HIT Standards Committee
Final Transcript
June 22, 2011

Presentation

Operator
All lines are bridged.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, operator. Good morning, everybody, and welcome to the 26th meeting of the HIT Standards Committee. This is a Federal Advisory Committee, so there will be opportunity at the end of the call for the public to make comment, and a transcript of the meeting will be on the ONC website. Just a reminder, please, we've got a number of members on the phone, to please identify yourselves when speaking. Now, let's go around the table with introductions, starting on my right with Jodi Daniel.

Jodi Daniel – ONC – Director Office of Policy & Research
Jodi Daniel, ONC.

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

Judy Murphy – Aurora Health Care – Vice President of Applications
Judy Murphy from Aurora Health Care.

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

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

Stephen Ondra – NeHC – Senior Policy Advisor
Steve Ondra, Office of Science and Technology Policy.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Carol Diamond, Markle.

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

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

Walter Suarez – Kaiser Permanente – Director, Health IT Strategy
Walter Suarez with Kaiser Permanente.

Anne Castro – Blue Cross Blue Shield South Carolina – Chief Design Architect
Anne Castro, Blue Cross Blue Shield of South Carolina.

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

Jamie Ferguson, Kaiser Permanente.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Stan Huff, Intermountain Healthcare and the University of Utah.

Natasha Bonhomme – Genetic Alliance – VP Strategic Development
Natasha Bonhomme, Genetic Alliance.

Judy Sparrow – Office of the National Coordinator – Executive Director
Of members on the telephone. Marc Overhage, are you there?

Marc Overhage – Siemens Healthcare
Good morning, Marc Overhage, Siemens Healthcare.

Judy Sparrow – Office of the National Coordinator – Executive Director
Cita Furlani?

Cita Furlani – NIST – Director
Good morning, Cita Furlani, NIST.

Judy Sparrow – Office of the National Coordinator – Executive Director
Kevin Hutchinson? Karen Trudel? Rebecca Kush?

Rebecca Kush – CDISC – CEO & President
Rebecca Kush, CDISC.

Judy Sparrow – Office of the National Coordinator – Executive Director
And Cris Ross?

Cris Ross – SureScripts
Cris Ross with SureScripts.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, and we've had some weather, I know, in the middle of the country so a number of members will be coming in a little late. Did I leave anybody off on the telephone? Alright, with that I'll turn it over to Dr. Halamka.

John Halamka – Harvard Medical School – Chief Information Officer
Well, the proud and the few, thank you everybody for traveling through tornadoes, through thunderstorms. I know we will hopefully have Dr. Perlin joining us in a few minutes. His flight was cancelled last evening, and I know Doug Fridsma will hopefully also join us.

Now, is Farzad on the phone by any chance?

Farzad Mostashari – ONC – National Coordinator for Health Information Technology
I am. Good morning.

John Halamka – Harvard Medical School – Chief Information Officer
Good morning. So, as usual, Farzad, of course, you get the first word. So, before I go through our agenda and discuss where we are in the summer camp, the standards activities April through September, happy to hear any guidance or words of wisdom from you.

Farzad Mostashari – ONC – National Coordinator for Health Information Technology
Thank you, and you can't see it, but I am wearing a bowtie today. John, I don't know if you are.

John Halamka – Harvard Medical School – Chief Information Officer
Well, you know, it was an homage to you the last time, but alas, I'm just wearing black today.

Farzad Mostashari – ONC – National Coordinator for Health Information Technology
We have a great lineup today as usual, and there are some technical, I think, training that Doug, I hope if he gets there in time this morning, can also provide some additional context and training for the activities that we're going to be discussing today.

In particular, I wanted to reflect a bit on where we are in the context for the metadata standards that we're going to be discussing first up on the agenda. As many of you recall, this was inspired by the report from the President's Counsel Advisory on Science and Technology, and we had a wonderful series of analyses and hearings including an unprecedented joint meeting of the Policy and Standards Committees and the workgroup we had formed under the leadership of Paul Egerman, and we had really terrific recommendations that said to us, and this is very much inline with our general philosophy of eye on the prize but feet on the ground and managing the tension between those two.

Okay, let's find a place to get started. We know that the long-term vision is the right vision of being able to have of creating learning healthcare systems with distributed data that stays close to its source and yet information from that can be ... for not only patient care but also for public health and for research and for quality purposes, but let's recognize where we are today, and let's do what we can today on the technical standard, and let's make forward progress.

The other recommendation was that there are policy and privacy issues that need to be resolved in terms of the specific implementation of the things like the indexing approach for discovery, but what the policy is what the PCAST workgroup advised was let's set a policy framework for forward movement and that is in the context. I think, John, that you had something to do with this idea as well. Let's find a use case, let's say, and the one that in particular that was recommended was giving the patient their own information, and let's use this example where clearly the patient has a right to their information as part of the Meaningful Use Stage One criteria, there's been a lot of good recommendations and support for expanding that in stage two. Let's use that use case, and let's make forward progress on defining if we want to have metadata, and I think there's a lot of recognition that it would be useful and a variety of implementations including within an organization to have data that can be tagged. How would those metadata elements be represented? Whether it's around privacy preferences, around identity, around provenance, and can we find some standards that already exist that we can repurpose with some modifications to meet the goals here? And I think that the staff have done a great job of combing through and looking through the existing information, and I think that we're going to hear from Stan and the Metadata Power Team in terms of how that's been processed and analyzed, but I think it's important for us as we have the discussions today to recognize a couple of things; one, that this is within the context of very clear policy bounds and a particular use case, and that this is the beginning of a process, and because these are new and we've really accelerated the timing on this to give industry and folks the longest time possible to really think through and understand the implications of this, as we discussed, our plan, our hope is very soon to be able to put out a notice of proposed rulings and specifically on these data elements for us to have an opportunity to really process and share input from the broadest range of stakeholders possible before then potential inclusion of these again in the notice of ... making that comes out with all the rest of the standards and certification criteria for stage two.

So, I just wanted to highlight the significance of the metadata for a whole variety of future applications not bounded with any particular policy implementations and also to identify the opportunity once hopefully, this moves forward, we can put it out for broader public comment and feedback prior to inclusion in the standards and certification criteria.

Is Doug, has he made it back from the airport yet?

John Halamka – Harvard Medical School – Chief Information Officer
We hear he's in a cab, so Elvis will be here shortly.

Farzad Mostashari – ONC – National Coordinator for Health Information Technology
So, he can provide perhaps some additional context for that. But that's all I wanted to highlight today. And again, thank you all for the incredible service that you're doing the country.

John Halamka – Harvard Medical School – Chief Information Officer
Well, thanks very much. So, let me just give a context to where we are. As you remember in April, Doug kicked off summer camp for us all, and as we have now worked through the last couple of months, I think we really know where we're going, and just to give you some details, so in April, Dixie brought up certificate recommendations and those were finalized.

In May, last meeting, we heard some preliminary recommendations on metadata, and Stan had brought some issues of the ID and provenance and where we were headed there. We heard some initial thinking on provider directories. It was interesting as we had that discussion, if you remember last month, that there was some pushback to say, well, be very careful to adhere to the Implementation Workgroup principles of engineering any selection of standards so the little guy can implement them. Be very careful about speculating about how an implementation guide that's never really been tested in the field might work. Be very careful about waving your hands and saying well it hasn't been federated but in the future it might be. So, you guys gave us a lot of very good input in May. We also had some preliminary recommendations on some of the vocabulary direction, and we'll hear more about that today.

So, June, we're now at the point where we're going to hear some final recommendations from Stan Huff on metadata. And I'll tell you that as Farzad has said, you need to think about metadata as well, an ID will probably always be on the package. Who is the patient? The provenance, where did it come from? You know, we didn't get to the point of saying oh it's at an institutional level, it's at a department level, it's at an individual level. It could be any of those. That's a policy decision, but you'll see that there is a framework, a very simple set of standards to specify where this data had come from, and then conceivably, there will be policies across the United States that dependent upon the nature of the exchange will require some privacy flags that you do your very best to be non disclosing, and of course, we send this in a secure package. We use appropriate certificate protection, so only the rightful receiver can even open up the package containing metadata, but as you'll hear, if it's a patient sourced data set, probably it's the patient deciding what to release so you don't need privacy of metadata. If it's a simple exchange, where the patient is standing there and say go get my data from one source, you probably don't need privacy metadata but if it's as the PCAST Report envisions, highly ..., federated queries with multiple sources from multiple entities, you may need some metadata that tells you: Warning the package you have collected has certain characteristics that may necessitate special types of consent. So, this is the theme of what Stan will discuss. It isn't that privacy flags will always be there, but that certain policies may require that they be there or it would be helpful in these kinds of highly distributed queries. But as Farzad has said, we of course in this committee want to start simple, keep it simple, and so I think you'll see the theme throughout much of Stan's presentation is simplicity.

We'll also hear provider directory recommendations, and we, again, sort of took all of your advice there and brought back simplicity; how to leverage the internet as it exists; how to use simple constructs so that they would be used across all industries rather than something that is healthcare specific, highly complex or speculative.

We'll also hear about some of the patient matching recommendation work, and this is something I care quite a lot about because as we have developed healthcare information exchange in Boston, we have needed to exchange data based on patient name, gender, date of birth and other demographic factors, and I have had the problem that Marc is going to discuss of the tradeoff between sensitivity and specificity, and I would love to have a set of national guidelines that tell me where that bar is allowed to sit because I, of course, want to care for patients and coordinate all of their information, but the last thing I want is to mix the wrong patient information together. So, guidance as to what data elements should be minimally required for such a match is quite important.

And then, we'll hear a set of vocabulary recommendations. We'll hear both some of those required from the standards and certification final rule perspective and some of the best thinking in Vocabulary Workgroup on where we should be going as we support stage two and other needs. So, I'll go through some of the other agenda items in a moment, but June is right on track for getting us those particular recommendations.

July; we'll hear a final patient matching recommendations. We'll hear recommendations on e-prescribing of discharge medications, syndromic surveillance recommendations and quality measure recommendations. That's next month.

August; simple lab results recommendations. Remember that's taking the cost of an HL7 interface from 10,000 to 1,000 making it so straightforward that we've removed a lot of optionality for the simple EHR lab results workflow. We'll hear transitions of care recommendations on how to put summaries together. CDA clean up recommendations on making CDA implementations easier and some preliminary recommendations on the nationwide health information network as the group starts to think through what are some of the necessary elements to converge many of the activities, direct, NWIN, CDA cleanup, certificate, so you can imagine, it all comes together in some of this discussion that you're leading, leading to a final recommendation in September as to how all these various components for the nationwide health information network should be considered.

And finally, we'll hear in September, a summary of all the work we've done throughout summer camp. We'll welcome Doug and so I'm glad you're hear because you're the summer camp guy. So, let me just reflect for a minute. If that's the schedule, I'm seeing some very interesting themes come out of each of these workgroups. Remember we've always talked about standards as content, transport and vocabulary. What I am seeing in the content standards world, is a push in all the workgroups to be as simple as possible. Instead of saying, oh well here's this healthcare specific, very unusual standard that hasn't been tried out of a laboratory. People are saying, oh you know there's this thing called the internet, you may have heard it. There's Facebook, there's Amazon, there's Google, and you know, they are actually doing things pretty well. And so, where is it that we can leverage what the internet itself is using, and so what you're going to see today is a presentation of many very simple XML constructs that actually don't have OIDs in them or don't have structures that require a medical informatics degree to understand that they are very simple, straightforward XML constructs. In fact, I would say in all of the work that you're going to be asked to approve today, there isn't anything that my 18-year-old daughter couldn't create in XML spot. So, if that's the criteria for the implementation workgroup, it's a certainly a very interesting theme I'm seeing from everybody.

And similarly, on the transport side, I'm seeing more and more themes about using DNS. Use the basics of the internet itself. Don't create a whole new structure for healthcare. In fact, it was interesting as we talked about some of the possibilities, we even considered such a saying as creating in the internet fashion a top level domain for healthcare, and the decision was made, well there's some interesting aspects for that, but probably the business value isn't there, so you don't even need to go that far. So you're going to hear again, sort of use the internet as it is. Use DNS as it is. Use emerging constructs that Google and Microsoft Bing and Yahoo are thinking about for semantic interoperability of all things on the web, not just healthcare.

And we will have some action items today. Now remember our action items can take really two forms. Sometimes, they're direct recommendations to ONC in the form of formal transmission letters that then from a legal standpoint, Jodi, I think a formal recommendation letter triggers certain activities within ONC and HHS. So, you'll see one of those, but also sometimes we provide guidance to the S&I framework, and that is remember what we said is sometimes there are standards that are just so good they're ready to go, sometimes there are standards that are pretty good and need a little polish and sometimes you need whole new standards to be created. So, sometimes our recommendations will be requirements, constraints, possibilities that we then hand off to the S&I framework, and it's not a formal recommendation in they launch the regulatory process steps. And we'll have one of those.

So, that is the agenda in general for our summer and then just more specific reflections on today. As I said, Stan will start with the metadata theme recommendations. Dixie will then continue with provider directory recommendations, which will be really in the form of providing constraints to the S&I framework. You'll be asked on both of those first two items to accept, table or reject them.

Then, we'll go into summer camp where we'll hear about the power teams, the patient matching, the nationwide health information network preliminary, and then from Steve Posnack on the standards and certification criteria vocabulary code sets, lunch break. After lunch, we will hear about the final, final, final recommendations on Meaningful Use Stage Two from the Policy Workgroup and its implication for our work. And of course, Doug, the question that I would have to you is if our summer is already filled with recreational activities, how do you add five new activities or whatever George will discuss with us to the existing schedule? So that will be an interesting challenge with the timing and all that. We'll hear from the Clinical Quality Workgroup on their best thinking. We'll hear from Jamie on the Vocabulary Task Force and where we're going on trying to make sure their code sets available for all the purposes supporting meaningful use. And then, the Implementation Workgroup will give us the findings from their Federal Advisory Committee blog posting of a survey on some certification issues. And then, adjourn by 3:00. Now I hear rumors of thunderstorms this afternoon, so we'll try to beat the weather.

So with that, now Judy, did we have minutes that you wanted us to, we do? Okay, so you should have in front of you minutes from the previous meeting, and any discussion or objectives—Yes?

M
One item on the minutes, I noticed on page four, in the middle, where there's the item talking about SNOMED, we've posed that question to Paul Tang about whether the problem was intended to be essentially sort of anything that's thrown in there including procedures, medications, whatever or whether it was really intended to be more about findings and disorders, and his answer was very clear, he said from Policy Committee perspective, it was more of the latter, that it was the problem this was intended to be more findings and disorders or disorders and findings and not the broader construct, so I'd like this to reflect that please.

John Halamka – Harvard Medical School – Chief Information Officer

Okay. So, other than that, any other edits or refinements?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I provide an input to Judy on there. On the recommendation from the Privacy and Security presentation, and HL7 was misspelled besides, but that the real recommendation with respect to enterprise EHR queries, enterprise levels, provider directories was we knew that the Standards Committee get together with the Policy Committee and with the ONC to refine the requirements for the nationwide ELPD, and I've given that to Judy.

John Halamka – Harvard Medical School – Chief Information Officer
Great. Okay. Well, if there are no objections then, we will approve the minutes with those two edits, and then we will begin our agenda. So, with that, Stan, please take us through the Metadata Power Team recommendations.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Great. Excited to be here today. I would have been more comfortable if John said that the bar for understanding was my 80-year-old mother rather than his 18-year-old daughter, but we'll shoot for that. These are the folks on the power team, and please members of the team, jump in if I miss something important as we go along here. The charge for the power team was to identify metadata elements for patient identity, provenance and privacy, and we've already talked about the patient identity and provenance, and so, we're going to focus on privacy. We'll review just briefly what we said about identity and provenance, but we're going to focus mostly on the discussion of privacy.

So, with patient identity, we've summarized the elements that would be in the message would be patient's name, date of birth, current zip code, patient identifiers, and patient identifiers for the committee, those are numbers like a driver's license number or last four of a social security number, numbers that are not assigned by the healthcare provider but other organizations that allow you and have high discriminating value in terms of knowing that this patient is the one that you're interested in and then the address. The standard chosen for that set of things was the HL7 CDA R2 header format. It's an XML based format, and it really covers all those elements.

There were two suggestions; one, that we enhance the patient name field to include a full name the way a person would normally be called along with the other data elements that were already there, so it was only a mild sort of addition to what already exists in HL7 CDA R2. With the provenance summary, there would be the tagged data element identifier, a time stamp, the actor and the actor's affiliation. I think the affiliation we would always require and then the actor, and that gets to some of the things that John said, exactly the level that we need for affiliation where we know this is at a departmental affiliation at the departmental level or just at the institutional level, that's going to change some based on the particular use case where we're trying to apply this. And then, the digital certificate that guarantees basically the integrity of the data and that digital signing there can correspond then to the actor or the actor's affiliation. So again, the metadata elements express using HL7 CDA R2 format. It covers what we needed to do, and it also means that for both identity information and provenance information, we're using the same standard, so that drives to that simplicity theme.

So, with that summary of what we'd already covered, I'd like to jump into privacy, and following the theme that we started, its useful to think in this context about the use cases that we're trying to fulfill, and sometimes in the discussion, it's useful to think specifically about a use case because there's some things that can be done simply. And then, for some of the more robust capabilities that we're shooting for, we need some more sophistication, but three kind of use cases that came out of the PCAST analysis are listed here, and the first is a very simple sort of thing where the patient has their PHR and they want to

push data or they're in a tethered PHR and they want to select from that and push data from that tethered PHR into another provider. So in that case, it's the patient themselves who are actually in charge of, if you will, sort of saying what gets sent. So, the patient has complete control of what's being shared and they're directing it to who they want to share it for, so in a sense, there's not a great need for sophistication inside the packet of the privacy information because of that simple circumstance.

Now, the next situation is a simple query that's authorized by the patient, so this is a situation where the patient, for instance, may have come to an emergency room, they know they have records at a different institution, they authorize at that time access to that information, and so a directed query is made to institutions that are known to have records and the data is retrieved, and you have now the party that's responding to that query, have to now respect policy, privacy policies that have been set and make sure that they need to authenticate that this is a valid message, who it's from and know the patient's preferences in terms of the privacy and before they send the data. And so, you now need that privacy information in the message as envisioned by the PCAST report so that people know what their obligations are when they receive that data. And then, there's the even more complex query, which envisions sort of the whole distributed query mechanism much more like the internet and involves DAS, these data sources that have index sets of data that you can now query and you're looking for any institutions that have information about this patient. Then, you're going to follow that up with specific queries to the institutions for the kind of data you want, and in that circumstance, that's more complex yet, again, and you have more complex policies around because the patient isn't approving this particular instance of query. They've approved a policy that now has to be implemented in a general way for accessing use of that data.

So, the whole point of this slide is that we have a gradient and the idea would be that even though we've put data elements to try and cover the most complex situation, there are many cases when those elements would not need to be used. We could do something simpler, and there may be, in fact, as we get further into the complex query mechanisms, we may need to add something more or understand a use case more because I'm not sure that we've ferreted into every dark corner of what that complex query scenario might be, but we think we've covered it pretty well with what we've done.

Now, we have sort of a matrix, or not a matrix, but sort of a graph or a flow chart of sensitive information, and I wouldn't make too much out of this. The thinking though was can the envelope contain sensitive information, and you say yes or no. If we said no, the problem that you get into going down that path is that almost with a simple queries, nothing's needed, but with the more complex queries, you basically don't have anything that you can see that the logic to discriminate what kind of data is in this, in a packet or in a message, and so it becomes less useful and in some use cases, in fact, it's inadequate because you need to know what's in there a little bit in order to treat it according to the patient's preference or according to state law, and we may get John to tell us about Massachusetts again, about their HIV disclosure policies, but so your point, here's the issue is that imagine that some states have consent to disclose but some states have consent to view and it may be consent to view at an incident or encounter level. So, let's imagine the record contains HIV information and that HIV information, in the DEAS, the hospital in which that was a diagnosis made is listed, if consent to disclose is achieved, but then as the package is prepared, it is delivered to a state that requires consent to view. So, how do you even know you need the consent to view unless you say the package you're about to receive requires the patient's consent to view? And it's sort of an interesting problem. Basically--

Farzad Mostashari – ONC – National Coordinator for Health Information Technology
Sorry, this is Farzad. I think this is a very interesting discussion, and it's easy to get into the details of this. I find myself wondering if what we're talking about isn't the ability for the disclosure to be able to do the computations on considering the privacy requirements of the two different states and being able to

express that and getting down into those discussions, but I'm mindful of the principle that we want to be able to make some forward movement without solving all of the toughest problems first. And I'm wondering if we need to consider, again, the most policy complex issue around how this would be used in the DEAS context and whether for the purposes of the recommendations today, we can't focus really on the simpler within institutions analyses.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
That's good advice, and I think we can do that. As far as we know, what we're recommending works for both the simple and the complex case with the caveat that maybe with more discussion, we might uncover something, but right now I think what we're talking about are things that we do understand and we feel comfortable with the recommendations we're making. So, I hope—

Farzad Mostashari – ONC – National Coordinator for Health Information Technology
I just want to come back to the point that John made earlier, that in the, for example, in the context of the message that is being relayed, even though we're talking about things being in the CDA header, that entire packet, for example, in the direct protocol would be encrypted, and we're not talking about the, in this example, which is the meaningful use use case that the PCAST workgroup proposed for stage two, it could be done through a directed direct message from the provider to the patients where they want it delivered with all of this information encrypted within the package. Am I accurately stating it?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Yes. I think so.

