we have different requirements in the work that we're doing in different standards that exist out there. Part of the tooling, there are a lot of tools that have been developed. In fact, XML Spy, is that right—?

M
Correct.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
They actually have a NIEM plug-in now that helps support some of the work, so there are some commercial vendors that are beginning to support some of those activities. Now that having been said, if we extend the definitions that are in the IEPD, and we include behavioral and functional components, we start to get an incompatibility with the tools that have been constructed in a more limited domain to the broader range of things that we have as well. So that's one of the places in which we may have to take their existing repository browsers and things like that and create extensions that will allow us to access the kinds of things that we want to be able to access with regard to services and other kinds of functions.

John Halamka – Harvard Medical School – Chief Information Officer
Just to clarify, though you have adopted the NIEM process in a way of integrating all these multiple functions, there is no intent to replace existing NCPDP, HL-7, etc. with a global XML, completely different data type or approach using totally different tools that may be customized to that XML structure.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
No. I think we have to recognize that we have different requirements, and we don't have the greenfield, as you've suggested. So it's one of the reasons we created the mutant flower in some regards.

Otherwise I think we would have been so highly constrained that we would have had a lot of challenges with incorporating some of those things.

John Halamka – Harvard Medical School – Chief Information Officer
Now let me turn it over to John Perlin and run off to Capital Hill. I see a number of questions popping up.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Congratulations, John.

Jonathan Perlin – Hospital Corporation of America – CMO & President
… Massachusetts. I know it'll be well represented, so I look forward to hearing the entire litany of awardees from the Safe Rx.

John Halamka – Harvard Medical School – Chief Information Officer
Thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Doug, this has generated a number of comments, I think, around this thread, so you may want to come back to … but do you mind taking the questions now?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
No, we can take a couple questions now.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I saw Wes, a lot of questions. I tell you what, if you don't mind, Wes, we'll just go around the world and start with Nancy.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Can you mention how the existing work? You've got all these contractors in place. What's your vision for taking input from all the work that's been done through, like through various participants from vendors and from government and from individuals and so on?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
It's one of the questions that we're going to get to, and sort of the big questions that I want to ask the committee. Obviously there are things that we need to do with regard to meaningful use, with regard to the velar projects, and some of the other high priority things that are being supported with ONC. I think that given that, there are a couple of approaches. One way is to try to take all of the existing things that we've got and try to backfill that into the infrastructure that we have and create some sort of common way of approaching that, and that's sort of from a technical perspective.

I think, more broadly, we have to think about how do we establish priorities for the work that we're going to be doing? Certainly this committee here has been providing recommendations and input into the ONC, and that may be an appropriate role that would continue. But we also have other stakeholders that are interested in participating that may not have shown up on meaningful use that haven't come up with some of the priorities from the policy committee, but still are important to our federal partners, to other organizations that have an interest in interoperability, but aren't part necessarily of meaningful use at this time. So our hope is that all of the work that we do here, we can provide a platform or a framework that those folks can be engaged.

I think, realistically, we will always have more work to do than we have resources to accomplish it. So we do need to figure out a way to provide some prioritization around that. I think part of what we're going to have to do with standing up this framework and getting input from this committee is the best ways to do that. That is both allows us to move forward operationally and get our work done, but at the same time, that provides for the kind of input that we need to do priority setting and to get that broad range of input.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Let's go to Cris Ross.

Cris Ross – LabHub – CIO
Doug, I apologize. I'm feeling, I think, particularly stupid today. I think I get the process, but I'm not clear what systems are going to be built as a result of this. Is there an inventory of, for example, federal systems that will be built or modified using the NIEM approach? Will private exchanges and systems that need to connect with federal systems be modified to use the NIEM standards? What's the mandate or requirement for that? Is ONC going to be building software and running services on behalf of other agencies? I just don't understand. At the end of the road, if we name the systems and what they do, is there a map for that yet? Is that forthcoming, or should we already know that?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
No. I actually took out some slides that sort of said here's the future state, and what we would expect if people are going to be interacting with this process. If you were a use case developer, what might it look like? If you were a vendor or someone trying to implement, what that would look like. The output of this really is implementation specifications tested by reference implementations and, in some sense, trying to address that one-stop-shop that we have that's been articulated in the vocabulary group, not just about vocabulary, but about what the data standards might be, the metadata that would be required, those sorts of things.

The process itself is not that dissimilar to what HL-7 does with their development, their HDF framework. It's not that dissimilar to what CDISC does in developing their standards around some of their modeling efforts to integrate their suite of standards. So in large part, this is a way for us to manage the standards development process or the implementation specification development process so that we reuse things across different use cases so that patients and prescriptions and other things like that are defined in the same way across all of the use cases that we might have. This is really an attempt to build some of the tools and infrastructure that will make that process more scaleable. But we have no intention to build specific solutions per se, but to help coordinate how those things might get constructed so that there's reusability, and it can be kind of leveraged in other ways.

Cris Ross – LabHub – CIO
For on the one hand, federal agencies, let's say, and on the other hand states or private entities, is NIEM a strong suggestion? Is it a recommendation? Is it a mandate? What's sort of your viewpoint on where that's going?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
I think certainly within the ONC, this is the approach that we would like to take to help coordinate this. Part of that decision was based on its use in other federal agencies and the success that they've been able to demonstrate in saving money in how they created implementation specification. There are also a fair number of states that also use this approach, and so we didn't make the decision in a vacuum. We actually tried to look at federal and state and other participants that have used a similar approach, and recognizing that it's not that dissimilar to other approaches that are out there. But in terms of whether this is going to be required and those sorts of things, I think that's probably above my pay grade to make those sorts of recommendations.

Cris Ross – LabHub – CIO
When and how do you see that progressing so that people can understand that sort of stuff? Maybe going back to the vocabulary discussion, I think the questions I'm asking are really around clarification and not simplicity. Just to understand, if this process proceeds in a certain way, how will stakeholders who are affected by this understand when the systems they're building and the processes that they run and the businesses that they manage, if it interfaces with the federal government, will need to adapt to these standards? When will we know that it becomes a mandate rather than a template?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability

I think in the short term, our goal is to be able to provide support for implementation specifications that are currently part of meaningful use stage one. We hope that as we mature this approach, state two and stage three implementation specifications can also be part of this as well.

Jonathan Perlin – Hospital Corporation of America – CMO & President
We'll go to Wes Rishel.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I would just like to congratulate Cris. I think he got to the heart of the concerns that I feel with his questions without all of the whining that I was planning to do, so I'll try to limit my whining at this point. The feeling here is that there is a process that worked for greenfield specifications of relatively simple data in an environment where the agency sponsoring it was sponsoring the purchase of the systems that were going to be implemented to do it, and it worked pretty well, apparently. I take your word for that. I haven't investigated into it separately. And that we're going to adopt it for more complex data in an environment where there's a lot of existing systems and a lot of existing standards that we work to.

I personally have come to believe that there's a lifecycle for standards that we very seldom get to the end of, but it goes like this. It becomes a charge for some group, either one of the recognized bodies or a new, self-appointed group to take up the standard. It goes through some level of consensus building. People try to implement it. They come back after trying to implement it. They change it. In changing it, they widen the scope because they're all excited about it. They take out.

Now it meets the first requirement, but the widened scope it doesn't quite meet. It comes back, and it's only when a standard has been through two or three iterations like that, and in the process has been reasonably adopted, that you can expect to go for mainstream adoption, that you can expect to go for. You now are going to put this into your system, and you're going to use it for some years because that's how long before the next time you update your system.

I see that you notice the concerns been raised. This is all happening in closed and intent with the drapes closed, and we don't have any ability to know how it's going to be addressed, hence the concern. I note with some interest that with NHIN Direct, we did everything we could possibly think of, and things that I never would have thought of personally, to make the information about what's going on available to the public. We still got huge amounts of whining, and I don't mind informed whining. But it's the uninformed whining when the information is right there that bugs me. I'm whining, but I think somehow this process has to become more public before there can be the possibility of comfort with it and I worry.

One thing that I do see is that the output is an implementation specification. I wrote a paper a couple years ago about profiler enforcer groups where I expressed the concern that unless that group somehow had an interest in implementation, if it was a commercial enterprise, you'd say got paid when it got implemented rather than got paid when they produced the specification. You really haven't closed the loop, and so I'm concerned about that.

I recognize that we don't, we can't always close the loop. We can't pay doctors for treating a patient's diabetes by waiting ten years to find out if the patient still has their eyesight and toes, but you have to have some intermediate means. But right now I'm afraid we're not closing the loop between implementation and development.

