

**HIT Standards Committee
Final Transcript
November 16, 2011**

Presentation

Mary Jo Deering – ONC – Senior Policy Advisor

This is Mary Jo Deering in the Office of the National Coordinator. Welcome to this 31st meeting of the HIT Standards Committee. This is a public meeting. There will be a transcript made. It will be available later. I would ask all of the members to identify themselves when speaking. There will be a chance for public comment at the end. I will begin by taking the roll. Jonathan Perlin?

Jonathan Perlin – Hospital Corporation of America – CMO & President

Good morning.

Mary Jo Deering – ONC – Senior Policy Advisor

John Halamka?

John Halamka – Harvard Medical School – Chief Information Officer

Good morning.

Mary Jo Deering – ONC – Senior Policy Advisor

Dixie Baker? Anne Castro?

Anne Castro – Blue Cross Blue Shield South Carolina – Chief Design Architect

Good morning.

Mary Jo Deering – ONC – Senior Policy Advisor

Aneesh Chopra? Chris Chute?

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards

Present.

Mary Jo Deering – ONC – Senior Policy Advisor

John Corrigan? John Derr?

John Derr – Golden Living LLC – Chief Technology Strategic Officer

Good morning.

Mary Jo Deering – ONC – Senior Policy Advisor

Carol Diamond?

Rebecca Rockwood – Markle Foundation

This is Rebecca Rockwood. I'm calling in for Carol Diamond.

Mary Jo Deering – ONC – Senior Policy Advisor

Thank you, Rebecca. Jamie Ferguson?

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

I'm here.

Mary Jo Deering – ONC – Senior Policy Advisor

Jim Cromwell?

Jim Cromwell – Department of Veterans Affairs

I'm here.

Mary Jo Deering – ONC – Senior Policy Advisor

Cita Furlani? Martin Harris? Stan Huff?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

Here.

Mary Jo Deering – ONC – Senior Policy Advisor

Kevin Hutchinson?

Kevin Hutchinson – Prematics, Inc. – CEO

Here.

Mary Jo Deering – ONC – Senior Policy Advisor

Liz Johnson? Becky Kush?

Rebecca Kush – CDISC – CEO & President

Good morning.

Mary Jo Deering – ONC – Senior Policy Advisor

Arien Malec?

Arien Malec – RelayHealth – VP, Product Management

Here.

Mary Jo Deering – ONC – Senior Policy Advisor

David McCallie?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Here.

Mary Jo Deering – ONC – Senior Policy Advisor

Judy Murphy?

Judy Murphy – Aurora Health Care – Vice President of Applications

Here.

Mary Jo Deering – ONC – Senior Policy Advisor

Nancy Orvis? Marc Overhage?

Marc Overhage – Regenstrief – Director

Present.

Mary Jo Deering – ONC – Senior Policy Advisor

Wes Rishel?

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

Here.

Mary Jo Deering – ONC – Senior Policy Advisor

Cris Ross? Walter Suarez? Sharon Terry? Karen Trudel? Jim Walker? Have I missed anyone? Thank you very much.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thank you, Mary Jo. Good morning, everybody. This is Jon Perlin, and I thank those of you who are here in person and also those who are tuning in online. This is a very important and interesting meeting today. It's one in which we change a bit of the trajectory from looking somewhat retrospectively at what standards are ready to be applied in terms of supporting Stage 2 Meaningful Use, to really picking our head up a little bit, looking across the horizon, the ecosystem, about how really we can move to model driven health tools that really support the aspirations of higher performance healthcare, and that is extraordinarily exciting.

I'll make some introductory comments about that, as will co-chair John Halamka, in just a moment, but I don't want the moment to pass without recognizing a couple of transitions. One very important and exciting is a new deputy national coordinator, someone who's well known to the group, has a distinguished career in health informatics at Aurora Healthcare and is in the process, as she said, of transitioning from the private to the public sector, and so what a great opportunity to recognize the new role of Judy Murphy. Please join me in congratulating Judy. Judy, we were going to take you to an elaborate breakfast, but now as a public sector member we will have a box of Cheerios for you –

Judy Murphy – Aurora Health Care – Vice President of Applications

....

Jonathan Perlin – Hospital Corporation of America – CMO & President

... that is under the \$20 ethics requirement. Congratulations. Judy, any comments you'd like to make?

Judy Murphy – Aurora Health Care – Vice President of Applications

Just that I'm really, really excited to be able to do the public service for this portion of my career, if you will, and to be able to stand on the shoulders of not only people like you all in this room, but the folks that I've worked with for many, many years at Aurora Healthcare. I've actually been there for 36 years, and been doing implementation for the last 25, IT implementation. So certainly I have a lot of expertise, but that expertise has come with numerous other folks helping me and shepherding me along the way. So I thank each of you for the expertise over the two and a half years on this committee that I've been able to glean from all of you.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thank you, Judy, for ... up on this ... service and for all that you have contributed. John Halamka, I believe you have

John Halamka – Harvard Medical School – Chief Information Officer

Right,

Jonathan Perlin – Hospital Corporation of America – CMO & President

And Arien Malec is joining us, so we will certainly welcome his expertise. We have changes, some departures, but you'll be here, just in a different hat, and Arien, we certainly welcome your participation.

Arien Malec – RelayHealth – VP, Product Management

Thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President

I don't believe she's here yet, but we'll acknowledge Cita Furlani's retirement from public service and Dr. Chuck Romaine, Charles Romaine will be joining in her stead as a member, and we'll do an introduction shortly. Before we move to the introductory comments I'd ask that everyone please have a look at the minutes or bring forward any comments for amendments, corrections, recommendations. Hearing none, we'll assume consensus on the very thoughtful minutes of the last meeting and thank the Office of the National Coordinator and staff for really all of the good work that it takes to put together such a thoughtful synthesis of very complex discussions.

By way of a segue, I mentioned that this is an important meeting where we really work with our ONC colleagues to not only scan the horizon but to look somewhat holistically at the ecosystem of healthcare and health information and the linkages between the models and specifications and certification, so in that regard we'll get some pragmatic insights from Liz Johnson, Judy Murphy in her past life, and from the Implementation Workgroup in terms of some recommendations that we've been building toward, honestly, in the last few meetings, based highly on the experience of the uptake of the standards of the Meaningful Use criteria and the mechanisms for certification and testing of certification and implementation guidance coherence.

But that's an important theme, because that's really a theme that will pervade the discussion, in fact the demonstration of technologies and approaches from the Office of the National Coordinator in terms of thinking about those linkages between model specifications and certification. It's really a compilation of an ecosystem of model driven health tools, and we'll have a discussion about the implications for really maximal effectiveness and maximal, to use, I believe John Halamka's favorite word, parsimony. I think that's a very helpful construct in terms of contemplating what is a very complex ecosystem but offers some potential for really creating linkages between the patient, the care experience, and the population, both in a forward aggregation of information from patient to practice, for care, and for population health, and we'll talk more about that.

I don't want to steal Doug Fridsma's thunder on this, but we'll have a very important discussion about this segue of the continuity between a learning model in a theoretical sense and a very practical model, with care delivery and population health. As we move forward in our discussion today we'll also be having a conversation about quality metrics. This is really at its completion one of the ways in which a lot of the recommendations for care in the practice setting, a lot of recommendations ... population health come together but can only do so with a coherence of data systems across that individual patient experience, that practice experience, and the population experience, and that requires a data model and a set of vocabularies that really works, that one can make sense from the electronic data.

We, candidly, have done, working through a hybrid environment with aspirations for measurement of different aspects, different parameters of care, some of which derives from the data model and some that don't. As the standards committee, and I appreciate Jim Walker's leadership in this regard, we really need to think about how we can help support the quality measures in a way that is really a transparent byproduct of the data models that themselves derive from this set of model driven health pulls. What do I mean by that? Specifically that the data for the things that we seek to measure are not only valid and reliable but have data elements usually in a ratio and a numerator and denominator that emanate directly from the information available and do so in a consistent and reliable way, ... Floyd Eisenberg with great recognition for the many contributions that you have made and will make in that regard. So a very important set of conversations and demonstrations.

Now, if you look at the agenda, as this is a somewhat forward-looking agenda and one that has a number of presentations from ONC and demonstrations that will be, quite appropriately, punctuated by a lot of discussion, it is possible that we may move more rapidly than perhaps we thought when we constructed the agenda originally and with the consent of the committee if we seem to be on a roll John and I would like to suggest that the innovation imperative ... presentation follow after the other ONC discussions. On the other hand, if we need the time then we will break for lunch. But if it's agreeable to the group we'll push through, if that seems to be a good trajectory. Judging from the body language, the heads nodding, I would say that seems to be a popular idea, so let's approach with that. For more specific detail on each of the areas that we'll discuss today and the relationship specifically to the standards that will be under consideration, I'll turn to John Halamka.

John Halamka – Harvard Medical School – Chief Information Officer

Well thank you. If we put all of our work of 2011 in context, April through October was giving Steve Posnack all of the recommendations he needed to thoughtfully create regulations. As you said, today is now really moving forward to new work. One of the things I try to do is since I get e-mails from all of you continuously and get comments on blogs is to try to keep a tally of some of the big issues that we all have

identified as needing further work. Let me just go through a few of them, and you'll find I represented on today's agenda, but also will set us up for additional conversations in December and January.

We recognize the transfer of care summaries is quite important. We recognize that we've been on a continuum of going from CDA through CCD to C32 and now to a templated, consolidated CDA approach. But I think if I have a dream of what the future looks like it goes something like this, why did CCR have any market traction? It was because a 16-year-old with XML spy could create a document and it would be parsable. The only challenge was it was not model driven nor was it expandable. So if we get to the point where HL7 maintains a reference information model, and that's wonderful because it guides all their work, but implementers are given templates that refer back to the reference information model and can, using XML Spy in simple green CDA over the wire, create a set of transfer of care documents that are really easy to implement, low cost but rich enough and model driven we're going to enhance interoperability. So this is a continuum, it's a journey, there are still controversies of what goes over the wire, etc., and so Doug will be teeing off a variety of those topics today and a consolidated CDA discussion.

Quality measures, you already introduced quality measures, and people have heard me describe it, as I went through the meaningful use process sometimes the quality measures seem slightly challenging to compute because data elements weren't part of an EHR data model, they weren't gathered as part of the standard process of care, and there were too many exclusionary criteria. So as we go forward to quality measures in the future, especially given the Implementation Workgroup focuses on implementability, how is it that we as a standards committee say, okay, CMS, NQF, all other parties, here is what we think are the kinds of terms that should be used in quality measures because they're in EHR data models and they're actually reasonably implementable, and doctors, nurses, and other caregivers capture them as part of the process of care, and do you know if there's a quality measure you can't actually compute based on what we have, I'm sorry, it's going to need to be deferred to the future. A lot of work on how we model out quality, how we represent the quality measures, and make these quality measures easier to compute, so we'll be talking about some of that today.

Now, a couple of other things on the content space, radiology reports and images, huge economic value in the world of healthcare reform, eliminating redundancy and waste is a necessity, and yet we don't have, through the Standards Committee, a set of implementation guidance we have recommended for radiology tests. And we're going to be working on that I'm sure as we go forward into 2012. And you already mentioned population health and recognizing there is this federal effort, query health, we will be hearing more about the efforts to send the questions to the data instead of consolidating the data, and there's a whole series of standards that need to be developed there as to how one forms a query, how one gets a result from the query, etc. So that will be a future meeting.

In the world of vocabularies, Jamie's work has done some really great deliverables on how quality measure vocabularies now are quite specified for each domain of medicine. But can we extend that beyond quality measures to, in fact, the EHR itself, and every aspect of problems, meds, allergies, labs, etc., and what are the necessary mappings. Because it may very well be directionally the right thing to do, but we have a non-greenfield, and how do we ensure that NLM and other parties have the mappings to take us from where we are today to that set of vocabularies used ubiquitously in the future. So there's work to do there. We'll touch a bit on vocabularies in the quality discussion, but ongoing vocabulary discussions will need to be had, and of course Jamie and I have a favorite topic and that is the lab ordering compendium, the canonical and singular lab ordering data set that everyone in the country will use so lab interfaces go from 10,000 apiece to \$500 apiece, and of course NLM, a variety of folks working on that, but future discussion.

Transport, we've already had a rich discussion of transport and Dixie asked me to just call out two things. She modified her slides that we had presented at the last meeting very slightly just to further clarify that this was not a bake-off between Direct and Exchange, but Doug used a wonderful analogy this morning, and that is it's like saying we have a tire and a car and the car is a whole lot more complicated than the tire. Well, they're different purposes. We're looking, in Dixie's slides, at the usability of the tire as a tire, and she's just clarified the language to make sure people really understand that this was not meant to be

a comparison. It was a singular evaluation of appropriateness of the standard for a given purpose. Jamie and others raised the issue that we really need to gather rich testimony from those who have implemented the NwHIN Exchange in the field and make sure their opinions are well represented. ONC has published a blog on this particular topic and sought written testimony, and so that is out there and we want to add of course all of that implemented testimony to the body of work that we've done, so that's the process.

Today we will have a transport discussion, and we recognize ONC has been very hard at work doing two important things: taking all of the fine work that Arien and team did on Direct and further polishing the implementation guidance, so it's just as clean as clean can be, as unambiguous as it can be, so that implementers will implement Direct consistently. As well as to look at NwHIN Exchange, I mean, Dixie, you of course identified those ten implementation guides, some that needed some additional work, and so ONC will talk about some of the work that you've done on the modularization of the NwHIN Exchange activity so that one could imagine as certification criteria are written it could be a lowest common denominator of modular components which are good enough as opposed to a complete and comprehensive stack.

So, more work being done there, and of course the favorite discussion that many of us have had is wouldn't it be great some day if there was a RESTful standard with TLS and ...that would just be very low cost and straightforward, not for discussion today but this is going to be an ongoing discussion that we're going to have in 2012, so, Doug, you can imagine that ONC puts forth a portfolio that says we have SMTPS MIME, we have a series of modular components that support a SOAP kind of transaction, use what you will given the use case, and we have a RESTful set of components. We will be working together on transport, and you'll hear a little bit about that today. When you look at the presentation, the agenda for today, consolidated CDA, quality teed up, and I didn't see transport there but we will say just a few things about it and then hear from Will on innovation and where are we going with things like the SHARPS projects, so I look forward to the meeting.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thank you, John. Wes has a card up in advance of the presentation, so good morning, Wes.

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

I guess you're all surprised. I just wanted to understand, of the things you mentioned, John, what we'll be discussing today versus what are future topics. And if they're not today I might want to just make a comment for the minutes today.

John Halamka – Harvard Medical School – Chief Information Officer

Again, if you look at the agenda as written it's the transfers of care, consolidated CDA, how will we start thinking about Green CDA and its role. There's that whole suite of topics. There will be some demonstrations around the tooling to support consolidated CDA and Green CDA, quality measures, how do we start thinking about representing quality measures and the modeling around getting those to an EHR so that it doesn't necessarily require ONC to maintain a set of Java script every time a new quality measure is invented. And then I think, Doug, you did want to make a couple of comments on the transport cleanup, but it's just a few comments. So those are the three issues today.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Was there something you're looking for specifically on ... just so we can –

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

Yes. First off, I didn't quite understand what the other John said with regard to a lab compendium. Is it to get to a standard national compendium, or is it to get to an operating mode that allows more spontaneity in labs?

John Halamka – Harvard Medical School – Chief Information Officer

Jamie, maybe you can comment on what a future state of a lab compendium might look like.

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

Well, this is work that hasn't been done yet, but we have previously talked about having a compendium of order sets and all the orderables in a consistent hierarchy that could be used across labs for consistent interoperability.

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So again not a topic for today, but just recognizing that it's an ONC goal to get the cost of a laboratory interface down to a very small number that we would not only need to specify content standards, as we've done with HL7 2.5.1, but also the vocabulary necessary to display a result, which we've done, but also to order a test, which is work that has not yet been done but many in the industry are looking at it.

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

ELINCS, the California Healthcare Foundation, has spent a bunch of money, got a bunch of people together, had a bunch of meetings about lab ordering, has a completed specification, CHCS, as I understand, funding on the order of a dozen different implementations of this specification around the country and not specific to California, and working with HL7 for this to be a draft standard for trial use. I would not want to see us embark down this path without recognizing the source of relatively mature input that we have to go forward.

John Halamka – Harvard Medical School – Chief Information Officer

Absolutely. So recognize that in the HL7 2.5.1 content work it was how do you take the work of ELINCS, HL7 and put those together into a set of implementation specifications, and I think this body of work would look at the same thing. What has the NLM done? What has ELINCS done? And figure out what is that representation that seems good enough.

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

I just want to emphasize the words "have they done," meaning have they run all the way through an implementation cycle and learned the lessons that one learns that way.

The other comment that I wanted to make sure I understood the timing of was reviewing the work that has gone on, that has been done with regards to NwHIN Exchange, I think I've learned a lot about what has gone on in the last six weeks and I think it's definitely something that this committee needs to understand. I would like us to take it a step further, which is to also identify ad hoc information exchanges in production running on XDS and XCA that are not necessarily under the NwHIN governance in the particular governance group associated with NwHIN. And I'd like to see us have a specific goal of looking at the full suite of NwHIN specifications and understanding which ones are used in day to day as bread and butter and which ones are given token implementations, yes, the only role we have as clinicians, and which ones are just not being used in many cases. And if we can get to a core nucleus of specifications that are being widely used, then I'd like to see us promote that as quickly as possible.

John Halamka – Harvard Medical School – Chief Information Officer

I think two things. One, Dixie, we have the blog where we're going to get a set of comments from implementers to understand their experience, all implementers who have done this stack of NwHIN Exchange specifications, and there is the modular cleaning up that will give us some components to look at in a way that we then would be able to conceivably have certification criteria around components that were widely used. So we'll hear a little bit about that.