John Halamka – Harvard Medical School – Chief Information Officer
This is what Farzad has said. What we're talking about here is really policy, making sure that there's metadata where policy variation may occur, security is protected. As you said, Farzad, if the transmission is going from provider to provider at the patient's request, patient to provider with the patient push, all of that transmission information such as the use as a direct protocol, it's going to ensure it goes to the right individual with appropriate encryption and security protections, this is really metadata to say, once it has arrived at the right place, in a secure fashion, are there policies one needs to apply as you begin to unwrap the package? And as we talked about, you may not need any of this metadata for many of the use cases.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Exactly. I think that's a very nice clarification. So, nobody in the room or the public should be confused when we say that the envelope itself is encrypted, so if we were looking at if you had a package ... on the network, on the internet, all you would see is encrypted packages going by. Nobody's seeing this data. The only people who are even seeing the data that we're talking about is a person who's an authorized recipient of this message who can now is starting to unwrap it and understand the security and privacy obligations that they have around that data. So, I don't know that the rest of this discussion adds very much. We can come back to it I guess if people have questions, but I would just summarize it to say that once you receive the package, it's felt that there's a certain amount of information that needs to be outside the envelope in order for people to accurately use the data and to ensure that they're meeting the privacy policies that have been set for that individual and for that circumstance. So—

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Can I add something?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Sure.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Sort of taking off from what John said, I don't think that we can say that the packet is encrypted to the individual, but the task of this power team is really to look at the metadata for content that separately has to be protected from the security perspective whether that be enterprise to enterprise, like if you use TLS, it's enterprise to enterprise, and then it's encrypted, but the responsibility for assuring that that content with the metadata is protected from a security perspective, encrypted from person to person is really a technical architecture question not a metadata question. So, I just want to make sure we don't overstate this point.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Sure.

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

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Yes.

John Halamka – Harvard Medical School – Chief Information Officer
Carol, do you want to speak now or wait until, be first in line when we get to the question.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
I can wait.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Okay. So, the rationale for the metadata that we suggested sort of focuses on the content metadata data type sensitivity and coverage and could have included request metadata recipient affiliation and other obligations and the approaches for storing the policies could be that the information all of the security policy is self contained that is an individual message contains all of the security information and stays in violate for the lifetime of that data element or it could be layered with a policy reference by each TDE. And because policies can change, the security policy and the preferences of the patient can change, the idea that we would include it in violate in each instance is not a feasible approach. And then, just in terms of scope, the obligations and the required metadata of the recipient is basically out of scope for the discussion that we have today. So, the suggested metadata elements are policy pointer, which is the URL that indicates which privacy policy governs the release of the TDE. That implies that there is some external place that I can go to get the actual policy. And then, the content metadata itself contains a data type that says basically what kind of information is here and a sensitivity flag that says something about what kind of sensitive information if any might be in this packet.

There was the discussion about coverage about who paid for this information and people felt that is actually data if you will rather than metadata about his, and so it was eliminated for their consideration. So, we agreed to concentrate on the content metadata with the goals of enforcing current federal and state policies. Other information, we agreed basically not to talk about at this stage, so in terms, we weren't talking about the recipient, environmental data such as location, time, policy specifications including obligations, those things were out, and external policy registries, again, would be needed, but we didn't address how that would actually happen or be accomplished.

So, the folks from MITRE did a nice summary. This is a summary table sort of going through the content, elements that we felt were required and lining those up with existing standards. You look at the four standards that were investigated in depth. Two of them are built for online businesses and don't capture the kind of content that we looked at, and so that leaves the BPPC IT XDS standard and CDA R2 PCD with CDA headers, and the rationale and choices basically were to take CDA and modify CDA or enhance CDA in some respects, and we'll go into the details of that or modify XDS so one of the advantages of XDS is it allows new tags to be easily added. There are ways to do that as we discovered also with CDA and document types or create a new standard where we did, basically started from scratch and included exactly what we needed. We're trying our very best to use existing standards, and so the recommendation basically, well, I'm going to do a little more example here, I guess, before we—but the recommendation actually is going to be CDA. But looking at this example with IHE XDS, you have a very generic format, which is sort of its strength and its weakness because the generic format relies on context to find irrelevant fields and then you're finding legitimate values defined by an infinity domain. When you look at restructure, you don't know if you're just looking at the instance, the tags don't give you much of an indication of what the meaning of this data field is. So, you're not positive what generic image or restricted or referring to without knowing those affinity domains.

In the CDA, you have a clinical document, and in that, you have a class code that tells you that the class of document that this is, and you have, for instance, you have now the names of the tags in this XML structure tell you this is a realm code, this is a type ID, this is a confidentiality code, and then you have the actual code that can tell you this is a psychiatric consultation note which is coming from the LOINC terminology. And then, what we're pointing out in that highlighted box is that the set of confidentiality codes that exist in the CDA standard today are probably not sufficient for what we need to do in terms of what we need for the metadata standard.

So, the standard chosen was HL7 CDA R2, coded values for the data type, we have the HL7 class codes that are basically high-level codes that say this is an image, this is a document. And then, you actually have the document type codes which are LOINC codes and those can be as specific as you want and they can be added by asking or requesting the LOINC Committee to add new codes for new kinds of documents and so that adds a degree of extensibility that is a nice characteristic for that standard.

So, the coded values for sensitivity, this is a straw man list of things that would indicate that the data contained in this package, talk about substance abuse or reproductive health or sexually transmitted diseases, etc, and one of the recommendations suggestions is this is a straw man list and we need somebody from policy or somebody from somewhere to, we need a public vetting of what are the right categories for this, and I don't know that we have a great deal of experience there, so we need to try and capitalize on smart people to say what these categories should be and how they would be used. And so, we strongly encourage that these values be extensible by adding new levels in the hierarchy as appropriate.

So I think that's my last slide, and again, the recommendation was to complete three of a kind. We're using CDA R2 for identity information, for provenance information and now the recommendation as well for the privacy information in the metadata.

John Halamka – Harvard Medical School – Chief Information Officer

I could just briefly summarize, as we saw last month that the ID information is really generic, and that is it is the name, it is the date of birth, it is the gender, it is simple XML with URI and not an OID, so this is very, very generic XML on the patient identifier. The provenance is similarly really generic XML that allows us to talk about the name of the organization or entity and attach a certificate that could have whatever granularity is required, could be an organization, could be a department, could be an individual

and all of those first two, the ID and provenance, you would expect would be on every transmission of data in every use case because whether it's a patient pushing it to a provider, a provider to a provider, provider to public health, that information would be typically included. This last bit that you've heard, some notion of some privacy flag is probably not going to be included most of the time. It is purely to say as there are use cases that require from a policy perspective some notion of having a flag which would imply additional special consents or processing, have a choice of a standard to support such use cases, and as you've said, you now get three simple sets of XML all based on the same standards family, so that recommendation in essence but I imagine, especially on this last point, on privacy, there'll be a fair amount of discussion so Carol, I think you had your card up first.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Well, I am thoroughly confused by this, and I guess I felt a little better when John said well for most things, you won't need this standards because that leads me to say then why are we doing this. But nonetheless, I want to make sure that I understand what you're proposing, that data type including specified to this degree is part of the header. Am I hearing that right?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
That's correct. It could be and I guess I would say, extending what John said, in a use case where you need it, it would be there.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
So, what am I missing? Because data type is very disclosing in the header.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
And it goes back to the use case that we talked about that if we are to meet Massachusetts requirements for—

Farzad Mostashari – ONC – National Coordinator for Health Information Technology
I'm sorry. I have Carol's same question, but I thought we answered it already that when we're talking about the header, it is not the unencrypted header of the message where you have the encrypted package separate. What we're talking about is within that encrypted package, the PCAST workgroup said take your CDA, that the person now has unencrypted and can view, they actually have access to the actual information.

M
Moving along. It seems like a good direction.

Farzad Mostashari – ONC – National Coordinator for Health Information Technology
And add to that metadata that can help facilitate the processing of the information that you actually have now legitimate access to the actual information. It's not that the header provides you with information that tips you off to what's in an otherwise encrypted package. These are both part of the package, and the header, in this case the UAL wrapper provides you with some shorthand information about what you already have a right to see. Is that Carol, is that--?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Maybe. Who is the person who opens that package?

M
How long most of the pieces of that in—

John Halamka – Harvard Medical School – Chief Information Officer

Marc, I think we need to have you mute. So, it's either the facility or the actual clinician caring for the patient. Marc Overhage, if you could mute.

Okay. So to re emphasize what Farzad and Stan have said, this is assume let's say it's a direct transmission, that is the patient has authorized information to be disclosed, an encrypted package goes from one organization to another organization and arrives in the hands of the caring clinician, but the purpose of this metadata was to say now rightful recipient who has rights to read the entire content of this, be warned before you read that there may be some policy implications on this thing that you have received that you have a right to read and ensure you have obtained necessary consent.

Farzad Mostashari – ONC – National Coordinator for Health Information Technology
And John, the other potentially use case would be as I'm extracting and loading this information into my own system where I keep the information I'm importing, I would associate this data element in an enduring way with that metadata tag. Even if I have the right to view it and all's good, that data element that I extract from this package could durably then be associated with the fact that it came from substance abuse clinic for example or whatever.

John Halamka – Harvard Medical School – Chief Information Officer
And Farzad's point is extraordinarily good one because it ... we segregate data on mental health conditions into special lost containers, and we actually wouldn't know to segregate this message into a locked container because natural language processing is imperfect. We wouldn't have a computer able to do this division unless the metadata told us this package should be segregated. But so this is not so everyone is very clear, it's been said multiple times, I worry about the problem of, as we all would do, sending information that itself is disclosing. A Betty Ford Clinic visit is described within. A psychiatric diagnosis is described within. So, this is purely metadata when it has already been clear the patient has disclosed this information and it has arrived at the rightful individual to then be able to either obtain necessary consent or categorize it for appropriate storage in the system in which it is received.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
You can in fact do that themselves, that there is no help in the middle required?

M
Or if in fact—

Farzad Mostashari – ONC – National Coordinator for Health Information Technology
It's not in the middle Carol, right? It's the source that is provided.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Right. So Carol to that point, imagine that I chose in my systems as we received it, to display this information to the individual receiving it in different ways and apply actually different business logic to my internal systems because of the metadata. But there's no intermediary who's seeing this information. This is not being viewed by the HIST or any other entity.

John Halamka – Harvard Medical School – Chief Information Officer
So we've got, let's turn to David and Wes and I think Chris also. So, David.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
David McCallie. I have one easy question and then one that kind of follows on Carol's. The easy one is that John, you said we didn't have to look at OIDs anymore but the previous slide had an OID on it and

I'm curious to know if in the CDA R2 header that are we going to rethink along green lines or other proposed modifications for CDA to simplify these headers even more than they are here? This is just, I'll just flag it as a technical question. I don't necessarily need an answer here, but we've got OIDs here.

John Halamka – Harvard Medical School – Chief Information Officer
Provenance is what I was referring to. We removed the OIDs replaced them with URIs. I think referred to this.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
So, we may want to simplify these two.

John Halamka – Harvard Medical School – Chief Information Officer
Yes. The I think what we want to focus on with these standards is that this is the logical structure. These are the logical data elements and we're showing X amount. I don't think that precludes us from going to green CDA or some other form. There's going to be something after X amount too and what's important here is that is the definition of the logical elements that we can assembly there regardless of exactly how we encode them.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
That's the clarification I wanted. I like that answer. And then, back to the more substantive question, following on from Carol's, it sounds to me like this model is useful for indicating to the recipient that special handling is required, but it wouldn't be useful to enforce the patient's privacy preferences.

John Halamka – Harvard Medical School – Chief Information Officer
Because you'd have to know what's in it to enforce it. In other words, if I've allowed my data to go into a health information exchange, but I've said I don't want, pick one of these categories to be discussed, let's just say sexually transmitted disease, I don't want that to be exposed, this data would not allow the exchange to make that decision because it's all encrypted and hidden away, as I'm understanding it. This data is at the same level of protection as the actual data, so the header data and the actual data are protected to the same degree or I would say unprotected to the same degree, so you couldn't use it to gait preferences of a patient's privacy policy. It just flags to the recipient, wow you need to pay attention to this because it might be sensitive.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
The code to it basically allow you to know this thing contains a hematocrit or it contains a sexually transmitted disease result, and so it's I think actually the granularity is available if you want to execute, if you want to go out to the policy, get the policy and say now does the policy allow this particular data element to be disclosed, you could do that without seeing the result that's inside the data itself. It's on the outer side of the envelope.

John Halamka – Harvard Medical School – Chief Information Officer
The issue is as follows, which is we have been pretty clear in our discussions about direct that no intermediary will be able to examine the payload or anything that could conceivably be disclosing. Let's imagine, say in Massachusetts health information exchange, we had a patient's privacy preferences application, and I could say, whatever you do, please don't send my HIV related data to anyone. Well, the answer is the health information exchange is never going to see this metadata, and so the health information exchange can't enforce such a policy. It has to be up to the end actor who has the rights to receive the data to then apply this metadata to the patient's preference.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

But that precludes the usefulness of much of health information exchange because now I don't have, if I'm doing a query response, I'm going to query and I have no control over what I get, I have to take it all or take nothing. There's no way if this can't be used to filter the response to a query to an HIE and HIO, then how do we do HIE? How do we make that work? It either has to be exposed to allow sub filtering before you reveal the data in some way or it's not very useful. So, if it's all wrapped up inside the package—

M
Jamie wants to offer a friendly comment.

M
I'm just confused.

M
David, the way I understand your point is that this does not control what is disclosed by the disclosing entity that's originally sending records, and that's correct, so I think this is about handling at the receiving end but I think what you said is how do we ensure that the patient preferences are enforced by basically the EMR that's originally doing the disclosing. Well, this doesn't do that. This is about what happens after it's disclosed, but I think also what you're saying is that somehow the HIE should be controlling what the EMR discloses. Is that?

John Halamka – Harvard Medical School – Chief Information Officer
Or possibly filtering—In one conception, HIEs the XES model, the BPPC was ever reduced to executable code would enforce from the registry of available data, the subset that was allowed under the policy to be exposed based on who the user was. This does not support that use case.

M
So my reading of this, and Stan correct me, but my understanding is that this is it's up to the disclosing entity to meet whatever its policy rules are for disclosure, then there's the secure package that goes to its destination and once it gets there, this helps you follow those right policy is at the receiving end.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
That's exactly right. And I think you're getting into an, I think an area where I would like to have more discussion, more opportunity, is to really get into that in a sense you're kind of in to that third use case. The first two I think were covered pretty clear. What's not exactly clear, what I would like to have more dialogue about is when we get into that third use case where we're talking about DEASs, when if I'm holding information how does that get indexed and catalogued by the DEAS? What's available to that indexing authority and then when someone makes a data request to the DEAS, what data is available to it to discriminate what they had set and what's allowed by the disclosure?

M
This isn't that use case.

M
Exactly.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
This is out of scope for what we considered here.

M

Farzad, did you have a comment?

Farzad Mostashari – ONC – National Coordinator for Health Information Technology
That's what I was trying to ... the context for in my opening remarks. That there are difficult, complex policy issues around the, as we heard and discussed around the DEAS issue and that our goal is to make forward progress on a defined and limited use case that can help further the identification of what would ... from the data tags that could be applied in a variety of policy tags. This is not a discussion, again, of the larger more specific application of the metadata tag in a particular search function.

John Halamka – Harvard Medical School – Chief Information Officer
So, we have several accountants from Wes, Chris, Dixie, Jim Walker, and Walter.

M
Marc would like to get in the queue too please.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
So, I'm already nervous.

M
I'm a teddy bear. I think my main concern was already addressed in the discussion that went forward. Another way of stating that concern is who do you ever trust in the middle, and if so, how? And certainly a lot of the sort of care and transformation practices that have been discussed and put forth emphasize the confidence that the patient has in their provider in terms of discretion of using information as opposed to any other entity that's essentially invisible to them sort of like trusting the phone company. I have two questions; one, provenance, the term implies a history dating back through multiple exchanges perhaps, often through information being consolidated into documents maybe pulled out of a document ... so forth. Have you looked at the issues of how to create the history or have you pretty well just been focusing on the getting information ...?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
We discussed history and actually in the original proposal about provenance, it was a set of data instead of being a single so that basically it was modeled in a series of actions or transactions or information transfers where each time the information was transferred, you would have who transferred it, what time did that happen, all of those kinds of things, and that just became basically what we said is if we, that looked like a snow ball rolling down the hill, so it starts out simple and then every time somebody exchanges this, you have the increasing information, and in most cases, what I really care about is who's giving me the data. If the last person that gives it to me isn't trusted, then I can't trust anybody else down the line either. And so, the idea was that that kind of provenance information on the whole history would be tracked in individual systems and what we would exchange is basically who gave me the data this last time and if I wanted the history, then in a sense it's outside of the scope of what we specified, you would ask that institution can you tell me the history of this data in an instance where you wanted to know all of that detailed information.

Farzad Mostashari – ONC – National Coordinator for Health Information Technology
And that would be typically your lawyer calling their lawyer.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Exactly. Essentially, implicitly what we're saying is recognizing that every provider looks at every piece of data no matter how rock solid it looks with some subjective probability that validity. If it's a lab test, it could be wrong. Right. In this simplified version of provenance, if I'm a provider looking at a piece of

data, all I really know is that the provider has sent it to me, trusted it. I don't know why or what that, so that's, I think that's an acceptable compromise as long as we understand what we're saying there. I am and have been for some years now very concerned about the codes that fill in any blanks in these kinds of actions. In fact, in talking about in prior previous testimony whether the rules based services for evaluating these privacy decisions were really ready to implement or not, my concerns are not with the technology itself but with the ability to achieve a set of codes that was complex enough to describe what people need and simple enough to be implemented by three doctor practices in Keiser or Intermountain Healthcare. And I'll point out some specific examples of that, role has been described as everything from provider, not provider to cardiologist working today in pediatric cardiology in different enumerations of, for example, the HIPAA work .... The danger of being too simple is that you're simple enough for one state and not for another. The danger of being too complex is that you're forcing institutions all across the country to go back and re implement their whole user authorization role based steam to take roles as the known institutions that has any unreasonable why the heck are you doing this, so it's a very difficult case. LOINC codes, my understanding, I could be out of date, is that there are LOINC codes for classes of reports that are different according to whether it is assigned by a resident or an attending, same report, different ... signature, different LOINC code. Getting institutions that haven't built that distinction into their system to recognize that, to update it when it's countersigned to do all those sorts of things, seems like a very burdensome implementation requirement, and as is often the case with LOINC, I think we need a systematic way of creating hierarchies of these codes such that those who need to characterize them at greater depth can do so, those who don't need to characterize them at greater depth can understand them at a higher level in the syntax and that the interoperability statement is the information you get is the less specific of the sender and the receivers models, basically. So, and I think these are issues that really stand between this idea, which is already greatly simplified and actually implementing it, so I think this is an important idea to visit. Thanks.

John Halamka – Harvard Medical School – Chief Information Officer
So, if I were to summarize that, I would say that our job isn't done until for the coded elements that we've described here, we actually have a workable set of codes for those things, and so that's additional work that we need to do to finalize that and then a caveat on the LOINC codes, that the LOINC codes include who authored it, not who signed it. And so, is this an attending note or is this a medical resident, who is the author? So, that doesn't change, and so you're going to have to change the LOINC code in the life cycle. And then, it's not really usable, but you can define exactly what are called context specific or user defined hierarchies so that you can do the rollup that you described and actually implement and machine that if this guy cares about the attending cardiology consult note and somebody else just cares whether it's a cardiology consult note, you can do that automatic inference of the fact that this attending cardiology note really is a cardiology note and you implement exactly the kind of least common denominator data sharing based on that mechanism.