I think, having test implementations is a big help. I certainly do, but we haven't really created the feeling that if it doesn't roll out on a large scale, we haven't succeeded for the implementation developers yet that we need to get. Sorry to be—this is not the first I've been called Debbie Downer, but sorry.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Let's got to David McCallie.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Wes and Cris have covered a number of the things I wanted to say, so I'll just make a really short comment, which is a plea to harken back to the early days of our standards committee. I was sort of stunned to hear that this is meeting number 17, which just sort of blows my mind. But way back in fairly early in our process, we got testimony from a number of people who have tried top down, model driven, standards development efforts, and the general consensus was that they didn't work very well, that you had comprehensive models, but they weren't adopted by end users in large measure because of the complexity and the comprehensiveness of the model made it bewildering as to how to get started.

The NHIN Direct work, which is participated in pretty aggressively, we tried very hard to do as much bottom up as possible and to follow the IETF model of rough consensus working code, iterate rapidly and quickly, and the proof isn't done yet. We don't know exactly how successful that's going to be, but it's worked well so far and through a very organic iterative process that it involved a number of trial implementations, which some of which were scrapped and reworked. I think we're converging on something that has a pretty good chance of success. Much as I appreciate the need for model driven, top down thinking, somehow in the process, and maybe it's by Wes' suggestion of more public exposure, as you go along the way, that bottom up, real world implementation experience needs to filter in, or you'll end up with something that's beautiful and complex, but sits on a shelf. It's just a concern, and I know you're aware of it, and I'll just register it for the sake of the record.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
I'm going to go to my next slide. Then I'll answer some of these questions, but I think it's illustrative of what our approach is. First, we have this notion of a use case steward, so Arien Malec would be the equivalent of a use case steward. He's the guy that's really sort of interested in making the NHIN Direct project succeed. He has the technical knowhow, and he' really trying to drive that all the way through, kind of a horizontal integration across the process.

I presented these slides before, and I'm going to reiterate them again because there is nothing about this approach that is intended to be top down. In fact, what we're trying to do is get to the point where we like bottom up, which is sort of thousand flowers bloom, and top down, command and control, merge together in some fashion. So what we want in an ideal world, and this is kind of where we'd like to go is we'd like to have NHIN Direct like projects use the standards and interoperability framework as a platform so that we can coordinate across all of these other projects that are occurring. So think about it as a bottom up standards development within sort of a top down kind of coordinating mechanism so that if the next project that comes down the pike has an overlap with some of the NHIN Direct specifications, there's a way that you can figure that out without having to do that from a top down perspective.

There are a lot of folks out there that are doing similar projects and that you'd like to be able to reuse things. The problem is that if you haven't standardized your standards, and you don't have a way of taking the NHIN Direct project that is documented using a particular way, and then having the next project and say, well, maybe there's a way that we can modify the payload on the NHIN Direct project, and we want to be able to take the C-32, but we don't want all of it. We want half of it. It's the C-16. It's got half of what's in the C-32. How do you make sure that that specification matches to some degree what's going on with the C-32?

SSA has made extensions to the C-32 so that they could meet their use case, but are they going to create yet another standard that is going to get a new number, or can we say it's 90% of what's in the C-32 plus some extensions? So we want this to be consensus driven. We want it to be open and collaborative. We want it to be driven by business needs and elaborated in real world use cases. We want it to kind of come from the bottom, but we want to also make sure that it doesn't become a thousand different things that we spend a lot of time trying to coordinate.

If we can provide the resources that says we've done NHIN Direct. It's in this repository. We know what the data elements are. We know what the services are. If I have the need to have a similar kind of service or a similar requirement, let's see if there's a way that we can reuse what's there. If you can, great. If you can't, then at least you've done sort of that due diligence. So what you want to do is the model itself, top down, sort of, you start at the top. When it's done five years later, and everybody has

moved on to do other things, the model will always be incomplete because we'll always be coming up with new use cases and new ways to manage it. But it's a way of sort of beginning to coordinate these bottom up strategies.

I can address some of the concerns about openness. I mean, part of this is that we'd been under this incredible contracting world, if you will. When you're writing contracts, and when you're trying to evaluate contracts, and you've got a lot of money at stake, it's important that we follow the rules about not giving certain groups competitive advantage versus others and the like.

I am delighted that on Saturday the last of sort of the major contracts were awarded because that now gives me the flexibility to have a lot more openness about what's going on. So there is a need for this to be successful. There has to be that sort of approach. So once we get through this kind of main push, I can start opening up the doors a lot more and providing a lot more openness to this as well.

I know that there's probably some misunderstandings about what's out there, but it will be sort of my job and others to help me sort of assure that this is meant to be bottom up driven. The one slide I don't have, I've presented here before, that focused collaboration. To me, that is getting projects like NHIN Direct tied together with sort of a platform for this development and then being able to drive the coordination across the different projects that might be occurring. That's, to me, that focused collaboration.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
That's very helpful context. I will watch with interest to see how it evolves and to see how those tools get used by communities that need those tools, the control issues. With NHIN Direct, we had a very autonomous wiki that pretty much anyone could edit who had simply signed up. It worked out surprisingly well, although there was kind of a master key in Arien's hands. But it didn't have to be used very much, and that was a benefit because it allowed new ideas to come into the process unexpectedly and influence it, in some cases fairly dramatically. So the control issues will be interesting nonetheless.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Yes. I think we need to be able to provide as much flexibility. I mean, Brian Behlendorf is someone that is working with ONC and providing some help and direction with how to engage those communities.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Brian was very helpful with us in NHIN Direct for that exact role, so that's good.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Exactly.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Doug, I realize there are still a number of cards up. Were you going to present additional slides on issues to discuss? I imagine that there is … theme of this thread of the applicability of the NIEM framework and the relationship of organic and control and the concern about a model that leads to completeness, maintenance capacity, etc. Did you want to tee up some additional issues and broaden the discussion at this point, or do you want to continue with this thread?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
I think it's up to the committee. I'm in the service of the committee how you'd like to proceed. I'm happy at this point if we want to have the user-generated questions that come from the committee. We could do that. I had teed up some other questions that may need to be addressed.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Let's continue around, but if they are on this thread that we've been discussing, let's keep this crisp because I think that concern is central. It's obviously registered with a number of individuals and appreciate the context you've provided back. If it's on this topic, let's keep them crisp and go around. Any others on this specific topic? Good. Then we'll take the others, and we'll continue around the room.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Not to detract from the previous comments or that thread of discussion, but in a different area. You've mentioned, I think, a couple of times, Doug, the need for prioritization and process governance. I'm wondering sort of generally how you see that working and how do you see this committee figuring into that, if at all.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
I think that we have the need to be able to do strategic priorities, sort of what's our goal. What are the goals that we're shooting for? How do we prioritize that? There also is some operational priorities. For example, there may be dependencies that say I need to do this work first because it is foundational to lots of other things that are occurring. Then we need to have the ability to sort of have day-to-day priorities in each of the functional teams as well.

I think that the thing that will be, I think, open for discussion, and that I would like to get some feedback on. We have a clear mandate from Dr. Blumenthal to make sure that we support meaningful use. I think that this committee and the policy committee are going to be charting what those strategic priorities are going to be with regard to that.

However, there are a lot of other activities and other people that may be outside of meaningful use that I think are either foreshadowing things that may be coming down in stage two and stage three. So I think some of the work that's going on with NHIN Exchange and NHIN Direct, for example, are activities that aren't part of meaningful use now, but are tremendously valuable towards those strategic priorities and goals that we might have. So we need to be able to figure out a way to incorporate that. I think the federal partners also have needs both within meaningful use, as well as with NHIN Exchange, and there's a need to be able to incorporate that. There may be, again, other people that don't have a seat at the table, per se, but are interested in being able to provide interoperability solutions, and they'd like to be able to demonstrate that they can make their standards compatible with the things that are coming out of meaningful use and the like.

I think we've got a variety of different stakeholders that need to come to the table, and we may need to have some organization that can help us coordinate that kind of feedback. Does everybody have to come through the policy committee or the standards committee to have their voice heard? Is there another mechanism that we can use that will help us coordinate at least the tools and the other resources that are out there that would be helpful? I mean, I think I want, to Wes' point, I want as much as possible to have the broadest input that we can, and to make sure that this becomes not just a resource for meaningful use, but a resource for interoperability across all of those various stakeholders.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Let's go to Dixie Baker.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I have a pretty specific question actually. On your slide ten, this one with the two columns, at the bottom, next to the last row, NIEM only addresses data content, but transaction behavior and security provisions are necessary for health information exchange. It seems to me that both DoJ and DHS would have similar needs to specify transaction behavior and security.