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

As we get on the path I hope we'll have at least a day of testimony specific on this point, because we're always concerned that we're finding we have to make up new standards to go forward, and I think we're sitting on an opportunity here to go forward based on a nucleus of experience. And I don't know for sure, but I'd sure like to see us find out.

Jonathan Perlin – Hospital Corporation of America – CMO & President

I appreciate your raising both topics. Let me just mention on the first one, ELINCS and the implementation, sometimes the Clinical Operation Vocabulary Workgroup ... in preparation for..., so I

don't know, Dixie, if you want to comment on the transport in terms of some of the work that you're doing and how we would incorporate it into the agenda.

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

Yes. I think, Jon, you may have assumed that we'd already announced it to everybody, but the set of questions that you and David and others on the team helped put together for testimony to respond to this committee's recommendations have gone out with a set of questions regarding which of the exchange specifications are being used, how they're being used, for what purposes they're being used, as well as what alternative stacks are being used. And those questions, you'll remember the set of questions, were posted last week on the Standards Committee blog and public comment is being solicited for 30 days exactly on what you just discussed.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Okay. I'd like to transition into the agenda. There are two things first. One is that we're now joined by Dr. Cita Furlani, so I want to acknowledge and have the group acknowledge a career of service and your retirement, and thank you so much for all of your work in the public sector. We'd like to turn to you for any comments and introduction perhaps of Dr. Chuck Romaine.

Cita Furlani – NIST – Director

Yes, he's here. We left NIST at a quarter of eight, and we thought we'd be here in plenty of time. But Chuck, I want to make sure, he will be the ... Director of the Information Technology Laboratory as of Monday, and I'll be retiring probably in January. So I wanted to make sure that everybody had a chance to meet Chuck and that he had a chance to see you all and hopefully get together at the break. It's been a wonderful ride. This is a fantastic group of people. Even though there have been a few turnovers, most of us have been the same from the beginning, and this is good work going on. I appreciate very much the opportunity to say something. Thank you, Jon.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thank you so much and sorry your cross-town commute was so challenging. Those of you who know the Washington area well know that it gives new meaning to transport standards.

The Implementation Workgroup, as we transition to the update from the Implementation Workgroup, it also says here ... transition acknowledged earlier of Judy from her membership in the Health IT Standards Committee to her new role at the National Coordinator and Liz Johnson, note that ... council of Jim Walker asking that we identify at the outset what the action items are and that at the end of this presentation will be an action item, which would be support for approval of the recommendations that, just to be very clear, is our endorsement, that's not necessarily a task order for ONC but would represent a consensus of recommendations from this group. As well just to be clear on the agenda for the day, it would be helpful, I believe, to ONC that following the presentations we feel as well that Green CDA is directionally correct and will appreciate the input from the group on that. So if we keep those two things in mind and maybe some other things that arise at the outset of the agenda, those are a couple of the areas that we would like to address. So let's then turn to Liz Johnson and Judy Murphy for a presentation from the Implementation Workgroup.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

Thank you. This is Liz Johnson. As always, we want to quickly just remind you, there is a large group of folks that are working together routinely in the Implementation Workgroup, there on the next slide, if you'll change slides, please. Okay. Thank you. I guess I will change slides. This group has been working very diligently together. We have identified some recommendations that you've seen earlier. We want to review them and formally put them into a transmittal letter following the approval of this group. Certainly if you have input give it to us today and we will make those appropriate changes moving forward.

You've seen these recommendations before. We reviewed them again with our Implementation Workgroup just a week or so ago, made some further clarification. We'll review them with you now. First of all, as you all know and saw the beginnings of the work last time we met, of a grid that will certainly clearly show the standards and certification criteria, the testing methodology and implementation

guidelines for each of the Stage 2 Meaningful Use measures, including the quality measures. So although today we certainly have completed the certification criteria for the measures that we are aware that we've been recommended, that have not come out yet in NPRM, we are waiting for those quality measures and will add that to our work as appropriate. We would also like to see a unified HHS Web site that serves as a single source of truth for CMS' MU and ONC certification programs. This is a request not only from us in the Implementation group, the Standards Committee, but our constituents. We want to see the establishment of a clear process to manage updates to specifications for the Meaningful Use measures and the quality measures. We are suggesting that we need version numbers and release notes so we can identify what is most recent and clearly understand what has changed since the last update. And there needs to be a clarification in those updates whether this is mandatory or optional as we move forward.

Moving on to the fourth recommendation, this is a long one but it really, I think, expounds on our need to understand what it means to possess and to attest to the use of EHR technology. We need to simplify the rules for the providers. We need to simplify the certification process for the vendors and the accrediting bodies. We need to consider requiring providers to possess EHR technology certified only against the measures that they use for Meaningful Use, list the products included in a certified system by name, and indicate the meaningful use measures supported by each named product. And finally, we need to give providers the flexibility to pursue several options, a single, complete, certified EHR, and all modular EHR comprised of certified modules, a complete certified EHR plus certified modules, and pieces of complete certified EHR plus certified modules. This sounds like a laundry list, but this is what our providers are doing and we want to make it clear that this is appropriate so they have guidelines which they can follow as they have success in getting to a stage of Meaningful Use.

Number five is we want to build realistic software development and implementation timelines into the regulatory requirements. On many occasions we've heard that this needs to occur. We need to align certification requirements with the stage of meaningful use that we're in, and we need to establish effective dates at least 18 months following publication of the NPRM for new certification criteria.

Number six is to publish the HHS process for conducting meaningful use and certification compliance audits and clarify how the frequently asked questions will be used, and identify the type of documentation the provider will need for the audit process.

Number seven, publish the timeline for the publication of Meaningful Use Stage 2 measures, as well as the associated proposed and final regs and certification test methods.

And we just have four more. The next one is to revise individual certification criteria and test procedures based on specific comments. As you know, we've done a significant amount of work on the certification criteria. We're moving now into the testing arena. We need to create scripts with combined test procedures that permit the vendor to satisfy multiple certification criteria at once. We need to look at this carefully, but we have seen redundancy in testing methodology and we want to work toward eliminating that. We need to publish more guidance for providers in order to clarify the difference between the certification criteria and the meaningful use initiatives, the requirements thereof. And then finally, we've heard many, many times from you about taking the workflows in the process of caring for the patients and putting those together and ... in the testing methodology. So we want to identify pre-defined bundles of certification criteria standards representing key EHR elements that make up the complete EHR and reflects the way that providers think about health IT.

Jon and John, I don't know if we'd like to discuss these statements before we talk about where we go from here, or whether we move forward.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Let's take a moment, if there are any comments ..., Chris Chute and Wes Rishel, Dixie Baker, and Arien, in that order.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards

Thank you very much. These are outstanding summary points, and I suspect we'll endorse virtually all of them. I do think that number two, which is the unified HHS Web site, could bear some clarification and expansion specifically. I think it would be prudent to incorporate some kind of repository that would include the value sets associated with the elements and obviously the specific data elements in a machine interpretable form that would be available on that site. All too often we have Web sites that presumably tell us what to do, but do so in a narrative, prescriptive form rather than include, or at least have pointers to, the kind of technical content that I think implementers really need.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Reflecting on the complexity of government, I thought you might be going after a different comment, which was not the technical specifications of what was available but not to, in any way, place ... the complexity of inter-agency shared work space on a Web site, but I appreciate that comment. When I contemplate the standards I think the specific reason I noted our capacity to offer those recommendations is with some acknowledgement of a very real challenge to separate agencies, albeit within the same department, of a consistently coordinated single unified Web site. But I think there's much in the spirit of that suggestion, and ... actually want to respond with that mind to Chris' comment on what's included.

Judy Murphy – Aurora Health Care – Vice President of Applications

If I can comment on that, that's exactly the kind of thing we were thinking about, Chris. Today's reality is that not only do you have to balance the CMS and the ONC Web sites and figure out how the two relate, but on both of them there's subsequent links that branch you out to other things. And then when you get to those it might be a 20 page document and you're like what am I supposed to be getting off of this, so to include the link as background material but to have the cliff note version of that on the core Web site, which is what you're talking about, here's the value set and by the way here's the background where that came from is exactly the kind of thing. So we could add specificity to that one which would be helpful.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Good. Wes, I believe you were next.

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

Thanks. In these recommendations I would like to see a little bit more attention paid to the certification of systems for semantic interoperability. It's a very tough topic, but looking through the experiences of the NwHIN and other implementers based on the C32, there's a lot to be learned and I believe there are other efforts going to incorporate those learnings. But two very important principles are that it is not sufficient to pass for certification to say "I accepted a C32." It needs to be "I accepted and a user can now use our system to find whatever the data points that are being tested for in the right places." It's exactly the same thing that Surescripts and the major labs do in order to certify interfaces into their system and it deals with a whole lot of what remains to be ambiguities in the C32 or difficulty in just understanding what the C32 says. There are some cases now with the C32 where the discussion among the testers basically gets to the point of sounding like ... disputation, where the holy documents are the C32, the C83, and so forth.

The second part of that is that it applies both to incoming and outgoing interfaces, so that if an EHR is cast with producing a C32 or a consolidated CDA, whatever the new number is, that there be a benchmark system that will just simply display selected contents in a way that it's maybe not user friendly to a clinician but it's tester friendly to a certification person to see that the data is there represented in the right code and accompanied by text, those various topics.

Finally, it is critical to make that material that would be used in testing available free on the Internet for all developers before they come to testing. Now, obviously as within any test you may change the data, you may find the square root of two on a public Web site and go for the square root of three in a test, but fundamentally there is just no reason why anyone, any of the 200 or so EHR vendors or self developers that we've already certified shouldn't be able to shoot off a test record, a test document, see it interpreted, or receive a standard test document and see on a screen how it's supposed to be interpreted, so they compare to that, it's not that it's not work and it's not expense, but the work and expense can be so valuable in terms of both shortening the certification time and bringing to a head issues where you do

need to get some rabbis disputing much earlier in the process than the actual testing process. Thank you.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

Thank you, Wes. This is Liz Johnson. As I listened to your very astute comments one of the things that comes to my mind is the next set of work that we're going to be on is specific ... testing procedures, what should be available, how should it work, and can I suggest to you that we would bring those recommendations forward as part of that body of work in addition to making mention here?

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

Sure. If you let me know when you're going to have that, I might actually attend the –

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

All right, I will do that, sir. I will do that, because I think your input's very valuable.

Judy Murphy – Aurora Health Care – Vice President of Applications

In the meantime, I think the recommendation, just to say it out loud, for the first part of your two points, would fit under number eight, where we talk about revised individual certification criteria and test procedures based on specific comments, which meant comments from the survey, but we could add this specifically calling out the exchange standards and making sure it's very clear what you're expected to do.

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

Thanks.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Let's go on to Dixie Baker.

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

Thank you. I'm not sure that it should be as part of your recommendations, but I would like to see the Privacy and Security Workgroup's recommendation for changing certification against the security criteria. You'll recall that at the last meeting the Privacy and Security Workgroup recommended, and this committee accepted, the recommendation that in order to encourage sound security architecture, engineering, and integration that each security criterion be treated as addressable and that the vendor would either need to incorporate, meet the criterion within the EHR module, complete EHR, or assign that function to an infrastructure component or an external service, and I would really like to see that as part of your body of recommendations.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

That's very straightforward, but just like we'll add Wes' comment we'll add this to the script –

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

Thank you.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

You're welcome.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Let's go to Arien Malec next.

Arien Malec – RelayHealth – VP, Product Management

Thanks. I just want to double underline Wes' comments, and I think that you can treat transition in care, so for example a referral or a discharge or an admit the same way that you can treat CLIA or you can treat ePrescribing certification. I've got a question on recommendations five and seven, so in recommendation five you're looking at 18 months from the NPRM to the publication and certification criteria. Does that mean that the certification criteria are published by NIST or that the certifying bodies

are available for doing business, or does that mean that products are certified, right, so those are three different statements?

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

Three different statements.

Judy Murphy – Aurora Health Care – Vice President of Applications

We just want more time than we have today.

Arien Malec – RelayHealth – VP, Product Management

Yes, I know. The second question ... one, so it would be useful just to clarify what's meant by that. Then the second part of the question is, given that a certifying body is up and running and available for business, there's obviously some lag time between the time that NIST publishes the criteria and the ACDs are available to start certifying, what's a realistic expectation for developing software, upgrading the software, and going through the training that's required to actually achieve meaningful use.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

This is Liz Johnson. That's where the 18 months came from. We had long exchanges, not only in this committee but in our workgroup, about the fact that without 18 months to get software out there developed, have it be testable, have it live in an environment and be able to begin to collect the measures we need 18 months. You're absolutely right about 18 months from when is the really tough part, and so we're trying to back up into it. We also, frankly, so that we put it for the record for the committee's consideration, recognize that even as we're moving forward to the NPRM for Meaningful Use Stage 2 we probably do not have 18 months to get it all done, but we have to get a longer period of time, so we're asking ONC and CMS to really take into consideration the burden that's being put on the implementers of how can we make that better.

Arien Malec – RelayHealth – VP, Product Management

And the follow on to that is if we're thinking about Stage 3, and I know the Policy Committee right now is thinking about publishing mid next year recommendations for Stage 3, what's a reasonable cadence for thinking through the entire value chain for the stages to occur? And if we think about the penalty phase, and ongoing certification, what's a reasonable cadence to start road mapping through, if you will?

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

That's an excellent question and one that we've pondered. We really have just pondered it through Stage 2 not because we're not considering Stage 3, but we've often talked here about the fact that our constituents and we want a road map that we can drive our activities to and I think that will be part of the work of the Standards Committee going forward in Stage 3 certainly is to get on that road map. It is not really apparently on the road map today.

Arien Malec – RelayHealth – VP, Product Management

Thank you. Then the last one is on recommendation ten. There was a lot of discussion about what does it mean to do meaningful use and to use the certification criteria to achieve meaningful use. So for example if we imagine that there's a transport requirement and there's a requirement to do transition in care, does doing transition in care through proprietary transport meet the intent? Do you have to use the standard transport? You get these very practical questions of I've got a certified EHR, it's got a set of certification criteria, and I'm doing the things that are required by meaningful use but I'm not using that feature, does that count? Was that the intent?

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

That is the intent. And that is a question that gets asked at every hearing and every survey, and you're absolutely dead-on.

Arien Malec – RelayHealth – VP, Product Management

Thanks.

Judy Murphy – Aurora Health Care – Vice President of Applications

Just to add to that, this is Judy Murphy. There was confusion I think on the part of providers how much they should be looking at the test criteria. If they were trying to meet a measure and they didn't totally understand what was expected by the measure and they couldn't pull everything together in their own mind, they would look at the test procedure and say, oh, that's what was – which got confusing then because they're not really expected to do that.

Arien Malec – RelayHealth – VP, Product Management

Thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Terrific; and Jamie, last words?

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

Thanks. I just wanted to support both Chris Chute's and Wes Rishel's comments about the materials that need to be available on the Web site and having a single source of truth, which is your recommendation number two. But I also wanted to reflect that this isn't the first time we've forwarded that recommendation to ONC. We had a series of recommendations passed by the committee specifically around vocabulary for the required vocabulary standards themselves for the value sets that are used in the measures, the convenient subsets that are used in different medical specialties, as well as the required cross-maps for implementers will also be available in one place. So what I'd like to request as the friendly amendment is that those previous recommendations be included in this new recommendation.

Jonathan Perlin – Hospital Corporation of America – CMO & President

I appreciate that. At the outset I teed this up as a set of recommendations to ONC, and Wes alluded to complexity that is sometimes ... scholarship. In fact, changing metaphors slightly, this is a ... part two, and it really is a set of desired attributes to the extent that any single agency can coordinate other agency's activities. I think the discussion is very overt about the complexities of that, but I think the desired characteristics, that is the ..., are really well articulated by a number of individuals. So Judy as you enter your new role –

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

Steve, are you taking notes?

Jonathan Perlin – Hospital Corporation of America – CMO & President

Terrific. Let's just take stock. We're comfortable recommending a set of ... to ONC. I heard consensus on that. Any objections to that? Any amendments? Notwithstanding the comments made, great, then I think we have consensus on the recommendations and I think some very pragmatic and what I'm sure will be much appreciated guidance and some tall orders for ONC and CMS and colleagues.

Terrific, that actually provides a good segue to the next phase of the discussion, and, John, you provided such an eloquent introduction I believe you may have – did you want to make a –

John Halamka – Harvard Medical School – Chief Information Officer

The only question was you had one last slide.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Oh, I'm sorry.

John Halamka – Harvard Medical School – Chief Information Officer

....

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

That's all right. Very quickly, we just wanted to give the committee an update on where we're going next. Obviously the population of the 'Grid' is continuing with the testing procedures. We really are using the workgroup to gain a perspective from both the provider and vendor on what the expected changes should

be in the testing procedures related to Stage 2. We need to really look at the possibility of should we move from visual inspection of testing and attestations to formal testing. Some of you may know that in many instances related to the certification of our products there's not actual formal testing. It's an attestation that says they probably can do "x" or "y." We need to explore that further. The quality measures came up this morning, so that will be added to our body of work to really begin to look at those quality measures and how we move forward. We will present you with a formal timeline of both the activities and when those deliverables can be expected at the December meeting. Thanks, Jon.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thank you very much. Well with that done, thank you, John, for the reminder that we did have that one more slide which is an even better segue into the next set of activities. Doug Fridsma is going to lead a set of discussions from the Office of the National Coordinator. And Doug, it will be helpful as they join to introduce the various members of your team. Okay.

John Halamka – Harvard Medical School – Chief Information Officer

Recognize that this conversation about transfers of care and CDA is going to be an extraordinarily important body of work, especially as further comments that everyone has made about the need for semantic interoperability as one certified system speaks to another certified system. Doug?