M
So, if everybody implements around that way in their system then—

M
It implies that you need a terminology server that can do inference, which you need for pretty much any kind of decision support.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
I agree. I think that we have to be careful that we're not killing the great simple new idea that's going to revolutionize healthcare by using iPhones. So, I would say that the work is not done until you have either settled on a subset that is small enough to implement in the smaller organizations or settled on a profits

for inference as you described that is simple enough to implement in the small organization, and the rules around what's understood when you do that. I favor the latter although in the press of time, we might want to consider the former, I think.

John Halamka – Harvard Medical School – Chief Information Officer
Chris Chute and then Dixie Baker?

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
Thank you. I had picked up on the URN OID in your example, but I guess we've discussed that. What I really want to talk about is your example value sets that you showed, your straw man value set, not so much to quibble about its content because obviously that wasn't your intention to describe whether these are the right values or not but to point out two things. One, in terms of good vocabulary practices, this example includes monigs as code identifiers, and I think if we are going to be the Standards Committee, we should sort of eat our own dog food and recognize that good vocabulary practices are probably required even in the exempt bar if only so that we don't sort of casually slide into the seductive space of trying to use the monigs for identifiers in a lot of use cases. I know you personally agree with that.

The second is to point out that his is an example where the U.S. realms, the once in future U.S. realm, is actually going to be needed. I know there is a philosophy that thinks the U.S. realm should have maybe a score or less of terminology contents, but I think this use case illustrates the likelihood that we are likely to encounter hundreds of small but use case specific value set coding systems kinds of requirements that would require a scaling and a scope of U.S. realm to accommodate them.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Yes, I agree with all of those, both of those major points.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
This is Dixie Baker. I wanted to go back to the points we made about it's absolutely true that the access mediation is done before this package is ever sent, and that the content is encrypted needs to be encrypted within the entire content is encrypted with the metadata with the data element. But I want to make clear because we're talking, I heard several comments about well that person at the other end, it's encrypted all the way till it gets to that other person, and I want to make it really clear that yes the entity that decrypts the package then can act on the policy, but there are nuances here having to do with an encryption versus point encryption and ensures it's the only way that you can make sure that whole content package is encrypted to the very person or entity that is intended to receive it is to encrypt that whole thing with the metadata using that recipients public key, so that only the holder of the private key that matches it can then decrypt it. But then, the question is how do you communicate that to users and how do you communicate that to systems? That's not really easy to do. So, the challenge might be to enable an EHR to provide some understandable options. Do you want to send this to Mayo Clinic or do you want to send this to Chris Chute? And depending on who you want that ultimate recipient to be, the EHR might encrypt it accordingly, but really we need to make that distinction for the sender, I believe, because I think a user needs to know whether they're sending this content to an individual versus an institution, and I think this is an important point that we need, it's not a metadata point, but it's a security question that we may want to pursue.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
And you could imagine that could evolve over time because today, just the interest of simplicity as Farzad had said, you start somewhere where ... entity exchange and once the data arrives at the entity, the entity takes care of securely routing it for the individual but the cryptography and at the border of the entity.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Unless you encrypt that content using Dr. Halamka, say the key versus Beth Israel's ... key.

John Halamka – Harvard Medical School – Chief Information Officer
And we simply chosen not to do that because the logistical complexity at the moment but of course that may change. Stan?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
I don't have anything to add. I think it's a valid point, and I'm glad you're on the committee to keep us abreast of those security issues.

John Halamka – Harvard Medical School – Chief Information Officer
Jim Walker?

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Just a couple of questions, Stan. For provenance, does this have in view of the provenance of an atomic data element?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
It could be because we've tried to not specify whether this for instance whether the content of this were CCD document or whether it was a hematocrit. The contents could be either of those two things, I think. So if I understand right, on the creator of the information is not going to be part of the provenance, then you would have a situation.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
It would be or could be inside the content itself. So this is not, we're talking again about, again, what's outside the envelope, what's inside the envelope what's actually in the content in fact could include provenance data for each individual element of data. In the fact—

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
So in your model, knowing who created the information would be inside, knowing who sent it last would be outside.

M
Exactly. Two different function. Thanks.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Second question; the policies that would be at the URL are those free text or are those ... structured ...

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Well, they would need to be computable but we didn't get into any detail of that at all.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
So future work okay.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
We want to be computable but the exact form we didn't talk about.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
One last question then is on the privacy suggestions, the coded values for sensitivity; it sounds like you don't see a layer at which it would be useful to just know that there's something sensitive inside and not

reveal any more than that. I would see that I guess as part of this discussion and sort of follows on with what Wes was saying. What should the exact code set be here. Maybe there should be a code in this code set that just says sensitive information.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
I don't understand the details of the proposal, but it seems to me there would be situations, say the receiving entity, if it just knew it was sensitive then it could apply a set of rules to it. We don't have audiology techs who can use the EHR looking at sensitive information period, for instance. So it seems that that would be a more non disclosing but very useful layer of characterization above the specific values.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
That's a good point.

John Halamka – Harvard Medical School – Chief Information Officer
I think that's actually a point that we're stressing that as today we seek your approval of the proposal, I think we all recognize that the vocabulary that would be used to describe sensitive information is clearly still work that needs to be done. This is the straw man showing you the kinds of things that could be used because from a statutory standpoint, again, my weird Massachusetts use case, you need to know the sensitivity of the envelope inside is HIV related, but from a practical standpoint or a policy standpoint in my institution, just the fact that it's sensitive information of some kind is in here would then allow me to route it to a different part of the EHR as nothing to do with knowing whether that's substance abuse, mental health, HIV or whatever. So, very good point. Walter?

Walter Suarez – Kaiser Permanente – Director, Health IT Strategy
Yes, thank you. I have a couple of comments and couple of quick questions. The first comment is about some work that another ... committee, the National Committee of Vital Health Statistics and the Privacy and Security Workgroup Subcommittee, with respect to the issue of sensitive health information, there's a lot of policy related work hearings and whole body of work, and in fact, the last, late last year, the national committee submitted a letter to the secretary with recommendations on how to approach this concept of sensitive health information from a policy perspective, so I think there's a wealth of information, and the good thing is there is very much of consistency in the, in fact, the slide that I see on the slide a consistency in the themes or the topics or the areas where sensitive health information should be so prioritize. One of the interesting points about the recommendations from the national committee was that in some instances, entire records whatever that is defined or however that is defined maybe considered sensitive because of certain circumstances of that patient or that individual, not just specific elements. So I think there's a wealth of information to your point earlier about someplace on how the policy question has to be addressed.

It seems like another point is about the difference perhaps that I understand between the metadata on the envelope versus the metadata inside the envelope associated with specific data elements, and I think there might be some confusion about whether the data is out there and some people may be able to see the envelope and metadata on that envelope without entering inside a payload and seeing data and some people would have the ability to actually get inside the data and then see the payload, the actual content, and metadata associated with that specific content. So, I wanted to ask perhaps some clarification about that distinction, that the metadata that is in the envelope of a package that relates to the entire package and then any metadata inside the envelope that is associated with the data element.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

I mean, we haven't got into the structure of the data inside the envelope, well the content itself and what metadata. You have to have, if the package is containing something that's a collection, it's obvious that different parts of that data could come from different people and it may be important to know all of the circumstances of that measurement. And so, the assumption is that yes we have detailed metadata inside the envelope at the level of each data element that's in the collection. And then, there's metadata outside, and then, I think that goes back to the discussion that we've had. At the level of a network or an intermediary, somebody in the middle, you know, it's encrypted, and it's only when the information is received by a recipient that's authorized and to receive the disclosed information that they can start unwrapping, and what we're anticipating is yes, there's actually sort of a two stage thing here, one where I unwrap, so I get the encrypted package, I unwrap, that and now I can see metadata that's associated with the whole package, and then based on that, I can take special steps to say okay, who now can look at the content inside of that of the real content part of that package and that's the process we're envisioning. But what we really talked about here is just the metadata that would be on the outside of the content itself.

Walter Suarez – Kaiser Permanente – Director, Health IT Strategy
Okay. A couple of more just very quick ones, so there are some important preconditions that need to be explicitly stated about this case, this use case, perhaps. It seems like one of them is the assumption that the package and the recipient of the package is able to active and see it, that there's no expectation that someone is going to send out something and based on the outer envelope and the preference that someone will be able to actually see it, that ... release action or for someone being able to see it is something that needs to be very clearly stated as a precondition that they have the ability to see it. The other precondition it seems to me is that really in the metadata itself is expected to be enforced, if you will, in the sense of I can have a piece of information that I am sending, I'm releasing that I am the releaser of that information that provides the entity that's disclosing that data and I mark it. I flag it as this is sensitive with whatever code, and the recipient of that data would be able to use that and within the context of the policy environment might be a different state in which Dr. ... might not be considered necessarily sensitive and might not trigger additional steps, so the important part is that the metadata is not something that is universally enforceable and is a more informational in nature, if you will, through the recipient to be put in the context of the jurisdictional legal environment.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
That's right, again, so there's complex use cases that we're not covering here so this is really intended in the environment where somebody requests information from another party that has clinical data, and that party evaluates for instance who's the identity that's asking for this information, what is their role and they decide whether based on that information that they want to send them data back, so this is data that by whatever policy they assume that there are permissions to disclose. And what we've talked about here then is what's in the data that's sent back, and we haven't talked about, for instance, and that's sort of what was on that first slide. We haven't talked about what is the data that a recipient has to provide that allows a data source to determine whether data should be disclosed. We haven't talked about that at all. What we've described in this metadata is assuming that that disclosure is accurate, they send an encrypted packet to me now and inside of that packet, they've given me information that tells me how I should be able to legally and properly use that data and that's what it is. It's guidance to the recipient about how this data should be handled within my system to respect the preferences of the patient in how this data should be handled and how it should be shared.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Just for the record, Stan, we should say that we did use the NCDA ... letter as input to our power team.

John Halamka – Harvard Medical School – Chief Information Officer

Well, thank you. And to just summarize both the points that Walter made and that Jim Walker made, this is an envelope that can have many different kinds of packages. It could have a CDA inside, in which case, the CDA inside the envelope would have its own header. It could be an HL7 version two it could be NCPDP, it could be X12, so this is truly recognizing your point is that there are additional ID or provenance information or even additional privacy flag information within the package that could be within the payload itself. This is the wrapper level as it's being sent from entity to entity or individual to individual. So, Marc Overhage, last words?

Marc Overhage – Regenstrief – Director
Thank you, and I'll be brief. In that this is a follow-up on Walter's point that the National Committee on Vital Health Statistics letter to the secretary talking about these categories, Walter described some of the issues that were described there, but one in particular that we seem to have ignored here, which is the challenge of the EHR and the EHR user to identify these data, the example that we spent a huge amount of time on in the NCVHS discussions is the text note that talks about depression or talks about family situations and the near impossibility of the user flagging the used data so that they can be put into these categories, which is why the NCVHS letter suggested that that was some of the work that needed to be done was careful evaluation of the cost benefit of categorizing these data and how granular we wanted to get. So, while I appreciate that the straw man list that's provided here is just that, I think we need to take the deliberations of our sister organization into consideration in terms of do we really want to suggest that it's possible to categorize things at this level at this point in time.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
And I think that's an excellent point.

John Halamka – Harvard Medical School – Chief Information Officer
... you wished to offer some restatement.

M
Actually more of a comment, I want to recognize the power team for just tremendous work. It was incredibly logical exposition of some fundamental concepts that would facilitate interoperability, really ... with the goals in PCAST and the aspirations of the overall activity. So to Stan, to you John, to Wes, to Steve Ondra and all the power team members with a debt of gratitude. It's pretty clear that in areas such as the values for sensitivity and the fact that the discussion of whether it's employee sensitive, non sensitive at that level, there are policy inputs, but if we step back from this level of discussion, many of the comments or the questions that were asked were really dependencies on moving forward on this set of activities. I think it was a tremendously logical exposition that in terms of realizing the aspirations that were available would enhance patient care, cross geography time, episode, etc, that it would seem to be something that we need to move forward with both in terms of the overall goals of the group but in terms of being able to address these next level policy issues such as the value sets for sensitivity or all the controls that were asked for, so just many thanks to the group, many thanks for the discussion and John, let me frame it in terms of how we perceive because it does tee up the next body of work.

John Halamka – Harvard Medical School – Chief Information Officer
And so, the action item to propose to you all is that given this work, which identifies the CDA R2 as a standard for patient ID information, the CDA R2 as X.509 certificates for provenance information and the CDA R2 as a mechanism to convey privacy flags fully recognizing that additional work needs to be done on specifying the vocabulary of those privacy flags and that is obviously to take into account policy committee input, NCVHS or other input, can we get the acceptance of the committee to move forward with recommendations to ONC that the CDA R2 be used for these three categories of envelope information? So, let me just start off with are there any objections to that? I see some comments.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
This is David McCallie. Depending upon how the details are fleshed out, this could involve substantial work to create. So even the simplest thing as a digital signature, which may be the most valuable thing that we've discussed here, actually capturing producing, tracking, forwarding onward would be really profound changes to most vendor systems, so I'm uncomfortable with endorsing this as an implication that is all just going to happen without more details. And what happens in vendors has happened in—

John Halamka – Harvard Medical School – Chief Information Officer
And so let's turn it over to Farzad for comments on that.

Farzad Mostashari – ONC – National Coordinator for Health Information Technology
And again, my initial opening framing, I want to underscore the goal of this is to get recommendations to us so we can then seek much broader comments and feedback in an ... specifically on this and the implementation issues and so forth, prior to going out with the ... NPRM at the end of this year or early next year around the standard certification criteria. So, the goal this year is to do exactly that is to get something the people can respond to in a more structured, formalized official way.

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

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
So I just have a process question then, Farzad, which is it's great to get comments, but where are we going to get implementation experience before this becomes a standards requirement. I think it could become a recommendation for pilot projects or for testing, but where do we get that experience before it becomes a required standard?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
That's a great question and there's at least three phrases where I could see that happening. One is, we awarded some breakthrough grants to states, state health information exchange grants to try out some of these very same approaches. So, that's one place where I would expect to get some experience. The second is within organizations where there could be for example, the DOD or VA or other large delivery networks under which are represented here. Maybe able to pilot some of it, and then the third would be we could potentially do an initiative that or innovation challenge ... of what there other mechanisms for spurring this but really also seeking comment on places that have already done some of this. I don't think for the provenance and identity, I don't think it's that new or disruptive at all, but the identification of sensitive information, there may be more experience out there than we know of and it would be a good opportunity to an NPRM to get that sort of real life experience. So, the proposal then is we've forwarded standard's recommendations which would then lead to consideration through formal processes at ONC which would lead to NPRM which would lead to formal comment processes which would, as Farzad has outlined, presumably once refined lead to projects in which this would be implemented inside and outside of government between organizations and inside organizations where experience could be gained and then applied more broadly as refined by that experience.

Marc Overhage – Regenstrief – Director
John, this is Marc, if I could ask for a clarification of the thing we're being asked to recommend for further evaluation of this or for incorporation of this, this goes a bit to David McCallie's comment into NPRMs and whatnot that might turn into regulatory requirements.

M

It is to recommend to us to put out in as a initial NPRM that would then inform another NPRM so there's more bites to this apple.

John Halamka – Harvard Medical School – Chief Information Officer
So generally Marc, I think the notion is, is that we had a body of work from PCAST, if I just take the big view here that said as one thinks about future data exchanges where envelopes are needed and envelopes should have ID and provenance and privacy information so we are providing recommendations to ONC that if you need an envelope and that envelope has to contain these things that we have a standard which we think is useful for those three things in that envelope, but it is certainly up to ONC and policy makers to determine when and if and what context such an envelope would be used.

Marc Overhage – Regenstrief – Director
So, in clarification question Farzad, is so why does ONC need a NPRM to explore this further?

Farzad Mostashari – ONC – National Coordinator for Health Information Technology
It is the best process we know for being rigorous about collecting stakeholder feedback in a way that's completely transparent and open.

John Halamka – Harvard Medical School – Chief Information Officer
... comment on that, but it's just not for the process on our end, is that what we can do is enter into the process a review of then any provenance and sensitivity that is sensitive to a review of the standards that are available and the delineation of how those surfaced as at least the straw recommendations to become part of the NPRM process arose through considered input and obviously up for the consideration would take into account the public record of this discussion points that require further work. Jodi, I don't know if you want to comment on the technical aspect, but I think the practical aspect of transmitting to ONC, it's a couple evaluation that was done ...

Jodi Daniel – ONC – Director Office of Policy & Research
Thanks John. I think what we were saying what Farzad said, I think the goal is to have recommendations come from you all to us on what standards and issues we should be considering from ... areas. We need to get more input as to how this is to be used and how we get public input and that's something that we will determine and we've heard. All of us are here listening to this conversation, so we've actually been talking offline here while this is going on and trying to think through how to incorporate some of this discussion into our policy thinking, so I think what we need today is we'd like to have recommendations from you all as far as the metadata standards and if you want to input into the recommendation that we have further input on these, I think that is our anticipation, so that would be fine as well, and I think we need recommendations both on privacy as well as on the provenance and identity that you all discussed at the last meeting so it would help if it has all that packaged together.

M
... as does the group believe that for identification for provenance and for the indication of a privacy flag that CDA R2 is a reasonable recommendation to what is going to be a many, many more steps process.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Jump in here because we have in this group had a preference for not recommending standards that haven't been broadly implemented and tested across diverse environments and we are making a recommendation for use of a standard that I don't think we have that kind of data for. I'm comfortable with making a recommendation based on the best we know or based on the information that was presented today, but I'm worried that the only process for input is an NPRM whereas with standards unlike some of the policy issues that have gotten discussed today, with standards you learn through using

them through implementation and I think we all in ... some of these we all have some concerns about the implementation and feasibility of some of these, and I guess I'm not comfortable with just what do you think in a common period. I think there has to be a commitment to test these and to evaluate their ability to deliver what we think they're going to deliver in real world environments.

John Halamka – Harvard Medical School – Chief Information Officer
I think that's a very fair recommendation to ONC that what we've tried to do as I said in my introductory remarks is pick something that's so simple XML that there shouldn't be technical barriers to implementation, CDA headers have been used pretty ubiquitously, but we actually even suggested further simplification to the CDA R2 as it exists today, so if we say we would recommend to ONC is the power team evaluated all the possibilities through the simplest possible list of patient identifier provenance and privacy flag elements and found what seems to be in the industry a set of practices that are already existent for certainly the use of provenance and ID, and there are header information elements that HL7 has proposed for privacy, we've recommended four simplifications, two of them in that real world implementations of these be tried before ... is required. That would be the nature of our recommendation. Are there objections to that?

M
The only thing I'm concerned about is that the proposal, the slides, related to some very specific excerpts from the CDA R2 and the way this has been described is let's use CDA. It hasn't been focused on these excerpts so what language you've been using in saying here's what we want to recommend. I'm sure that's an oversight. But I just want to suggest that we make the question that you're calling, that we recommend these excerpts from CDA R2 would be the recommended to ONC subject to validation through comments and real world experience.

John Halamka – Harvard Medical School – Chief Information Officer
And that is exactly what the intent was. So if I misspoke by simply saying CDA R2, that's not in fact, we said on call after call, we actually went down the data element level in the header and what we were really saying is what we have shown today are the more specific header ....

M
I'm more playing amateur lawyer here than anything else.

John Halamka – Harvard Medical School – Chief Information Officer
So your comment is what we intended.

M
Just another question on process. This is interestingly different from some of the other recommendations that we've made where we forwarded to the S&I framework process. I'm just really concerned that this is so underspecified that it's premature to even get comments on it. They'll be so all over the map. Is it ready for comments? Maybe in the broadest policy sense, it's ready for comment, but in terms of anything to do with real world implementations, it's particularly around the notion of what gets signed and packaged, individual results, groups of results, documents, imagine a reference lab digitally signing a message that has 20 lab results in it. Does the system now have to always package them together because that's the only way you could validate the signature? If you separate them out and store them in a repository as discreet elements, you can't validate signature anymore. What does that--There's so many questions that come to mind, that I just I think is underspecified at this point.

M

I'd like to comment on that. I think it's fair to say that this is a sort of ... stack but it's difficult to get to meaningful conversation about the dependency if you identify with health specifying from ... as a plane from which to work.

John Halamka – Harvard Medical School – Chief Information Officer
To put it another way, what I heard from ONC was they were desirous of a standard to be chosen to describe provenance where provenance would be needed, but we haven't yet specified where provenance would be needed. There just starting us out on the ground floor. Underspecified.