So I have two questions: Number one is, why were those two excluded? Are there inherent limitations to the process, to the NIEM process? Secondly, how were these needs handled by DoJ and DHS?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
If you take a look at some of the artifacts that they have, they do have the ability during analysis requirements to come up with business rules and some of those functional specifications, but those aren't required as part of the IEPD. The question as to why those things haven't been included is a question that I certainly can bring to the NIEM team. We haven't really asked them that question specifically, so why you didn't do that, although I think we've got very positive feedback when we've approached them to

say we feel, for interoperability, to have the full understanding of how the exchange would occur to have descriptions of the services and the transactions and things like that.

They've been very receptive to that sort of, in some sense saying, that's been on our list. We haven't gotten to it. So in large part, I think, that's one reason we've tried to engage them because I think we can be helpful in sort of expanding the way in which they describe that to make it better in some sense.

As far as the security, I don't know. They may have already sort of baked that into their infrastructure, and so they didn't need to have it described as part of their data interchange, but I don't know. I can take that question back.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
It might be instructive in both directions.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Sure. Thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Chris Chute?

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
I commend you on your efforts to balance these tensions that you're grappling with, both in terms of contractual confidentiality versus openness, as well as top down and bottom up. I have two observations. One of them is fairly minor, and the other, I think, is fairly substantive. The minor one is also on the same slide ten. I urge you not to overlook the terminology services efforts that are going on in OMG and the common terminology services specification, as well as, frankly, what is now a reference implementation of that, including fairly robust value set handling in CaBIG … EVS.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Is this the CTS2?

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
CTS2, right. You enumerated a few, but you left that one out. Not that I'd notice, but ….

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
We're on it.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
But the more substantive issue, I think, is really this tension, as you've characterized it quite well, between bottom up and top down. I know that's been a long conversation. However, as a panel member, I want to put in my plea for let's not overlook the advantages of coherent coordination in a sense with an artifact that can be publicly viewed as an overarching model or context for these bottom up activities. I agree with the prevailing wisdom that if we were to create an excruciatingly detailed, top down, artifact that is not doing anybody a favor, and is not consistent with timelines or expectations. However, I think it is plausible to dynamically create the big picture and keep it out there as a work in progress updated, dynamically maintained artifact so that people can see the context of where these components fit and how they operate.

It was one of the great tragedies in my mind of HITSP that the big picture was never published or even articulated, never mind studied. It's not clear to me in the structures that you've outlined whose job it would be, other than perhaps yours, to maintain. I don't think you want to do that personally, to maintain this dynamic, large picture artifact, but I think it's terribly important to do. That can be something that can inform not only the public and provide transparency, context, and perspective, but quite frankly can facilitate the coordination of these components, as they emerge and evolve in a way that I don't think HITSP ever achieved.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Walter Suarez?

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
I too have to say this is an amazing process. I totally understand the challenges of being able to communicate a certain point, certain information, and finally being able to begin to unveil because I assume this is just the beginning of a full unveiling of the whole process.

I have two questions, I guess, related to the process. The first one is about the retrofitting or the realignment of the artifacts that have been developed in the past that have been adopted and recognized by the Secretary, and how is this new process, this new framework going to take those and expand them, modify them, change them? How do you see that being done? This is not to try to bring back from the death HITSP efforts, but more importantly to try to understand legally and structurally how this artifact that has been developed and recognized and legally adopted will now bear into this framework. Then I'll have a second question.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
One of the things that we did a number of months ago when we were first looking at using this process as a way of managing standards is we took the C-32 specification, and we said, can we construct from the C-32 an IEPD? I mean, can we map those things in and produce an XML description of that? We can. We can kind of go back and forth between that.

The important thing to recognize is that the standard, as adopted by the Secretary, don't change. It's still the C-32 with the implementation specification, the CCR and the CCD as the standards that were constructed. Those things don't change. But what we're trying to do here is to be able to organize and manage that so that we recognize that these XML constructs within the CCR are the same ones that we see with CCD, and that there's a similarity between those. Now obviously HL-7 has done that a part of CCD construction is to take the CDA template and create the CCD, which is really ….

But we want to make sure that we understand what the concepts are and the data elements are sort of independent of how they're packaged for a particular standard. So if you decide to exchange using a CCR, or if you decide to exchange using a CCD, we hope that we can make sure that there's consistency with how those concepts and the data would be represented so that when we say patient, we mean the same thing. When we say provider, we mean the same thing. This is a way of us helping to manage that. This doesn't replace those standards. It's a way of us helping to manage all of the complexity of the standards that are out there.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
And because besides C-32, back in the HITSP days, developed several, well, in the 50 or 60 realm, of interoperability specifications, including areas like privacy and security and a number of others. So I think all those will be important to understand the path for where they will be in the coming framework, in this new framework.

The second question I have is about the process for engagement. It used to be that life was a lot simpler. We only had HITSP. We had a lot of other things, AHIC and, well, other activities, but now there is several teams and several bodies being established. What is the official, formal process to being able to be engaged or participate? Are there going to be announcements of we're inviting participants to join this team?

Among the many challenges that HITSP back then had, and many shortcomings perhaps, one of the features, which was also a challenge, was making always sure that there was a very open engaging process. Anybody could join. Anybody could participate, and everything was very open and available. For those of us that want to make sure that we are able to participate in this new framework, what is the formal process for being able to join any of these teams?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Given that use case contract was just awarded on Saturday, we haven't had those discussions with them just yet. I think though that you've highlighted something that's important, which is that there are things that we're trying to do in this framework that allows us to have sort of computational artifacts and the ability to leverage use cases and standards and kind of data elements, if you will, across multiple use cases by having a computational model to do that in. That's something that I think is an extension that goes beyond what perhaps was done with HITSP. But there were a lot of things that were very good about HITSP, and I think their ability to engage the community and to create interest around that and have people participate in the process was a tremendous asset.

Our goal is to start getting that back put into place and so that we can have the engagement. It may be that the way that the engagement happens is that you want to solve a problem like NHIN Direct, and that you want to be able to kind of work on that from the entire lifecycle. So your engagement with a standards and interoperability framework really just is the touch point as part of that larger project that you're working with. Those are the kinds of conversations that we're going to be having with regard to this because I think, again, our focus, and I'm just going to put this slide up here again. I mean, our focus here is just to make sure that we leverage this excitement about solving real problems and kind of articulating them like NHIN Direct, but doing so in a way that allows the kind of coordination that Chris is talking about where we want to make sure that we do have some consistency and sort of the big picture of things and where those projects fit into the larger picture.

We have a few minutes left. I know 12:30 is when we're supposed to sort of end. What I'd like to do is just go through these slides briefly. I'd like to then go through the set of questions. We've actually talked about some of them already, which is great, and talked to you a little bit about what we've been looking at, and so we've talked about this already. NHIN Direct has been tremendously powerful as a consensus driven process, leveraging the expertise that Arien Malec and that Brian Behlendorf bring to the table. It's been very open and collaborative, and these are all things that I think we need to learn, and we need to leverage, and we need to incorporate in how we do community engagement. Again, driven by business needs, sort of bottom up, working all the way through to the real world pilot and implementation, and the importance, I think, that we've learned from the Direct project is the importance of sort of the workgroup leads and sort of having the right person as the thought leader and organizer with this.

We've also done similar work using the eligibility and enrollment work. What we found there is that having dedicated resources to drive the project and decision-making makes a difference. We need to have those resources to keep things going. I think early on, and we had such a very tight timeframe with this, it was important that we clearly define the problem statement at the project initiation, and there was some movement back and forth, as we went through this. That makes it hard to be able to define the expectation for the artifact, and it makes it harder for us to get sort of community enthusiasm because we haven't really been able to clearly articulate what that project is.

We also recognize through this that we need tools to increase our efficiencies, and we did some work at least in terms of creating these models and artifacts. We need to have some guidelines about how to represent that so that we can do that in consistent ways. So, so far, we've had two projects. One, which was the Direct project, and one was eligibility and enrollment. I think we've learned from both of those. There's a lot of things, I think, that we want to leverage from the Direct project going forward that had we had sort of more time and the like, would have made it possible for us to get the eligibility and enrollment work more focused. I think we will probably continue to work on the eligibility and enrollment workgroup to start to take what we've learned I the Direct project and refine it and help to support this as well.