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

Thank you so much. In this next section there are three things that I hope that we can have some discussion on and get your feedback about directionally where would be some good things to do. The first is, and this is at the request really of Jon and John, is to make sure that we have some additional discussion on the transitions of care work, understand its relationship and get some feedback about how that relates to activities in HL7 around the Green CDA, and then also to demonstrate some of the tools that we've been working on within the S&I framework and that has in fact be a project started by the VA long before we had the activities that we've got within meaningful use, but a tool that I think is going to be very powerful and useful for us to get that computational underpinning of the things that we do around the standards work to support meaningful use. So we'll have some time to demonstrate that and show how that all works.

We'd like to spend a little bit of time talking about quality measures. Now, we're not prepared right now to give you a full accounting of all of the things that we're doing with regard to quality measures and the like. I think that's a presentation that we should tee up perhaps in the future and have CMS and our colleagues there that are helping with that. But I think one of the things that's important is that when it comes to quality measures there is a part of the quality measure ecosystem that has a responsibility within this committee in terms of trying to make sure that the standards and the data and all of those things, the value chain, if you will, around quality measures is maintained and that we've got consistency and unambiguous ways of representing the quality measures.

The last thing, and I know we've had tremendous discussion and in fact Dixie and John have already taken some of the thunder, but to talk a little bit about the modular specification work and to provide an update to this committee about the work that's going on with regard to Direct. We're working very closely with NIST right now to make sure that we've got testable specifications as well as taking a look at the NwHIN specifications strictly at the secure transport layer and to see how comparable those two things are. So we'll just get a brief update of those activities as well. I liken comments that John has said about the notion of a portfolio, and what that suggests is that we need to have a variety of tools in our toolbox. We can't have just screwdrivers and we can't just have hammers, we need to have a whole host of things that will allow us to get the work of interoperability done. I think the work of modular specifications, the desire to simplify and create substitutability in the tools that we have, I think is an important part of things. So those are the three things that I want to cover. I'm hopeful that we can quickly move through some of the slides, spend some time on the demonstration, and then we'll come back to a final discussion around the quality measures and the specification work.

So, just to recap, we have, through the Standards and Interoperability framework and the transitions of care initiative, established a set of use cases that correspond to key transitions between meaningful use.

The thing about our approach and what meaningful use has tried to do is we're not so concerned about things inside the box, but the interstitial spaces between organizations is a part in which standardization really can provide benefit. So by establishing a set of use cases and identifying and prioritizing the information that can be exchanged really from a clinical and business perspective that team has been able to take a look at the clinical document architecture of the CDA as a standard and begin to simplify and create representations or standards that are closer to that clean CCR approach to information exchange, but maintaining a lot of the power of the clinical document architecture.

Today we'll talk a little bit about the CDA consolidation just a little bit more, talk about some of the tools that we've got. Now, these tools, I think it's important for people to recognize that these are not tools that we would expect providers to use. But these are tools that standards developers and implementers may find useful in getting to this use of a model driven way of looking at our standards and the CDA work. And then briefly, a description of where we might go ... CDA and to have some discussion here as to whether directionally that is something that this committee would support or would provide us some guidance about how best to proceed.

The S&I framework identifies essentially three primary areas of concern regarding the C32 and the CCD. One was the notion of inadequate and confusing documentation, and I have a great diagram that I'll show you that I even found confusing, and so that's illustrative of the challenge out there, so we had CDA document section and entry data templates that were balloted by different organizations and scattered across the dozen or more documents. The C32 is a five page specification but its implementation information is spread across eight different documents totaling hundreds of pages to be able to implement. One of the things that we did over the summer, and we had great participation of members of this committee and with the community, we are close to 900 in terms of the numbers that are currently signed up within the S&I framework, and of that at least 400 are participating in weekly meetings. ONC fostered bringing together the standards development organizations and the implementers to come up with a consolidated set of templates that has now gone through the HL7 ballot cycle. We addressed and resolved over 1,000 comments, primarily from implementers, and we've done that over the course of this summer.

This is a diagram. The HITSP C32 is realized by the HITSP C83, which references the HITSP 154 and the HITSP C80. Those things of course have references to the IAG XPHR, the IAG PCC, and there are selections that are made from the ASTM CCD, CDA R/2 and the HL7 RIM. And this is a diagram of what an implementer was confronted with when they take a look at trying to implement these things. What we've tried to do instead, and this is just illustrative, we're playing with a lot of different ways to do this, is that we've got a set of document templates, some section templates, and some entry templates, and so, for example, the clinical summary might have – the templated CDA focuses on the reusability of those components and so rather than having a CE 83, or a C80 or whatever, what we've tried to do is say here's a document template, maybe it's something called the clinical summary. It doesn't have a funny number, but it does have a name that people can recognize. And within that there may be a series of sections, there might be an allergy and medication or problem list, a procedure or a result section, all of which would be important to include in that template.

Then within that there are different entries that would be collected. So a clinical note, a kind of template, might have all of these things in place but a consult note may require different sections from that, so some of those sections might be reused from a clinical summary and a consult note. So you might take sections one, two, and five for a clinical summary, and a consult note might still include the demographics and some of the other information but include other templates associated with that as well. The thing that's I think important to recognize is that going from the C32 implementation to the consolidated CDA there's beginning to be a desire to have names that clinicians and people familiar with the business can understand so that a plan of care has meaning and that analogy section has meaning associated with those things. That approach is really, when we talk about the greening of the CDA, is really directionally where the Green CDA is headed, is to try to create things that mean something to people when they take a look at it. I describe it like if you wanted a programmer to develop seamless code that was error free but you didn't let them describe their functions in terms of draw a box or draw a square and instead what you did is you gave it some odd template ID and you had another table that you'd look that up in and your

variables had to have nonsensical numbers as well, and then your job was to make sure all the code worked by referencing those numbers. So greening of the CDA is part of getting those business friendly labels that we can apply to things.

The second problem that we dealt with within the S&I framework was the lack of implementer tools and resources. One implementer described the tool set ... to wade through the CDA based PDFs consisted of really three important tools, it was a laser printer, a yellow highlighter, and a legal pad, and that software engineers, when confronted with those PDFs and all the documentation, had to take those three tools and use them to digest the hundreds of pages and to get all of the stuff together. I don't want to disparage Ph.Ds, but it says here that they have to have a Ph.D. in CDAs in order to implement them. I have a Ph.D., not in CDA, and it's still hard to do all of this work. The thing is that our metric of success is not in developing the implementation specifications. Our metrics of success is in getting people to use the things that we construct and to benefit patients by the exchange of information. So where there are barriers to getting to that success goal we need to really work hard to try to reduce them.

One of the things that you're going to see today is some of the work that we've partnered with the VA on and IBM Research, to develop what we call model driven health tools, an open source project, that's changing the way in which we view standards and specifications so that it's not about the models, it's not about the documents per se, but it's about the underlying models that help us then develop tools. So rather than having a PDF, which is a document, let's create databases, let's create models, so that we can build tools on top of that that will aid in the ability for engineers to implement this and so we can give them things more sophisticated than laser printers, yellow highlighters, and legal pads. So we'll have some demonstrations on some of those tools that the VA has started working on and that we have been partnered with them on.

The third is this notion of overly complicated XML schemas, and I described that a little bit in the diagram about how the relationship between the C32 and the IAG profiles and things like that. And when it gets complicated, again it becomes really hard for implementers to do it and it becomes hard for them to do it right. And we want both of those things to occur. So one of the things that we've done going from the C32 to the consolidated CDA is we've made that first step in trying to bring things together, to consolidate them, if you will, and to identify what those templates are. But I think one of the next things that we need to think about is whether or not we should continue this journey that we've begun on simplification, to begin saying, well, listen, let's continue to reduce the complexity and see if we can get to this notion of Green CDA that allows us to have simple business labels, so rather than having code equals "x," have things like result type that are more descriptive of what the result is or what it means. Quite frankly, supported by the consolidation project and the modeling tools we believe that Green CDA provides a mechanism to simplify some of the specifications, making it easier for us to maintain them over time, easier for us to be able to certify that people are doing them correctly, and that then once they have been balloted or standardized, being able to develop transformations that allow the early adopters who have led the way to be able to make transformations between the ways in which a traditional CDA represents its information and the way in which a Green CDA might be represented as well.

With that, I guess I'm going to turn it over to my colleagues, John Timm and David Carlson, who have been working on the model driven tools and can give a demonstration. Perhaps before we do that we can see if there's any particular questions as well.

John Halamka – Harvard Medical School – Chief Information Officer

Yes, Doug, I was going to say if we could just take a moment for comments. So many of us actually were there for the creation of what I'll call this indirection problem. And it wasn't because we wanted to do it this way. It's because alas the intellectual property restrictions at times would prevent us from creating that single, simple to read consolidated document. As Jamie's group has made recommendations, we've all made recommendations, we implore the future to be a single that's easily readable, that contains all contents necessary for the implementation of the transition of care summary, and so lessons learned.

Another important lesson that was learned from this activity was the importance of having an underlying reference information model, and I said that in my introductory remarks. The challenge of course is then,

as you describe it, if you create a model that's so complex that it's hard for the implementation community to put into code then you've done the community a disservice. The goal, which I now look forward to comment, is how can we get to the simplest but not simpler parsimonious transfer of care approach that is widely implementable but yet based in good informatics principles and well grounded in information model. David?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Thank you. David McCallie. Doug, that's a great summary and those are really useful slides to ponder and digest, but I want to drill into the notion there of transformable to canonical CDA. I see the parenthetical there that it's potential, so I understand that some of these may not be settled issues, but do you see that transform as one way or is it two way and is it required? Or is it a one-time process? In other words, is it something that we maintain? And obviously it's the is this lipstick on a pig, or is this a new animal? Is green just a surface layer to make it easier for certain people to understand what's going on but the implementers still have to deal with the full complexity, or is it in fact a new and simpler beast?

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

I don't know. That's why this is parenthetical. I think one of the challenges that we have with Green CDA is that it shares the same problem that V2 has, in the sense that there isn't standardized templates in which you can map, say, the canonical CDA into those templates. Until that happens it's really hard to do that round trip transformation. I think the hope would be that we would be able to do that round trip to try to have a discussion about what are the trade-offs with that, because obviously the canonical CDA has a lot more power behind it in terms of its representation, but that may be important for a small percentage of the kinds of exchanges that we might have, and it might, in fact, not be relevant for most of them. Is there a way that we can make the right kinds of transformations between those?

I think it's also a recognition that there's been a tremendous amount of good work that's gone on before looking at the CDA architecture and there's been early adopters that have been tremendously successful and have provided a lot of input into how to do it right and how to do it better. We want to make sure that those folks don't necessarily have to retool all of their infrastructure, and if there's a way that we can do those transformations then if somebody who has decided to adopt Green CDA as their first way of representing things, they don't necessarily have to transform things into a CDA to send it, they could send it as a Green CDA and the receiver, who may be more sophisticated, can make some of those transformations. I don't know. I think we just need to make sure that we think that through as we consider Green CDA. But I think there is this notion that we would be able to do the transformation in a two way approach once we've got some of those templates standardized.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

My concern is one that comes up frequently in our discussions here is that "or" means "and" if you are an implementer, and if you are required to support de facto both on the wire green and on the wire full complexity, then the only thing you've really done is add work to the stack of things that have to be done. To be a simplification it needs to be something that can be used in lieu of the more complex, but not in addition to the more complex. Otherwise it's not a simplification. I think it's really the right direction to go, but you need to go all the way there. I think the other thing is that just because something is complex doesn't mean it's powerful. Certainly some of the rim mappings of the CDA complexity yields I think relatively little power in reality. A decade of trying to leverage the power of the low level rim has not yielded a lot of results in terms of semantic interoperability or other things. So I'm not sure we're giving up much power. We may give up complexity, which is a good thing. It's an opinion, obviously.

John Halamka – Harvard Medical School – Chief Information Officer

That sounded like one vote for go for it, in that direction anyway. Arien?

Arien Malec – RelayHealth – VP, Product Management

Thanks. First of all, to amplify it's either green on the wire or it's consolidated CDA on the wire, and to David's point, both on the wires doesn't work. I'd have another vote for green on the wire. I'm concerned that it's November, Steve's fingers are tired and cramping from writing regs, and as Liz and Judy just said, we have to give implementation advice to people who are actually going to, their fingers are going to get

cramped from writing the code. And you may not be able to answer this, but let's assume that we said go for it, green on the wire, is it realistic in the time frame that we have to get to green on the wire?

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

To get the standardized templates will require working very closely with our partners in HL7 and the like, and that will take a series of ballots to do that. I don't know. It's hard for me to say whether or not we're going to be able to get that for this next stage. I think we are late in the game to try to include significant changes in that way. But I think that it would probably take us, I don't know, nine months maybe to do a Green CDA, and that's a little too long to be able to get the –

Arien Malec – RelayHealth – VP, Product Management

Yes, if it's nine months then it's not happening.

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

Yes. I just think for us to get it standardized it's going to have to go through the HL7 process, and that's going to just take some time.

Arien Malec – RelayHealth – VP, Product Management

So if I'm hearing nine months, I think the conclusion is it's better to do a full bore attack on consolidated CDA and essentially set that as the goal post. My preference would be if we can get it done as green on the wire, but my ultimate preference is to make it as simple as possible for implementers and having the "or" problem makes it more complicated for implementers. So if I'm not sure which direction ONC's going to push me in, then I'm not going to get people studying the documents right now. I'm going to say, well, wait a little bit until they figure it out, and I think it's better to give clear direction now so that programmers and analysts and all those people can start internalizing the documents.

John Halamka – Harvard Medical School – Chief Information Officer

A very good point. So I guess a question for you, Doug, as we will get additional comments from Stan and Wes, is if the consensus of the committee is move forward judiciously but with haste, is that a direction that signals to the country that this is something we'd like to do and be

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

Yes, I think bullet three, and we talked a little bit about these transforms, mappings typically are ways of bridging between one way of doing things to another way of doing things. If our goal is to get to Green CDA, then certainly these transforms are going to be helpful if we can get to that simpler way of doing things. So what will be useful for me to understand from this committee is given our time constraints and things like that one of the things we don't want to do is lock in something in perpetuity that will potentially not get us to where we'd like to go. There are approaches like once we've got standardized templates developing transforms that are bidirectional that allows us to transition from, say, a consolidated CDA or a CDA architecture to one that has green on the wire, because we have a mechanism to do that and then over time people can make a transition to something slightly different. I think one of the things that will be helpful is when we see the model driven health tools approach, there may be ways in which we can simplify or provide tools to the implementers that will shrink the change that might be required.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Stan?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

I think Wes was first.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Wes?

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

I don't mind going last.

M

He wants more time.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

He wants to see what kind of stupid things I say and then he can correct me afterward. This is great work, Doug, and it's probably understated in saying how valuable it is to have the reusable parts and to start standardizing those parts. I think as we look going forward I would encourage us to think even broader. And what I mean by that is that as some of the folks have been working on information models for quite a while and one of the things that we're recognizing is that the models can be used in more than one context. So Green CDA has focused on message exchange and data exchange, the models can in fact be used to describe measures, they can be used to describe payloads for services instead of messages, they can be used for natural language processing and extracting data, and so the idea is that those models actually, you want to start thinking about those broader context and think about basically that they're models that are described independent of that particular use case and then reusing them in even a broader context. So it's not to say don't do anything you're doing, in fact, continue to do what you're doing, but let's think about ways that we can get even more value out of that model and expressing them more broadly because in the end it's not actually the Green CDA thing that's going to last decades, it's the knowledge of medicine that's implied by the structure of those models and can we put that into a technology neutral representation and then use it in many, many contexts, not just the messaging context but in the description of decision support logic and other things.

Then my other comment is a more general one, one that I think probably I would direct at John Halamka and Jon Perlin, and in a sense is a carry on from what we said earlier. We've made recommendations about terminologies and models and other things that haven't been acted on and what I see happening is that there's some really, really important things to do whose time frame for accomplishment is greater than we're allowed based on policy and mandated timelines and legislation. I don't know how we get around that, but it seems like there are some really important things that we need to do that aren't going to get done necessarily in a year, or in the measurements that were given. We're given certain periods of time that we need to do something and a regulation has to come out or something else has to come out, and I hope we can figure out a way that some of these really important things we can start and we can define a timeline that's realistic, because I think they will have really lasting value for the country if we can do that.

John Halamka – Harvard Medical School – Chief Information Officer

That's very well said. Of course I defer to Doug, Steve, and the folks who officially can comment legally, but to me what you have to say is if we're going to change behavior you have to indicate direction, and that gives people, thoughtful people an opportunity to contribute to the process, but it also avoids locking in a decision today that will head you in the wrong direction. So recognizing that you have these time frames in Meaningful Use Stage 2 and 3, it would be a shame to say, oh, we can't talk about detailed clinical models because we only have six months until the regulations are going to be finalized. The answer is of course we should talk about detailed clinical models and we shouldn't make any decisions today that preclude their adoption in the future and signal directionality. But I'd welcome comments from you guys.

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The path of least regret.

John Halamka – Harvard Medical School – Chief Information Officer

The path of least regret, okay. So the answer is we should feel free to take such direction. Wes?

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

Okay, if you all need to go out for coffee do it now, because I'm going to talk for a while.

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He's got notes this time.

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

I want to start out by replaying conversations we've had about the importance that the XML representation is intuitive to people. I was wrong on that when I was working with HL7. I didn't think it was. I thought it was the equivalent of binary code that one computer would use to talk to another computer. We found that there are several places where it being intuitive and parsimonious in terms of space was important. Parsimony because you've got to be able to get enough XML on the board to say at least this is a ... result, as opposed to having to scroll up and down in order to see that. The two areas where it comes in handy is when people are looking at examples, which is what they do to understand the general case. I would say that 95% of programmers look at examples to try to understand the statement of the general case, there may be 5% who just perceive the general case and go, but 95% may be even a low number, when they're debugging, when they get an error from a parser and the error states the names of elements that are like multiply nested, the same thing over and over again, and followed by an element-like act and they have to figure out that lab result. And so just in the process of making things go intuitive XML makes a difference.