M
I understand where we're trying to go. I'm just registering my concerns that it's so open-ended that—

John Halamka – Harvard Medical School – Chief Information Officer
I think folks from ONC, what you're hearing is it's concern that unless you're careful and you say you need to put a digital certificate on every lab datum, it would be become ... for the industry to adopt. The spirit of this is basically the use cases that are simpler. Here is a package of information with a thousand things in it, it is signed once so you know from whence it came.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
And again, the PCAST workgroup, the Policy Committee PCAST workgroup that had many members of this group participating in it also, identified a very specific use case that ... again both the policy bounds as well as the disruption to work flow and privacy issues, which was the transfer of the patient summary to the patient. So, it is within that context that they pass that to you to identify the metadata standards and start it on this path for moving ahead because we do have to as soon as possible get experience on how this would actually work in the real world, and we are not talking about every last result being signed as part of this discussion.

M
I think, David, the issue is back to our usual question is what is an atom, and if an atom is a complete medical record, that's okay. That could be an atom. It can be a complete summary, it could be a data element but that becomes more, as you say, a very strict implementation detail which is not yet specified but what we're asking really for today is just to give ONC the foundation to start work on ID provenance and privacy flags as part of an evolution.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
And at a high level, it seems to me that maybe it's the sense of the committee falling on David's comment that this be tested and carefully specified before it's put out for comment.

Walter Suarez – Kaiser Permanente – Director, Health IT Strategy
... quick comment, this is Walter, is there might be a distinction between the work that ONC can do and is doing with respect to standards and the work that is being done with respect to meaningful use. Some of us might be automatically thinking that any of these recommendations will immediately make it into some sort of a regulation or Meaningful Use Stage Two or something and that might not be the case so Farzad you might want to comment on that, but just to clarify that there might be other paths outside of meaningful use. Meaningful use is one leverage point, but there are other things. Is that correct, Farzad?

John Halamka – Harvard Medical School – Chief Information Officer
And so, if we could just get one last comment from Wes and then let's try to close this with a vote one way or another.

M
I'd like to suggest that we're getting a little big for our britches here. We're a step along the way, and the step along the way should be to get common and try it more. My favorite management book of all time was called "Muddling Through" and the idea of "Muddling Through" is you can't really figure it all out so go do something and figure out and then that helps you figure out the next step and so forth. And I think if we learned one thing from the internet is that if you can muddle through, keep it simple. And they are following that process, and let's not give this to weight that advisors give Obama whether to sign a bill or not. Let's just say move ahead.

John Halamka – Harvard Medical School – Chief Information Officer
Okay. So are there, to that spirit, ... we're muddling with an ID, a provenance and a privacy flag experiment. Are there objections to that?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
.... commitment to testing before?

John Halamka – Harvard Medical School – Chief Information Officer
Muddling. I think Farzad and Jodi, what we will have is a formal acceptance of recommendation of CDA R2 headers as exemplified in our discussions with a desire of the committee that is uniform to muddle and experiments and tests and refines. Very good. Well thank you.

Well, now let us move forward and I can tell you the rest of the meeting will be less controversial. I promise. And we will be talking about provider directories as already refined based on muddling that has been done over the past month, and so Dixie and Walter, we look forward to your comments.

M
John, while they set up, can I make a process suggestion? It seems to me that—By the way, thanks to Farzad for the framing and Stan, for the excellent report. Great stuff. It seems to me, if the committee knew the precise question it was being asked to address before the report started to the extent it's possible and then had it up on the screen in front of us as we're discussing, we would get where we need to get faster.

John Halamka – Harvard Medical School – Chief Information Officer
I think that's a very, very good suggestion. So let me actually try to frame Dixie and Walter's comments in that context. We are being asked a different question for Dixie and Walter's presentation than the previous presentation. The presentation that Dixie and Walter will give is about a set of inputs and constraints to be S&I framework process. It is not actually defining a standard. It is not selecting an implementation guide. It is a set of constraints and inputs to be considered through the S&I process.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Thank you very much for that framing.

Walter Suarez – Kaiser Permanente – Director, Health IT Strategy
I guess we have learned that there's more than just meaningful use in this world.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Okay, first I wanted to introduce you to a new member of our workgroup and to thank Chris Chute for this recommendation. Chad Hirsch from the Mayo has joined us as a member of our Privacy and Security Workgroup. Chad has a background in security auditing, and so we're really pleased to have him join us.

We're going through really two topics today. One is provider directory standards, and this is, as John said, an update to our work around provider directory standards. And then, at the end, we're going to introduce you to the next topic that we've undertaken and expect to spend some coming up, some time on and give you our recommendation. This is just a review to just to remind you of the charge that this committee was given by the Policy Committee. The Policy Committee identified a need for a national enterprise level provider directory ELPD system that would provide the capability to search for and discover information that's essential to supporting nationwide health information exchange, and they recommended that the content of this national ELPD system be limited to basic information about an entity where entity is an organization externally accessible information describing the exchange services that that organization supports, such as the direct protocol. And third, the security credential or the digital certificate of that organization. So, we undertook looking at standards around ELPDs with knowledge that the Policy Committee also was working on individual level provider directories and the ONC asked us to focus our immediate effort on EHR queries of such a national ELPD, and at their last meeting, you'll recall, that we presented our recommendations for a national ELPD as envisioned by the policy committee and most of our recommendations really to summarize could be characterized as a subset of the integrating the healthcare enterprise healthcare provider directory profile. The response from you was that thank you this is a very good overview of the current state of standards around provider directories, but we don't agree that a national level ELPD is necessarily essential for information exchange, and you told us that perhaps the direct project approach of using the domain name service, the internet domain name service to query for digital certificate may be good enough for the short term with maybe the vision of this national ELPD for the longer term.

The recommendation that came out of our meeting last month was that this committee would work with the HIT Policy Committee and the ONC to define the business requirements. So, to update you with activity since then, first of all, the ONC Standards and Interoperability framework, the S&I framework, has launched work on provider directories, and that work focuses primarily on community based directories, specifically on the discovery of digital certificates search and retrieval of provider information when the provider address is known and when it is not known. Walter has been working on that activity. So would you like to add anything more about that activity?

Walter Suarez – Kaiser Permanente – Director, Health IT Strategy
Just to mention that it just got started about a few weeks ago, only three or four weeks ago, and it's moving along very much in line with the work that the Standards Committee has been doing. So it's been a very interesting process, I guess, in terms of what the work of the workgroup in the Standards Committee has done pushing forward the envelope of understanding the provider directory elements and then bringing it down to some of the more specific technical details of sorts type standards. I think it's been a very interesting process.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Thank you. Without soliciting inputs, we received since that after than meeting, several proposals from people for alternatives that they perceived as being simpler than a national level ELPD. One of the suggestions was to broadly adopt the direct projects strategy of using the domain name service to retrieve digital certificates. For those of you that may not know the DNS or domain name service is what translates a URL like onc.gov into a numeric IP address, so we use it everyday to find entities on the internet and DNS is also capable of being used to retrieve digital certificates as well as that numeric translation of a domain name.

The second suggestion that we got actually from Paul Egerman who's in the Policy Committee is to create a health top level domain, or TLD which would be something like Mayo.meg to facilitate and end user search information about trusted health exchange points. The idea here is that if we had a health

top level domain and everybody who could or could possibly be engaged in health information exchanges would use that name that domain name, then entities would have a way of knowing whether particular entity is in truth a health entity or not.

Then, the third idea that was suggested was to use embedded micro formats to standardize tag data fields and vocabulary to provide directory information from a protected web page. The idea here is that you would have information on a Webpage that would be structured in a way and in a way using tags, metadata tags as well as vocabularies that would be predictable so that if a machine went to that Webpage, they could retrieve the information and if a human went there, they could retrieve the information and recognize it as provider type, directory type information.

And the privacy and security workgroup has considered these three alternatives, and I'm going to tell you our conclusion. The first is that while we thought the idea of creating a top-level domain, for the health industry sounded like a good, sounds like an interesting idea, we found that it really lacked a strong business case. The real value proposition, if you will, wasn't really there, and we concluded that the potential benefit would not justify a significant effort. Now as you probably know in the last couple of days, ICAN has announced that they're going to make top-level domains available for $185,000, and it'd be quite easy for anybody to create a TLD, so the landscape has changed a little bit since we concluded this, so probably the level of effort is probably not as much as we anticipated it would be. At the same time, we still lack a strong business case for doing that.

The direct project's use of the domain name service to retrieve digital certificates, we had Arien Malec to meet with our workgroup, and we asked for candid observations about how well this is working in the direct project, and it's basically working well. There are some browsers and email clients that don't currently support query of DNS for digital certificates, but the DNS specification itself does include that capability, so it is part of the standard, and they anticipate more browsers to be supporting it in the future and email clients. However, DNS can't retrieve more general directory information like your telephone number, your address, a list of your individual providers, etc. So it's working well for exactly what it's being used for which is to translate a domain name into an IP address and to retrieve a digital certificate.

So then, we came up with the idea how about if we look at the idea of using DNS for certificate retrieval and then combine it with publishing these Web pages that would provide the additional directory information and structured encoded content. As I talked about in the last slide, one of the approaches to do this is called microformat. So, here's the concept for using DNS and the structured and encoded web content. Basically, and I want to credit Wes Rishel and David McCallie for coming up with this idea and for really putting together a very strong presentation to a group about this idea, and Wes has also written about it a nice blog posting about it. So, the idea is that organizations would create public Web pages, Web pages that are accessible to the public that would contain directory information that they want to expose for search. I mean by the term directory information, I just mean the type of information that one might include in a ELPD or an enterprise provider directory. The provider directory information is structured and encoded so it uses standard metadata, standard data model, standard vocabulary, so that it's easy for a search engine to find it and work with it, and it's also makes it easy for a machine to extract that information like an EHR system can easily extract it without human intervention. At the same time, it's also understandable by humans because it looks like a traditional webpage. The organizations could add some assurance that this is indeed Mayo Clinic's Web page or Beth Israel's Web page, the organizations could obtain these extended validation certificates to provide more assurance that it is an authentic representation of provider directory information from that organization. The extended validation certificates are being used by a number of entities in the financial market now to do exactly that. Just as you have a little lock in the bottom in the lower right side of your screen when a connection is encrypted, if you use an extended validation certificate, you have a similar little lock in the address line so that you can

tell that yes this is indeed Beth Israel or whatever. So then, you use just a standard search engine to query for this type of information, standard browser to view the information, standard browser for extracting the information. And then, once you've found that information you can use DNS to retrieve the digital certificate because you'll have the proper domain name for the server that you use to drop information in and you use that server name it goes out to DNS and it retrieves the translation in its numeric address name, as well as, it retrieves the public digital certificate as well. So, the benefit to this is that it's very simple. You could put this up in a day. It's widely available. It's highly scalable as scalable as the internet. There are recently the three leading search engines; Google, Microsoft Bing and Yahoo have launched a site called Schema.org that has metadata, metadata data models for that are made publicly available, so you can actually publish on Schema.org a data model that could be used for healthcare provider directory information if we chose to go forward on this approach. The organization importantly, maintains control over what information is exposed, so instead of selling every organization, you must publish the following data elements in the national ELPD, they decide what they're going to expose to the public and make available, and you can start simple with the three data elements that the policy committee identified, and then build on that overtime if you want. It allows discovery of services and certificates using familiar names without requiring advanced knowledge of a formal identifier like an OID which the NHIN exchange requires or a direct address. If you just know Beth Israel, you can search for Beth Israel and ultimately you'll end up on a Web page and find this kind of information.

So our recommendation is that the S&I framework team consider this approach for meeting this need for nationwide access to directory information without requiring a national provider directory. I would also add that there are several standards that are out there that are used for this purpose. Google and Microsoft and Yahoo have adopted the metadata approach. There's also the microdata approach. There's also the microformats that I mentioned before, and there's something called RDSA, so there's three standards that are out there to use and we suggest that an S&I framework really look at those and look at this as a potential way to achieve the functionality and content that a national ELPD would provide without the complexity of a true national level directory.

So, the next topic is we're looking, we're starting to look at privacy and security for stage two. The stage two measures are I know we're receiving a presentation later today about the stage two measures that were approved by the policy committee, but the last I saw of those measures didn't look like stage two measures were very likely to significantly change the required EHR policy and security functionality or content. However, a number of the policies that have been formally recommended by the privacy and security Tiger Team do imply new EHR privacy and security standards and functionality. So right now, we have undertaken an examination of these formally recommended policies to identify new needs for EHR standards, implementation specifications and certification criteria, and this is the topic for our next scheduled meeting.

Here's some of the examples that I just put together just based on what the Tiger Team has recommended secure email, web transactions, such as those provided by the direct protocol, the retrieval of digital certificates, protection of a sender's digital certificate. If you store your private key on your computer on an unaccepted form doesn't provide much security there, so we need some requirements around the protection of an individual's private key. The use of a sender's digital certificate to authenticate the sender and also to authenticate the receiver as well. To detect and block problematic attacks and attacks from unauthorized entities, that's direct quote from a Tiger Team recommendation, to enable consumers to securely download their own health information, I know we discussed this in our meaningful use discussion at our last meeting. And that needs to include provenance as well, as Stan just discussed. The ability to audit events on consumer portals, the requirements to enable a consumer to log in before they access their health information and the standard metadata and vocabulary fields that

are commonly used in patient matching. This may be a clinical operations assignment, but it is derived from the Tiger Team recommendations so Jamie we may need to discuss where that logically belongs.

So, in summary, our only recommendation is that the S&I framework team consider the approach of using the structures and encoded web content for sharing provider directory-type information as an alternative to creating a national level ELPD, and we will present our initial recommendations for stage two at the July meeting and probably continue to work on them beyond that. You want to add anything?

Walter Suarez – Kaiser Permanente – Director, Health IT Strategy
Just that two comments. One is we expect of course, I over the summer and in the next July and August meetings of the Standards Committee and through the work of the workgroup, we will be hearing back from the S&I framework team, with respect to the evolution of this considerations that approved here by the committee and will hear back hopefully on recommendations, sort of what "final recommendations" about what to do with respect to provider directories that then can be formally adopted by the Standards Committee.

The other comment I wanted to make is with respect to the next work, next set of work items, what in essence we have done is create a map between the meaningful use requirements that will be presented later to our committee as approved by the Policy Committee as well as they Privacy and Security Tiger Team so we created sort of a map of what are all those things and what of all those things, what needs some sort of a standard or implementation certification, ... or certification criteria or all of the three and begin to lay out the work because again, those will be priority items over the next two months in order for them to make it into any proposed regulations for Meaningful Use Stage Two. That's why we kind of jumped off fairly quickly to get us going on that. And that might be something that will be needed for all the other areas of meaningful use, I expect, as a committee member exposed. That's something that we would want to do is create a map of what are the many, the various standards that will be needed, and I know the Policy Committee is making specific recommendations on areas so just those two comments.

John Halamka – Harvard Medical School – Chief Information Officer
Great, well thanks for that presentation which was very, very clear and just to reiterate this whole process, we've been thorough preliminary recommendations last month, now more formal completed recommendations today where we looked at all that at HPD and we said based on your input, hasn't been really tested in a federated fashion. There are issues with using it as a cross-organizational federated nationwide infrastructure. We considered the notion of a top-level domain and although we don't preclude that from every happening, it could. There was that announcement as you said, it's $185,000 you could be dot Cerner domain, have at him. Go for it. Not so hard. But the simple approach microdata, microformat, there are many proposals out there. There is one Schema.org as you mentioned that just came out recently of using a very simple schema for identification of organizational information that all the search engines would have like .... The recommendation is that as we stated that the S&I framework will now consider this as one of the possibilities for the use of directory information in addition to what has already been suggested for direct DNS as a mechanism of certificate distribution.
So with that, I look forward to comments.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Well your last sentence may have answered my question, which is the lack of mentioning DNS here because we consider it's already been recommended or was it specifically second thought here? I didn't notice when they were reviewing.

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

No. I should add that explicitly in this recommendation. That's a very good point. No, what we're recommending is that the S&I framework consider using both the Web page to get additional information and DNS to get this. Good point. Thank you, David.

John Halamka – Harvard Medical School – Chief Information Officer
Jim Walker?

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Thanks for the exemplary report. I support your recommendation. I just want to mention a grace note. Many small organizations won't have a clue about Web pages, and if it were possible to provide some kind of absolutely optional guidance that would say something like many organizations will find these slide categories most useful. Just some very simple implementation recommendations I think would help people to create robust Web pages who don't have that kind of analytic capacity.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
We expect, and we actually have discussed this, we really expect that a lot of the smaller providers will be using intermediaries, HIST, health information service providers and those were health information exchanges and those will be the places where these Web pages will actually be put up. I don't think a two-person practice is likely to, although a lot of them do, have their own Web pages.

M
I have in mind a three hospital organization that still may have not a great deal of analytics and if they just, if there was just something very simple it's many organizations find these five things the most useful.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
And come up with standard metadata and vocabulary even for the three elements that the Policy Committee. Good point, yes.

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

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
I want to take issue with one part of your analysis which was it seems to me on the analysis of alternatives, you looked at the idea of a top-level domain, but basically in your report you just said well that's too difficult and we can't do that. And then, John just now even made light of that, but I think that this was actually something that really should be looked at much more seriously now I think that the recent vote of the ICAN in Singapore was actually a major change that changes the landscape that means certainly now really has to look at it. There are currently over 300 top-level domains in existence, over 70-75 of which have trust anchors in the root zone, and I think that the list, the recent change to unlimited number of top-level domains essentially guarantees that it's easy to both create and maintain that capability, and this is can be complimentary to the recommendations so that doesn't not in conflict necessarily, but I do think that that the landscape has changed very significantly in a fundamental way with regard to the opportunity that we have to create and maintain and have top-level domains perhaps for this purpose or for other purposes in health and the U.S. and it's now relative scale cheap and easy compared to what it was before. It was always possible to do it, and I agree previously it may have been too difficult, but I really think part of the analysis may need to be redone now that there's been that fundamental policy change.

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

I didn't mean to overstate that the cost and the effort was the main reason. We did discuss what was the potential benefits and what we concluded is that the argument is that if you have a dot health domain name, then you have some assurance that you are a true legitimate health organization, but the truth is what the real proof of who you are is a digital certificate. And as far as the $185,000 TLDs, that may make it even more complex because now won't Mayo want a dot Mayo and Beth Israel want a dot Israel and dot Messenger and Kaiser want a dot Kaiser. It may make it more complex than ever.

Walter Suarez – Kaiser Permanente – Director, Health IT Strategy
The other implication that was noted also is that the fact that today everybody has their own domains and trying to go to yet another level so that dot org that are out there that use that as a way to communicate with necessarily if we were to go into some TLD would have to change to dot health or dot net or some other TLD, and so the cost of transitioning every single affect of their business, e-business, into a new domain at the top level would be will be quite significant, so it's not just a cost of the creation of the TLD itself, it's the implication of the cost for ... moving to that.

M
So if I can say, I think that's mistaking the idea of putting the directory services that are the subject of this discussion and finding its certificates with the complete business model so this is not about changing the whole business on the web. It's about just how do you find these certificates.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes. And I do, just to be clear, Jamie, I agree with you that we really should watch to see what happens with this new I can capability and if it and revisit this as it becomes kind of trivial to do, we may want to reconsider it.

John Halamka – Harvard Medical School – Chief Information Officer
Because it's summarizing this point, its agreeing to pursue the notion of simple web standards, microformats and microdata can be done affluent and parallel with the TLD and watching how it evolves because we can all keep our existent domains, but we can all agree that we're going to host a single web page in the dot med domain which will host our directory information. For example, which domain could have a trust anchor in the roots of?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
That's a good point.

John Halamka – Harvard Medical School – Chief Information Officer
And so, these are complimentary and not certainly mutually exclusive suggestions, and I believe both, we have two cards on their edges, so I think is Wes is your card up?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I'm not pointing it at you

John Halamka – Harvard Medical School – Chief Information Officer
Okay and then, Doug, I think your card is up, so Wes.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
So, if we're going to reevaluate the top level domain, I'd like to suggest we reevaluate it from the point of view of the actual scenario that has to happen in order to be able to easily issue trusted domain names. And first of all, you've got to get a top-level domain. Second, you have to have a top-level domain that you have to recognize your top-level domain as being more trusted than, let me restate that. Domain names that include your top-level domains, so if the top-level domains were dot U.S. medications, for

example, I don't think we want to imply it's international so if it were dot U.S. med, then we would want people to know that endoscopy.USmed was more trustworthy than endoscopy.meds-something else that you can buy from Fat Charlie right now for $15.00, and that's not made up. That is the name of the entity that sells that domain name. Fat Charlie I think used to sell used cars, and he figured there'd be a lot of this business selling medical domain names, smart guy. Certainly has no prejudice against those with the persuasion of the .... The next thing is we have to have a method for deciding who can get a domain name that's in this trusted set that ends with a path level domain. That's where the business model comes in. Fat Charlie's business model is easy. I guess good at what people want and if I'm smart I make money. And I sell them for 15 bucks each. The implication is that what is the implication? What is the trust we're going to put in this organization that issues these domain names? Will it validate that this is a business that is licensed? Will it keep track of the licensing? What will it do? There's all sorts of expectations we're putting on this business, all of which cost money to execute. And all of that money has to come through plus some portion of $185,000 has to come through into the price of an individual to buy the domain name. And then, we have to deal with the fact that all of the software out there that's used generically plus the internet relies on digital certificates not on the actual literal contents of the domain name in order to decide what to trust or not. We're asking people now to write their software to look at the literal domain name, forty years ago as a programmer I got my hand slapped for putting literals in my programs, but I don't know if it's changed that much since then. So fundamentally, I think such evaluation should not be as hasty as the prior evaluation was and should really look at all of those steps in coming up with a plan.