Issues to discuss, and I know you guys have already sort of addressed a bunch of these as well, but I'm going to put a couple out here that we were thinking about over the course of the last couple of weeks. So again, how do we get input from other stakeholders including those outside of meaningful use? What's the structure about coordination, priority setting, and also evaluating artifacts to make sure that what we've done at the end of the day sort of meets the needs that we've got? That includes Velar, our federal partners, other stakeholders.

We need to be able to also foster multiple working groups that are all kind of working on their projects, but have that unified view that Chris has talked about. How do we kind of create that environment to make that happen?

Ultimately, we want to create simple, maybe it's clear from a clarity perspective, easy to implement specifications that will drive adoption. So we need to be able to engage the SDO communities and develop one-stop-shops. How do we facilitate access to the SDO standards? This is sort of an IP issue that we've talked about before that will make it easy for providers to have access to the standards, and also support sustainable business models that will allow us to kind of keep our standards current and grow, as new technology comes out.

How do we foster community and industry participation to support balance and representative, balanced representation and diverse priorities? So we talked a little bit about Direct, identifying champions that can help us guide through this whole process. Be able to engage the community, not just at the use case, but throughout the lifecycle because there are folks that have technical expertise that say, I want to just sit down and write code. That's the way that I think I can contribute. We have to identify demonstrable pilot programs, and we have to engage and incentivize volunteers from existing communities, again going to Walter's comment about HITSP and trying to make sure that we have a vibrant community that's engaged in this process as well.

We need to think about where the appropriate interface points are with the HIT Standards Committee and the framework. We have to establish priorities. We have to look at implementation specifications. Certainly in the Healthcare Reform Act, this standards body was or this standards committee was charged with evaluating the enrollment and eligibility criteria, and that was something that showed up in that legislation. We need to make sure that we identify appropriate decision-makers that control points. Is it just at the beginning and just at the end, or are there control points in between that we have to make sure we're on track? Which is the organization that needs to do that? Is it an organization of all stakeholders? Is it an operationally focused one? Are there referrals that need to be made back up to the committee when we have challenges? Certainly large organizations don't run their organizations through the board of directors, but there are specific questions that have to come to the board that need to be addressed.

It's going to be appropriate for us to identify the right roles and participants in the framework. How do we identify and select tools as shared resources that foster collaboration? We need to work on establishing and adhering to agreed upon modeling conventions. There's no one right way to do things. But there may be some ways that will help us do it more consistently and capture that information.

What are the tools that we need to do? We have that tools contract that we really need to be able to support, and I think we've gotten some feedback from the vocabulary group earlier about what might be some of the things that we can provide. We need to be able to extend NIEM to accommodate the NIEM stuff in the healthcare domain. That includes some of the unique needs that we have because it's not a greenfield, and that there are in fact other standards that we need to address.

Some of the things that we need to be thinking about are, we need to take a look ahead for the next 6 months, 12 months, 24 months, and we've got a lot of things that we could work on. One approach would be to say let's take everything that has happened in the past. Let's spend our time backfilling it into the model.

The other way would be to say, let's focus on clear priorities and projects like NHIN Direct and maybe what the next one would be. Whenever possible, leverage the other work that happens and make that part of the model on an as needed basis as we go forward. So we could take a look at new use cases and say, how can we leverage what's been done in HITSP and other standards development organizations and other kinds of projects and focus just on the new use cases and the value sets and the things that are in meaningful use? Or we could try to kind of backfill it all and then have this rich model

that we've got, and then use that to drive sort of the meaningful use future stages and some of the additional work that's coming down the road.

So I have ideas about how we might want to do this. But I want to sort of have this as part of the discussion within this group about what might be good ways for us to organize our work. I'm happy that I went and I put together a lot of these questions. I feel as if the committee has also targeted a lot of the ones that we are also thinking about as well. So that's why having some additional input, I think, would be helpful.

I think that's it. I'm not going to go to lunch yet because you'll all just leave. We have just a few more minutes. I'll stop there and see if there are other comments that the committee has.

Jonathan Perlin – Hospital Corporation of America – CMO & President
First, I think that is also a good segue to this session that will occur after lunch about the priority setting ahead. But I also think it's an important capstone to the earlier discussion. I think someone had sort of framed the context of this mandate or template. If … really described it as a template that helps to provide coordination of what's organic, but allow an overriding set of principles to lead to a framework.

I'd be interested in the group's reaction to the list there on how this might be used. And in as much as many expressed concerns about rigidity, how do you use this to elicit both the coherence at the one hand, but also reconcile the reality that in the absence of some sort of structure that the entirely organic process may not lead to the end result. So I'm very interested in your comments. Nancy?

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
I'm glad that the implementation group mentioned early on that the first stage of meaningful use criteria are only going to have one test for an organization to send across for interoperability spec. To me, that would then make the case that the work that this framework should do should be focusing on two and three because we need to fit. If we don't put things in the pipeline today, like there is no terminology picked for orders, clinical order exchange, or some other things that have to be done for other kinds of interchange specs. We've got to get ahead of the curve of being able to fix some of the questions that are out there from the National Quality Forum on the meaningful use criteria for stage two and three.

We are already bouncing against it, and I would definitely think we should either look at the things that we know didn't work well in certain prototypes and tests for health information exchanges or NHIN and HIN projects, and/or we should just go leap ahead and start tackling the stuff that really needs to be done. I guess my one question to you is—and from my agency's perspective, virtual lifetime record is extremely important, but it's important because there are a lot of network providers, and those are all the ones, twos, and five physicians in group practices out there that are going to have EHRs that in a couple of years, we're going to need to have some specifications that these folks can test. Can they send us their lab results or their consultation? Those things need to be worked out now. So I guess I wanted to say, what do you think your mean time to specification might be?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
I'm not sure I'm prepared to answer that in terms of what it would take and how long it's going to take us to get some of these things. Part of what we're hoping is that since there is, particularly when it comes to content and the data that gets exchanged, there's oftentimes duplication across different use cases, so a clinical summary and a referral or the like may contain similar kinds of information.

The first specification that you come up with is going to take you longer than the second one because the second one we hope you'd be able to leverage some of the other pieces. But, we were able to—in fairly short order—get at least a roughed out C-32 back in December and January when we were working on this. That was one of the reasons why we thought this was a process that potentially, at least from a technical perspective, would allow us to develop those specifications fairy quickly. There still is the process that we have to make sure is addressed, which is sort of the consensus building and making sure that we've got engagement with the community. That probably is the part that takes longer with some of those.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
I guess one of the questions I would have then would be is how does a constituency for a use case then, one of the things to be worked at is how they're going to shepherd that use case across all of those different contracts or phases to make sure that it goes through in a fashion to completion that satisfies both the owners of the use case and the consumers of that use case. So, there are a lot of good questions probably more than answers in this.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Well, we've had success with the direct project and Arien's kind of leadership with that. So, we know that that's a model that I think with the right leadership can be very successful. We're wanting to take a look at that.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Cris Ross?

Cris Ross – LabHub – CIO
First, I want to return to sort of my questions out of ignorance before. I want to make sure that they're not received as critique because as you've described it, I'm a big fan of NHIN Direct. It was a great idea and it was very well executed. The NIEM process in the enrollment workgroup was very successful and helped accelerate our work as we worked on that a little bit.

I don't know how to answer the questions specifically around either process or priority, but I guess I would say if this is intended to improve on what was done with NHIN Direct, the NHIN Direct experience is still pretty fresh. I don't think all the lessons have been learned from it, but if there was sort of concerns or critiques that made sense to me, anyway, one of which was did the effort to create working code and so on create policy inadvertently. Did we have policy drive technology?

I don't know if that's a fair critique or not. I think what NHIN Direct is trying to do is new. I think it has been effective, and so I don't think we want to kind of strangle the baby. We need to let it grow a little bit, but that is a critique that people need to be aware of. So, I would say making sure, perhaps, to over communicate around the connection of policy and standards to this on-going work is always a good thing.

The second sort of concern that I hear is NHIN Direct is wonderful, but I don't understand exactly how it maps to meaningful use. That's one of the things that the implementation workgroup is going to pick up. It feels like a very effective set of train tracks that maybe don't completely meet, and it's not clear how to get through that switching yard to connect those two together.