But in addition, I've spent a lot of time working with non-technology business experts on the insurance side and it kind of crossed into the clinical side, and I'm sure it's also true on the clinical side, that people trying to understand how to tell us what we need to encode have to see examples. They can't see the generalized model and go with it. The example has a board full of characters and you put a little red circle, down here these three letters are important and way up here, these two are important, the paths between them makes their eyes glaze over. So the importance of having simplified XML is fundamental to the rate at which we can develop new intellectual property, standardized, new detailed ideas, so that we can be interoperable on clinical things and how fast we can roll that out once we understand it. Both are important.

On the earlier points of the necessity of being kind to programmers, a member of this committee who I consider a good friend said on one dais, "Well, if your programmers aren't good enough, get better programmers." I dispute that, particularly after having spent a lot of time talking to people who were involved in the NwHIN C32 work and invariably they say the programmers were highly competent with XML, highly competent in their programming language, understood the data of their system implicitly, but they didn't have the expertise in the RIM. They didn't have the expertise in the HL7 high level names and classes and things like that. So to me that's an example of why this is an important issue and it's an issue we need to address even if we can't address it in Stage 2.

I think the CCDA, the consolidated CDA is one of the best efforts and best collaborations I've seen in a long time in standards. When I was on the board of HL7 I was very concerned that the culture of the organization paid little attention to the people who had to implement it and the level of effort, which had to be substantial, the level of effort in terms of dealing with intellectual property rights, the simple fact that the CCDA is organized both to give clear specifications of one document at a time, and to increase the reuse of common phrases in XML. That's wonderful work, and I walked away from the January HL7 meeting feeling like between the HL7 leadership, between the folks who are on this committee in there and on the part of ONC we had established a substantially better working relationship than I had seen before. However, it's not green on the wire, and it seems like it has the potential to allow green on the wire to be very nearly computable from the CCDA, because there is a C83 that has business names, and if you're not artfully choosing the business names you're simply picking the names that the group has already agreed on. It should be possible to come up with greenish CDAs that have a very light ballot process because they're not breaking anything that's already understand, and it should be possible to get to the point where programmers can learn by example and debug in a day instead of a week, have to have fewer sessions with the other programmers where we call in our rabbi and they call in their rabbi and we dispute. And the process of building out those, what I call the molecules of information, the phrases of clinical data, can be more easily worked politically with specialty societies and things like that, because you can work with examples rather than an abstract model.

However, at the end of it CCDA is built on clinical statements, some HL7, check me if I'm wrong here, and clinical statements themselves have some of the generalities that make it difficult to understand the XML.

In the meantime, there is an open but not public effort going on that the group has gotten together and named it itself CIMI, and what does CIMI stand for, Stan?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

Clinical Information Modeling Initiative.

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

Initiative, okay. It is really an attempt to start with just those molecules, just those clinical statements in as clear a way as possible with very little assumptions about how it fits into the overall picture so that those same models could be used in many different standards and in many different ways. Stan started to talk about it this morning, but these molecules can not only be used to describe how data is sent over the wire, they can be used to describe what data must be collected. They can be used to drive the generation of templates in an EHR for capturing data. They can be used to describe how data is reported, maybe not at the high level of what you want to add up, but to have a standard description of what the things that you're adding up are is important. So it's a very important effort. Like any new standard ... effort you have to handicap it, you have to say, well, what's the chance that this one is going to ever get any traction. And that's what we do at Gartner, that's a value we provide to our ... and I handicap it pretty well. It has all the potential of every new group to evolve into dueling methodologists, but I think that what I've seen is it's likely to move from methodology to results very quickly and it's likely to just turn on the tap at that point and turn out about 4,000 clinical utterances all at once, because this work has already been done, it's already in the public domain, and it just needs to be turned down.

So I see CIMI as having no value for Stage 2 whatsoever. I think Arien pretty well helped us realize that green on the wire has no value for Stage 2 whatsoever. But I would really like to see us be in the position where we can choose for whatever follows Stage 2 between green on the wire and CIMI, or because we're looking at choosing among them we find they come together, which is often the best result of a policy issue. Right now they're running along different tracks to achieve the same goal, but I'd like to see that happen. As we go about organizing the work we do beyond Stage 2, which I understand is the main topic of this meeting, I would like to see us include in our environment scan, if you will, and our ongoing environmental awareness, the work of CIMI along with the work of Green CDA.

John Halamka – Harvard Medical School – Chief Information Officer

Thanks very much for that, Wes. I'm hearing from multiple parties some enthusiasm for a direction, detailed clinical models, or CIMI work, or working rapidly but recognizing that our time frames are somewhat constrained for Stage 2, but that should not preclude us moving forward directionally. Chris?

Marc Overhage – Regenstrief – Director

Marc Overhage put his hand up.

Jonathan Perlin – Hospital Corporation of America – CMO & President

I'm sorry, who?

Marc Overhage – Regenstrief – Director

Marc Overhage, thank you.

John Halamka – Harvard Medical School – Chief Information Officer

Chris Chute and then Marc Overhage.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards

Thank you. First of all, I want to commend you on the work that you have done. And incidentally, I've seen and used the tooling in our SHARP grant that you're going to demonstrate later and we're all deeply impressed by it. It's superb work. That being said, I'm deeply disturbed by Stan Huff's comments because he's vastly too modest and as usual understates the elegance and importance of the work that he's doing, and that's the CIMI work. I want to reemphasize, and I'll do this in my role as chair of ISO/TC 215, the International Standards Coordination, in my 20 years of international standards collaboration and activity I have never seen an initiative that has the buy-in, that has the participation, that has the goodwill,

the enthusiasm, and the functional output and energy that is going on in the CIMI activities. I will disclose, of course, that I'm part of it, so I'm not without prejudice, but that being said, getting the open air archetype people, the U.K. clinical statement people, the HL7 template people, the CDISC people, the litany goes on of people who are participating and collaborating and shockingly agreeing on material ways of moving forward in clinical modeling is, in my experience, without precedent for its speed, positive will, and energy.

The influence at an international scope that this CIMI activity is likely to have is nothing short of profound. I agree wholeheartedly with Wes' comments that it would be prudent to engage within the CDA modification process if we are going to revisit CDA architecture, and I strongly endorse that proposal and indeed that de facto activity that it's undertaking, it seems obvious if we're going to make fundamental strategic enhancements that would transcend not just the interchange of data but what I think we all share ultimately is to the degree practical standardization at source. It is not scalable to look only at the standardization of data at the interchange point, but if we're going to have efficient, effective modular electronic health systems in this country we really need ultimately to look at the standardization at source and I believe that the CIMI activities that Stan is leading, and leading brilliantly, I might add, lend critical importance to the kind of infrastructure that I think we're seeking to achieve in this committee.

John Halamka – Harvard Medical School – Chief Information Officer

Thank you. Marc Overhage?

Marc Overhage – Regenstrief – Director

Thank you. I want to tie these two threads together just a little bit. One of the things that Wes observed was the struggle that developers sometimes have as they try to understand, for example, HL7 V2 ... and then we went on to talk about detailed clinical models and the RIM and how those things do or do not support the work. While I certainly agree with Wes' point that you need models that to the extent possible developers can understand, and there are some good examples of wonderful models that very solid developers couldn't get their heads around and they couldn't make progress with. At the same time I worry a bit about the observation that if a developer can't get his head around, say, HL7 V2, that are we ever going to get to interoperability, because at the end of the day it seems we need to have developers at some level that share a common model in order to have semantic interoperability. That's the fundamental challenge is mapping from whatever model is in a particular system to a canonical model that you can then get into another system. I think that is the fundamental challenge and so I worry a bit about, while I agree with everything you said I'm struggling a bit with the notion of dumbing down to the level that it's easy, are we going to get to the level of model, as Stan and others were just describing, that we need in order to have a really interoperable system at the end of the day.

John Halamka – Harvard Medical School – Chief Information Officer

I think what I'm hearing, Marc, is that it's not to say that this is going to be ridiculously simple, it's just simpler than we have today and simpler than it needs to be. So obviously CIMI work provides rigor and, hey, some complexity, but it's a whole lot better than we have today than it would be endorsed. Rebecca?

Rebecca Rockwood – Markle Foundation

Yes, I'd just like to endorse what Dr. Chute and Wes Rishel just talked about in terms of the CIMI project because this is giving the research communities a lot of hope in terms of actually harmonizing at the element level and the small detailed models. We've been working on a project for the past four years, a shared health and research electronic library that would actually, I think, be a big asset for us going forward into meaningful use 3.

John Halamka – Harvard Medical School – Chief Information Officer

So to all the comments folks have made about CIMI I've just done Web searches and read about 27 Web sites from multiple different organizations, all saying this is the right thing to do. It's one of the first times I've ever seen that, so congratulations. Let me summarize, because I know we want to move on to tools

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... expectations that I'm not going to be able to fulfill. I'm very happy to have low expectations for all of this stuff and then surprise you.

John Halamka – Harvard Medical School – Chief Information Officer

All right. Flying cars, that's what we've got here. I know we want to move on to demonstrate some of the tools and then move on to quality and transport, but I think Doug what you were looking for from the committee was a sense of directionality, to say that this idea of moving to Green CDA over the wire, we've heard some comments about the necessity of having detailed clinical models and CIMI work and hopefully these coincide, but if I were to just take a pulse of the group would there be any objection to giving Doug and team a go forward direction of Green CDA over the wire as a further investigation, of course weaving into that this very important work on detailed clinical models and the CIMI project? Okay. Let's go forward. Thank you.

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

This has been tremendously valuable and indeed I hope that taking a look at some of the tools and the emphasis that I think we believe the future to hold is simple specifications supported by robust models and tools to help support that is clearly aligned with the work that Stan is doing. I want you to take a look at some of the stuff that we've been working on, give us some comments about how best we can utilize these sorts of resources, and those of you who have some familiarity can ask some of the more complex questions. What I'm going to ask Dave to do is we can spend a long time doing the demonstration, and I'd like to truncate the demonstration a little bit. We'll do a high level overview. My guess, just hypothesis, is that there will be questions from this group related to the tools and we can then use those questions to drive other features or to look at other components of the tool as well.

With that, I'm going to turn it over to Dave Carlson and to John Timm.

Dave Carlson – VA – Lead, Model Driven Health Tools Project

Thank you. This is Dave Carlson and I work with VA and lead the Model Driven Health Tools Project for VA. To start with John Timm, ... on research will provide a brief set of slides to introduce our purposes and background, and then we'll spend most of the time on the demonstration, as Doug described.

John Timm - VA

What is MDHT? MDHT actually started in 2008. It's jointly led by the VA and IBM and then recently, in 2011 ONC has come on board and has provided resources and is a major contributor in the work. It's an open source project. It's available in an open source community called "Open Health Tools" and the goal is really to facilitate the adoption of standards by making it easier to implement those standards. So it's a rather simple goal, lower the bar for implementers and you'll get adoption of the standard. What we're really looking to do with the effort is to focus on decreasing the time that it takes to develop, say, an adapter that leverages CDA. Originally we started looking at V3, but very quickly decided that CDA with all of the traction in the marketplace, was probably where we should aim our first efforts, but everything that we're going to talk about and demonstrate here is applicable to other standards, so keep that in mind.

We got involved in, we being IBM, got involved in MDHT really out of frustration. I'm a software engineer, and I was tasked with trying to implement some HL7 standards and I went out and I looked at what was available, what resources were available for implementers, and what I realized was it was all about PDF and Word documents and Web sites, and there were very few examples, I had a schema. And so starting with that I threw a bunch of different technologies at it, like a good software engineer should do, and see what makes sense and see what I could start to use, and unfortunately failed miserably. So I found the project and realized that with my background in modeling and model driven software engineering that I felt like it was a good fit to see where we could take CDA in the project and see if we can get beyond just paper specifications. That's where we started with it, and since then it's pretty much snowballed. So really we feel like we can do a little better than standards on paper, actually a lot better than standards on paper. If we can create computable models starting with CDA again we can use those

models and reuse those models to generate various artifacts that are relevant and valuable to implementers.

So what have we done up to this point? We have a 1.0 release that happened earlier this year. We've developed the methodology and a set of tools to actually express templated CDA in UML, we have an open source application, it's really design time tooling built on the Eclipse platform, and it really enables an approach that is familiar to software engineers, software developers, in that it's object oriented. We wanted to take the HL7 methodology and modeling paradigms and reel them back in and bring them back into a place that would be a lot more familiar to a Joe Developer or a Joe Software Engineer. Given the set of design time tools we also have models that we've actually created with the tools and then various artifacts and resources that we can hand off to implementers and they can get started and very rapidly come up to speed and really cut down on that learning curve and that development time.

I just want to show an architecture diagram here. We have some existing specifications that we kind of had to reverse engineer to get into this computable form, but what we hope to do is to cut out that reverse engineering and really start working with the models themselves and any new standards, really focus on creating models for those standards as the central artifact, and then look at generating the documentation, the validation suite, validation tools, software libraries, and alternate representations such as Green CDA. And so the focus really should be on the central artifact and the model itself and making that solid so that we can give rise to these other artifacts that are useful to implementers.

We're going to be referring to this slide as we go through the demonstration in the tools, so I'm going to hand it over to Dave and he's going to start with the

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Question, we don't have printouts here, right? We can't read the slides. Are those RIM classes there? What are they?

Dave Carlson – VA – Lead, Model Driven Health Tools Project

Let me just demonstrate that. In that case this is our UML representation of the CDA templates from the existing specifications.

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This is an after the fact UML model of the CDA model, not related to the RIM?

Dave Carlson – VA – Lead, Model Driven Health Tools Project

Correct. It's RIM only indirectly, and that's part of the process we've gone through is to create first a UML representation of the CDA specification, which indirectly as in ... incorporates the RIM. We have actually a basic RIM UML model such that we can look and say whether these types of objects are ... observations, and so on. But really this is a UML representation of the CDA specification and then models of each of the template specifications derived from CDA, so take a look at this. I know that this is going to be small to see on the screen here, but at least I can go through the overall purpose and what we've accomplished, and that we first created as a UML model of the CDS specification. From that as the base we then create UML class representations of the templates from the CCD, from the IHE patient care coordination, from the HITSP C83, so this has been an ongoing process and I like to think of this as actual specification development, in that you create these reusable modules and as we create those modules we assemble the entries into sections and the sections into documents, we assemble the reusable sections from C83 in a different document type, so it very much is creating these as reusable components that are assembled in different ways. It's agile and it's iterative in a sense that as we create these components for, what I'm showing here right now is a small part of CCD, problem section, problem match, problem observation, we can create this test that from the very beginning our purpose was to produce, in a fully automated way, software components from these models. The modeling is not the end result, it's the beginning of this process for us. So as we started this two years ago, we started creating these models from ... pieces for a fully executable job of libraries, tested them, tested whether they incorporate all the validation rules, and that we can validate both CDA documents from the Java libraries produced in the model, so we tested that entire development life cycle from the beginning, and only after

we were assured we had the process in place we expanded to all the other template types from specifications. Most people think of the UML model as boxes and arrows plus diagrams, and one thing we created as part of the project was a table like editor.

So what you're seeing here is a spreadsheet-like table that you can expand rows, the row shows you the elements of a class, or a template in this case, ... incorporated within this is also terminology. So we had a model of the model sets, or in case of large value sets the metadata outcome. ... we created a model for problem section in the code, and the code is restricted to LOINC and the LOINC code was 11450-4, that is incorporated as a terminology reference or a code reference, or in this case a value set reference, and that's built in the model and from the software tools we generate the complete validation test suite from this or we publish output from it.

This is a spreadsheet-like editor, but what's underlying this is a fully compliant UML model that any compliant UML tool can process, so we can also take, just for example, from the same spreadsheet-like view and create on the fly class diagrams. This was actually produced programmatically from the model. It's not something as crazy as boxes and arrows. We can expand all the super classes, so a large example here but you can see that it pulls in now all the super classes, so ... RIM classes, this is the class of a section and ... and an observation from the CDA model. This is all produced algorithmically from the model, so we talk about computable models, we have different ways of editing that are more familiar to clinical experts working on spreadsheets or other types of views. From this we're able to produce published implementation guides so for an example, from those models in a fully automated way we can produce a number of different formats of developer oriented implementation guides.

What we don't always have the best feedback on is an online hyperlinked representation, so we have a demo cycle, CDATools.org, which we use to host examples of the outputs from these models, so in this case from the models I just showed you we produce an HTML representation. If you folks are familiar with the technology for XML publishing ... something called DITA, which is a widely used standard for technical publishing, we actually use that to automatically transform UML models to a DITA representation, and from DITA to a variety of output formats for consumption by the users. So in this case I have an online hyperlinked representation and so with very positive feedback from people that come to this. Now this is a model of the current specification stack of C83, IHE, CCD, CDA, so the full stack is represented in a consistent way and then republished out to an online representation that is all interrelated. So I can navigate from the HITSP stack to an IHE template.

Within our publishing tools there's a small sample snippet of this template that's also fully automated from the model itself. It's not hand crafted, by looking at the structure of the model we generate a small XML example for developers. This is also searchable, so across all these specifications I want to search for the word "dose" so I can go across here and say, okay, I have these templates, something called tapered dose, and so tapered dose and I say, oh, that's part of the PCC specification, I see the documentation, I see a sample snippet. So this is all fully automated from the model and just without me going into detail, an example is a PDF output, and this is using the same DITA publishing process to take from the model, in a fully automated way, and produce a PDF output. So that's also hyperlinked within the PDF and has the same text.

That's the first output that, well actually it's the latter, our first process was to produce the software components. And after we had that we needed the implementation guide, which we produced from the same model that we used to produce the software. So the validation and conformance testing tools obviously is another key point from any specification. Now we're doing this work by, in a sense, reverse engineering and the HITSP specifications, and another member of HL7 has viewed this from the beginning to create a new specification for genetic test ... a product called So from the start it wasn't reverse engineering, it was a brand new model in the MDHT tools publishing the spec for For any of these specifications a key output is the validation testing, so by taking the models and generating Java library that incorporates all the conformance testing rules. To show a small example of how also extended this editing environment, this is an XML instance editor provided by the Eclipse project and we've extended the XML editor with CDA awareness backed by our Java libraries generated from the model, so when I go to say validate this CPD sample instance, it validates not only the XML schema for

CDA, but also validates all of the conformance rules from the UML model generated into the software library.