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

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
So I'll try to be brief and get us back on schedule. My only comment, Dixie, and I really like the work that you've done here is to follow up on Jamie's comment, which is to lead the evaluation of the top-level domain open, I don't think a top-level domain solves the problem that we're trying to address here, which is directors, and I think that was what Jamie was trying to say. We wanted to there are other things that we have out there, for example, we have governance around the NHIN that enforcement of trust around people that satisfy those conditions for example. There may be other use cases in which adoption of the name may provide us the business value and also make things like enforcing and making sure that we separate authorization to be able to exchange say with NHIN from identity, which is the authentication and certificates. Currently in the NHIN, we can site those and so that you get a certificate to be able to exchange information that identifies you, but it also permits you to exchange information. Putting those two together sometimes creates additional challenges. So, my only friendly proposal is to recommend what Jamie had suggested, leave this open. There probably needs to be some further evaluation, but it probably doesn't fit this particular use case, there may be some other ones down the road.

John Halamka – Harvard Medical School – Chief Information Officer
So Dixie, would it be a fair way to restate your proposal that you will DNS, which is already part of direct and certificate distribution is one recommendation, second is to use microdata, microformats, web formatting web pages, search technology as a mechanism of getting other information about an entity, and three as a top-level domain is left as an open consideration?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I would not quite. I would combine DNS and the microdata because it is important. Those aren't one, tow and three. That's one and two. But, yes that sounds good.

John Halamka – Harvard Medical School – Chief Information Officer

And then, that this committee would accept that as a recommendation to the S&I process, which would then provide the further granularity implementation guide testing etc. So, any objections to moving forward with such a recommendation? None? None being heard. See, I told you this was going to get easier. Now wait until we get to the summer camp. That's going to be really simple. Well, thanks so much for that discussion. Very, very good work. Okay, Doug, now turning it over to you to lead the discussion of patient matching with Marc Overhage. Dixie will be discussing the nationwide health information network and then Steve will be discussing the standards and certification criteria code sets.

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
So, again, thanks to everybody who is in summer camp right now and everybody is having a good time, lot of sunburn, but I don't want to spend a whole lot of time with any sort of introductory comments, I think we should really focus in on the work that's going on. What we're getting both from Marc Overhage and from Dixie are kind of an interim report on activities that are ongoing, just to sort of make sure that we're on the right tack and that we're moving in the right direction and give you a heads up because things are moving very, very quickly. And then, we've also got Steve here who's going to help us go through some additional work that this particular committee needs to weigh in on with regard to some of the updates we need with vocabularies and the value sets, just to make sure that those things are aligned, and if we can start ticking those off the list as well. So, I just want to say I'm very grateful for all the work and the effort that's going into all of our summer camp activities. It's been really exciting to see people dive into this work and try to tackle some of the really key problems that we're trying to address. So with that, Marc, you're on the phone, is that correct?

Marc Overhage – Regenstrief – Director
That's correct, Doug.

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
So, I'll run your slides for you and you can sort of go from there. So I've got the first slide up. It says patient matching work in progress. You just tell me when you'd like us to change and we'll turn it over to you.

Marc Overhage – Regenstrief – Director
Will do. Thanks very much Doug, and thanks everyone, and I just put a list on the screen that obviously a number of folks including a couple in the room, David McCallie and Walter Suarez who've been helping move this forward. If you go to the next slide, Doug, and as you said this is really a work in progress. Basically, we've reviewed the secondary and primary literature on patient matching, sort of white paper sort of material and had a series of teleconferences to help establish the scope, develop a framework and then begin to populate that framework, and what I'm going to walk through very quickly today, but would certainly appreciate commentary and feedback if we have a little time to shape this yet, is where we are snapshot in time.

Next slide, so a couple of assumptions. First of all, is that there are multiple use cases with different tradeoffs when you think about what is required and what the options are in patient matching and much of this discussion actually goes back to Walter's presentation on metadata this morning. We'll come back to some of those same issues, tradeoffs for sensitivity and specificity, and for our summer camp we decided to focus primarily on the direct patient care use case but keep in mind some of the others. The second assumption is that establishing a sensible false positive rate. In other words, out of the thousand queries for patients, how often are we willing to get back a incorrectly matched patient? Seems that the policy issue that we can try to help in form although the data on which to make that recommendation are somewhat thin. In other words, there's not a lot of data out there that really tells us what the changes in

the false positive rate will be based upon changes in the metadata if you will that's provided to match a patient list.

And lastly, Walter is very helpful about reminding us to focus our guidance around the electronic health record, where our tools are for whether certification or other kinds of things rather than focusing on what the organization or entity is that might aggregate or respond to a query might be doing.

Next slide. So, a couple of I've already touched on this a bit a caveat of that was the data maybe somewhat limited but also a sort of a recognition by the group that some of these patient attributes like email addresses and zip codes may vary significantly over time and so as you interject the temporal aspect to patient matching, if you're matching for example what ... at the pharmacy yesterday, this code may be great. If I'm asking where did, do you have any data about Marc Overhage who now lives in Philadelphia who used to live in Indianapolis, maybe not so great as a matching attribute.

Next slide. So, a couple of prints fold that we think are probably right. One is, is that specificity is probably more critical than sensitivity of the particular for this use case of direct patient care. In other words, missing a patient match is probably less egregious than making an incorrect patient match. And secondly, and thanks to David McCallie for helping keep this on our radar screen, it's important not to preclude new attributes from being added to the matching process. In other words, if in a particular market for example, there were a dominant payer and including the payer's member ID number would dramatically improve the matching for most of the care in that region, you'd want that to be a possibility.

Next slide. So a very simple diagram to try to begin to capture our scope, sort of a query source, query responder and knowing those EMR or EHR might serve both roles. If a EHR receives the lab result from a laboratory is in essence needs to match that result to its inventory of patients. Also, a large health system, a Kaiser for example, clearly is going to have to be in a position to be a query responder to answer a query request. So, the simple model that we've been working from is the first of all the query source captures and ensures the quality of data needed to create query messages. So, this is, and we'll come back to this, has become an important issue about where do we need to try to work on and improve the quality of the data that goes into the query in order to improve matching. A query message goes from the query source to the query responder and the query message contains core, and we haven't quite settled on a word optional or menu attributes about the patient to enable the matching, and the query response message, it returns matched patients, and we're thinking about, but have more work to do, on what kind of match message data we might want to see come back to help the query source decide how to use that data.

Next slide. So, the again while this is still somewhat in progress, there seems to be consensus on the name, date of birth and gender, the administrative gender being core elements and then sort of a menu or alternative elements recognizing that you need at least a few from that menu of alternative elements in order to achieve a acceptable sensitivity for matching. As you can imagine, lots of sort of back and forth about these various things. Some thought that for example full middle names instead of middle initials might actually provide a significant improvement in matching. That's work in progress and suspected not known. Other things like zip code obviously are in use by various large enterprises for matching but subject to some of the constraints temporarily that I mentioned before.

Next slide. Data quality, we actually had spent a lot of time trying to think through what on the data capture end would be important to focus on to improve the quality of the matching by improving the data. So for example, a street address might be validated against postal service records and you sort out the issues of street versus avenue, north versus just as a street name, things like that to improve it. But then, the flip side saying we've got to be sure that or at least have some suspicion that the incremental value of

improving that is there. Well if nobody's using street ID for the matching, then maybe we don't want to spend a lot of effort there. And so, as we walked through that, there were a couple of things that did jump out and obviously some other things to think through. The first is that one of the biggest things that we may be able to do to help improve is allowing users there's also for example a required field date of birth required field, you would think you would always know that. For a variety of reasons, you may not and so users have been very inventive about creating ways. They put in 11/1979. They use the 0000, which it turns out to be some of the false system date. They use a variety of ways people find to satisfy the requirement for data that then actually creates tremendous problems in matching, and so the notion if you could allow users to say look I really tried hard and couldn't get a value for this would avoid that type of problem, sort of the no data available flag similarly around approximate values or values that might not be certain. There are people who don't know their date of birth. Not a lot of them, fortunately, but they do exist. And second is, there's clearly value in simple edits; things like, is the date valid, and if it's a date of birth, it's got to be for today or maybe include today but not in the future. So, that's an example of simple things that can improve the matching significantly. Social security number can't contain all zeros or all nines in any of the three subfields. Things of that nature that will just eliminate some of these common work-arounds, if you will. And then we did have discussion, although this isn't well evolved about opportunities, if you will, cross field checks. Things like is the first name and gender concordant that you might be able to catch at data entry time but this is need further thought.

Next slide, and I've got about three more and we're out of here. The next thing and listening to Walter's discussion this morning, I think the group will go back and look again at the CDA R2 header format but at least we have been discussing building from the IHE PDQ XCDP implementation guides for how to structure a message. Now this gets back a little bit to Carol's comment earlier on in the day, how many places, how often has this been implemented and there are at least examples of the PDQ query format being implemented that we might be able to learn from. Similarly to the comments about metadata this morning, we need expanded guidance on name structures especially for Hispanic and Asian names to build consistency and completeness in their representation, and we've been worrying about how we might add dates to time variant data. In other words, this was the address in 1996, so that matching might better take advantage of those kinds of time variant data.

Next slide, and then the work that we're trying to wrap up is the match quality reporting. In other words, what metadata would you ideally provide back to the querier to help them interpret this data? Things like what is the match processes competence level in the match or perhaps this name is a commonly occurring name in the match source and therefore the matching competence would be lower, so they're great out because it's still very much a thinking process that the group is going through.

And the last slide is just the beginning of sort of sort of a bibliography if you will of key references so not important to talk about, so that's the quick run through if Doug would allow me and certainly advise Walter or David to clarify or amplify any of those things.

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

So, thank you so much, Marc, for that overview. I think one of the things that I have to applaud the committee on is that we have often times looked at the problem of patient matching and what's the data that we need to use, what's the fields that are relevant? But in fact, if you've got fields that have lots of errors in them and you don't focus on data quality as well, you could have very, very good standards if you will or kinds of data but not be able to do good match. So, looking at the quality of the data, looking at the formats of the data, I think all are going to be really important aspects of this. I think sometimes we sort of say well if only we used these elements and they tested against test data sets, and the data is all clean and you can sort of say look at the match we get. It's 90% or 95% but out in the real world, it doesn't actually get to that. And so, I think taking the multifactorial approach trying to chip away at all of

the different pieces, I think it's been a nice thing to take a look at, and I think it aligns well with the kind of tools that we have within our armentarium when we talk about standards, implementation, guides and certification criteria, all of those. There are ways that we could use those levers, if you will, to help us get to the data to quality the algorithms and the like.

John Halamka – Harvard Medical School – Chief Information Officer
Can I just make a very quick comment before I go around the room, and that is Marc, thanks very much. Very, very helpful presentation. When you have a bold point, this says check whether first name and gender are concordant. Is that the boy named Sue problem?

Marc Overhage – Regenstrief – Director
That is exactly the, and again, not saying what's right or wrong but simply saying is there those kind of thinking that we can build in that the data capture stage to flag the user where there are possible places where the data may not be right and certainly in many cases it will be.

John Halamka – Harvard Medical School – Chief Information Officer
You mentioned PDQ as something that hasn't necessarily been widely deployed but isn't it just an HL7 2.5 message using I think just MSH and QPD meaning it is as pretty much a generic HL7 2 message as one would see.

Marc Overhage – Regenstrief – Director
Exactly as a format and that's all we're talking about is the structure. I agree with you completely. And in fact, there is both a version two and HL7 B3 variance that have been evolved.

John Halamka – Harvard Medical School – Chief Information Officer
So, in that respect, suggesting it is just going to be HL7 2.5, isn't so the committee knows been a particularly controversial, and then finally, on the match quality reporting, this is such a key issue and so I have mentioned to some of you in the past, I actually ran into a real sensitivity specificity problem when it turns out Boston has in it's very zip codes different ethnic distributions, and in fact Boston searching on the name Maureen Kelly doesn't actually work very well. And we have had issues where there are four or five people named Moira or Maureen Kelly in the same zip code, with the same birth date, and you're correct in your assumption that only the last four of social security or their payer ID or some other discriminator, in south Boston only would be needed for that name. So metadata around something of that nature is going to be required to make this sensitivity and specificity tradeoff a bit better balanced.

Marc Overhage – Regenstrief – Director
Well, you highlighted another issue John, that I'd certainly invite anybody on the committee to thoughts to share with us, which is in this last section, we've had some thoughts about it's part of what should come back would be well if you could just tell me a X, Y or Z, I could probably tell you some more matched patients. In other words, give me a zip code, I could give you some more matched patients, whether that would be part of what is returned when appropriate by a query source.

John Halamka – Harvard Medical School – Chief Information Officer
So I think we have multiple cards up. I see David McCallie, Carol Diamond, Anne Castro, Stan, and Jim Walker. So, David?

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Yes. This is David McCallie. First, Marc, that was a great summary of our discussions. I wanted to point out one thing that you mentioned at the very beginning about keeping the process open for additional approaches in the future, one of which might be some form of a voluntary patient identifier so it went by in a hurry, but I just want to register that we would like to keep that as a possibility. It's not certainly widely

adopted at all now, but it may become that way with the use of something like a direct address, a personal direct address as a way to voluntarily help match your data if you have an interest in doing so. And second is the distinction that we are trying to make that I think is important for the certification process going forward around validating the accuracy of the data that's captured when the patient is registered. It's possible to put in place all sorts of technical capabilities to do that but the work impediment of actually running through all those validations may be overwhelming. So, we need to make a distinction and maintain that distinction between what's technically capable of being done to validate versus what's practical in a busy hospital setting, some sort of a best practice because you could validate everybody to the level of missed level three assurance if you wanted to, but it would take a day of patience, so that wouldn't work so making the tradeoff between what we would eventually certify that an EHR could do like validate a postal code versus what you would be expected to do in the real world is an important issue to track. We don't have an answer yet but—

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

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
So Marc, thank you for pointing out that some people don't' actually know their date of birth, I have an 85-year-old grandmother who made one up and sticks to it, only everybody else thinks its five years younger than she actually is. But I did want to ask a couple of things; the purpose of your work just so I understand it is to make some recommendations for EHRs to better capture some of the information that might be needed for matching. Is that right?

Marc Overhage – Regenstrief – Director
Yes. Along with a some suggestions for standards for how that query would be transmitted to whoever it's transmitted to and whatever would be received back.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Okay, because obviously I learned some of this from you, but there's just such, I think a level of education around how as John was just saying different purposes and different populations require tuning of what actually works to deliver the kind of output in terms of data integrity that you want, so I just wanted to be sure that there wasn't going to be sort of a recommendation of five core elements all matching and then again you can add others because it sometimes, as John was just saying, actually last name is really not a great thing in certain communities, and we certainly found that in Katrina Health as well. And then, the only other thing I wanted to ask is does the committee look at any other sectors? I mean, there's nothing health specific about any of these fields, and I'm wondering why the propensity to choose a health standard where there might be other experience to learn from.

Marc Overhage – Regenstrief – Director
We did look fairly broadly and didn't find any good example, so we thought that we'd certainly welcome further members of the committee have suggestions for other than those to look at that both offered the flexibility as David said to add additional things and was one of the other questions that we sort of looked at in that matrix was are there sufficient benefits over it that asking folks who are implementing these things to learn something completely new was certainly one of the factors that we thought about, but certainly we welcome good examples to look at further.

John Halamka – Harvard Medical School – Chief Information Officer

I had no idea for example, Carol, if this works well or not but one wonders if homeland security such as the things that when you are checking in at the airport, what demographic identifiers are used to establish your identity for travel? There may be within the mean process something that has been done.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
I'd be curious.

John Halamka – Harvard Medical School – Chief Information Officer
So Anne Castro?

Anne Castro – Blue Cross Blue Shield South Carolina – Chief Design Architect
A couple of thoughts, in my business we experience matching challenges all the time, and one of the things we do is partial matches, so when you were talking, it looks like it was all or none and in order to increase success rates, we don't do all of the last thing we do up to ... the last name or something like that so you end up coming up with compromises that increase your success rate because—

Marc Overhage – Regenstrief – Director
Right. And we did not try to prescribe in any way how the matching would be done. For example, there's pretty good evidence of probabilistic matching approaches versus deterministic approaches or superior. There are proprietary algorithms. There are, absolutely those are all things

Anne Castro – Blue Cross Blue Shield South Carolina – Chief Design Architect
Just as long as they're on the table, I just wanted to say—

Marc Overhage – Regenstrief – Director
Right, but that's not saying anything about how matching gets done. The key question though that you raised is, and we had even last evening some discussion David was trying to get on a plane trying to make it miss the meeting, was around the how far if you return not matched patients in other words, patients that are close, how might, again, this gets to the issue of how much of somebody's PHI are you willing to risk exposure of?

Anne Castro – Blue Cross Blue Shield South Carolina – Chief Design Architect
Well, let me help you with that in terms of our experience in that I don't know how directly it overlaps but 5010 requirements disallowed our ability to put upon a .. list or so now it's more of a direct match or there's a phone call. There's a customer service issue.

Marc Overhage – Regenstrief – Director
And then it kind of comes down to a question many times when you put up a pick list of what is the human know that the machine doesn't know that it didn't incorporate into the algorithm?

Anne Castro – Blue Cross Blue Shield South Carolina – Chief Design Architect
Right, and I go back to garbage in, garbage out, one of my thoughts and what we do is have address,, tight address that information that it's at the front end when someone registers and there's even more of those available now because of zip postal discounts, so we're sensitive to that but that help us have a stronger storage of information on the front end.

Marc Overhage – Regenstrief – Director
Yes.

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

And that's very prescriptive on how you fill out the columns of what's in each portion of the address so just some thoughts to share.

John Halamka – Harvard Medical School – Chief Information Officer
That's an important clarification I think Mark was that you are not specifying the method of match nor the algorithm but the elements that might be required for some algorithm whether it's partial, probabilistic, deterministic, sound deck, sort of doesn't matter, that's up to the implemented.

Marc Overhage – Regenstrief – Director
Correct. Okay, Stan.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
A couple of quick things we found useful just to put on the docket and one is an indicator that this person was part of a multiple birth whether like twin or something, and then the other thing was actually a practice it was this person had ever been mismatched before because whatever led to them being mismatched the first time, we're likely to do again unless we're aware that we mismatched them. So, just a couple of quick things you might consider.

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

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Thanks, Marc, great work. Couple of thoughts on the core menu, Carol sort of mentioned that I'm not sure what the difference between core and menu optional really is. If a patient matched on absolutely everything except date of birth, I'm assuming that would be probably very high quality match and then when we talk about content sensitivity and Maureen and in south Boston, it seems to me what we're really talking about is likelihood ratios that each one of these elements probably generically and then some of them in a context specific way have different likelihood ratios or something like that, and if we express it that way, I think it would be more useful and more applicable to local situations. The second thing that's probably already obvious to you is that the matching is really context specific, so that if I'm talking to one of those work team Maureens in my office, and I can say do you have diabetes, do you have heart failure? I can do a whole lot of additional human matching and either be practically certain or rule out the likelihood that this is the right person. If I have someone ... in the ED, then there's a whole different set of criteria.

Marc Overhage – Regenstrief – Director
And this is where we're going with this notion of perhaps saying if you could tell me some other things but still when you start getting into the clinical characteristics of the person, you know, it seems you're starting to tread on thin ice and terms of now you're going to say I got three candidate people on the list which one of them has diabetes? And plus when you say something like diabetes, I know you're just using it as an illustrative example, but many of those things are incredibly common, and so aren't terribly discriminatory even among the people with those names, dates of birth, and so it's a tricky space I think to come up with a clean solution for.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
I think you're right and in terms of rules or machine processing that but as a clinician, you obviously it's a problem list and allergies and meds, but you can do enough to be more certain than the algorithm could be that this is the right person or be pretty sure it isn't, and it's an out for that.