I would hope that what you do with this process could be as clear as possible around how does this relate to other work. Signaling exactly when decisions are being made. That may be explicit decisions or perhaps sort of epiphenomenal decisions—because we made the decision about this, it has all these other implications we didn't know about. So, I think my comments are really vague, but I'm hoping that if you pursue this process, which I think has tons of promise, but it just be clear when a decision is being made that may have implications around policy, around standards, and hopefully to involve the committees at the right point where you can anticipate them.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Doug, I think one of the reasons why it's critical that you sit with us and participate in the workgroup is exactly what Cris pointed out is that I'm having the same challenge. We've got two tracks going in the same direction. I think we're both headed for the same place, but it's critical that those two tracks come together. So, I think you're point's well taken. I think Judy and I will definitely not only engage Doug in the whole process, but make sure that the synergies are taken advantage of. It's a great point.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Walter Suarez?

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
I think one of the priority areas that I didn't necessarily see listed here—perhaps it's embedded in some of the concepts—is health information exchange messages. In the following sense, I think the state efforts that are going on to develop health information exchange, one of the very specific and most immediate challenges is what are the messages we're going to exchange within the HIE. In discussions that I've been a part of in some of the states we do business with or in, there is a very concrete set of these are the top five or the top seven or the top ten messages that we are going to being exchanging.

A few examples: One is discharge summaries, just a .... Emergency department reports, which are also, in some places, considered discharge—emergency department discharge. Those kinds of specific, concrete, defined messages that are the priority focus of health information exchanges are the kind of things that I see are going to be needing to have the implementation specifications defined beyond C-32's and beyond these concepts. Because that is what HIE's are going to depend on in order for participants to see value of it.

So, I'm hoping that that would be considered part of the priority setting within this framework is that 50 states ... jurisdictions, other jurisdictions, are about to begin to go down the path of establishing themselves .... Some of them are launching the information exchange at the end of this month, like in Maryland. Other states are already moving ahead with specific issues or initiatives.

The one element I found is common across several of them is this concept of what is it that we're going to exchange now in this exchange. These are the messages we see as a priority because the hospitals that are participating want to send the data back to the clinics where the patient goes to that the patient went to the hospital or vise versa and the communication between them are done in this kind of discreet type of messages. So, defining those and establishing the specification for those, I think it's going to be very critical for HIE's to really take off ....

Jonathan Perlin – Hospital Corporation of America – CMO & President
Let's take three ... comments before lunch. I have a feeling this conversation will continue into the priority setting and so ... don't feel that we're limited specifically by time. I think I saw Wes, then Dixie and then Linda.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Just a quick question: Jamie, don't you have a project going on that's trying to modularize the C-32 or something like that?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
When we talked about the hospital discharge summary, we talked about the process of creating templates for templated CDA as an approach to solving that particular issue, which Walter just referred back to in the HIE. So, it's not clear to me, frankly, how that approach fits into this framework.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Not to push it on you, but it sounds like in terms of having a mechanism for identifying the cases you want to deal with, if it does what it apparently does that it would be helpful there in terms of being able to go to templates. It would be a good way to test its ability to adapt to rather preset artifacts out of the standards world as opposed to having to recreate them. So, it seems like it's a possible. At least a trial look, it seems like a way to do it.

I want to comment on a concern for over coordination. So, I'm going to just reverse myself from earlier. I think that we have learned partly through the implementation group that the process of running down the road getting something to work shapes it. It becomes a little different. It's value cases become cleaner. We have learned that I think there's a lot in life where you do something, you try to anticipate a problem, some level of problem happens and the question is always, "Well, did you not anticipate the problem right or would it have been a lot worse if you hadn't anticipated the problem?"

I think in the case of NHIN Direct where there's people who have a hard time understanding how to fit it into the framework they had for understanding health information exchange or whatever the challenge is, interoperability, the only answer you can give is, "Well, there's this number of people who think it will be helpful," and put a lot of energy into making it happen. Let them try and then decide as opposed to get it all worked out in advanced because it's changed considerably in the course of just trying it.

So, I would encourage the use of the NIEM process as a way to avoid miscoordination, that is to make sure that efforts that are going on are not for reasons of inattention, making things different that don't need to be. But, be concerned that it not be sort of the gating process for deciding when to do something new. That we somehow need to have this ... standards effort and give that flower some time to bloom before it gets locked into the NIEM method.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Dixie?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I noticed that many of the ... that we discussed in the vocabulary working group presentation are also applicable here. You pointed this out, like they're embedded standards, embedded value sets. There will be versioning issues. You even used the same terms the vocabulary group did of wanting a on-stop shop. So, it seems to me that the general framework that will be developed for addressing these issues in the vocabulary management should also apply to the lifecycle management of implementation specification. So, I wanted to encourage these two efforts to come together in addressing these issues so that we do have one approach for both.

Linda Fischetti – VHA – Chief Health Informatics Officer
... an issue of … I think one of the things that we know is embedded in a number of these initiatives is empowering the consumer with their own information and I think that we should in some way tag that because that's probably one of the most important things that all of us will do in the next five years, and I'd like to see that pulled out explicitly. There's a lot of work to be done there. I think we know a lot more about how we're going to represent managing information within our provider system. We do not have those answers for the consumer systems and so I'd like to see that as a priority on any priority list.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I think this discussion has definitely proven that simple is not simple. I want to capture a couple of themes. I think it would be impossible to lead this discussion without two sort of parallel threads. One, an appreciation of a need for a framework for the S&I framework and, Dave, you argued the name as a vehicle for helping to coordinate concept, development mechanisms, timeline, etc.

At the same time, I think there's some concern that too much rigidity or form tucked down without sort of allowing some real world betting or, as Wes just mentioned, the ability to let certain activities develop somewhat organically is a bit of a counterbalance and I suspect unavoidable. What I think there is great consensus around with the statement is the need for an articulation of big picture, whatever the framework for framework is, and the need for input of priorities for a variety of stakeholders and Linda just remind us, importantly, this activity should meet the end goal of empowering consumer and the targets of improving healthcare.

I think we also had a thread of discussion about the balance between mandate versus template. Inevitably, one of the ways to reconcile that tension is to use it as a template, take the intimate, organic development, but having some degree of coordinative organic development by virtue of being able to articulate that big picture.

What I think I've also heard is the need for a number of fail-safes and also some unresolved question that may, in their own right, serve as fail-safes. Defining mechanism for input. Defining mechanism for priorities. Calibration to real world implementation activities that Liz spoke of. I think, in this particular slide that's still up, the connection to meaningful use as a sort of framing of the universe—the universe being broad enough in absolute sense and meaningful use is already extraordinarily broad. I think the

question remains the current activities ... may fall under that templating and fostering organic development.

I think this will be an ongoing and continuing activity. You showed the relationship to the Health IT Standards and Policy Committees and look forward on behalf of the committees to helping to guide some of that balance. I think the architectural metaphor is really well taken. Offline, we had some discussion of other entities where there's a need for filling a portfolio of services and being purposefully oblique but they don't implicate ... particular agency.

In the absence of a framework for the framework, when we're using a house as a metaphor, the house that exists had 11 bathrooms, 14 garages, no kitchen, no living room, and no oak stairway between the first and second floor. Clearly there's not where we want to end up. On the other hand, I think the concern about overly mandated and rigid would probably not get the sort of adept adoption that one ultimately seeks without some of that real world development. So, I hope this discussion has been useful in terms of helping you in your thinking, but more importantly, in terms of really moving toward a framework for framework.

I'm constantly reminded that taking the theoretical practice is messy and we've gone to Albert Einstein and … this morning, so let me add my favorite philosopher, Yogi Berra, who offered that in theory, theory and practice are the same; in practice, they're not. I think that really is true. We need to work from a theoretical framework here to end up with a house with all the appropriate rooms, but make room as well for the reality of the world that may not be quite as able to adapt to a perfect construct. Indeed what we need to get is the, as you've said so many times in this, the good, the perfect … the good may be a barrier to advancing for all of the noble purposes to which this was intended.

Let's break here for lunch. I have 12:45. Let's take 45 minutes and come back here at 1:30. I appreciate all the inputs. Doug, thank you very much for leading a very provocative discussion.

(Lunch)

Judy Sparrow – Office of the National Coordinator – Executive Director
Welcome back, everybody. Let me turn it over to Dr. Perlin.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Good afternoon, everybody, and thank you very much for a robust discussion this morning. I can assure everyone listening, the discussions extended through lunch and really just a terrific set of conversations today that affirm my optimism not only for what's been accomplished but in terms of looking forward.

I think this next conversation is a particularly important one in terms of thinking about next steps. Again, I'm delighted to welcome back to the podium Doug Fridsma to really to facilitate—see if he'd like to sit there. ….

M
You can run but you can't hide.