This is an alternative to Schematron, but it comes with the same end goal of determining where are the conformance errors, so ... sample return testing, 22 errors were detected, you can see the list of errors plus warnings, double click on those and go right to the document, which is highlighted with the errors and warnings. So a part of this is how you make these specifications and testing tools more consumable and more in the environment that not only hard core software developers but analysts would work with, and without spending a lot of detail on it, I'll just show you another alternative view to take the same validation libraries and put them behind a Web site. This is on CDATools.org once again. It's a Web service that embeds the same validation tools generated from the models and I can select that same CDA sample, CCD sample instance, validate it by going live to our Web site right now, and get the test report out here with errors and warnings. All of that is from the models.

We talk about the benefit of computable models, the UML model is definitely not the end game, it's the beginning, producing implementation guides, validation, and test libraries. It's an iterative process for specification development and as we develop a new spec we can create individual components, test those components, turn them loose to the developer environment. So for the past two years we've been producing the software components from these models, distributing them, this is an entirely open source project, and getting active feedback from companies such as Mirth, who has embedded this library through some model into their product as an enabler for them to read and write and validate C32 document instances, and then they wrap their other value added solution on top of the library from our project. So through not only them but other organizations we've had feedback on this doesn't work quite right, maybe I can fix the model, and when you fix the model you regenerate the validation tools, regenerate the implementation guides, and regenerate the components. It's all very quick and iterative.

In producing the libraries, I have two more quick topics I want to touch on and then I want to get back to open for questions and discussion. One is from the software component, one objective we've talked about here already in this meeting this morning is how to simplify the interface in more clinician friendly terms, and from C83 there's the business names or the data dictionary names, so we can apply those into the model as an alternative business name for classes or attributes. From that we've already been producing Java interfaces and can produce other implementation that incorporate the same business friendly naming on a programming library that reads and writes full CDA.

So just to show you an example, this is also on the CDATools.org site, this is a Java doc, so the documentation is generated directly from the programming object. The benefit for making these easy to use, and it reads and writes full C32, we have class names that are familiar, the way the software components should be self-documenting, in that the names of the classes are the same as the template names, they're familiar. This is a condition class, and includes the documentation, this is all fully automated from the model as well as documentation in the model that was put right into the Java implementation, and there are familiar methods based upon the business names, add problem entry, and so we have a problem entry class with this documentation and the names within this method also are documented, the conformance rules, and the documentation of what those are for. Again, the idea is to make those more consumable to implementers without having to go back to the specification at all is the ideal, and when they do go back to the specification they're fully aligned, all the names of the classes, the attributes, apply the same business names.

The last topic I want to touch on is Green CDA that we've been talking about today. We've just started work on how to produce these greenings. So what is a greening process? We believe that greening should be, first of all, it must be methodical. It's not something that ... deciding what's green and what's not. It must be methodical. And it should be algorithmic whenever possible. So we're testing some ideas to take these computable models and we're really writing programming tools that analyze and walk through these UML models that you've seen, and produce XML schemas from that that are green. The first attempt is to do that in a fully automated way by taking his... business names so that the XML structure is familiar. Then the second principle of the greening is to hide the things that are fixed because you only fill in really the variable portions. Then thirdly, to eliminate optional content that's at least not

relevant for a particular use case. So we do the first passes that say eliminate all optional content, and then take a clinical and implementation expert to go back in and say, now re-add the optional content that's necessary for this.

So just to show you the process and how we want to work through auditing this from a model driven way, we've created a tool chain to take that entire stack of HITSP, IHE, CCD, CDA, and can flatten that into a single flattened model and then apply the business names and the default greening rules. So from this green model now I have a simplified UML model, and from the simplified UML model I can create this interactive class diagram to visualize it, and from the class diagram of conditions it contains a condition, a problem entry that eliminates all the fixed values of codes, class codes, ... codes, and then from this within the tools ... generate an XML schema. This was actually produced on the fly right now by transforming the simplified green UML model into a green CDA schema that has business names and hides all the fixed and optional content. So part of the iterative process, again, is to go through now into that green UML model, add back the optional content, adjust the business names, and keep going through this process of iteration. The basic principle of agile software development is to engage implementers early and often, and that should be a principle for creating a green CDA, and it's not ... and turn it loose on the world, but produce it module by module, get involved in getting feedback from implementers, and we applied that same approach to our software development libraries and we'll do the same for a green CDA schema. I think that covers at least a quick run through of the life cycle. Again, the entire life cycle's important to us from the beginning, the model at the beginning to the end.

M

Doug, back to you.

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

Dave, I just want to thank you for that. I realize that was a little hard to see on the screen as we went through both these slides as well as the URLs and stuff, and we'll make sure that the committee has an opportunity to take a look at those and spend some more time if they'd like to, to see what happens.

I think that I want to place this in context, because this is a lot of information and it's highly technical, but I think understanding where it fits in the ecosystem is important. Remember back a year, a year and a half ago when the S&I framework was just a glimmer in our eyes, one of the goals that we had there was to get away from a document-centric way of managing all of our standards into one in which we could create tools, because I can't develop a tool to a PDF, but I can develop a tool to a model or the like. Dave and his team reached out, we met at HL7 and realized that the VA actually had been funding a lot of this work and had preceded a lot of this effort. This seemed like a good tool to take a look at, and today can we begin developing a framework in which the way we manage and maintain over time our standards development work, let's base it on models; let's not base it on documents. So this work really is an effort to do that. One of the things that I think you're hearing it from the work that Stan's been doing and others, is that this is becoming a worldwide phenomenon, that people are realizing that the way to advance standards development is to have it be driven by underlying models. And you can see if you get that model right you can generate an implementation guide from it. If you get the model right you can actually get testing scripts that will help. If you get the model right you can actually begin to do things like making sure that your code, you can generate snippets of code directly from those models, and so it becomes a way of creating that value all the way from your use cases and articulating that model all the way through to the testing scripts, the implementation guides, all of those pieces.

So this is something that I wanted the committee to see because as we started talking about things like the work that Stan's doing around creating these models, if we're developing tools and iterating those over time we may be able to find ways that it doesn't matter. As you can see, it doesn't matter if it's green or if it's something else, if the model is consistent and represents the concepts that we want to construct, we can create ways then of taking those concepts and saying what would this look like in a green world, or what would this look like in an HL7 V2 world. I think that becomes incredibly important. We have a whole series of modeling efforts. There's the Federal Health Information Modeling effort, there's efforts that are going on with Stan's group, and we certainly have a desire within the S&I framework to have models that support transitions of care, or that support query health, or support those other things.

To Chris' point, this notion of getting the data standardized at rest or where it sits as opposed to just worrying about exchange is really all about bringing the question to the data, that's really what query health is about. So we've got a number of different pieces that are all coming together, but this work I think has been, it was inspired and led initially by the VA hospital and brought in with IBM and I applaud the VA for their vision in being able to think ahead, because when we took a look at this we said this is something that may be beneficial. Now, it may not be in its current form the final version, but it certainly I think has demonstrated that if we can get good models that represent the concepts and the things that we think are important to be included in ... transitions of care, we can maintain consistency in our documentation, consistency in our testing suites, and actually aid the developers in developing consistency in the code that they use to support us. I just want to thank the team and to thank Tim and the VA for the work that they've done.

John Halamka – Harvard Medical School – Chief Information Officer

I think we have one question. David?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

First, this is very impressive work. I think these tools could be very helpful in the current state that we're in with the current consolidated CDA. The notion of using models to generate interchange formats or data instances is certainly not new, and HL7's been doing this for more than a decade to try to do that with V3, so I think that the question of should there be tools like this is not the important question. The answer is of course there should be tools like this, but the question is what's the underlying model against which these tools are working, and is that model correct and appropriately composable and extensible and understandable? If you have to have a complicated tool to simplify a bad model you haven't gained very much, a good tool with a good model and we could really go places. So the tools are great, let's just make sure we have the right model underneath it, whatever that means. I know that's a really complicated question. Stan's CIMI group has been wrestling with this for decisions I think that are going to be made fairly soon about what is the right underlying model from which you generate these instances. But the work on the tool was terrific.

Charles Kennedy – WellPoint – VP for Health IT

This is Charles, and I've got one quick comment on that as well. This should not be seen as a tool that is specifically for CDA, but rather exactly to your point, CDA is one base model that we've used for this case but the concept we're looking at here is completely generalizable, that's that an alternative base model would follow these cascading set of constrained archetypes, to use the open air and I've looked at the CEM and considered that as an alternative base model following a very similar approach, so we very definitely have that in mind in our development plan.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

It's a very impressive tool and I really like it. And I think you're on a path to answer my question. My question really was how tied is your tool to UML and/or to HL7 RIM, because I think there's some indication that those things are not perfect and that there may be something that we want to do different. So how adaptable would your tool be to use some other basis like ABL as the native ... as opposed to UML, OCL, etc.

Dave Carlson – VA – Lead, Model Driven Health Tools Project

I'll first comment about UML. As a modeling language the unified modeling language it was designed from the beginning to be extensible. So although it's seen as too general and maybe not applicable in some cases, the key part of our methodology here for the past three years is to look at how do we use the standard as written to create stereotypes that extend it or characterize, if you will, classes in CDA-isms or in CEM-isms. And so that's one approach is how do you specialize you'll know because it was designed specifically to do so. Alternatively, underlying the UML we're using here within the Eclipse project there's something called Eclipse Modeling Framework, or EMF, which is based upon an OMD standard called MOF, the Meta Object Framework. So in that case the one approach would be for the archetypes is to create, if you will, a MOF-based or EMF-based meta model. I'm being fairly technical here, but one approach to do that is we use those same underlying meta modeling tools that could be potentially

applied for alternatives. But I think our first approach would be how to use UML as a generalizable language and see how it could be specialized for that purpose.

John Halamka – Harvard Medical School – Chief Information Officer

Thanks. And Wes?

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

I was very interested to hear about the generation of validating code out of the model. I think it's long been recognized that the schema parsing tells you a lot of things that might be wrong but leaves a lot undetermined in the validity of an XML instance for some purpose. Schematize is a very ad hoc effort to add, well we know we want this to be true, we want this to be true, ..., it's a typical problem that in talking to people about the C32 and why it's such a long time harmonizing implementation to C32, specifically around ..., and one of the issues that comes up is that there's an agreement that this specific piece of information is important to send. The spec is ambiguous in terms of where it might be sent, and typically all of those places are optional. In fact, system A may be sending this information at one X path, system B may be looking for it at another X path, find it not there, and so that's okay, they just didn't send it. In fact, it was sent somewhere else. Is there anything in the way you generate validation that would allow that to become part of what's automatically validated?

John Timm - VA

This is John Timm. The way we approach it is we actually don't look at things as paths in a tree, so much as we actually model the CDA templates as first class citizens. They're their own classes. We use UML specialization, so CDA template classes actually extend classes from CDA and when we actually formulate our constraints, some of which are generated, we formulate them in terms of those domain specific classes. So it doesn't say anything about necessarily the path, it's whether or not a particular object of this type exists in the tree, and so it's expressed more in terms of type, which is a lot more natural when you're trying to think about it, does this document contain conditions, does it contain conditions with a particular diagnosis code versus is there something at this X path over here, is there something at this X path over here, and then you end up with all these rules to try to figure out. We try to express things a lot more naturally in terms of their type and we create essentially logical associations that traverse a lot of that ... that you have in the CDA document, and part of I think why we had arrived on that ambiguity is because CDA as a base standard is underspecified, it allows for deeply nested instances and you can say the same thing in many different ways. So by templating the CDA you really restrict the usage of that schema and instead of saying, well, you can have a problem here and a problem here and a problem here, you say, no, you have a problem in a problem section it must exist in this place and it's this type of information. And if you can constrain it to that level, then it makes it a lot easier to exchange and extract that data back out on the receiving side of things.

Certainly there's implementation guides that don't do a very good job about actually fixing the place where that information should go. Ex-... is a perfect example of that. You can actually represent results and specimens and things in a lot of different ways. It's that restriction and removing the optionality that's going to make things easier to implement. We try to make that easier to do in the way you actually model templates and relationships between templates and the way we express our constraints. That's how we're trying to manage them.

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

Just trying to translate that to my specific question, your method, the code you generate to evaluate the content of a document, we'd find it wherever it was, which if everybody parsed that way it might actually be optimal, but if other people are using X paths to find data it would leave us still with A sending a valid document, B validly concluding the data wasn't there because it was at a different path.

John Timm - VA

There are two kind of places in the actual implementation. Currently, I think Dave mentioned that we generate job APIs. The job APIs that we generate actually evaluate the OCL, the Object Constraint Language expressions that existed in the model. So there's actually an OCL interpreter at run time that actually evaluates those against objects, and it's really looking for objects of a certain type. It depends on

how the constraints are specified. If it's a situation where you actually don't care where it's located, just that it exists, we have utilities that also use OCL to go and find those things in the document and make it a lot easier to extract those. So there's a lot of utility and convenience that's built into the APIs and things that we provide for both validation and actually to consume and extract data out of a document that go beyond what you would get when you just use more conventional XML technologies, like your Schematrons and your X paths and those types of things.

Dave Carlson – VA – Lead, Model Driven Health Tools Project

... also it's to reduce the optionality, as John was describing, and to put the constraints in. Back to a comment made earlier on agile specification development, get the implementers involved early and often, and we should not be surprised years later that there's ambiguity on how different implementers are determining it. So we can't test for constraints that haven't been written, however, you may determine an additional constraint needs to be added to remove the optionality.

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

Does your tool help to identify these ambiguities?

Dave Carlson – VA – Lead, Model Driven Health Tools Project

One part of testing a model, we can validate a model in addition to validating a CDA instance. You cannot validate a PDF document. So what we're working toward now, and we certainly would invite community involvement in that, is what are the rules in which the model is valid. So given that the model is computable and testable how can we test for such an ambiguity? That's a somewhat vague answer, but I think we have a direction toward specifying constraints on the CDA specification itself.

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

A common issue is how many levels of recursion deep in the model does the data show up? Right now I'm going to take that answer as a no.

John Halamka – Harvard Medical School – Chief Information Officer

I know we want to get to quality and to transport, so Arien last comments and then we'll move to the quality.

Arien Malec – RelayHealth – VP, Product Management

Yes, I just want to connect this recent dialogue to where we started with the Implementation Workgroup, with this notion that you need to go all the way from what's clinically represented on the screen in one system and what's clinically received on the screen in the second, and I think this question, and the question that Wes started with originally with regard to the Implementation Workgroup, ends up being the same question, which is, and also potentially the work that CIMI's doing, it's really important, and we try to do this work with the transitions of care work and I'm not sure how well we finalized all of that work, but it's really important to start with what you clinically want to say in a referral or a consult note or a discharge, or what have you. How that work gets represented in the interchange format in an unambiguous way is that there aren't two slots that I can put the same thing and then how that's understood in the receiving system. And what I'm hearing in this discussion is we're part of the way but not all the way, and to do the kind of testing for Stage 2, the kind of tactical work that we need to get to for NIST certification, I'm hearing there's a gap that we need to find a way to address and fill with regard to getting the clinical intent married to the interoperability representation. Is that right?

M

I agree. I see Doug shaking his head.

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

No, I agree. This is incremental progress towards that, but obviously there's additional making sure that the use cases are about the problem that's trying to be addressed is represented in a way that it can be linked. Good software to – go ahead.

M

Just if I'm speaking really tactically around Stage 2 Meaningful Use, if we're going to get some level of semantic interoperability for Stage 2 Meaningful Use it's going to be important in the very tactical certification program to be able to solve that translation from clinical intent to interoperability specification and back again.

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

Agreed.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Doug, I want to thank the modeling team for their presentation. It is a very impressive piece of software. Thank you. Let us move on to the quality and to the transport sections of your presentation.

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

We'll try to go through this fairly quickly. In large part we want to give the committee an update on some of the issues and some of the things that we're working through. This is by no means intended to be a full accounting of all the work that's gone on in quality measures and hopefully we can find some time on the calendar or on the agenda, perhaps with a working group or the like, to be able to do a little bit more work. But I think in large part one of the things that we want to do is that as the HIT Policy Committee develops policy objectives and many of those are around quality measures and developing quality measures, as CMS develops quality measures that then can be implemented and used as part of Meaningful Use there's a portion of that that probably falls within the purview of the HIT Standards Committee in terms of making sure that we've got good representations and good standards that are used, as well as making sure that we've linked all of the pieces together so that quality measures and the data that's being used there is linked to the kinds of data that's being collected, the kind of data that's being exchanged, and the like.

With that, I'm going to turn it over to Avinash, who's been working very closely with the team in ... Allen Traylor, who has been leading a lot of the quality measure efforts. This is an effort really to focus more on the technical aspects of things and to just tee up some discussion with that.

Avinash Shanbhag – ONC – Director, NwHIN

Thank you, Doug. I appreciate getting an opportunity to speak in front of this team. As Doug mentioned, this is a brief update. The folks from CMS and ONC are working hard and have indicated that they will be able to present much more details of the work and progress next month. Really in terms of the agenda and looking at the goals for this activity I think at a high level that conversions to this need to simplify the computation of e-measures, so that's a goal that the folks are working towards. And also where do you think the level of effort that is needed in bill complying with the qualitative reporting requirements, again I think in Stage 1 there were about 44 quality measures that were put into e-measures and the goal for this round is to get all the 113 quality measures to be identified and to be able to do it in a way that both provides ease of compliance and also the ability to compute it.