Marc Overhage – Regenstrief – Director

This has been a point of a lot of discussion on the committee. Can you be certain or is it just that you're incorporating more data and if you're incorporating more data then perhaps that should become part of the match?

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
That's reasonable and just Marc, so you know, in my actual example that I gave to the committee the two Maureen Kellys both have diabetes, both have issues with fair skin and sunburn and both have hypertension. And so in fact, with the medication list that alerted us to the problem.

W
I just wanted to say thank you Marc, it's been an interesting challenge thank you. I just wanted to mention that in a federated environment where identity is shared across organizations, one of the attributes that often is shared is how the person's identity was authenticated, and I was wondering whether it would be possible to use that here if you if you refer back to what David McCallie said if the person was authenticated using a biometric, shouldn't that the fact that they were authenticated using biometric be shared when the information is shared?

Marc Overhage – Regenstrief – Director
That's an interesting point about and I guess one of the fundamental questions and this may be in this realm and as David said future ... which I love that phrase that the ability to include a biometric flag or something in that matching. I'm not quite sure where you're headed when you say so the fact that I now this person is authenticated by a biometric within your system, I'm not quite sure how that gets to you so maybe you could say a little bit more

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Just to proved more confidence that my information that I'm sharing is in fact belongs to that person. Or maybe that's outside the realms which you're addressing.

Marc Overhage – Regenstrief – Director
Good thought. Food for thought there.

John Halamka – Harvard Medical School – Chief Information Officer
Well I left out I want to make Marc is that Dr. Perlin here has provided you a challenge. So I need you to tell me about the gender name association of Gayle Warden, Frances Scott Key, Carol O'Connor, Jackie Gleason and Jamie Ferguson.

Marc Overhage – Regenstrief – Director
Just because Jamie can be spelled in many different ways and I actually have several female Jamies spelled differently than your name.

M
Absolutely.

John Halamka – Harvard Medical School – Chief Information Officer
So let's give an example of where we might be able to look cross fields in order to improve data quality and not necessarily of those so the example appreciated like you say a challenge to whether that could be done or not.

M

... behind time but Dixie gives preliminary view of the NHIN, and Steve if you just wanted to present they update on LOINC and CDX version.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Okay, alright, this is the I care the nationwide health information network power team and these are our members of the power team, we have people from the government as well as from private industry, and I want to thank everybody for participating. We have just barely gotten started. I believe we've had two meetings at this point, and so that the background to this is that the NHIN definition, the definition the ONC has given to the nationwide health information network is a set of standard services and policies that enable secure health information exchange over the internet. Point is, that NHIN is not a thing, it's not a group of wire. It's a set of standards and services and policies. The existing specifications for these services, standards and policies exist as artifacts of pilot implementation most specifically direct and exchange and more broadly focused use cases such as the IG profiles and the ... standards. Given that meaningful use reimbursements are not only seeking to but are attracting a broad population of providers that range from the small clinical practices to large integrated delivery networks, the ONC wants to be able to give to this broad range of consumers of the meaningful use reimbursements if you will a well defined set of NHIN transports security and content components from which a provider organization can select those that are most suitable for their environment and for the nature of their exchanges and be able to integrate these together and be able to exchange health information, so the charge for our power team is to begin with the NHIN exchange and the direct project, use those as our primary inputs to recommend a modular set of these components. Transport security and content components that in any provider organization could selectively combine and integrate to enable the trusted exchange of health information technology, and the emphasis on this work is on simplicity, ease of implementation and cross modularity among the components. In other words, it's a components actually tend to use together. We plan to present our recommendations at the September meeting, so the current status is that ... who leads the ONC's NHIN effort team at this point, first brief the team on a pilot that the ONC has launched to be that will extend through the end of this month to develop and cast a process for modularizing the existing NHIN exchange specifications. So they started with the corset of existing exchange specifications, and they are identify the secure transport building blocks. They're filling any gaps in the specifications and the developing criteria for testing the conformance with the testing that could be used to test conformant with the specifications. They plan public reviews through September, and so this work is the key input into our work. That work will not ultimately just be limited to exchange, but also will include direct. So right now ONC is preparing this initial set of specifications, a list of the initial list of specifications that are used in both direct and exchange, and they're doing an evaluation of these specifications, components, if you will, based on their maturity and the breadth of adoption of that particular standard for our power team to review. So this initial kind of grid, here are the components, here's their maturity and the breadth of their adoption will be presented to their power team on June 30th, later this month, and then, we'll provide input back to them regarding the process and the specifications that suggest additional components that we believe should be included, suggest where the components they've identified might be further broken down, etc. That's it.

John Halamka – Harvard Medical School – Chief Information Officer
There as we said, we're going to get formal finished recommendations in September and that was lined up with Doug finding the requirements because this was a very, very significant body of work so look forward to hearing the specifics.

M
... into perspective that's modularity building blocks and that directionality is so incredibly helpful so reports.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I would also like to add that I've seen the work so far out of the ONC team, and it's very admirable. It's excellent work. Thank you.

Steve Posnack – ONC – Policy Analyst
Between you and ... again, I think that's twice now, Judy, and I have to see if I can slip you something. As a policy guy, I'm starting to spend a lot more time in front of the Standards Committee. I don't know how I feel about that but there's definitely policy issues that we're talking about as well. We did attach a one page memo from Doug to the chairs explaining the process and the reason why I'm here today. So hopefully, you've had a chance to scan that in advance but the bottom line to get to Jim Walker's point, why I'm here today, is for the HIT Standards Committee to recommend to ONC that we seek the secretary's acceptance of a few new versions of code sets for the voluntary use as part of testing certification. And so, a little bit of background is that in the standards and certification criteria we're making as well as certification programs we're making, we acknowledge that certain vocabulary standards, more specifically SNOWMED, LOINC and CDX code sets, are updated and maintained in a more dynamic basis than say for instance HL7 2.3.1 as opposed to vocabulary standards. So to make it possible for testing and certification to be code sets to stay in sync with the updated code sets, we developed a sub regulatory approach that would let us go forward to the secretary to kind of raise the ceiling from our version of the codes that stipulated a regulation to expand the versions that would be permitted for testing and certification and use. And so, since then, both LOINC and CDX have been updated as we expected and the update dates are in the back of the memo there.

Again, to keep certification in sync with these newer versions or code sets we stated that we would check in with the standards committee to see if you all, as experts in these areas - and I'm sure that some of you have worked on maintaining these code sets as part of your day job, your side job, or your night job. So you're very familiar with them to see whether or not you had any input into a reason why we shouldn't raise the ceiling, essentially, for voluntary use as part of testing and certification. So the secretary's acceptance of these new versions would again simply just keep testing certification in sync with how they've changed. Just to give you a quick example with respect to CVX, there was a flu code that encompassed both preservative and non-preservative varieties of the vaccine, and that was split a few months ago into two separate codes to represent preservative and preservative-free. So CDC rendered code 15 inactive, although it could still be used in a retrospective type portion. But codes 140 and 141 are to be used to represent preservative and preservative-free. So that's come up as part of, "Can someone come in and use the newest code for CVX?" And this would allow them to do that as part of being tested and certified. That would be, presumably, and update to errata as part of a NIF test procedure to acknowledge that this data is available for testing and certification. So your input would be graciously appreciated and keeping your ears open for public comment in case there is any at the end of the meeting. After that we would just have a simple transmittal memo from you all acknowledging that depending that you don't have any problems with the newer version we would go ahead and acknowledge that these are accept – go through our process internally to get them accepted by the secretary.

M
So to ask the committee, recognizing SNOMED, LOINC, and CVX are widely used any many of you are quite familiar with the implementation details. Do you have any concerns about saying LOINC 2.34 is just as good as LOINC 2.33 and that CVX version March 20, 2011 is just as good as CVX March 17, 2010. Are there any concerns or controversies? So with that I presume the formal acceptance that you need to send this to the secretary. No objections to such formal acceptance?

Jodi, how does that work? She is the world's foremost expert on vocabulary.

Jodi Daniel – ONC – Director Office of Policy & Research
Can you come up to the mic and just identify yourself, Betsy?

Betsy Humphreys – National Library of Medicine – Deputy Director
I'm Betsy Humphreys, and I can ask a question maybe if somebody on the phone or Stan knows – I just noticed that it said December 30, 2010 for LOINC, but I would assume that maybe we are expecting another version of LOINC in a day or two or something? And I don't know whether this gets nailed into place, that we can't go for January 30, 2011 if one is coming out soon.

M
Yes, there is – I don't know the exact date, but we were working with essentially a Beta release of the next release at the tutorial at the LOINC lab meeting two weeks ago. So I think there is a new release of LOINC that's coming up imminently.

M
…in fact, it may have been our very first meeting, there were certain standards that are well instantiated. In fact, it's likely to be compromised by trying to course it through either a statutory or regulatory process. So we appreciate – and …Betsy Humphrey, National Library of Medicine. We appreciate your comments on that, and it's just the …

M
So, I think this is a catch case. In our rules, we created a bifurcated process where the public would let us know when there was a new version of the code sets, or we could proactively scour our landscape and say, hey, a new version has come out, etc., we should do something about it. So, if something comes out in the next few weeks you'll see me again in July, whether you like it or not. Then we'll just go through and process the July versions to kind of raise the ceiling again, acknowledge that that's available for testing clearance.

M
…comments – We'll just keep them crisp so that we can - and Floyd Eisenberg?

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant
Is there a way to change the wording to say that versions as they become available? That way you don't have to keep coming back here?

M
…point. Are you recommending that, Steve?

Steve Posnack – ONC – Policy Analyst
No, the process is – there are other regulatory aspects to how we pursue certain things. This is the process that we stipulated. We're just going to try and follow that.

M
So brief amendment to specific dates to identify Jim Walker.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Just very quickly, I think it's a matter of policy. I think it makes sense for us to do this. It doesn't take that much time. I think it's worth – and I think that's what Steve's saying maybe, or implying. It's worth taking this much time to just check it and make sure that the latest, as it's actually out there, is okay.

Steve Posnack – ONC – Policy Analyst
I mean, to give you test case that we had included in our preamble – If I came to you and said we adopted ICD-9 in our role, and now I'm recommending for voluntary acceptance of ICD-10, that would be a substantive change that we would, as the department has already gone through, rule-making to require as part of testing and certification. So these are really to grab hold of the regular updates.

M
It's a regulatory process that the pathway is rational, and as Jim Walker just indicated, allows a formal process, but is not overly burdensome. Nancy Orvis?

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Nancy Orvis with DOD. I would also agree that it's a good idea to do the quick approval of versions, but I also know that so many of these versions, terminologies, also just have quarterly releases or triennial releases. Those are going to go forward without having to come to the committee? Or is that –

Steve Posnack – ONC – Policy Analyst
We would, at each point in time – So we have a baseline in the rule and that is what people can come and get tested and certified to. What this does is allow for them to come forward with the newest version as it comes out. We would just come and check in and say, has it changed from being a five-digit code to being some nine-digit alphanumeric code, which would substantively change how systems would need to handle the code.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
That's a version change versus an annual update or a quarterly update to some of the proprietary code sets – so say like procedure codes which come out, or annual releases of the ICDs. We're talking about versions.

Steve Posnack – ONC – Policy Analyst
So we only identified LOINC, CVX and SNOMED as the code sets that would go through this process.

Betsy Humphreys – National Library of Medicine – Deputy Director
This is Betsy. Can I make one more point? This document clearly indicates the distinction between a new version of LOINC, which is a total replacement, and CVX where they've moved to a situation where they just issue a version or an update and you need to use the previous ones as well as the current ones. They're adding things, as I understand your notes here.

Steve Posnack – ONC – Policy Analyst
Well, interestingly enough, CDC took a different approach after we put out our interim final rule where they had just listed a date for their whole list of code sets, and now they're taking up vaccine code by vaccine code, indicating when it was last changed. So that's what the versions…

Betsy Humphreys – National Library of Medicine – Deputy Director
Okay, I misunderstood you then. I thought perhaps that the March 26 version just contains that one change. And if that's the case, which it probably isn't, but if it were the case you'd have to very clear that people are using multiple things; they're not just using the latest update with one code in it. So that's how I was reading what you said here.

M
Liz Johnson?

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Steve, my question builds on Betsy's question: You just need to be clear, because I'm not clear listening to you – is this an "and" or a singular requirement? Because you're telling us we have to update to the latest LOINC now, or I think it's an iterative process, correct?

Steve Posnack – ONC – Policy Analyst
No one has to do anything. If someone wants to come in and get tested and certified tomorrow, this would allow them to use the most recent code.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Got it. Just so we're very clear, because if the public listens to this, it's going through their minds, "I got to go fix my LOINC."

Steve Posnack – ONC – Policy Analyst
This is totally voluntary. Totally voluntary. Thanks for that clarification. Wes Rishel?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I've been hiding my head in humility here, because I didn't know what CVX was. I find I'm not alone on the committee, so I thought it would be worth asking.

M
Steve, why don't you take that and explain, to some degree, referentially in the document.

Steve Posnack – ONC – Policy Analyst
Codes for Vaccines – CDC administers this code set.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Today marks the very first. I'm sure it's because of hunger. Okay, with those clarifications, and Steve Posnack has identified a process where those routine updates would be brought before for acknowledgment. Essentially, it would allow a sub-regulatory process allowing people to certify against the most recent criteria. Was there a consensus, or any objections against that?

John Halamka – Harvard Medical School – Chief Information Officer
With none, Steve, with the committee support staff process. Thank you very much for the exposition of that. I will work that into the woodwork. We've got important discussion following lunch. Let's reconvene sharply at 1:00. So that gets us just shy of 40 minutes. Thanks to all for a great discussion.

(Lunch break)

John Halamka – Harvard Medical School – Chief Information Officer
Welcome everybody back from lunch. A very productive morning, and this afternoon we'll be focusing on meaningful use, stage two, and its implications from a standards perspective. You guys have seen some previous drafts of meaningful use stage two, so you recognize that there are really two kinds of work in meaningful use, stage two. There are thresholds of existing metrics that are enhances, but then there are entirely new transactions that require novel security, content, and vocabulary standards. So George, we welcome your comments and look forward to the discussion.

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair

Thank you, John. Okay, here we go, and I know my goal is to be done maybe by 1:30, maybe not quite that. Thank you to my members of the work group. So the agenda is, first I just want to go quickly through the recommendations that were approved by the policy committee, specifically the timing proposal, the matrix of objectives. I don't want to spend time on each objective, though, because I want to get to the requests for the standards committee.

So the timing of – we seem to have a formatting problem on my version, because we considered three options, the third of which we accepted and is off the slide. Actually, fortuitously the diagram serves as a third option. We considered leaving it alone; we considered delaying it by nine months by allowing a 90-day reporting period; or we considered delaying it in such a way that only those who adopted in 2011 would stay in stage one an extra year. So if you look in the diagram, you see the highlighted stage two. That would become a stage one. What this does for us is it allows the vendors to have a full year to implement our recommended changes. Yet, since it only affects those who started in 2011, it affects the minority of the adopters, and furthermore only affects them in one year. So this, we though, was the simplest way to get the maximum benefit.

Okay, so here are the objectives: Seen in red are the changes since the last time Paul Tang and I presented it to you. On this slide we see mainly edits for clarity. For example, on CPOE, making it clear what we meant by 60%. It's 60% of the unique patients, not 60% of all orders.

This one, we did some clarification on advance directives. The challenge is we don't want people creating numerous advance directives, a different one with every doctor they see. We'd like this to have a canonical copy somewhere and access to it. So therefore we reworded it to say that they should either store the objective, if it exists, or at least have access to a copy of it. In other words, access to a copy could mean they're storing it or they're accessing it somewhere else, and that's going to come up in my later slide.

Here we see again some rewording to make sure the denominators are accountable and so forth. So no major changes on this slide, although some of these will come up again in the …for the Standard Committee.

Engaging patients and families: The major change you see here is the second row – the discharge instructions - is being combined specifically with the following row about hospitals' view and ability to download information about the hospital admission. Under the argument that most patients when they leave the hospital actually want a paper copy of their instructions. So we weren't so sure how many people would actually want to have an electronic copy of their instructions. And in fact, that need to give the instructions is mandated in several other ways in health care. So we just want to make sure that the relevant information for the next objective, view and downloading, includes discharge instructions as one of the elements. That would ensure that whatever discharge instructions are given are included electronically. So it basically just simplifies it or makes it more accountable, but still stipulates that the discharge instructions need to be available electronically, even if the patient wanted a paper copy when they left the hospital.

Here we see what we had were several objectives initially: summary of care, care plan, and care team, which we then merged into a single objective, worked on that for a while and realized that we had to split it out again. So what we see here are four objectives: The first one should record the summary of care records; the second to record care plan fields, specifically goals and instructions for stage two, although I note that our threshold of 10% was voted in favor by a majority of the policy committee, although a minority wanted a 50% threshold. The third one is to record the care team member. For stage two, it can be in an unstructured form. The fourth one is the actually transfer of this information, collectively – the

whole thing – electronically to the eligible provider or the post-acute care facility. Ten percent of the cases of EP, EH is eligible hospitals, and at least a count of 25% in the case of eligible professionals.

Here we see public health does not change much. We have this signal to create a single standard and I'm going to talk about that in our later slide.

Finally, for privacy and security – pretty much mirroring the privacy and security hybrid team April letter, which the key factors are shown here. It's more detailed in our letter that I believe was distributed to, which is the letter that the policy committee sent to ONC. So, this set of objectives was voted on at the last HIT Policy Committee with a vote of 12 to 5 in favor. With those who were not in favor, mainly specifying the combination of where we're still going too fast or doing too much, which is really part of the same issue.

So now we come to the items that come about from the objectives that are important view beliefs of the Standards Committee. The first one is about the clinical decisions before its attributes for certification of an EHR. These are recently derived from I believe the Electronic Health Record Vendor Association list which Paul Tang then summarized in this list: Display source and citation of the clinical decision supports, make sure it's configurable based on patient context, presented of a relevant point in clinical workflow, or presented to users who can actually act on those alerts, and then it's integrated with the Electronic Health Record.

The second query, electronic and medication administration records, we have certain attributes we're looking for certification. Mainly, they're our goals. We want to make sure we check for the right patient, check for the right medications, check for the right dose, the right route, and record the time that the medication is administered. So those are the properties that we're looking for in the EMAR.

In the view and capability to download information objectives, and remember there's one for hospital and one for eligible professionals. We want to make sure the number of views and the number of downloads, because we need that to count the measures for compliance.

Next, the summary of care, record, and plan: That's that objective that I said was three, combined to one, split to four. In stage two, we think we would like to look again at the data elements – first of all, that we're included in the summary of care record, which is previously defined. Now that we're adding the care plan, we want to specifically look at that. Our recognizance says that there is no single, reasonable standard today for a care plan. So we've adopted, we believe, in stage two, care plan fields like goals and instructions which might be a free text – it might be an unstructured list if necessary. But basically, we put in those two key components: Goals and instructions.

Here are three objectives: One, hospital labs is now an objective in stage two. The hospital labs for sending data to others to structured electronic lab results. We believe that that should be done in LOINC where available.

Next, with regard to timely electronic access, the privacy and security tiger team is considering including a warning message before downloading personal health information. So in other words, when a patient – we're pushing the view and download of information. Once that information passes out of the provider's hands in to the patient's hands, the patient may not realize that they're now responsible for the privacy and security of that information they just downloaded. So perhaps there needs to be a warning message about that.

For the public health objective, there are really two things. It's a little bit statement ambiguous. One is, a single standard should be used for the submission of all public health data. So when we're looking across the public health objectives, we're basically doing different forms of surveillance. We want to make sure there's a single standard used across those data types. But in addition, we're beginning to look at uploading of reportable conditions that are not merely lab results. So non-diagnostic reportable conditions. There, we're looking for standards to be developed.

For privacy and security, as I said, we're mainly just mirroring the April 18th transmittal letter of the Privacy and Security Tiger Team, encryption of data at rest, single-factor authentication for patient online accounts, OTIS trail, date of providence, and view and download function being secure, and pointing out that stage three may require meeting conditions of participation in a nation-wide HIN. That would, therefore, in stage three, have certification implications.

Further, for stage three, we're looking to add new fields in demographics as per the recent IOM reports, in student medicine reports, specifically or especially about ethnicity and race. That is going to a finer granularity. IOM report dates exampled how this could be done, but suggested there need to be a standard creative. We recognize that different areas of the country need to go perhaps to different levels of granularity. If you only see a certain group very rarely, you may not know how to subdivide that group well at the point that the patient enters the healthcare institution, whereas if there's a lot from that group it may make more sense to subdivide.