Jonathan Perlin – Hospital Corporation of America – CMO & President
That's right. We embarked together in conversation about setting priorities. As John Halamka mentioned, the calendar and the terrific coordination that Judy Sparrow and team provide will allow us to meet about a week after the Policy Committee, and indeed, not only this week's but the October Policy Committee meeting, they're going to be working through thinking about stages two and three.

In our roles, we have a bit of a … to identify the standards that support the meaningful use, but there is also the opportunity to weigh in, in terms of thinking about how one best supports two and three and to also bring back, as I think is so valuable and was valuable in the earlier conversation, the experiences from the different stakeholders. Again we'll welcome the public input to that conversation. I just can tell you that the one I continually am thinking about is really not just stage one, but how do a sequence of

activities across meaningful use line up for not only stage 2 and stage 3, but the realities of healthcare 5, 10, 15 years out.

Don't want to preempt Doug on that point. I know that, John Derr, during lunch, you noted that one of the stakeholder groups is of course, long term care ... not only apropos of Linda's comments that the help that the individual patient as consumer is an important touch point, but you wanted to make a comment, I believe, as well.

John Derr – Golden Living LLC – Chief Technology Strategic Officer
Well, I just wanted to say I got a placed on a technical expert panel that was supposed to meet next week—now is not going to meet until November—on who gets paid incentives in stages two and three. I just want to remind the group about the nursing homes and the homecare when we talk about pilots and we talk about stage two's and three's, that we are very, very interested in being in pilots. I know the company I work for has just obligated $100 million to infrastructure and connectivity in that and we're taking those. Shelly ... just told me that there's an EHR for pharmacy now and we also have certification under CCHIT for homecare and for nursing homes. So when we talk about that whole spectrum of care, besides just the ... ones.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Indeed, that is the go forward trajectory, thinking about the continuum interoperability of information across different environments and again, to the patient is a touch point to the patient, in particular.

So, invariably I'm going to catch Doug while he's chewing, but while you're finishing that bite of sandwich, let me apologize. Because of an air travel mix-up, I'm going leave a little bit earlier. I appreciate Jamie Ferguson chairing the remainder of the meeting. Let me turn over to Doug to offer some introductory and linking comments to our colleagues at Policy Committee and, of course, back to ONC.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Well, I think the last slide that I had just before lunch with thinking about some of the priorities that we have I think sort of articulates at least some of the things that I'm thinking about with regard to setting some of the priorities. Certainly, the things that I've heard from the various testimony and the work that Jamie has done suggest that there are some barriers to getting adoption—some of them around the IP issue, some of them around the value sets that need to be articulated.

One of the questions that I would have for the group as well is as we go forward, there's a couple of models that we could use for how we might set priorities. One would be to say, "We've got a broad range of things and we want to build the foundations across all of these different things that might happen." We have to define what that foundation is and what the important elements might be.

That's a slightly different approach than, say, let's take one or two key problems and let's try to solve the whole stack of issues that we might have. NHIN Direct said let's take a small problem and go all the way from kind of articulating the use case, developing the specifications, testing the reference implementations, and sort of making sure that that whole stack works. Those are two different ways of attacking the work ahead of us as we look ahead to stage two and stage three.

I'd be interested to see what the committee thinks about the trade-off. I mean, we've talked a lot about trade-offs today, between sort of command and control and a thousand flowers bloom. I think our success, in part, depends on kind of finding that sweet spot between those things.

If you a depth first, if you sort of go and you solve one problem down, the advantage is whatever you learn there, you can generalize as you kind of go across and broaden out the kind of use cases that you might have. If you get the foundation right though, maybe then it allows you to build each of those things on a strong foundation that has that sense of interoperability. So, I don't want to bias the discussion, but I do want to get a sense for what people think about those options because I think once we do that, it becomes easier for us to set the priorities because we have an approach to how we might do that. Or maybe we do both.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I appreciate your teeing it up and with the completely unfair advantage that I get to walk out of the room and jump on a plane because ... breadth and depth aren't necessarily mutually exclusive and there may be a sort of optimum that combines depth where you need it, breadth where you need it. I try and I hope that I'm as unbiased as is possible in this, but thinking as somebody coming from a large provider group, just the context that we're looking to set up activities from isn't necessarily depth versus breadth. But really, what does stage two and what does stage three look like and what is the universe of meaningful use?

That's a universe, actually, that if, when we're drawing a Venn diagram, is a circle that's in a larger diagram about what we project the future of healthcare to look like and what we need to do to be a viable business and all those sorts of things. But in terms of coming at the question of adequacy of depth and breadth, I would just wonder to what degree does very pragmatic look at to the … which we can understand at a certain point what those stages two and three mean may create a different sort of frontier in that depth versus breadth chart.

One might, in a sort of abstract context, to agree that our next set of activities— In fact, I think we need to really consider parallel sets of activities. One is that we know that there are some gaps that still exist in terms of our aspirations for this first set of activity. Second, we know that—remember, early on there was a matrix of envisioning a set of activities for stages two and three. Are those sequential or does one actually come to that depth versus breadth optimum by virtue of looking at stage three and sort of projecting back to stage two?

I would say this: Very succinctly as an end user, the degree to which stage two allows one to thread the needle for stage three, the more likely I feel it's representative of broader constituency ... to succeed. Hitting the stages sequentially where they're not accretive and goal-directed towards the end states I think is less valuable than future—you're sort of a set of trade-offs—the depth and breadth that satisfies a sequence of activities that fulfills an intermediate, not really hurdle, but really a check to make sure one's on target to that more interoperable health environment that we look forward to.

So, just to ... out, as I said, a little bit of a chance to think about this part of the agenda, to be a bit provocative in answering or commenting on Doug's questions about depth versus breadth.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Let me just say, before we do that, just to paraphrase what you've sort of articulated: From this committee's perspective, if we know what the target is in stage three, with regard to the kind of functionality that we expect or the kinds of standards and services that might be required, we can back track and say, "What's the weigh point on the way towards that," and, "Can we use that to see if we're on track or not?" Then make a correction if we're above the mark or below the mark so that we hit the target in stage three.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Chris Chute?

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
I think one of the lessons—again, harkening back to HITSP—was that in the end, modularity had significant advantage and significant generalizable value. One of the early problems was that we did do a vertical use case-driven effort. The interoperability specifications that came out of that were neither coherent with each other nor particularly generalizable.

My concern, if we focus myopically, on phase two and phase three of meaningful use is that we are at risk of doing the same darn thing in a way that would not be generalizable or coherent. I think a sweet spot—this is hardly the only one and it may not be the right one but nevertheless—is to think about standard specification in the context of these modules or components where, sure, they're originally initiated or brought forth to fulfill a particular use case, but the goal clearly has to be—as was true in the closing

chapters of HITSP—that they are cast as specific generalizable components that can be used ideally in multiple places.

We won't get it right because—we won't, but that's not the point. The point is if you iteratively refine those components so that they do evolve to match the generalizable use cases that we anticipate and if we acknowledge from the outset that that's our strategy, then you're not at risk of making these rigid artifacts that only fit within that vertical pipe of a particular use case, but have trouble integrating across a multi-variant breadth of application.

That's a deliberate design choice as we evolve these kinds of standards into the future. I think we have to be careful not to put our own blinders on—I'm repeating this but it is an important statement—not to put our own blinders on and think only in terms of meaningful use phase two and three, but more generally the ... that fits within the cohesive framework as we migrate forward.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Let's go to Floyd Eisenberg.

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant
Actually, what I'd like to do is echo Chris. I could never say anything as eloquently as he does but, and he said it very well. Just the experience harkening back to HITSP of getting very broad and overly comprehensive use cases, but as far as everything that's needed for that particular use case often led to nonreusable components until they were then re-established and reviewed and redone, considering other uses. So I think Chris's compromise is a very good way to look at is as if you're looking at them. One is I would recommend the use cases not be too deep and be a little more simple, but to look at the infrastructure components from a wider perspective than just the use case.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
One of the things I'm struck by is that in software engineering, oftentimes you develop a piece of software to meet a particular purpose and it's lean and it does all the things that you want it to do. Then you get feature creep and you start expanding that and it starts doing lots of other things. You sort of end up with this bloated piece of software that doesn't necessarily have a lot of the efficiencies and it's not really using all of the components effectively.

So in software engineering, you go and you re-factor the software. You go through and you say, "Given all the functionality that we have now, we need to create a more modular, a better way of taking a look at that." In some sense, Chris, what happened in the last stages of HITSP was a semantic re-factoring of the standards that they had to try to create those modules.