Currently also the work that's undergoing within the ONC and CMS teams are looking at some of the ... standards that the e-measures are built on top of, and I'll go a little bit about those standards and the work currently is on reviewing them, analyzing them, to see how best to move forward. Then definitely I think, as Doug mentioned, looking at this group to determine what is the most appropriate way in which we can tap into the expertise of this group.

Again, as I mentioned, the idea is to come up with clear and platform independent specifications. I think we heard in the morning that currently, at least in some of our Stage 1 activity we have some of the computations of e-measures embedded into Java script and another implementation specific artifact, and the goal here is to extract out of them and make them independent specifications that can then be used to generate code and implementations that will be integrated easily into EHRs and be used for compliance of measures.

Also, the group, I think the ... committee had provided recommendations on user standard vocabulary and value sets that has been accepted by the team and they're working actively to integrate it within the development of new measures and are also working to get them integrated with the underlying standards that the quality measures are based on.

Just a brief summary of the work that's going on in terms of the standards that underlie the quality measures. Clearly the quality data model from the National Quality Forum is being analyzed and reviewed to ensure that the semantics and the syntax that underpin the grammar for e-quality measures are unambiguous and used the value sets and vocabularies that have been recommended by the Standards Committee. That work is going on. In addition, the specifications for e-measures are currently being looked at through the work of HL7's health quality measure format, which is really the foundation for building the e-measure specifications. That work, again, is being looked at, again, to clarify the specifications and to ensure that the specifications are unambiguous.

Finally, there is work going on to look at the measure of a tool that's being used by the National Quality Forum to look at it to improve its usability, to ensure that that is ... management that occurs, just to kind of again ensure, as we heard in the morning, that there's the appropriate ability to have artifacts that are versioned and are able to be looked at and reviewed as we progress from Stage 1 to Stage 2 and moving further.

Finally again I think there is, again, the concept of what we want to achieve long term versus the ... that always follows through the need to ensure that the Stage 2 requirements of having all the quality measures that have been published are all part of the road map, and that's again being looked at.

In terms of really the next steps are to complete the analysis and focus on areas of our improvements needing to be made in this standard and to ensure that the improvements do allow us to make it simpler, computable and easier to develop and maintain e-measures for the long term. Also, our work is being planned and Allen is continuing to ensure that there is a robust transition implementation strategy for ensuring that the recommended vocabularies and value sets are implemented in a road map that makes sense and is implementable.

Finally, again, the goal is to ensure that our Stage 2 Meaningful Use quality measures are taken care of while they are planning towards long term improvements.

With that, I think again, as Doug mentioned, this is still in the early analysis phases and the team will definitely look up to this group to get ... guidance, but open up for any areas where we could leverage input from this panel. Thank you.

John Halamka – Harvard Medical School – Chief Information Officer

Is Jim Walker on the phone, by any chance? Okay, so you see the great thing about not being at our meetings or being on the phone is that you then run the risk of having work assigned to you. Jim, of course is the chair of our Quality Workgroup and as we talked about at the beginning of the meeting it is the desire, I think of all of us who are implementers of EHRs to have quality measures that are well specified, platform neutral, and easy to compute. I think you've identified in a lot of the testimony that you and Liz gathered that we didn't necessarily have that in our Stage 1. So hence I would think, Doug, it would be appropriate for Jim Walker's group to, in coordination with ONC, to take testimony on these various standards and work in conjunction with you to develop a path forward. Is there any member of the quality committee who would like to speak for that committee in proxy? Oh wait, Dave, you had your card up. No. Of course I'll pass that along to Jim Walker to ensure that coordination occurs. But David, you had a comment.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes, and you may have mentioned this and I just missed it because I stepped out of the room for a quick second. There have been, over the last couple of years, a number of ONC grants out to groups like Partners, Thomson Reuters, and some other external entities to work on defining standards for

interoperability for quality measures, and I'm curious to know whether the work that those groups have done is feeding into this process and how that's coordinated. I know Bob Greene has done work, Tanya Hongsameyer at Partners has done a lot of work, and Jerry Ashroft, there's a number of people circling in this space, I get invited to review their work periodically and I know several colleagues around the table also, how does that coordinate with what's going on here?

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

Some of this predates me, and some of it isn't necessarily e-quality measures, but it's the flip side of that same coin, which is the clinical decision support is I think though that point is illustrative of why I think that, and I like this notion of perhaps reinvigorating the Quality Workgroup just to start systematically going through them. There's a number of standards that are being used and contemplated as part of the work that's going on within the e-quality measure, but to your point, David, we need to make sure that that work is also aligned with where we'd like to see clinical decision support go. We want to make sure that it's aligned with the way in which we do our data collection, and we want to make sure that we have an iterative approach that allows us to get the ball going and improve over time. So we don't need to spend a tremendous amount of time talking here, but it sounds to me that there's head shaking that we need to probably circle back with our CMS colleagues and then maybe think through what would be the kinds of things that a reinvigorated working group around the quality measures would need to know from a standards perspective, that makes sure that the standards fit into that larger ecosystem. I know that Paul Tang is keenly interested in making sure that that value chain is maintained so that the data that's collected is high quality that can be used for the quality measure calculation, which then matches to the kinds of things we might want to see in clinical decision support that ultimately will help support a learning healthcare system and the way we want to do analytics. So I think it's a great idea to get those pieces together and get the quality group looking at that.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Thanks for that clarification. I made the connection in my head and I didn't say it.

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

But it's such a good one, because you are absolutely right, that they're the same thing only the other side of the coin.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes, if you define value sets and details to drive clinical decision support in order to obtain high quality one hopes that the same criteria defines what you're measuring when you assess high quality, otherwise there's a disconnect and why did we see all that decision support that's not actually driving off the same criteria. So it would be bad to have many different, independent, uncoordinated ways to specify what those criteria are and then we're stuck with not knowing what really to put in front of our clinicians who have enough interruptions already. What we need for the group I think is a slide you diagrammatically drew this morning that shows patient panel population and how quality decision support are two sides of the same coin, so December.

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

I will turn my napkin into a slide and then we can talk about that at one of the upcoming meetings.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

An area. To take that one step further, when I received the lab results that said the patient has a hemoglobin A1c that needs to translate into the decision support rule and into the quality, I just wanted to drill on, you mentioned value sets and this is an area when I was in a previous role, Doug, that you and I talked a lot about, and I'm wondering what, we need a consolidated list of value sets, both for quality measures for decision support and for interoperability for lab results for prescribing for transition of care.

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

... that recommendation before?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes. Jamie's made the same recommendation, so Jim Walker's group and Jamie and others, yes.

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

Arien, you're a new member, so are you on any of the –

Arien Malec – RelayHealth – VP, Product Management

I've yet to be assigned.

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

Interesting.

Arien Malec – RelayHealth – VP, Product Management

Yes, indeed.

John Halamka – Harvard Medical School – Chief Information Officer

I think there may be some work in your future.

M

Thank you for volunteering.

John Halamka – Harvard Medical School – Chief Information Officer

Thanks so much for that discussion, and we'll get back to Jim Walker. The transport discussion was one that's very important that we wanted to hear, without stealing thunder, all of the great work you're doing on the creation of a portfolio of components. Thanks very much.

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

I think the last thing that I want to do – do you want to do this or do you want me to? This is your work.

Avinash Shanbhag – ONC – Director, NwHIN

Okay, I'll start over and then –

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

....

Avinash Shanbhag – ONC – Director, NwHIN

I can start over and when I get into trouble you can –

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

I've

Avinash Shanbhag – ONC – Director, NwHIN

This work really started just, this is Avinash again from ONC, the work on modularizing started, just at the onset to give a history, started at the onset of summer camp activities of, well, my name is officially there, as the summer camp activities started ... team one of the challenges that we faced at ONC was to look at all the portfolio specifications that comprised both Exchange and Direct and look at what would be, again, the same question of what would be the core set of building blocks that were used substantially in most implementations and how could we simplify them, and really this effort that has gone on since early summer and is really a result of trying to answer that question. Just to give, again, a little background, the kind of goals, the need to simplify in creating a portfolio of standards, services, and policies really is the basis that we feel is needed to achieve interoperability among healthcare systems. Again, I think it falls neatly into our need to both enable standards that we heard in the morning, this process is to kind of now try to curate that portfolio into specifications that can be easily used and then again we have our enforcement to ensure that those are being used. As we talked about a lot the whole definition of NwHIN has progressed into something which is much more of a set of standards, policies, and a portfolio approach that is used by implementers as needed and kind of looking at it and picking and choosing based on the use cases, so this really was consistent with that need.

In looking at our modularization work this graphic on the left side shows the list of specifications that Dixie's team looked at and reviewed using that variation criteria. As that process is going on, what we found was that we could easily divide the specifications on the left side into two areas. One was the foundational components, the foundational specifications that really were needed to build any additional value added services that were needed. And then there were the value added services. An example would be in the Web services ... you have the messaging platform, the underlying messaging platform and the security components were really foundational in the sense that all other value added services were utilizing them and implementing based on those specifications, such as the patient discovery or the query and retrieve document specifications that have been used.

We took those foundation specifications from Exchange and went through a process which the diagram really shows a cartoonish view of where we looked at the specifications, made sure that the specifications were re-factored, and I think the term that we used is "... up," essentially flattening the specific ..., looking at every statement where the specifications were traceable to a requirement, had an example snippet of XML that the implementers could use to ensure that they knew what the ...that specification and importantly have one ... implementation that was not production ready but the implementation was sadly accurate to what was written in the specifications. So in a way it proved that the implementation would prove that the specifications were implementable and conformed to the specifications, that was one of the goals, and also to build a set of product new ... test cases. Again, that was all traceable, so you essentially had a set of specifications that were traced to example snippets that had traces to test cases and could be linked to implementations that could be put as a package and made available to implementers on the right side so that at the end the implementers could look at the examples and be able to understand how to use the specifications.

So that was the goal of this activity and we looked at two main areas. In the first space we looked at the authorization and the messaging platform from Exchange as the foundational specifications to build this modular package called exchange base secure transport. And now currently we are in a process of doing the same thing on the Direct specifications, and here what we are trying to do is build out the Direct base secure transport packages for ... and also with using XDM as the attachment and the connection to XDR.

Here's the current work, again, as I mentioned, the first phase which was really to exchange specifications and have them packaged together as ... basic transport was completed, has been completed, it went through a public review process, and again to emphasize, there were no new requirements added. The idea here was to do really a cleanup and to stay true to the requirements that came from the exchange. In a certain sense, the package ... all the requirements and use cases that were a part of the exchange needs. Similarly, for the rest, which is currently in progress and hopefully ... is going to be completed by the ..., the idea here again is to ensure that the specifications, the two specifications that comprise the ... statement of secure health transport and XDR and XDM work is similarly done in ... that provides this modular set of artifacts.

Again, I think, as I mentioned, the goal in refactoring the specifications was to ensure that the specification readers, the implementers who read the specifications, were able to do a traceability on the specifications knowing exactly what the specification mentioned as to how to do, as an example, a snippet and then to be able to understand how to implement it, again, it cleaned up much of the optionality requirements that were found in the specifications and be able to essentially make that into a smaller, thinner document that is much more amenable to be consumed by the implementation community. An example, it's difficult to read it, but I have links to the Web site and here's a snippet of the traceability metrics that is a common pattern for all these specifications. And the idea here is that if there is a specification then there are links to examples, there are links to the underlying specs, and there are links to the example XML snippets that will help implementers work on implementing it.

Similar to, again, once we had the specifications on the other side of the coin ensuring that the test implementations are valid and also that the test cases are written in a product neutral manner and tested, and here for Phase 1, which was a SOAP-based ... Web services, I do want to mention that we worked very closely with NIST to ensure that the NIST based test ... that have been built to testing really does

utilize all these components and were able to validate the test implementation using these with the neutral test cases. He worked very closely with the team and all of those capabilities are in the NIST ... which will enable us to have independent implementations be conformant and be tested in a conformant manner.

Here's an example on the testing side, the typical set of artifacts that are created, and here, again, this is illustrative only of to just provide an instance of how the requirements were traced into test cases and then linked back to the implementation. Again, I think the screen shows about ... test cases for the current ... specifications, and clearly I think the idea here is to build out that model and be able to have that tested working with NIST. Again, we are working with NIST to ensure that some of the direct components that are needed, such as the XDR and XDM are part of the NIST test tooling, again, to ensure that implementations have a neural test tool to test components.

Again, these are, just an example of some of the architectural elements. They're not really pertinent to the actual modularization effort, but showed that implementers could use these artifacts and test implementations as guides towards building their own systems. Here's a link to the Web site where the artifacts for these activities are published regularly and clearly I think as we have public calls that have given us important feedback and have improved the specifications and the test packages.

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

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John Halamka – Harvard Medical School – Chief Information Officer

Avinash, terrific. I think Doug was flagging for a comment.

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

Sure. I just wanted to, first of all, thank Avinash and his team for the work that they've done. I think it really is tremendous and has really helped, I think, in two ways. First, we want to be on the record that we are not rewriting the direct specifications, although some people have been concerned about that. But as you can see, the notion is to make sure that we have a clear specification that is linked to the testing and conformance and making sure that we can make sure that we have the testing harnesses in the suites that help with that. And so the work that they're doing with the ... is to really continue that whole requirements chain and make sure that the specs are cleaned up and that they can be certified that people conform to them.

The second thing that I think is really important, and it goes to the comparison between the tire and the car that you stole earlier this morning, and that is one of the things that we have been emphasizing is this notion of a portfolio and that there are certain things that are important for different kinds of exchange and other kinds of exchanges that require different kinds of services. We want to be able to have the tools that this committee and that people that are out there implementing will need to be able to correctly implement and most efficiently be able to demonstrate exchange. So the specifications, the Web services over HTTP and SMTP with a secure MIME attachment have dissected out a lot of the complexity that existed and that has been identified by Dixie's group over the summer within the NwHIN working group and sort of created equivalencies that are based on existing standards that are out there that are reflective of IETF standards and Internet based standards, of which are foundational for a lot of the kinds of exchanges that we might need. Two years ago we looked at the Nationwide Health Information Network and we said what is it, and we said it's a series of standard services and policies. It has taken us some time but I think we are beginning to populate that portfolio of standard services and policies and that the modular specification work is an effort to really begin to construct those building blocks that then can be assembled, pairing the right transport with the right kind of package and with the right vocabulary so that we can accomplish interoperability. Thank you.

John Halamka – Harvard Medical School – Chief Information Officer

Before we move on to questions, Dixie, I know you've been very close to this. Would you like to comment?

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

Yes. I was getting ready to put my card up. This looks like really good work, and Avinash it's been a pleasure working with you on it. One comment that I had was not on the NwHIN Power team but on the direct assessment that I did I think at summer camp last year or something, different team, one of the recommendations was that XDR and XDM be extracted from the Direct specifications. The idea was because XDR is SOAP-based it's adding a level of complexity that the little guy may not be capable of undertaking. So I was thinking maybe we should consider, or maybe you have considered, putting the XDR specification from Direct into the Exchange specification so it would share the SOAP transport on both of them and would really place the burden of making that on ramp, off ramp on the big guy instead of the little guy.

Avinash Shanbhag – ONC – Director, NwHIN

Excellent comments. I think we'll definitely take it back and look at that and see how we can do that, ... that in both places so that it shows the transition and the bridge.

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

Right.

John Halamka – Harvard Medical School – Chief Information Officer

In the conversation that Jon and I and Doug had this morning, the notion of having a very simple, streamlined SOAP transport, stands alone and is a very simple streamlined S/MIME SMTP transport and then it stands alone and in the future there may be others, but that is you could draw on those standalones as you needed to do.

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

Yes.

John Halamka – Harvard Medical School – Chief Information Officer

Okay, so we have Tim, Kevin and Wes. Tim?

Tim Cromwell

Thank you; Tim Cromwell. Doug probably knows what I'm going to say, and Dave probably knows as well, but I think we've heard really good results and I think we're on the right task with respect to tooling and specifications, and I think there's one more piece of the puzzle that's missing and it's going to show up in Exchange and it's going to show up in Direct, and that is this notion of payload validation. The payload validation that is occurring right now when we receive information through the NwHIN from Exchange is being done by clinicians. They're looking and seeing what we've got. I'd like to see us extend either the tooling that we're doing in MDHT or in some other way to get to the point where, and I'm not saying that every transaction has to be validated, the payload has to be validated, but I'd like to see us work on validating the payload as someone who's ready to become an Exchange partner or sending information through the Direct stack just so that we don't have to have clinicians do that work.

John Halamka – Harvard Medical School – Chief Information Officer

Doug?

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

I agree. I think we need to make sure that we've got validation at all levels that we want to do. I think the challenge, and I think we have to be very thoughtful about that, is that we really would like to, when we talk about validation, use Postell's Principle, which is making sure that when people send they send conservatively, but when they receive they receive liberally. What that means is that we want to make sure that people are validated, that they conform to the standards when they send it, but when they receive it they don't reject it if there was an error some place, because I think it's more important that we get the data moving than that we reject something because it's not perfectly conforming. I think we've talked about that, the vocabulary working group talked a little bit about that notion, and we need to think about how that would apply to payload because I think it's absolutely critical that we start thinking about it. But we want to make sure that as part of that validation we build robustness into the system so that the

sending is conforming is best we can, but the receiving has some flexibility. So that if it isn't perfect we do our very, very best to extract the relevant information from the clinicians.

M

In the Villa Health Projects that's absolutely the principle we're following, I didn't know it had a name, but that's what we're doing. I think it's going to wear thin on clinicians after a while that they're exposing information right now that we're getting from private sector sources and they're willing and able and ready right now but it's going to wear thin and they're not going to be willing to do that and they're going to want to know why they're receiving information that isn't complete. So I think we need to figure that one out.

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

And that means we just need to step up our validation on the sender to make sure that we do that, yes.

John Halamka – Harvard Medical School – Chief Information Officer

Kevin?