Next is standards for recording family history. Next is capability to retrieve the advanced directives from the electronic health record. This again goes back to the idea that we don't really promote having a million different distinct copies of the advanced directive in different electronic health records. We really eventually want to end up with a single copy that can be reached from any professional who needs it. The mechanism for how patients will be entering data in stage three, which is something we signaled a while ago, and also remember that we also signaled there may be patients correcting their data. Then, related to that is patient-generated data being submitted to public health agencies. I think that does it. So now is Josh there?

Josh Seidman – ONC

I'll just mention a couple of the things that came up in the discussion. Some of the items on the stage three list are just things that the committee, in a sense, was also turning to you all to say, "Are there, for example, standards for recording family health history that could be used? Are there – before we get to new fields in demographics, are there potentially value sets within existing fields that could be considered for stage two?" And then something that came up – Jim Walker may discuss in the quality measure discussion, but the issue of patient-reported data as a goal for some new measures for stage two would obviously have important implications for standards and certification criteria. So those are some other things that in a sense could be part of stage two, but I wanted to get input from you all on that.

John Halamka – Harvard Medical School – Chief Information Officer

Thanks, Josh. So now a question for Doug, and these are process questions. We have heard about the potential policy requirements for stage two functionality and its implications for the standards, some of which may not exist or some of which may not necessarily be in a mature enough form to …regulations at this point. So, what I know about the timeframes, even though there's a year delay, that the intent is to try to get an MPRM out, let's say in December-January type timeframes and conceivably get final regs in mid-2012 with the idea that then there'd be lead time for the vendor community to implement software changes and have them rolled out. So let's say those that were tested in 2011 would begin their measurement period on October 1 of 2013. So even though there's a year delay, which I'm sure the industry suspects very, very much, the length of time we would have to get all these standards wrapped

up is short. So from on ONC perspective, is there through is to process, looking through each of these – and of course as a team, discuss some of these today, because some may be, as was just said, more of an evaluation. Are there such standards existent? But if you're starting to get into much more granular, let us assure there is a canonical set of standards for all public health reporting and vocabularies and one implementation guide that's not so easy. So, I welcome your thoughts.

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
So, I'd hoped to have the analysis done today, but we probably need another week or so to do that. And that is, if you take a look at all the things – the policy objectives that are coming out of the policy committee – and last year we created sort of a spreadsheet that had all the meaningful use policy objectives and of course finding sets of standards. We're going through that and updating that internally, and once we get a draft of that, that could be something that we would want to share with this committee and be able to get some feedback. I think the thing that's important – my big fear is that we're going to miss something and that there will be a big hole that is going to take us 12-18 months to do something and we just didn't think about it, because we didn't realize that.

So I think there's a couple of things. I think the first is, there are likely going to be things we need to do related to meaningful use stage one that need to be updated and fixed. So, I know that Judy and Liz have been charged and they got a survey out there, but what happened with certification? There'll be reporting I guess – is it today that you're going to do that? (Yes) And that will give us a sense of what some of our tasks are going to be with regard to updating those criteria. We have three levers to work with – we have standards; we have implementation guides; and we have certification criteria. And every policy objective should have a certification criteria associated with it. That's sort of one of the things that I think we need to be sure. Some of them will require standards, and most of the ones that have standards will likely require some kind of implementation guide. So one could imagine that similar to what we're doing in transition care, for example, with the public health reporting, is that if you came up with a series of building blocks that define the standard, you could come up with a couple of different implementation guides that said for case reporting of microbiology you need one and five plus two and three, and this is how you would implement them in the vocabularies that you would use, and the like. I think our preliminary analysis would suggest that although we have a lot of word to do, some of the work has started already. So, things like transitions of care – there's a group there that's looking at care plans and trying to figure out how that would fit into that. I think, when it comes to some of the implementation guides that we need the CDA consolidation project has done a good job of trying to figure out how to constrain that and make that easier to implement as well. I think the big thing that we probably need to put some effort into is going to be around certification criteria. I think last year when we went to …Use Week, we got standards, we got implementation guides, but we really didn't have an opportunity in this group to really think through the certification criteria. I'm hopeful that this year we'll have an opportunity to do that a little bit more quickly. So in terms of a time line and the like, I think we can help this committee by doing a little bit of that pre-populating of that spreadsheet with some of our best guesses as to what might go in there or where we need to have some additional work. Then, if we can send that out before the HIT Standards Committee in July, maybe we can have a little bit of time to just discuss that. Not as a formal presentation, per se, I mean, we can certainly summarize that, but more importantly that members of the committee have an opportunity to take a look at that, to annotate that, and then come prepared at that meeting to be able to say, "I like this criteria. This one isn't quite right." At the end of the day it's that the proof is in the pudding, and that's going to be sitting down with ONC, the HIT Standards Committee, getting NIST involved as well early in the process as they develop their certification criteria. So we've begun that process already. What we will need from this committee will be work from Judy and Liz to help us organize some of the certification criteria to see what worked last time and what we need to do going forward to make it better. We can get that spreadsheet to you and you guys can take a look and see if there are any holes that we've got there. I think one of the clear messages that we also have to

think about, and it comes up in some of the names we use, is that we have to continue to focus in on some of our early objectives, which were to begin to constrain the various standards that are out there so that we don't have 16 vocabularies for drugs, for example, but that we actually begin making some hard choices. And that will be something else that I think is queued up in August? Is that when we're going to talk about some of the vocabulary stuff and some of the constraints? So we owe you though some of that analysis and we're right now just going through our first draft, circulating it internally, and as soon as we get a draft that we can share we can distribute that to the group and you can review.

John Halamka – Harvard Medical School – Chief Information Officer
To just to drill down on this slightly further, so imagine we're talking about certification criteria for the EMAR. So, getting clarity to the country on what an EMAR actually is and how it should function and what is bedside medication verification requirements associated with that. You could say check with the right patients. Now, is that simply a statement that is functional, or does it say you are allowed to use Code 39, UPC, RFID of these three flavors, 2-D barcode, some print or retinal scan. Okay, can you show us, of those six I just listed, one is used by your system? Is that the level of granularity we would get to, because we'd better get barcode and RFID experts added to this panel.

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
Well, I think in some circumstances, particularly when, and Carol's not here right now, but when there are existing standards and there are existing functions that seem to have fairly widespread adoption, we may be able to name some of those things. But, what's important is to reach our policy objectives. If we can do that with a well-written certification criteria and allow innovation to occur around how people achieve that, that may be a better solution. I think when it comes to interoperability, those are the places where we're probably have to do more constraining. Because that requires everybody to have at least a similar way of doing things, whether it's transport content or the vocabulary. But, we can use the certification criteria to help us. We've talked about this before in the vocabulary group, and I think even here, where identifying a vocabulary and then testing it, both for the ability to handle a subset of that vocabulary as well as not breaking when somebody sends you a code that you don't recognize. Pairing those two things together provides some future-proofing of the technology, because as the CDC comes out with a new H1N1 test code, or something like that, that we have a way of dealing with that and making sure that we can manage that effectively. So I think, what I'm hopeful is that where it becomes important to let innovation thrive, but still make sure that we have achieved the policy objective. We're going to want certification criteria to test that functionality without specifying a particular technology. I think when it comes to interoperability, we're going to want to be much more prescriptive about what it is we expect people to be able to do so that if I do it the same way and you do it the same way, we have some assurance that we're able to exchange that information effectively. I think the interplay between the standards, the implementation guides, and the certification criteria – using certification criteria as well to help us advance that notion or that goal of interoperability. So even if there is a glide path where everybody can't do it exactly the same way, providing a mechanism with certification that assures that at least the exchange of information is occurring, if not in a computable way.

John Halamka – Harvard Medical School – Chief Information Officer
So the last controversial question: Now, George, did you say that the vote on this particular set of recommendations was split 11:5?

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair
Twelve to five.

John Halamka – Harvard Medical School – Chief Information Officer

Twelve to five, okay. So I'm assuming that there are certain numbers of these recommendations that would be considered somewhat controversial. So as we do this analysis, here's what you wonder: "Okay, Dixie, it turns out you need to come up with a canonical standard for counting clicks and it needs to be used throughout every electronic health record by October 1, 2013. But it turns out that's one of those that was considered really controversial." Then when you go to the public comment, everyone in America says, "Are you kidding me?" So, wait a minute, we will have done work for a year on a standard that then turns out not to be required. So I just want to be very careful.

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
Excellent question. So the ones that were controversial we recorded in the matrix and we disagreed on whether it should be 10% or 50%. It was that one objective. So that's the only one that we singled out as being a little different from the others, and we purposely wrote it down. So the five dissented, as I said, were a vague feeling that this was doing a lot, but not a ranking of objectives that this is the one to go out, or that one is the one to go out. So it could be expressed in one of two ways, because it's a full package. I think the five who dissented felt – some expressed as this was too much and not flexible enough, and others expressed it as, this is going too quickly. And Paul Tang pointed out that those are two sides of the same issue. But I think, for the most part, people agreed that this was a reasonable set of objectives. Other than that 10% versus 50% in the discussions leading up to the vote, the policy committee went along with the objectives on a one-by-one basis. So I don't think it's going to be possible – Yes, CMS might decide, just as they did the first on stage one, that something can't be implemented. For example, EMS decided not to do documentation, clinician notes, in the first round, although we're suggesting once again on stage two. So there's always something that can be dropped, but I wouldn't look at is as a policy committee coming back to lop off five of these at a later date. I think really the work has to be assumed that it's all of them, and then it will be up to CMS to decide. CMS has several options it could. It's not our recommendation, but they could make some of the menu. So they would still leave the certification and standards updated. That would be one way of making it more flexible. They could delay it further by saying it's a 90-day reporting period. You'd still give them the certification in time. So I think CMS has a lot of options to slow it down in case adoption is slow. On the other hand, if adoption occurs very quickly if our experience in the field is very strong, then CMS will want to go with exactly this.

John Halamka – Harvard Medical School – Chief Information Officer
… had a comment…

Jonathan Perlin – Hospital Corporation of America – CMO & President
Just to help to reflect the policy committee discussion: On the individual objective, there was basically consensus. The people who had reservations and didn't support the final recommendations, it was because of the aggregate that they were making those comments. You will see in the letter from the policy committee the sense of the policy committee was that the recommendations were actually part of setting the context of what are the goals for delivery system reform. What are the expectations giving their recommendation for a one-year delay with stage one being a three-year stage. That's why overall the sense of the policy committee was to recommend this full set of objectives.

John Halamka – Harvard Medical School – Chief Information Officer
Thanks Josh, thanks John. I think your question, John, was very good because the …is a huge amount of work, and Doug, as you've indicated, there is clearly policy intent. And, in the past, we've simplified the world. We've simplified the worlds in terms of standards in three ways: We've set their certain standards, and Shannon…isn't here at the moment, that are probably adoptive. To make sense and sort of check that box. There are standards that are adopted largely there but need a little bit of modification…And the third bucked is we're just not where we need to be. So I think John, you're hinting at the question of how we're efficient in this process, relying on that set of simplifications – maybe one that helps us be very

pragmatic about supporting the policy attempt. I think the other piece, and this is by way of – before the first quarter and before we're about to switch ends of the fields and have a minute to reflect, because we're not quite a halftime yet. But it is an extraordinary moment when you think about July 1st and all that is possible at that point forward. We'll hear from the implementation work group. Clearly, we've had discussions about the ways to better use certification criteria as a vehicle to define the policy attempt. In fact, in …ways to better certify. You may recall prior discussions about the linked objectives in the certification process and in a sense for those of us who's been in health management for a while, you may recall the joint commission used to test criteria in isolation, and now they do a tracer to sort of see what happens when you put things together. So if we're just learning about the survey and the input there and what creative ideas we can bring to the table to provide more coherent between not only identification of the standards, but the linkage with implementation guidelines and the certification criteria. But that said, I think we do have a tool at our disposal, which is parsing into ready for Primetime, needs a little work, we're not there, and linking to what appears to be – and then, Josh, those were comments, an aggregate – a selection of activities for which we really need to take stock. By the way, some of that is developmental or evolutionary from stage one, so another simplification may be that it's not all de novo work. Much of it evolved. I think, Doug, you're point that there are certain areas where interoperability is required, to have interoperability by definition, greater constraints than areas where the functionality is what is being sought and there is not as hard a requirement for a singular mechanism to achieve that functionality. So I hope that's helpful in terms of whatever charge really is, to find the standards implementation guidance and ultimately certification criteria in support of the evolution of the medical use criteria. But that is a terrifically helpful question, John.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I feel so much better, because I was hoping that ONC was going to give us a Christmas this year.

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair
Okay, so actually, I have a couple of comments and one, from implementing the clinical quality measures that were added into meaningful use – a lot of the feedback that we've heard at NCUF and I know have come to this committee as well, is many of the requirements to calculate these quality measures go above and beyond what was in meaningful use for certification or for even meaningful use. So one of the concerns would be, in some of the areas where I heard, George, you mentioned, and this can be answered in unstructured text, will create a problem if that content of that field that you're looking for has to be structures to meet a clinical quality measure, especially around care planning where for patient engagement and for including patients within care plan and care coordination, those are all up for meaningful use stage two quality measures. So that's one area. Another area that might be concerning is that the meaningful use metrics – the increasing up to 50% for reconciliation for meds and to include some other criteria – real standards for how you would capture that within a record. I'm not sure that they've been identified sufficiently. So we would need to identify other than its clicks. So it might be something to identify that CPOE was used. What does that mean? How many orders per patient? It's one thing to define a measure, but it's the other to say what's within the record that's captured. Another area I think around CDS – there may be some benefit for looking at, is it capable of managing triggers as well as getting all the input data required to manage CDS. Then, can it provide the recommendation. So there are a couple of steps that might be worth looking at. I had heard talk earlier that there was consideration of problem list reconciliation. So if the problem list might be where a clinical quality measure is expected to find a condition, or clinical decision support, and the problem list is not reconciled and kept up to date, that may be problematic because it won't operate necessarily the way you're looking for it. So, those were a couple of comments. The last was this issue of structured electronic lab results in LOINC. I think it's the resulted test in LOINC, but the result itself isn't in LOINC, it's the test that is resulted that you're talking about? Just to clarify.

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

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
George, I had occasion to look at stage one regulation this week to get a clearer definition of what a transition of care was, and found it was almost clear. Consider the situation where an institution that has a taxpayer ID number is fulfilling their meaningful use requirements using multiple products that are EHRs. Those are an EHR as far as meaningful use is concerned. Is there any time when a transition of care from one of those EHRs to the other counts as a transition of care in terms of the requirements in the meaningful use requirements? I would assume it would be the same for stage one and stage two.

M
Thanks, we had an explicit question on one of the objectives about, well what does count or doesn't count if it's within your group? Is that a transition that can count towards the total? Well, you want people within groups to talk to each other also, so it does, although by just talking within your group you meet some threshold and don't have to talk to anybody outside. That wasn't our intent either. So the way the work gets done, some of this will have to be worked out probably at the CMS level to come up with a way of putting together the metric. I mean all we're going to do is accomplish what's reasonable, so we want to be able to count what people do internally, but we want to encourage. The whole point is to encourage external communication in that example. Whether CMS would actually have to come up with a composite measure that somehow splits the metric between the internal and external, I would hate for that because you don't want to make this thing overly complicated. But it's not the kind of thing we could figure out at the level of the policy committee discussion.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I think that's fine. I think it's clear that there's an interaction between the number that's chosen – the numeric measure, and that definition. As you implied, as long as it's clear in the ERM then people can react to the choice of number. I had another question, but I forgot.

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair
I'm sure it will come back. Dixie?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Hi George, this is Dixie Baker. I'm a little bit confused about what's in the chart for meaningful use objectives versus what have I then identified as priorities with respect to privacy and security? For example, in the privacy and security objective, it has addressed encryption of data at rest, and that's also a priority. Secondly, I'm also confused about why the April 18 transmittal letter is the only one you listed there. The privacy and security tiger team has sent a number of transmittal letters beginning in August of 2010, all of which implied some security functionality. So I'm trying to figure out exactly what we're targeting to include in stage two relative to Tiger Team and relative to meaningful use objectives.

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair
Thank you, Dixie. Thanks for the opportunity to clarify it. So the first version of it was just to perform or update security risk assessment and address efficiencies and do whatever the privacy and security Tiger Team said. Then, in our discussion we referred back to the April letter, and remember that the Tiger Team is being voted on both the policy and standards committee. So in effect it's a parallel process and we don't want to – What we're trying to do is hand it off to the Tiger Team, in effect. So we don't have to just highlight that one letter. It's not that the policy committee said only follow that letter, that's the letter that we were pointing to in our discussion. Now how did encryption of data at rest come out? During the discussion, that was highlighted as an important one, specifically to highlight. And actually, Josh, do you remember the discussion why we highlighted that one over the others?

Josh Seidman – ONC
I honestly don't. Just to build on George's point, if I may. I think the meaningful use workgroup was working in parallel with the Privacy and Security Tiger Team and was basically saying that meaningful use workgroup was deferring to the Tiger Team for the purposes of the privacy and security objectives and meaningful.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
So the privacy and security workgroup has launched an activity where we're looking at the transmittal letters beginning August of last year for implied certification criteria and standards in all the transmittal letters. So that is an appropriate way to go. Okay, thank you.

M
Now, Doug, is that in your card? Speak up.

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
The only comment I wanted to raise, and it kind of steps back just a little bit, is that I think it's really important – Although we've got this division between the HIT Policy Committee and the HIT Standards Committee, I think everybody around this table understands that there's a very, very tight linkage between those things. Those who are software engineers will get this analogy, but we don't want a waterfall methodology where policy objectives are thrown over the transom a we're left to just try to figure out how to do that. In fact, I think what we really need to do is have a dialogue and a conversation, and that conversation sort of starts now in that if we identify either a real significant barrier, because either the standard isn't there or the certification criteria is hard, or whatever, I think it's important for us to be able to have that dialogue with the policy to say, "This is really hard how you've done this and how you've described it. But it may be that if we tweak it this way or we do it a little bit different or we divide it up into a couple of other pieces, we might be able to actually achieve your policy objective in a slightly nuanced way." So I want to give the flexibility in this group to be able to have that conversation as well.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Well, thank you for that. So that will be wonderful. In fact, what happens is the rush to get through is what …attempts to do. Josh gave an example earlier of the family history of us wanting to go to the standards committee, "Have you really assessed family history? Then come back and tell us what stage should it be in based on the standards that might be available in time." So instead, we end up with this process where we try to guess what the standards will be, often by talking to members of the standards committee – put in some reasonable first cut at it. Then it would be great to have a conversation. Then, of course, I would expect the standards committee to comment to ONC to CMS on if there's an objective that can't be done. Even if it's too late for the policy committee it can still be given to ONC to give to CMS.

M
…Josh's comment and Doug's comments and your comments were all converging on something much more reassuring, which is basically Doug will do a first-pass analysis, as was done before. We will take a look at that together. We will probably end up breaking that analysis into A, B, and C, you know, the three things that you suggested. It may very well be that you get certification criteria but you don't get standards because of the immaturity of the standards and the additional work that needs to be done for stage two. Now Wes, you remembered your second…?

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

I remembered. Thanks for getting me in the back of the head, Judy. So, I note that there are measures, there are objectives in here for sending information about transitions of care. I didn't see any about receiving them. That may be appropriate for the reason that I'm about to describe, but my question is, is it an oversight or is it something that's been considered. We all cut our teeth on data interoperability with lab data being imported into EHRs. In terms of the thought process necessary to import that data, that's as close to a no-brainer as there is. When some kind of a patient summary comes in, I think we learned a lot in the last few years that it's an active reconciliation process that has to happen. It's not simply, if you take it just as a report that's available, then you can sort of compartmentalize it like a lab result. It's a lot harder if you're going to take those allergies and problems and diagnoses and procedures and fiddle with the data that the physician sees while they're caring for the patient. My sense is that where the industry is going on this is that the vendors are more or less competitively developing ways to streamline the workflow of taking in this information as opposed to making it automatic to update problems, allergies, and so forth. I think we should at least recognize that and have some position on what we're doing. Maybe it's more appropriate for a stage three measure. It seems to generate some sort of functional certification issues as well as technical standards. I just think we should be explicit on that point.

M
Thanks for that. Walter and then Stan, and then we can move on to clinical quality.