Now, you always try to, when you develop software, to start out with a good architecture that allows you to sort of promote that and that includes kind of layers of abstraction and interfaces and all sorts of good ways of developing that software. That gets you a lot further down the road before you have to eventually do some re-factoring. But I think the point is that if we think about this in terms of creating an architecture or creating a framework where we start out with the idea of modularity and generalizability, focus on solving some of those problems, we may still at some point need to do that re-factoring. But I think we'd get a lot further down the road even if we are solving specific kinds of problems because we have the ability to extend and have some generalizability.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Let's go to David McCallie.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
On a similar note, I don't know that our timing is going to allow for any kind of assessment of the decisions that we made in stage one before we implement or recommend stage two, but we really have undertaken a number of pretty important experiments. With some nod to some sort of scientific process, we ought to see how those experiments turned out before we continue down that same track. So, we've endorsed both CCR and CCD at a time when there are several new proposals that simplify both of those

to slimmer, more focused XML snippets; things like hData or Green CDA. We have NHIN Direct and NHIN Exchange, which don't theoretically overlap, but which will, in fact, cause some learning to occur about the best way to share information.

Is there a cycle or a timing process that would let us make an assessment of some of that before we bless the next stage? I think the timetable might be too tight to do that, but it sure would be nice to have some kind of feedback.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Doug, I don't know—I think we all know what the actual calendar requirements are and they're brutal.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
I agree entirely. It's so much better for us to be able to make choices and decisions based on real world experiments and implementations that have either succeeded or failed. I think that we are going to be kind of against kind of the iteration, but I think that's maybe one of the points that's giving us a little bit longer timeframe to start thinking about stage three, in some sense. Because it does give us a little bit more to say, rather than working in 18 month cycles— I sort of liken it to driving a car just looking over the bumper at the road beneath the bumper and how difficult it is to sort of stay between the lines. Whereas if we have a little bit longer direction, I think it's going to be easier for us to not hit the guardrails quite as often.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Walter Suarez?

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
It seems to me that we have already decided to go down the path of using use case development of the starting point or the approach. We already have in the framework that box and a vendor selected. It is the similar path that was used with HITSP. In HITSP, we started with much more general use cases, much more comprehensive ones, and then started to go down into more refined types of use cases as I recall. Then started to getting to use cases that were subject matter-specific, if you will, like security and privacy. So, a lot of that common across any type of exchange infrastructure elements were and have been built into those.

So my question or my thought here is really what should be the scope of the use cases. What should be the conceptual characteristic of this new use cases that are now part of this new framework? Are we going to continue going down the path that we started back with HITSP of very large scope use cases and then much more refined, specific type of message exchange needs? Or are we going to step back and look at this concept of a use case totally differently and try to find, now that we have the building blocks built as blocks and established in many respects, could we take that use case element of the framework and look at it much more from an integrating the building block process?

I think you probably mentioned some of that in your remarks, but I'm just going back to the definition of the use case under the new framework and whether we might take this opportunity to step back and look at— We're not going to continue doing the use cases the way we were before, which was this 99 different topics, we're on topic 15 and we have 80 to go, or 84 to go. We might want to step back and say, "Now we have the building blocks. We might develop a use case that helps the users integrate all those building blocks in a specific situation."

I don't know if you have any thoughts about how the use case perspective in this new framework will change from the previous approaches that we were using with HITSP. How do you see the use case component be?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
I would be delighted if what ended up happening is that we define use cases in manageable, small-sized projects that have a clear beginning and end that we can manage over the course of less than a year,

from beginning to end. So I think about the Direct Project. They didn't try to boil the ocean. They solved a very specific problem and they carried it all the way through.

If we want to evaluate—and this was sort of a quick question back to David, about can we know what works and what doesn't. One of the ways that you can know what works and what doesn't is to drive it all the way down to actually putting it in practice and seeing if it works. If what we do is we spend a lot of time sort of in abstract, kind of coming up with big use cases and never quite get us to the level at which we can implement whatever that framework or the whole use case might be, we never know if we've actually succeeded or not because we've never been able to actually take the test and see if we've captured that.

So, part of making this iterative, incremental, and focused on value of what we're trying to do—that to me, if I was going to set up the priorities and have just principles for how we would do that, I would want us to do something that we knew could be iterative, knowing that we weren't going to try to solve all the problems. That was incremental, that built on stuff that we already did and provided sort of extension or additional components or building blocks, if you will, and then focused on value. When we think of value, I think it's important to kind of go back to first principles with meaningful use, which is it's not about the technology. It's about improving patient care, making sure that we engage the consumer, that we've got the providers the information that they need at the time that they make decisions.

Again, looking beyond kind of what we've got so far, what's the piece that's missing that would provide the biggest bang for our buck that we can try to accomplish in a fairly constrained period of time and that will be one of those additional building blocks? That, to me, should be one of the top priority use cases that we might want to take a look at because that gets us focused on what the providers in the communities and what the patients need.

So, we've got some standards around prescribing. We've got some standards around the exchange of clinical information, kind of clinical summaries. What's the next piece that we haven't done yet that would be high value that we can do incrementally—not that we have to boil the whole ocean or anything like that, but incrementally—that would improve quality and that would help us in the larger goals of meaningful use?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Liz?

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Doug, I would say those value propositions are appropriate and I think what we'd better do is concurrent kind of strategies. Why I say is although we want to look to three—and that's really almost too short already to be looking at three—we're still phasing stage two. If we don't run those two activities absolutely concurrently and in sync because we're going to do what you were talking about—Walter, and others have talked about as well—we're going to end up with disjointed approaches. Ignoring two, we can't do that.

So, somehow we get to three, but we run concurrently to get the answers for two because if we don't do that— Our public's out there already asking us, "How do I get stage one implemented?" It's the natural inclination to jump to three because we know that's the end game and we need to be thinking about that now, but we've got to back up to two, keeping the values in mind that you've espoused because if we're not talking about quality of care, then we've missed the whole reason for the law in the first place, in my opinion.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
I think the sooner we can articulate what that is, the easier it's going to be for people who are making decisions this week about what kind of approach they might want to take, realizing that we've given people options because that's kind of where we are. But at some point, making one choice versus another could commit people down a path that makes it harder for them to get to what the goal might be with the stage three.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Chris?

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
So, in response to exactly that, I think what we've been talking about, implementation group, I'm wondering if it might make sense, Doug, to think about sort of a portfolio of vary small, micro kinds of focuses as well as some larger ones. Because I think about what we might not be able to anticipate that might happen in a couple of weeks where we may find that a whole set of practices run into a common problem where they just don't know how to solve it. If there was the availability of the swat team to really solve that problem—not in the scope of, like, two months, but in the scope of, like, two weeks—it might be helpful.

Because I'm sitting here thinking, "What would people who are listening to us talk want us to do?" I would be happy in that role if we were focused on some of the longer term problems in the way that the thoughtful conversation has been here. But if we let some urgent problem languish in the short term, people are going to say, "A pox on your house. You're letting us struggle while you're thinking all these grand dreams." I think we've got to have some resources available—I'm talking about your resources, but I think it'd be good if ONC had some resources to act as a swat team to deal with some micro issue as it arises.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
I think that's a great idea. Let me say, as a clinician, what are the things that I need to take care of a patient? It's helpful if I know what their problem list is, what their medications are, if there's any relevant labs that have come back recently. When I think about decision support, a lot of those things are going to be the same: problems, medications, allergies. Maybe we need to start really getting those things. Now, lab is not necessarily something we have an exchange standard for. We don't really have a way to do that. Maybe that's part of thinking about what, in the short term, a focused project could be that we could solve.

I can put on my technology hat and I can say, "Well, what are the things that are going to be hard for physicians and others ... use the standards?" I think it's going to be value sets and just being able to take all of this SNOMED vocabulary and distill it down into what are the most important problem lists that we have. Of the drugs, what are the top drugs that we need to include? It's one of those 80/20 rules. We don't want to spend 80% of our time solving the 20% problem. But I think what we want to do is we want to be able to sort of really focus on those things that are of value. So to me, it's going to be things like laboratory exchange. It's going to be value sets that drill down and give people the things that they need.

The clinical narrative is important, but I think we shouldn't try to completely code the clinical narrative. That's part of that 20%. Maybe it's part of that 3% that we shouldn't be working on. The thing is, if we know that we have a process that allows us to iterate and update, then we don't have to be frightened about not getting it right the first time because we have a process that— I mean if you've only got one shot to do this, there's a lot of, sort of, hesitancy in trying to advance it, but if you know that you can iterate, you know that you can do this incrementally, you know that you can build on other work that's happened, I think it reduces some of the barriers because, well, let's try this and let's make sure that if it works. If it doesn't work, then at least we have a migration path to try an approach that does.