Kevin Hutchinson – Prematics, Inc. – CEO

I think Doug answered my question, so I'm going to turn this into a little bit more of an editorial. But I won't break Wes' record, I promise. First of all, I'm having déjà vu over here with respect to when we first started Surescripts, having the same conversations but there were only about six of us in the room trying to figure out how to connect 60,000 pharmacies with hundreds of different EHRs and ePrescribing systems, and the purpose of moving information around and my editorial is just to commend the work that, Doug, you and your team are doing because I think, we've been at this now for several years and it seems like this meeting is the first time we're starting to see the glue, the things that are actually going to make this implementable. Because I remember in the early days we didn't always, knock on wood, 100% comply with the NCPDP standard because as we started implementing it into the industry we realized that there were certain shortages, certain things that, to Wes' point, he's made before about the words "and" and "or" and certain things that were optional in the standard that we really need to make required if it were really going to be a workable solution in the industry. So we took the word "optional" and said well, we're a private entity that can actually make these things required versus a standard setting organization, and I think we're going to come across some of those same things as we get into this implementation tools.

The second part of the editorial, I would just say is let's not get him back to the timelines that have been brought up on multiple occasions about we're getting crunched and crunched as we move into 2012, because of the process that we have to use both in the federal government and regulations and comment periods and things like that. However, that being said, that doesn't mean that this advisory body can't come up with recommendations and solutions that can be implemented in different ways. The question I was going to target toward was how does this impact Direct? How does this impact the Nationwide Health Information Network and the work that's going on there, and there is real work going on in both of those ..., with real solutions moving real data. I think taking what's been discussed today and the processes and approaches and now driving them into those processes is not only going to be informative back to this committee as to what's working and what's not working, but I think it's also going to prove out how scalable this actually is. I want to commend you for the work you're doing. It's actually starting to feel like there's substance to how this is actually going to work.

M

Thank you.

John Halamka – Harvard Medical School – Chief Information Officer

Great. Wes?

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

Can you put slide number four back up? One way of looking at this slide is that out of a rich set of functionality, for interoperability on the left we've selected a few things to say, well, those are really the same for two different use cases, but the functions we're meeting are the same and that's the right side of

the diagram. I would say that towards what we need is probably another block on both sides which has to do with identifying trading partners, being able to know who you can trade to beyond the ad hoc mechanism of we know their direct address and there's already a mechanism I think in the NwHIN spec. But I'm curious about another level which has always been one that I alternate between being not too worried about or scared to death, according to how richly people implement it, and that is effectively role-based access control. So I think it's XUA in the IHE spec suite that can be used to determine whether a given receiver, a given requestor ought to have access to some information based on their role and a set of rules set aside by the entity that owns the information for now. We had testimony about a year and a half ago from VA and other places about it. My fundamental concern is that if it's as simple as it's either a clinician or not, then ... is probably overkill, but fine, it's a good way to do it. If it gets down to it's a third year residents and the people on the other end only have a policy that goes up to second year residents just coming through a common appreciation of what to put into the SAML in order to do it is a mind boggling experience.

Going a further step, we asked somebody testifying at that meeting how they would explain the more complex examples they gave to the patients and they said, well, we imagine there will be a new job title in the VA called "Patient Privacy Counselor," and they'll be able to go to their patient privacy counselor to figure out how to fill out that form, which certainly solved the problem of complexity and it added more cost implementation than I was anticipating. So where are those things that are role-based access controls in this picture? Are they part of the leftover part on the left under Exchange, do they get modularized, how does that happen?

Avinash Shanbhag – ONC – Director, NwHIN

This is Avinash. Conceptually, and I think we talked about it in the NwHIN Power team, I think there were some specifications that were developed in the Exchange trial implementation ... access control and Again, I think they would theoretically be on the left side and then we'll have ... base on again implementability, need and those criteria to see which ones would flip over on the right side. It's a good point to note that I think during the evaluation we talked about the great ..., there were some specifications that were needed but didn't have the level of maturity, so I think that would be a very important element for us to review the criteria, work with the Standards Committee to decide which ones have that sweet spot, and these two specifications really had the sweet spot of being mature, had implementation and were foundational, so they met the cross-section of need, maturity and usability. But again, as additional use cases emerge I think these specifications get populated.

John Halamka – Harvard Medical School – Chief Information Officer

Dixie Baker may have some insight from the Privacy and Security Workgroup.

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

Yes. I would say that the direction we're going is really to move that privacy rules to the enterprise, and remember, that both Exchange and Direct are organization to organization, not person to person. And if you'll recall, the Metadata Power team specified the metadata that would go on the wrapper, the universal exchange language wrapper that would specify the privacy of this content. The way I would see it is that you'd have a content blob going from one side to the other, whether it be over Exchange or Direct, and the receiver enterprise, not NwHIN, but the enterprise would then look at that wrapper and use their own role-based access control within the enterprise, the enterprise level not the network, to determine who could see it.

John Halamka – Harvard Medical School – Chief Information Officer

And Kevin Hutchinson, your card is back up. You may have some experiential observations.

Kevin Hutchinson – Prematics, Inc. – CEO

I agree 100% with what Dixie just said. I think that the roles-based process, which I agree with, Wes, I think should exist. I think the question that needs to be answered is, is it the responsibility of the Exchange, the network, or is it the responsibility of the certification process of the applications that are going to plug into the network to have that capability from a security and privacy standpoint. And I'm actually twisted on that question because there's a validation of the user that should be occurring at a

network level that is a valid user that can connect in, which has the role, but it seems to me from a roles-based authorities it belongs more in the application that will be viewing the information. But again, I have this argument with myself all the time.

M

I think what I'm hearing is one model is there's this network-based broker that either allows the data to go or doesn't, according to complex calculus of roles and assertions and rules. The other is there's trust. I'm going to send you this data with my preconditions on it being shown and I trust you to implement my rules, or I will send it to you and I trust you to have reasonable rules, not even against my rules. That's fine. I did want to also respond to this comment that Tim made about provider based validation of the interface. I'm right now pushing to make sure that we do that as opposed to we not do it, to the extent that if the test data says there's a blood test result here and it comes up on the screen and says it is straw colored, that someone is able to recognize I don't think that's a valid blood test. I don't know. I think there's a lot that can be done to train people who are testers or certifiers to be able to recognize that it's the right data, that would unload the need of a real clinician to do it, but right now the level of interoperability testing that's common for certification is did they reject the package. We've got to do more than that or we will end up with two certified systems just being embarrassingly not interoperable. So we have to balance the two.

John Halamka – Harvard Medical School – Chief Information Officer

Well said. We are currently running about 15 minutes ahead of schedule and if people's blood sugar will tolerate it – oh, okay, well, Jamie. Okay no problem.

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

Just a quick one on that, I'm very much in favor of clinician validation, however, I want to recall a particular story that happened in the California Privacy and Security Advisory Board, in some of its early recommendations they thought it would be entirely reasonable for clinicians to spend half an hour per year with each patient in their panel explaining their privacy rights and options. And we did some quick calculations and pointed out to them that that would take more time than all the working hours that are available in the year for them to do that for their entire panels. But they thought that was a very reasonable use of clinicians' time. So I think that when we're talking about seemingly reasonable amounts of time that clinicians would have to actually be involved for system validation or for the Privacy and Security example that Wes used, or for other things, we just have to be very careful.

John Halamka – Harvard Medical School – Chief Information Officer

Right. So one of the things that I propose is a new position in medicine called a "healthcare knowledge navigator" that you meet with and actually scrubs with you all of your data, cleans it up, in a reconciliation, because it's clear that if our primary care physicians are going to actually evaluate, prescribe, pick quality measures and all the things that healthcare reform does, validating your data may not be within the 40 hour or 80 hour work week.

M

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John Halamka – Harvard Medical School – Chief Information Officer

Good point.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Okay, the concept, though, does have a certain resonance in terms of the comments that were made about the privacy counselor earlier and ... navigation is going to be an emerging area of challenge and discussion. But I think that also the sequence of presentations is really a tour-de-force on the development of early tools for the management of knowledge. Avinash, thank you very much for two presentations today, and Dave Carlson and John Timm, just a tour-de-force in terms of, I think for many of us the first time seeing a new tool that has early applicability, not only in this space but more broadly. And I think, Doug, to the point that you were making at the very beginning in terms of the ecosystem for model specification to certification, and Arien, you really captured this thread that there is an ability to

both validate, project, test, and perhaps even automate some of the activities leading both to the efficiency and things that work well, ..., is correctly ... or defined or pointing out in the other direction the importance of getting the model right in the first place. Those will be interesting, important discussions, so just terrific, terrific work. I think Kevin Hutchinson said it so well, this is really the instantiation of a lot of things that were really, and not just concepts but loosely constructed concepts at the outset, so just great work and I look forward to ongoing dialogue about that.

Okay, if people's blood sugar isn't too low, I hope you enjoyed lunch, that 30 second break there, but if you are up for continuing on, and I see heads nodding, it does make sense then to hear about the SHARP program updates, Wil Yu from the Office of the National Coordinator is here, and ... look at the materials just a broad range of activity that, Will, you'll be covering, so welcome.

Wil Yu – ONC

Hello, everyone. My name is Wil Yu and I help lead innovation related programs at the Office of the National Coordinator. I must confess that I'm not a medical informaticist by training and my knowledge of the nuances of standards development is at a very basic level, so if you ask me a very deep, thoughtful question about the technical side of standards development I'll nod at you very thoughtfully and say "That's a very important issue and bears further research."

What is that I actually do within the ONC? When I was approached by the former national coordinator to help lead up innovation efforts he said this is a very important area and we will be engaging in significant development over the next two years and I would like you to help lead up some of these programs. And I thought, that's a very important area and I'm very honored to do so. But what does it mean to be innovative? What does it mean to encourage innovation from a policy perspective? I guess the purpose of this presentation is to lay out some of the perspectives that we've developed within the ONC. I work with a very dedicated team of individuals who have labored to support a number of programs and initiatives toward that space, and we would welcome your perspective on how we've done so far, how can we can improve our efforts, and really what suggestions you have for helping to further the state of innovation within both the public and private sector.

There was a bit of a mix up with some of the slides, so I'm actually going to start about halfway in really talking about what we're doing from a federal standpoint with regard to encouraging innovation that will be required to enhance the health and well being for all Americans. I think this starts on slide five or six into the presentation. I'm going to dovetail into some of the programs that we're very proud of and have launched over the last few years, including the SHARP program. I'm very glad to see one of the PIs, Chris Chute, who leads the SHARP ... project ,and we will be talking about some of the other efforts that we're currently engaged in to work to support new products, new services, and new ideas in support of meaningful use health reform and the achievement of a high performance learning healthcare system. I must note that there is an alternate side of the innovation equation, and those who would adopt innovations and those who would develop new care models and reimburse models and that I'll defer to some of my colleagues at the new CMS Innovation Center, we're really talking about the supply side of the equation, those who would develop new products, new services, and new ideas based on some of the work that is taking place within ONC as well as the department at large. We work very closely with the Office of the Chief Technology Officer, Todd Park, as well as the CMS Innovation Center, as well as the White House, who has been very supportive in terms of championing innovative developments.

What are we talking about when we say we're trying to support innovation? As we begin to study what is needed to make many of the policies that have come forth through HITECH and the Affordable Care Act successful, we see that there's an innovation The technologies that we need to have to achieve the dream of meaningful use as well as the promise of healthcare reform don't currently exist in static form. They're constantly evolving. And we really see it as our job to help accelerate the technological development, new services, technologies, tools, if you will, to support an accelerating We see as these make us new programs, especially on the care delivery and reimbursement side begin to evolve it assumes a level of technical infrastructure that will be required to make them successful, and Meaningful Use and Health Information Exchange are just the first steps to achieving that.

With regards to supporting innovation through Meaningful Use I think that the Policy and Standards Committee has done an excellent job in terms of messaging to the broader stakeholder community at large. In our conversations with vendors and developers and those who would seek to develop new health information technologies we're seeing a great deal of interest, especially for those who are working to develop certified EHRs. I think that looking at the number of certified technologies, there's been quite a robust level of development over the last few years and that pace seems to be on track to continue. Over the long time, though, we have invested significantly in the research and development in terms of addressing areas that will seek to remove barriers to health IT adoption. That really is the genesis of the SHARP program. I won't go into significant detail into the program, but I have included within my presentation backup slides for each of you to dive specifically into the minutiae of each of the programs. I don't think I would do it fair justice to talk about each of the programs in the amount of time I have allocated, but in brief, the SHARP program is a \$60 million program that has funded four significant projects addressing privacy and security, improving physician workflow, improving physician support, helping to develop new networking platforms, and of course facilitating the exchange and secondary use of EHR data.

In terms of supporting health reform we're really trying to address technologies that will simultaneously pursue the promise of Triple Aim: better care, better health delivery, and lower cost through continuous quality improvement. By doing so we're championing initiatives that will facilitate partnerships between the very stakeholders involved, really helping to increase the level of communication and collaboration that are taking place within the ecosystem. This includes developing partnerships with patient advocacy, those who would help to redesign the models of primary care, and those who would help to improve population health management. The CMS Innovation Center is currently on a trajectory of encouraging the development of new care delivery and reimbursement models, and we are currently holding active communications with them to try and facilitate what is the technical ... infrastructure that's needed to support these new models.

Finally, we had the promise of a development of a long term, high performance learning healthcare system, the creation of a sustainable learning system that will get the right care to the people who need it and to capture the information for our future technological development. This includes engaging hospitals, insurance industry administrators, healthcare providers, and to facilitate a trained healthcare workforce.

What I'd like to introduce to you now is a framework for how we're supporting innovation. What I have on the slide before you is really a conceptual framework for how we understand the development of new innovations, new technologies and tools. So on the left hand side we have the development of new concepts and new ideas, followed by development of prototype, achievement of a proof of concept, which is a crucial stage in health IT development, early adoption, the optimizing and refinement of that technology, and then late stage adoption. What we've seen is our role within ONC and through the various innovation related programs and initiatives is to help organizations, new developers, new innovators through the various stages of this pathway. Certainly on the left hand side we have cost and risk being the highest, and it's really incumbent on us as the federal government to help those who would seek to develop new technologies in support of our policies to move through these various stages. This includes helping to increase the level of transparency with regards to what we intend to do from a policy perspective over the next few years to decrease the level of risk, not only messaging to the innovators and developers in the space, but also the supporting stakeholders, the investors, those who helped develop partnerships with the overall ecosystem, including working with those who would support the implementation of test beds. As we move through prototype development and proof of concept, we see various opportunities for the federal government to align new innovators, new developers with existing programmatic efforts. As we see, those who would develop technologies in support of meaningful use and health reform aligning them with the existing programs such as the Beacon communities, such as the REC programs, and the state HIE programs, developing partnerships with forward-looking healthcare organizations to support what I call clinical health IT trials. There's a new effort underway called "Innovation Exchanges for Health IT" where we do matchmaking efforts between those who develop and those who adopt new technologies on a limited basis in order to refine and further evolve the technologies that will be innovative and will support health reform.

What I've done here is lay under this conceptual framework for innovation the various programs and initiatives that we currently have under ONC and across the department. This is just an example of what's currently taking place, but as you can see, once a developer moves through the various chains they have opportunities to work with existing programs, such as SHARP, such as a new effort focused towards innovation scanning, we have a prizes and challenges effort to help incentivize the developers to pursue innovative models, and we have the opportunity to work with developers to conform their technologies toward existing standards. As we get to the later stages of adoption we can align these efforts with more robust efforts such as the Beacon communities for adoption.

The core values of innovation are laid out on this slide. We wish to passionately inspire innovation. We demonstrate bold leadership by connecting the various communities, identifying opportunities for collaboration, and certainly identifying opportunity support through direct grants and contracting efforts as well as providing incentive systems such as our prizes and challenge effort. We're trying to support these efforts judiciously by allocating the limited resources we have, but we really see this as the best time for innovators and healthcare, really due to a confluence of changing market and policy forces that are aligning to support both early stage and mid stage and late stage innovators.

With that, I'd like to stop here and open it up for any questions that you might have with regard to our specific programs. I can certainly go in depth into any of these specific efforts, but I'd really like to hear from the committee in terms of what they would like us to do specifically in terms of messaging to the broader ecosystem, and where you really see the work that comes out of this group I guess diffusing into the development community.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Will, thank you very much for a terrific update on the SHARP program. You did allude to the notion that we have at least two members of SHARP programs and I'd like to take the chair's prerogative to invite them to give us a paragraph or two on their programs. But as we do that, I think your comment that you closed with, the relationship of innovation to the work of the Standards Committee is very critical. At the outset you may recall that we had ... trying to optimize the rate at which IT adoption was supported, and that was a particular balance. The other is this tension, and a healthy tension between goal direction and innovation, and I think that's one of the points of convergence, as standards obviously imply a standard and a goal direction innovation doesn't have to be amorphous it can also be goal directed. But there's a lot of creativity that you can also serve goal direction and in that regard I think the experiences of at least two of our colleagues will be particularly informative, and you mentioned Chris Chute, but also John Halamka, maybe we'll start with Chris, just a paragraph or two on some of the work you're doing and then John.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards

I would of course engage in co-conspiracy, my co-principal investigator, Stan Huff of the SHARP ... grant. Simplistically it deals with data normalization, natural language processing, and high throughput clinical phenotyping from electronic medical records. Pertinent to HIT Standards Committee however, particularly in the normalization components is the implicit requirement that a standards target be identified against which we would normalize. And we have chosen the output of the ... initiative, which is I guess another covert reason for my endorsing it this morning, simply because from that ONC perspective through the SHARP grant it is a preferred mechanism by consensus for representing detailed clinical information for secondary use. That is ultimately what our data is about. Secondary use, of course can include quality activities, it can include research, it can include a myriad of infrastructures, but what we've recognized, and many of us around the table have recognized this for a very long time, is that any kind of scalable secondary use is impossible absent an underlying comparability and consistency of the data you're trying to secondarily use. Hence, the importance of identifying a detailed clinical target which, as I said, is Stan, did you want to add to that?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

Thank you again, for, number one, for bringing me along as a co-conspirator in SHARP, but the thing that I would add is also our interaction with the SMART group, which is the SHARP 3 group. Many of you may

be familiar with that, but what that group is doing is they're trying to make standard APIs so that people can program an application that is vendor agnostic and create, if you will, create the opportunity to create an app store sort of environment for healthcare. So they're trying to create a very standard API, they're working with all of the Web development, they're part of that environment, to be able to create a generic service that would say give me the patient's problems or give me the patients and have a known API that they can actually build an application against that would do that, and then the obvious overlap again, I only have one subject that I know anything about. The payload of those things has to be that same model that Chris is talking about, you have to have a known logical structure of the data in order for anybody to operate on that data.