I just think that iterative incremental and focused on the value that we have for patients and for providers and getting the quality that we want. That, to me, are the principles for setting the priorities and then from there, we can drill down based on what we know, what we've learned, what are the swat team issues. We almost have to have, in a sense, risk reserve that says, "We have a bunch of resources that we're going to hold back because in case something comes up, we need to be able to put out that fire and respond to it.

M
When, not in case.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
When, yes. Just in case. In the abstract, if that would ever happen.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I think we're almost at time for this session. Do we have a question on the phone?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
I've been listening today. It's hard to participate as robustly on the phone, but I just want to raise a caution that the discussion around prioritization and standards sounds a little academic to me. What I mean by that is if you are wildly successful in this effort, government and the process that's being run here is not the bottleneck that has to be overcome and competing priorities don't need to be triaged. Going back to some of the early principles on this, which is to make sure that the standards that are being used separate transport from messaging from content, sticking with some of those first principles enable more to be done than viewing this as a single thread.

The question you asked about, "Well, if I'm a clinician, what do I need?" My answer would be it depends on the kind of clinician you are. If you're a radiologist or a pathologist or a dermatologist or a pediatric oncologist, the answers to some of those questions can be different. I think rather than creating a nine year roadmap of priorities, we should be thinking very strategically about enabling enough of a foundation and enough of the, sort of, catalytic elements to exist so that lots of parallel development opportunities emerge inside and outside of meaningful use. I think that's success. I do hope that we factor that into how we're thinking about this.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Walter, did you have a quick comment?

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
A very quick one, I guess. Just as to follow-up on Chris point, I think it might be from a pragmatic perspective, it might be helpful to distinguish between some opportunities for use cases that are intrinsic to an EHR, that some of the core elements that might be intrinsic to the use of an EHR, following the meaningful use requirements. But there is another area that is really about health information exchanges.

I mentioned earlier that that right now, 50 states are looking at what are the top priorities of exchanges that we are going to have between our hospitals and our clinicians. They have to start with one, two, three, or four. I think that is a source of looking at doing some research on what are the priorities. That might be a source for ONC to look at. What are the top five exchanges that HIEs around the country are going to be focusing on because I can assure you there's going to be a lot of top five common ones at the top. Developing the type of tools and harmonize interoperable communications documentation for those that can guide all these state HIE efforts will be very, very valuable.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Wes, one last quick one.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I hear us giving Doug a lot of advice, each individual piece of which you have to agree with and you can't agree with all of it. I think that he probably has specific measures of success for the program, maybe we could hear those. We may want to have some formal discussion in terms of what we think might be measures of success, if only to create a position where we have to trade off different schools of thought and advice on how this should proceed.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
So just to reflect back on this discussion for a minute, I think we've heard a couple of alternatives thrown out. First, from Doug, one being build out some crosscutting foundational elements first, another being pick one or two use cases and do sort of a vertical slice. I think to a large extent we've been discussing how to combine those two to achieve the most value. We have talked a lot about focusing really on stage

three as a goal stage, and then backing into how to achieve the highest value in stage two. While there's been also a lot of discussion about how to integrate existing building blocks, we want to do that in parallel with developing the new content—the new specifications, if you will—for stage two. So I think that that was a very interesting discussion.

We also talked a lot about what should be the scope of a use case. There's, I think, perhaps I could even say consensus that—dare I use that word anymore here—but I think we have a general agreement that the scope of use cases should be small so that modular solutions and specifications that solve for those really are highly generalizable and can be re-assembled and absolutely get more value. So, those are just some of the themes, I think, from this discussion.

If there are no further comments, I'd like to open it up for the public.

Judy Sparrow – Office of the National Coordinator – Executive Director
This is the public portion of the meeting. If anybody in the audience cares to make a comment, if you'd please queue up to the microphone in the room. Just a reminder; your name and organization and there is a three minute limit.

Tom Bizarro – First DataBank – VP Health Policy & Industry Relations
Thank you for the opportunity to comment. My name is Tom Bizarro. I'm Vice President of Policy and Industry Relations for First DataBank. First DataBank has a wealth of experience providing vocabularies for use within health information systems. We have in the past and continue today to support the development of national standard vocabularies to promote interoperability in exchange of health information.

Our experience has shown that these vocabularies must follow good vocabulary practices. They must be timely, comprehensive, and accurate. They need to be well-maintained long term with support that addresses the needs of the user and deals with gaps and errors in the content. Lastly, there must be a realization that these vocabularies will be integrated in patient care applications used at the point of care and will impact the quality of care that the patient receives.

Judy Sparrow – Office of the National Coordinator – Executive Director
Robin Raiford?

Robin Raiford – Eclipsys – Director of Government Initiatives
Hi. Robin Raiford from Allscripts but for the purpose of this comment, I'm just part of the HITSP nation that finished their contracts. I would encourage Doug to seriously search to look at IS 107 and the EHR-centric piece that came out of HITSP that got the processes and everything that were there.

To John's comment about long term post acute care. One of the most interesting things that came out of that summit was the huge, huge, huge advantage that long term post acute care has. They have defined data sets, minimum data set, and OASIS home health assessment, and there isn't that little comment over here that there isn't the standard thing, other than the CCD has 400 elements in it and we've looked at—HITSP 32 has, like, 8 of those 400.

One of the most concerning things I heard last week in HIT Policy was maybe vendors would have 18 months notice of the concept, but they wouldn't know detail until much later. If you don't know detail, you can't write the code. I can put anything you want in a document. I can put it in a document, not a problem. You want that to be discreet data push and pull? You've got to tell me, you've got to give me warning or I'm going to break things down the food chain for what's there. Vendors are, like, begging for that and you can't tell somebody six months before an implementation and before a certification, "Oh, guess what? We have a new feature of what's ...."

So, the last thing I wanted to share is I share sometimes when people don't understand semantic interoperability what that means. So somebody who doesn't follow HITSP, HIMSS or anything else, to say, "Get it down to this. You take your kids to the puppy store and you show them this really cute little

puppy, and you tell them, 'Just wait. Daddy's going to bring it home to you.' What you come home with is a black and white picture of the puppy. You have to imagine what this puppy does." That's kind of what we're doing in healthcare. We push and shove a text file and you can see it, but you've got to imagine what it's supposed to be and imagine the attributes of that. Then we got sophisticated. We got a color picture scratch and sniff. We need to send the whole puppy and all the attributes of the puppy, and we've got to know.

So if you've got a Tiger Team and a Cheetah Team, I suggest you design this puppy and tell people what the puppy needs to do because otherwise, if you're going to reach that whole thing of decreased re-admission and all that kind of stuff—if all we do is focus on the 400 elements of the CCD, we've done a lot. The functional assessment, what can you do? I know I'm at time, so I just want to say, help design the puppy and tell them what the puppy has to do and you've got to give them more than six months.

Judy Sparrow – Office of the National Coordinator – Executive Director
Next in the room?

Shelly Spiro – ASCP – President
My name is Shelly Spiro and I am the Director of the Pharmacy EHIT Collaborative. The Collaborative is made up of nine of the National Pharmacist's Associations. Our pharmacists practice in all practice settings: all the way from hospital, hospice, long term care, home care, even the community pharmacy.

We are here today to let you know that we have created a pharmacist EHR, as John most kindly said for us and we appreciate that. As pharmacists, we provide many services outside just of the transfer of prescription information. We are finding this, especially our pharmacy groups who are involved in the state HIEs. They're asking for information because what pharmacists provide, and in many cases are the single caregiver in many locations in the rural and in the community setting. It would be very important for us to remember that the role the pharmacists are playing is very critical as it comes to medication management, medication reconciliation.

So we are here to help you. We are here to thank you for all the hard work that you're doing on the Standards Committee, and want to continue to be part of this group. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director
I'll turn it back to Jamie Ferguson.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Are there any public comments on the phone? No. Okay. Well, then I just want to thank everybody for being here and contributing today. It was a great discussion and I look forward to our next meeting. Thank you. We're adjourned.

Public Comment Received During the Meeting

1. If the ONC is to establish a National Standard System, Intellectual Property must be turned over to the Government, so that it is truly a national system. The committee should recommend that all IP on code sets be controlled by the Government and should not have any license fees for using national standards.

2. Does the committee thing it is on a trajectory to solving anything for the Meaningful Use deadlines?