So I guess I would advertise to people that whole concept of the SMART platform that they're working on in the SHARP 3 group, which becomes another consumer for the models, but I think is important also in the whole aspect, it gets us in a way outside of the usual box of thinking about data exchange and other things and thinking about ways that we can transform medicine entirely by a different paradigm, and there are some aspects that I think are really PCAST-ian as well that we're not having a chance to talk about and have appropriate public dialogue about that would be a lot of fun to pick up at some point. I would only add that our collaboration with the SMART group makes us the dumb group.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Okay, ... a great object lesson in certain excessive activities. John,

John Halamka – Harvard Medical School – Chief Information Officer

The SMART group which is Zach Kohanek, and a ... and a variety of folks at Harvard, David McCallie at Cerner involved, and you said it very well, which is it turns out Cerner has a dazzling ePrescribing application. It's a whole lot better than Epic's, I'm making this up, and what we really want to do is we want to take the Cerner ePrescribing application, vendor A, and put it on Epic, So here if I don't like my book reader that I downloaded this morning, I'll get another book reader. And there's no issue because this is a set of APIs, it's a standard environment, and so I should be able to take pieces of Epic and pieces of Cerner and pieces of GE and vendor A, B, C, D, and E, and glue them together to create my ideal Nirvana. But unfortunately today we often don't architect our applications that way and if we had consistent APIs with consistent data flows and ways of representing the data, you would then be able to have an ecosystem and an application programming interface that runs in the context of a container so that if in fact Cerner decides that it wants to create SMART-enabled containers and the world wants to write cool applications, you have thousands of developers like we do at the app store capable of using Cerner data in novel ways. David, comments you'd make about your involvement?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

This is David McCallie. It is a lovely goal. It's a lot of work. And as we've heard in the discussion I think all day today these pieces that need to come into place around agreeing on what the data is that moves back and forth across these interfaces so that two systems interpret that data the same way is I think the immediate challenge in front of us, so that when you have pluggable modules, or even interfaceable modules, if we want to go back to the metaphor of the last decade, we have some trust that the data means what we think it means as it crosses the wire. And this focus on capturing the data in that format from the beginning and not just mapping to it at the time you do interchange I think is a really important idea that needs a lot more visibility. And that has profound implications on usability, on safety, on workflow, that's a really big notion. I think, Chris, or maybe Stan you brought it up earlier in the morning, some of these other things like the pluggability and substitutability will fall out from that much more naturally than they will now because we don't have that. We don't have that agreement on how to represent even simple clinical ideas like a lab test.

Jonathan Perlin – Hospital Corporation of America – CMO & President

I appreciate your sharing those aspects of the program. It was very helpful. We have a number of cards that are up, more general comments and discussion, and then we'll go Doug Fridsma, Arien Malec, and then Wes Rishel.

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

Thanks again, Will, for all the work that you do here. I think one of the challenges that I would present to this group with regard to some of the innovation groups, and as we move forward we need to use every piece and every tool at our disposal to get us to where we want to go with regard to interoperability. We have a variety of mechanisms. We have our regional extension centers and we have our state HIE programs, and we've got the work that's going on with the Beacons, but I think one thing that we have to also consider is the work that Will is doing around innovation. And we have Challenge grants and we have other things that can help incentivize and help get some early feelers out there about what's possible and what might not be possible. Not everything, and we're working on this now within my office, doing a programmatic review of the S&I framework, taking a look at some of the tools that we've got, and trying to make sure that we're leveraging the tools that we have in the best possible way, making sure that we're not using the wrong tool, if you will, within the suite of things that we can do at ONC for the wrong purpose.

For example, there's a lot of interest around micro data. Is micro data something that should happen as part of an innovation grant? Is it something that should be as part of a Beacon challenge? Is it something that should be within the S&I framework? Is it something that should be part of certification? There's a whole set of things that we can do. So I think one of the things, and the reason I think it's so useful to have Will come and give a presentation here is to sensitive us as we're having discussions that sometimes we need to set up a workgroup to do some specific action, but maybe the other thing we need to do is think about what would this look like as an innovation Challenge grant, and if we frame it appropriately can we as a committee here learn about a direction or a way that we might want to proceed. I think this is one of the tools that we need to think about because there may be ways that we can say, gee, I wish we could understand better how to do X, there's ways and other tools that we have that Will can help us with in terms of formulating those.

Wil Yu – ONC

Ultimately, I see this as a way of engaging the private sector at large. There are thousands of startups currently within the health IT space that we're actively tracking, about 1,500 at last count, and all of them can be engaged in some level to further the work of the Standards Committee. I really see these as opportunities to really encourage development and really broaden the ecosystem.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Great comments. Arien ...?

Arien Malec – RelayHealth – VP, Product Management

If you think about a class ... fund you've got a lot of stuff on the early end, some of which doesn't work and some of which does, and one of the things that I think ONC could be doing a better job of is helping us all think through, first of all, what's in the funnel, do we have the right things in the funnel, are there things that should be early stage in the funnel because we're going to need them down here, but also the interesting lessons of what did we try that didn't work and why didn't it work? And what did we try that did work and how can we get access to it? For example, I know that SHARP C has done some really brilliant work on usability testing and usability test frameworks. I don't know how well that work is exposed and diffused and available for other folks to use. The work that Chris and Stan just mentioned, is actually stuff that I'm working on right now and would love to be able to steal from the best and the brightest from the work that SHARP S is doing in terms of advancing security. One of the things, I think there's a really useful role that ONC can play in terms of saying, first of all, what's in the funnel, where is it in the funnel, what have we learned that is just too hard and why, the kind of negative results that are just as important as the positive results, and then do some matchmaking for some of the stuff that played around in the funnel that's useful to help us in the private sector take advantage of that work.

M

If I were to reflect back on what you said, it seems to fall into the bucket of a greater level of environmental awareness as well as case studies of successes and failures that are taking place within this space, to further inform those who would iterate on those successes and failures.

Arien Malec – RelayHealth – VP, Product Management

And links, right? Here's where to find it and here's where to go to get it, exactly, packaging.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thanks, Arien. Wes Rishel?

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

My company uses a graphic called a ... Cycle to describe the development of new ideas. You can match up the Chevrons here to two points on the Cycle. It's interesting that typically by the time you get the prototype the public is already going negative on the idea. That's because it went so positive as a result of ideation and there was no attempt to assert that this was linear to time on the other side, but the time from early adoption to late adoption in our version is three or four times as long as the early part. Nonetheless, and we've learned some lessons by modeling about 8,000 technologies over this over the years, one of them is that a negative finding isn't always a negative finding, that there are many ideas that it's like Thomas Edison said, "I haven't failed to build a light bulb yet, I've just found 10,032 ways not to build a light bulb." And in the negatives it doesn't always mean the idea is kaput, it means it needs to be rethought. What I'm interested in is, and it was stimulated by this mysterious bubble here, DC to VC, what does that stand for?

M

The DC to VC effort is really an initiative to communicate what are the developments within healthcare policy, within healthcare IT policy, to those who would invest in these early stage technologies, the early stage investors, the entrepreneurs, the angel investors, that would help to champion and support the business development of these organizations. They are hungry for information because they really see a lack of information as risk, and if the risk is high enough they refuse to engage in any process of investment. So by bringing policy makers and investors together to have robust forums where we can communicate what is the goal and trajectory of healthcare policy, we can help to increase the level of transparency and hopefully increase the amount of activity that's taking place within the traditional investment space.

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

So DC as in the federal government, to VC as in the venture capitalists.

M

That's correct, VC being a fill in term for both startup entrepreneur as well as the early stage investors, etc.

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

Sure. Okay, well that was what I was hoping you were going to say. Thanks.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Okay. What a thoughtful note in which to close the formal agenda of today. Doug, I particularly appreciate your tying it back into areas that really we should think about, where further work is necessary. Will, I appreciate your curating essentially a number of efforts in a more formal way, and very much appreciative of the comments of John and Chris, Stan and David, and some real world examples of the type of work that's going on in that process ... not only of the immediate applicability but ... PCAST verbia I appreciate, Stan, that contribution.

Let me just ask before we go to the public comment period and a couple of summary notes if there's anything that anyone wants to put on the table for further contemplation today?

M

Of course we could mention that although Judy will never be replaceable, Cris Ross has been approved by ONC as now being Liz's compatriot to lead the Implementation Workgroup.

Jonathan Perlin – Hospital Corporation of America – CMO & President

I'm sorry Cris is not here. Thank him for volunteering.

M

Actually he –

Jonathan Perlin – Hospital Corporation of America – CMO & President

... full knowledge. ... appreciate Judy working past the John, do you have any summary comments you'd like to make?

John Halamka – Harvard Medical School – Chief Information Officer

I think a very good discussion, as we always organize our work on content and vocabulary and transport, I think we had great unanimity and hopefully that's helpful to you, Doug, as we think about the simplification, but not too simple, of content which is going to be easily represented but backed with a very robust framework of detailed clinical models and I think that was very good guidance. I've been doing clinical summary work with all of you for almost a decade and today was one of the best statements of what we really need and stays true to the principles of the Implementation Workgroup, of engineering for the little guy, and I think the work we saw on the transport side also brings us some very good artifacts. I've said many times that if you can just connect everybody, and this is probably paraphrasing Arien, then cool things will happen in the ecosystem and money will be made. And what we're really getting to is a level of specificity in that portfolio where that transport is no longer going to be the barrier.

Jonathan Perlin – Hospital Corporation of America – CMO & President

I want to turn to Doug in a moment, but building on that ecosystem and the capacity for an exchange of information, I think it's also notable in our conversations today that the word was not specifically healthcare but health, and the implication of the ecosystem, at least in my mind, fully included the patient ... who the patient identifies as proxies in their interest that was not exclusively referential to the formal health system. But I think it's a tremendously important feature and that's why the public comment portion is also so important and I just want to recognize that that was fully a part of the contemplation of ecosystem Doug, let me turn to you and any comments that you'd wish to offer in closing.

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

First of all, I just want to thank this committee for all of the excellent work and the advice and thoughtful considerations that come through. I think it's tremendous. I want to make sure I've heard everybody correctly too, because I'm taking notes and I want to make sure that I'm hearing the right thing. I think with regard to the transitions of care work, that consolidated CDA is a step in the right direction and it's part of the transition, if you will, from the C32 to something that's a bit more template and that the direction to continue towards Green CDA is correct. So I'm going to take that message.

With regard to the implementation working group, a series of very, very thoughtful recommendations that we need to take a look at, one of which is an integrated Web site. That will I think impact things like Chapel, it will impact our S&I repository that we're developing, we didn't have a chance to show it here today, but it's something that I think may also help answer some of those questions, and we'll take that back and be very thoughtful taking a look at the other recommendations that we've got as well.

With regard to the demo, we need to make sure that we have models, not only just the models that we've constructed, but we think about how the information models that are within the S&I framework and those that are being developed internationally, making sure that those things are considered and incorporated and harmonized in some way. So we have some work to do there, but I see that as something aspirational and directional for us to begin working on.

With regard to the quality measures, it sounds to me like the quality working group needs to be revitalized. I think we need to come back between ONC and CMS, develop a charter, and some of the questions that we see as being critical and go back and work with that committee to establish a charter, to get some work going on that, and then perhaps arrange some time where we can do that deeper dive that we didn't have a chance to do today. So I'll take that again as an action item going back. Then third, just

an update on the modular specification. I think the emphasis there that I'm hearing, and I've heard repeated a number of times, is that what we're doing is we're developing a portfolio. We've got a series of tools in our toolbox, and we need to make sure that we are leveraging – oh, I just made a mistake I guess in my summary. The card went up, so public, please wait, stay on the line as we complete this. Just to make sure that as we develop out this portfolio that we include not only our transport standards that we've got, but we also have some knowledge that we need to take a look at payload and we need to take a look at vocabulary and the other things that we've got going on as well.

I apologize for having raised the card, but I then turn it over to Wes.

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

Actually, I was slow on the draw. It was quite a ways earlier. What you said at one point, Green CDA is important to keep going in that direction and I endorse that. You didn't mention CIMI –

M

....

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

Oh, you did. Okay.

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

I didn't use CIMI, I used some words –

M

....

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

Internet Modeling Effort.

M

... international –

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

I couldn't remember on the fly. I saw the card going up and I panicked.

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

No, no, I was that far behind you. I just think it's important to consider it as an alternative to Green CDA, consider that closely not as just another effort that's going on.

W

..., Doug. Oh, I'm sorry. Since you were keeping the action items I think we have an action item left from this last presentation as well, and I think Arien worded it the best, in that there needs to be more of, I'm going to call it a model of how the innovation stuff relates to the other work that's going on and what things are being just thought about and then how they funnel back into actual work in the committees that are doing the things like meaningful use, like creation of the standards, the S&I framework. I think some of the stuff is more just out there until we can decide, but some of the stuff is actually more overtly feeding it, and I think Arien mentioned doing it, how those things fit together. I feel like that's an action item, so we can see how the programs all relate.

M

And the action item of this committee is to think very thoughtfully about all of the different ways that we can achieve our shared goals, one of which is being is there something that we want to help interact with the vendor community, is there a Challenge grant that would be helpful, is there other ways that we could do that? But that's not on my action item, that's on yours.

Jonathan Perlin – Hospital Corporation of America – CMO & President

We're going to give the last word to Dixie Baker.

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

I'd like to just nominate, take you up on your mentioning earlier of micro data and submitting that to this innovation to one of these innovation channels. I don't know what it would take for us to do that, but I would like for us to at least investigate that as an option.

M

... write that down.

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

All right.

M

I have volunteered Beth Israel Deaconess' 3,000 physicians to be micro data represented next week if you want.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Okay. Doug, that was a terrific summary. ... international but with the additional implications in there we had an agreement with that as a set of work activities for ONC. Terrific. Then with that consensus, Doug, proceed in that regard. Let me, I missed the opportunity again to recognize a career in public service in which you're retiring, and all the contributions to this committee, but to Cita Furlani our gratitude. Thank you very, very much for that.

Our meeting next time, just by way of housekeeping activity, this is hard to believe it is November, but we have a virtual meeting in December and I think in many ways they require closer concentration and I appreciate in advance all the attention to the activities that will come up. It really does take recognition of the difficulty of travel and organizational requirements that each of us have in the month of December, and so I appreciate your participation at what will be an important meeting.

Let me turn to Mary Jo Deering for bringing in public comments, and certainly any public comment here.

Mary Jo Deering – ONC – Senior Policy Advisor

Thank you, Jonathan. Operator, would you open the lines and see if we have any public comment. In the meantime people in the room can come forward to the table. (Instructions given.) Thank you. Do you want to go, Gary? Would you like to sit down and introduce yourself, please?

Gary Dickinson – CentriHealth – Consultant

I'm Gary Dickinson. I'm a consultant representing CentriHealth. I am very pleased to hear the discussion about a standards framework starting at the source of information because that's a burden of mine and it has persisted since I first dove into the HL7 standards pool in 1989. In any case, we've done a fair amount of work in that area in HL7 as well as in ISO. I would particularly point to ISO 21089, which is trusted end to end information flows, which gets at that very point of source point of data origination to ultimate point of use. So I hope that that is helpful, at least as a point of reference, to this committee in consideration of that. I also would like to point out, as I looked at the ONC Web site yesterday it turns out there's 553 systems that have been certified under the EPS systems, EHR systems, and 116 have now been certified as for inpatient use. Those are tremendous numbers, I think, well beyond what many of us might have expected at the outset of this, and I think that's to the credit of this effort and to the credit of the many innovators out in the private industry who have brought forward their particular solutions. The thing that I think would be particularly helpful in terms of taking that innovation and leveraging it and getting the most competitive value, if you will, of that effort, particularly to those vendors who are U.S. based and who may be only focused on U.S. requirements at this point in time, particularly the meaningful use Stage 1 requirements, if there was a way to tie the meaningful use Stage 1 and Stage 2 requirements to the ISO, and actually it's an HL7 originated standard, the HR system functional model

which is now ISO 10781, which was passed ISO ballot in November 2009 and is now published by ISO, if these criteria could be mapped and matched to the ISO standard, that would provide tremendous leverage to U.S. companies in the international market from the standpoint of competitiveness. I think that that would be something that would be well worth considering.

I also would like to point out that the current version is release 1.1 we are about to publish through HL7 release 2 as a ballot draft. That should happen in early December. It is actually going to a five way international ballot with ISO/TC 215 and of course HL7, .../TC 251, which of course is the European standards organization, as well as CDISC and IHTSDO. So it's a five way international ballot on this particular standard, and again if this could be tied to criteria for meaningful use, could be tied to the criteria and the functional model, I think that would be a tremendous step forward as far as moving U.S. based solutions into the international marketplace. So that's a particular point that I wanted to bring up at this point. Thanks.

Mary Jo Deering – ONC – Senior Policy Advisor

Operator, is there anyone on the line? No, we have no one on the line? Thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Okay, appreciation as always to Mary Jo Deering and the terrific ONC staff for all of your hard work and members of the public for your ... ongoing dialogue and the ... process, and to all the committee members for all the work that goes on between meetings. Thank you very, very much for that. I hope, in that notion of thanks, that everyone has a terrific Thanksgiving and good transport standards to all of you today. Thanks. We're adjourned.