Walter Suarez – Kaiser Permanente – Director, Health IT Strategy
Yes, this is Walter. Hi George, thanks for the update. The comment I wanted to make is to follow up on the comment that Dixie made and it's about a concern of a complete measure of the picture of what exists and what is needed from a standards perspective. Today we have heard about a number of areas, including patient matching, including some of the NW HIN provided directory recommendations, a whole host of things that are not lined up with or necessarily part of meaningful use. We're working hard on those, so there is a larger picture of all the different elements that we're balancing here in terms of standards. Meaningful use is a significant one now with this request. I think we need to – and that's probably the work, Doug, that you're probably suggesting that you would do: Line up not just this meaningful use stage two, but I think we've got to look at all the meaningful use elements plus all the recommendations from the other policy committee workgroups, including privacy and security, but the other ones that have made recommendations that impact or have some bearing on standards. Plus, all these other areas that we're working on including, like I said, the patient matching or provider directories which, again, also come from the recommendations of the policy committee. So I'm feeling like I'm lacking that kind of a complete picture and a good, comprehensive listing. The fear that I have is that we might be missing a particular element that we needed to work on with respect to the standards that is going to be critical in either meaningful use or some other program into the future just by virtue of the many areas we're dealing with. There might be things that might get missed. So my request, more than anything, is that we have a complete picture of all the different policy recommendations that tie to standards. The meaningful use-related, stage two-related recommendations and even going back to the meaningful use stage one standards currently and lack of some of the implementation specifications. All those that come together in some comprehensive document that we can have and then reference in our work into the next several months. Were you looking at that level of comprehensiveness, or were you focusing primarily on this meaningful use stage two in your documents?

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
I'm taking a glide path to where you want to go. What we need to do in the next week or so is to try to get at least this first pass through things. I share your fear. It's a thing that keeps me up at night, that we're going to miss something that's going to be critical. But it's also why I think having this shared with this larger group to make sure that we don't miss something, that we don't have blinders on because we thought something was there, and I thought you were doing it, you thought I was doing it, and nobody's

doing it. So, we need to do that, but I think we will have to sort of incrementally grow that and make sure that we get there. I think the other point that is important as well is that we have to focus at least on making sure that we've got the fixes for meaningful use stage one, particularly if there is a delay, that is going to last a little longer. We want to make sure that the certification criteria are correct. We've got a lot of work that we need to do for meaningful use stage two, but we should also, depending on the buckets that you put in, there may be some stuff that if we don't start working on it now, when meaningful use stage three comes around, we just simply won't have time to get there. So that's kind of what this spreadsheet is going to, I hope, get us at least that first draft. As people comment on it and as we expand it, hopefully it will become closer to that document that you're talking about, which will articulate where we are, what we need to be working on across all of the different policy objectives.

Walter Suarez – Kaiser Permanente – Director, Health IT Strategy
I think having that type of documentation and that type of a document will help us moving into the future, plot things into that document and keep it as a master plan, if you will, or at least a master reference point for the future.

M
So, I apologize in advance. This is a little bit off topic, and probably not even our business, but I don't know how else to say it – My concern is increasing functional requirements for certification, and specifically what I'm thinking is that I don't go to functional certification to decide what car to buy, I go to consumer reports or I go to somebody else. The real business, what we should be doing, is actually focusing on two things: Certification criteria, I think you can make the argument that that should be focused primarily on interoperability standards and enable the kind of data sharing, security sharing, secure environment that we need to support, and not function. Then secondly, the measures in fact are outcome measures rather than either process measures or some lesser form or measure. The reason I say all of that is what I see happening is people thinking, oh, I need to implement a care plan, when what I wish they would be thinking about is, how do I increase the longevity and quality of life of diabetics. How do I focus on reducing post-op infection rate? How do I decrease mortality for sepsis? What I see, basically, are people, if you will, teaching to the exam. They're focusing resources and not creatively about solving important problems but saying, I've not got to do family history in my report, or I need to do multidisciplinary care plans, which on the surface I think we would all agree that seems like a reasonable thing, but I think in some areas in fact, that will make us take our eye off the ball and think that we've accomplished something because we've got care plans in place. I say this particular one because we implemented care plans and found that we didn't have the outcomes that we hoped from that process. It had all to do with the fact that it didn't integrate well with the nursing and the clinical workflow. So the impact that you hope to have isn't there. So I know there's nothing actionable in this, I just worry that we're focused on stating functional things, which may not lead to the outcomes that we hope. I would hope we would focus more on interoperability and outcome measures rather than saying specific functional requirements that we have for this system.

M
… what a perfect segue to our clinical quality discussion, because presumably, Jim, you're going to solve all this, right?

M
I think actually, let me just take that as – Because I really do think that's an analog. Certainly, this group has had a lot of discussion, John, on – and this comes up between the policy and intent. Say for example, of reducing …thought taking that policy intent and mapping it to specific vocabulary and value steps. I think it passed through all elements, which include non-smoke forms of tobacco. I think you're segue of the direct analog to some of the challenges, and I think your recent hearing and input vocabulary

and value sets and work groups have been contemplating those elements in terms of realizing the greater policy attempt. I appreciate the framework that you've done, considering. So, but, in fact one reaches the intended policy outcomes but doesn't overstep the intermediate technologies that deliver that functionality. So, Jim, appreciate your taking it. I don't know if Karen Kmetik is calling in?

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Karen's not able to join today.

Karen Kmetik – AMA – Director Clinical Performance Evaluation
I'm on the phone, Jim, just so you know

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Oh, Karen is able to join today. Hi Karen. Do we have the slides up? So, I'm going to try to channel Dixie and use these old slides, but use Dixie's brilliant structure for reporting. We should have team members, but don't. John Derr is not on the list that is somewhere available. Our charge – the questions for you to consider today are none. We are on the way to having a substantial set of questions, I think, for the July meeting. Our charge that we're addressing currently is to address the NQFs quality data model in terms of identifying code sets that would be used for expressing each of the core concepts of that data model in a way that particularly measures guideline developers would be able to use so that they produced measures that were actually quickly implementable in the NQF, ONC, HHS, EHR, clinicians tunnel. Sorry, we have too many things here. So what we've done recently, we've had the joint hearing with the quality measures workgroup with the policy committee on May 19th and came up with some recommendations that are not quite so …to my report today. Then, beginning a couple of weeks ago, have had a set of preparations for the first joint meeting of the vocabulary workgroup and our group to address the quality data model and the code sets that would be necessary to use it effectively. That work has been prosecuted by Floyd Eisenberg, but Tom Tsang and Pam…and ONC by the Accenture consultants that have been working on those things. I'm going to go straight on to that. So, what we want to do is assign code sets to the fundamental concepts and the quality …model … said. You see that the Accenture group has done preparatory interviews with workgroup members, with measures developers and other subject matter experts. We had our first joint meeting two days ago. It was remarkably productive. I think having the two groups together was critical. The two skill sets need to be together to work together fast enough and actively enough to really solve problems and go on to the next thing. We worked through the first 7 or 8 out of 23 concepts. I think Jamie and Betsy were impressed with how many of them we were able to put on the vocabulary task force parking lot for further development. But I think they are pleased that they have a focused set of questions to answer that will really get us down the road. We are planning probably two meetings between now and the July full committee meeting. We believe that we'll be able to get through all the concepts and have maybe 75% of them with a clear consensus recommendation on a code set, and the others at least have identified a reasonable road map and issues that the standard committee may need to help us resolve. Upcoming issues, I will tell you when they're more upcoming. So, happy to entertain questions and get help.

M
That was very succinct, much appreciated and obviously a good segue into the next discussion on vocabulary and code sets. But right now, the only card up is yours, Jim. Are there any questions for Jim?

Judy Murphy – Aurora Health Care – Vice President of Applications
I'm not sure where the right time to bring this up is, but I'm going to take the opportunity to do it here. It's something I brought up at the last meeting, and that was we're getting a lot of transparency and discussion around the meaningful use metrics for stage two. The regular metrics, if you will, but not the quality metrics. I know that's not directly related to the quality model, but what I'm starting to think of is the grid that Doug was alluding to, where he talked about having the metric itself and then the standard and then the implementation guide and the certification criteria. Has there been any discussion about doing a similar thing with the quality measures? And I'm going to wrap it into this a little bit – use the QDM to sort of frame that? I don't know.

M
We have raised that issues. I'll just channel Walter. That's a critical need to be – there's so many actors involved in this to do what Doug was talking about, to really have interactive, productive conversations between us and policy but also between all of the different workgroups of the standards committee. It seems to me we really do need, and I think we're moving toward a spreadsheet that would have that sort of, here's the topic, here's who's responsible for it, which workgroup, by the way, is supposed to do it. And here the question their supposed to answer: What the code set? What's the other standard? What are implementation recommendations? I don't think we can see how we can work through all of this without that kind of communication tool so everybody knows what they're supposed to be doing next, and we don't, like Walter said, end up nine months down the road and say, "Oh, heck, if we'd started this last July, we'd be in a lot better shape."

Judy Murphy – Aurora Health Care – Vice President of Applications
Thank you, that helps.

M
QD will underlie those efforts more than frame the work, I guess would be the way I would express it, although I'm not sure that's right.

Judy Murphy – Aurora Health Care – Vice President of Applications
I think that helps on that topic, and maybe what I'll do is then ask the chairs if maybe at our next meeting we could get an update on the quality measures for stage two. There's been very little activity since comment period. That closed a long time ago, now that I think about it. I don't know if those quality measures have changed or – I just feel like we should have more transparency, not just for this committee but for the public.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Absolutely. We absolutely need to settle the measures and the timeline to work against.

John Glaser – Partners HealthCare System – VP & CIO
And to that point, Jim, I talked to my fellow CIOs across Massachusetts and the country. They say, "You know this meaningful thing, stage one, it's not so bad except for the quality measures. They're death." That is, they are perceived as so hard to deal with. Data quality issues and coding issues and extraction issues are just – I found CIO after CIO saying, "We can't attest to meaningful use stage one purely because of the quality measures." So as you and I have talked about before, things like making all exclusionary criteria optional, and what I worry about is your last point on your last slight. The capacity of EHR is to handle increasingly complex measures. Maybe we actually don't want increasingly complex measures. Just a thought.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
I think, rather than parsimonious, I'd like to suggest the phrase "minimally necessary." We want it to be as simple as possible, not any simpler. Without the measures and without that strong …of conversation that Doug's talking about, I don't think we'll do a good job of coming fairly close to minimally necessary.

Marc Overhage – Regenstrief – Director
This is Marc Overhage. I think the other thing that you're seeing there in your comment, John, is that we are forcing people with the quality measures to use the data that we were hoping to capture in phase one. All those issues that they describe of data quality and the difficulty of structuring it and making sure it's consistent are useful work, I think. There's a question of how far we push them, although I can still see John Glaser standing up saying, we need to make them flat. We're certainly doing that in a lot of ways, but I think that the only way that the data itself will improve is when we're using it, such as in quality measures. Say I don't know when is the right time and how fast to push that, but that seems like a positive effect of the quality measures.

M

However, let me counter, Marc, that one of the thing CIOs are telling me is that the data elements incorporated in the quality measures go actually beyond the data elements required in stage one. So they are changing their workflows around things that were never intended to be part of stage one. So, true or false, that's just what some people are telling me – things like comfort care measure documentation, etc.

M
…Floyd Eisenberg

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant
So, I really appreciate and understand everything we've just heard, and frankly that was the reason for my comment from the policy committee discussion, that if we are moving ahead with different kinds of quality measures and they're not in certification requirements, we're going to end up with the same thing. So I was just trying to indicate that. The issue is having a measure statement, which is what we've looked at so far. It doesn't really tell you what you're going to need to calculate the measure. So we did try to evaluate QDM around the statements, and until we actually see the measures, we wouldn't be able to know what impact there is for your CIOs; what impact there is for the standards. So I would support having that discussion of what are they. Are that's separate from whether they're endorsed or not. I'm just talking in general, for measures.

M
I think, consensus around the table. Just some final words, Wes, we're recognizing that the hour and a couple more reports outstanding.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
So, be quick – I just wanted to comment that certification is nice, but it's not responsive to the issue that John raised, which is physicians having to change their workflows. I mean, you can certify the system can do X, but that doesn't mean the way it's installed anywhere will do X. It just means if you try to do X, you might succeed. And the issue John is raising is that physicians are having to do documentation they did not always have to do, and I think we should focus on the bigger issue as we evaluate criteria.

M
It reminds me, again, hearkening back to our initial discussion about them, interaction policy committee and the aspirations from …The fast versus slow is one set of tensions. The rigidity of specification versus list the specification is another. Here, it's probably aspirational in the reach versus the adequacy of the vocabulary an code sets that are available and the data model. In a sense, I think the lower level of clarity around the quality measures and the certification criteria is demonstrative of that tension, where the intent was a little bit in advance of the data model and see fundamental elements that support that, notwithstanding the …comments on whether you can achieve an outcome by virtue of specifying the process. That's I think – very good point, but a different discussion. So we have a sort of tension here, and I really appreciate, Jim, you've done actually carrying the thread conversations since the very beginning, and so I appreciate very much this report and the work, not only of you and Karen, and the clinical quality workgroup, but I want to segue here to really the set of tools that helps us then unite the standards implementation guidance, the certification, and also helps bridge that tension between the aspirational nature of the policy intents and the tools we have to achieve them.

Thus, let's turn to Jamie Ferguson and Betsy Humphreys of the clinical operations workgroup, but specifically report from vocabulary task force. For those online, Dr. Betsy Humphreys, National Library of Medicine. Appreciate your being here. Jamie, many thanks to you for continuing the hard work for clinical operations worker.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes, thank you. Really, I'm going to do a brief introduction. I'm going to leave the heavy lifting to my partner Betsy here. So, in the vocabulary task force the charge or the requests really haven't changed. Our methods of operating really haven't changed except that we did have an important joint meeting of the clinical quality and the vocabulary task force just Monday of this week, which I think Betsy will go into

in some additional detail. Then, we're still dealing with this important issue of whether it's possible from a policy perspective to have a certification requirement precede a meaningful use requirement, so there's time to implement the capabilities fully in the EHR before you have to actually use it for meaningful use measures. To that end, we've been delayed. I know we talked about that in the last standards committee meeting. We've been delayed somewhat in scheduling a meeting with the right folks from NIST, so that's scheduled for later this week. So we'll be able to report on that next time, but that has to do with how NIST is managing that program. So we're also then talking about the requirements for subsets, and again we talked about this previously, but we're continuing discussions on the issues around using subsets for certification, where in fact a broader set of the underlying vocabulary standard may be required in actual use. So this gets to the point that I think has been made amply here just recently about the products being able to accommodate and not reject codes that are needed that aren't in the certification subset. So, I'm going to turn it over to Betsy now to take us through the bulk of the discussion here.

Betsy Humphreys – National Library of Medicine – Deputy Director
I think that, just to bring up some recent developments that are relevant to achieving meaningful use into some of the discussions or some of the issues that we discussed on Monday in the joint call. As of May 31, we now have another subset of LOINC which is the Top 2000 Lab Observations with a mapper's guide connected to it. This, I think, is certainly a very useful tool for focusing people's efforts on trying to get standardization perhaps connected to local systems that they may be using and focusing their efforts on the place where it may make the most difference in terms of the number of patients and observations that are affected. On June 6, LM released a sort of alpha draft of a subset of RxNorm that is attempting to focus on prescribable drugs – that is, drugs that are prescribable now. Obviously, in terms of the overall use of RxNorm in the analysis of patient data and in clinical data warehouses and many other purposes we could all think of, you have to have RxNorm having drugs that are no longer prescribable. But if you're focused on trying to implement capabilities for clinicians today, in terms of ordering then it would be nice if you could have a subset that kind of focused on the ones that make the biggest difference. As I think Jamie reported, the last time in May, this is a first draft and we have plans to incorporate in it the RxTerms view of the world, which sort of takes an aggregated view of certain types of dose forms and so forth and may also be useful in terms of facilitating data entry and recording, and also certain types of aggregation retrieval. The other issue we have, I think there has been a hearing on the issue of device nomenclature in the past, and I just wanted to alert everyone that as of May 26, CIHT STO which owns SNOMED and the Global Medical Device Nomenclature Agency are now in formal negotiations regarding the inclusion of the GMDN content in SNOMED CT. We'll see how that goes.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
And actually, if I can just jump in for one sec before we leave this page, on the RxNorm subset, I'll add that we're actively seeking input from those who are doing e-prescribing in the country who can provide input on OTC products that are prescribed using electronic prescribing. We would like to see added to RxNorm so that it's a more complete set of everything that's typically ordered including the OTC products.

Betsy Humphreys – National Library of Medicine – Deputy Director
And the issue there is to figure out which ones to add to the subset, unfortunately because changes and improvements in the flow of data from the FDA to NLM in terms of daily med and also we use that as a source for RxNorm. I think RxNorm is going very to getting a much larger set of these OTC products, but the issue is that some these OTC products, I have to tell you, we're hoping that physicians are not prescribing.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
And again, so just to clarify, this isn't products that are dispensed by the pharmacy strictly. We're talking about what is it that's prescribed using new prescribing.

Betsy Humphreys – National Library of Medicine – Deputy Director
Okay, so we started going through the set of categories that had been identified or key sets of values for the quality measures, and I think allergies was first because it begins with "A." This gets at the issue that was just being discussed – The fact that the quality measures have requirements that are not reflected

elsewhere in requirements. Floyd pointed this out to us day one a long time ago that you're over here saying you need these kinds of code sets for stage one, but in fact for a quality measure that might also be part of stage one, you need something else. So we've had a lot of discussion already in the vocabulary group focused just on the regular certification requirements for chunks of the record. We were not focusing on non-medication allergens. But hey, they are actually required. So, I think that we have started working through these issues. Some of them are very easy in terms of medications and active ingredients. Some of them are more complex in terms of inactive ingredients. I think that the clinical quality working group has very valuable impulse which we really applaud, to have the fewest number of different vocabularies that can meet the requirements. We're all in favor of that, but obviously, it has to be the smallest set that actually meet the requirements and line up with what's being used today that is really built in to workflows and so forth. So, we'll be back with more of this.

Medical devices – We had a very good discussion here and I think we were actually led to a good position by the experience of the measure developers. That is that as of right now, there are a limited number of measures that require some medical device terminology. Not a large number. This is bound to increase, and of course, given the number of devices that are in patients and are being used in homes and whatever, we all understand that we need to make progress toward a detailed terminology for medical devices just as we need to make progress toward having unique identifiers for the specific devices. However, there are reasons why it's difficult to pick one today and it's possible that the negotiation between the ISP, STO and the GMDN agency may remove one of the barriers to the use of GMDN, which Chris has pointed out on multiple occasions. As a very restrictive licensing policy, I think it basically makes it unusable in health care. So, this is good, though, because it looks like we can meet the requirements that we have in the short term by designating SNOMED as an initial interim one, and we'll monitor – the vocabulary task force will monitor the development and come back later with a recommendation about a more detailed, more comprehensive thing for devices.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Betsy, before you go on, I think it's important to also note that this is about a device terminology and it's not a unique identifier. (No.) And sometimes people mix those up.

Betsy Humphreys – National Library of Medicine – Deputy Director
They do all the time, and we need both.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
So, can you comment at all about some of the work that's going on with FDA, for example?

Betsy Humphreys – National Library of Medicine – Deputy Director
FDA, and we're all in cahoots on this – I think that FDA is going to be publishing a proposed regulation about unique device identification. Within the sort of minimal data sets that you have to provide to register the device, they are interested in requiring the use of a device terminology as one of the elements to categorize device. Their choice would be GMDN if the intellectual property issues can be resolved and the reason why that would be their choice is because it is sort of an internationally developed thing with regulators in other countries. However, it's clear to them and to us that they're not going to be a standard if it isn't one that is available throughout the U.S. in some reasonable form. So, I think that I did discuss this after our call with Jay Crowley at the FDA to say what would he see about this. Some SNOMED CT has a small number of thousands of device terms in it. It's not like there are none there at all. He thought this was actually a very good bridging thing and gave us a little more time to see if we can end up in a better place and make a choice based on what the fact are later on.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
If I can just augment that a little bit, you may recall that a few months ago we had a hearing which included a session on this exact issue. So the way I would describe it is that the long-term happy path is that GMDN becomes part of SNOMED CT and is specified in a FDA rule for the unique device identifier, and then can be used without those IT restrictions and implemented over a suitable time period of some number of years. That's a long-term happy path vision, if you will. In the short term, GMDN is not only not used in the U.S. for healthcare, it's not used anywhere in the world for health care devices today. So

it's actually just not used for that purpose. It's used for other purposes in a number of other countries. And it does have the IP licensing restriction. At the same time, the UMDNS is currently used by a large number of U.S. hospitals and other organizations for unique device identification. So one of the points that we discussed with the FDA in the hearing was about how to potentially bridge or provide transitional capabilities as part of the unique device identifier, to make those who are using the UMDNS today have a transition path do the GMDN in the long-term. So in other words, this is going to take some number of years to play out. So if a device terminology is actually needed for meaningful use and other rule-making purposes today, we'd have to go with both or all three. We could not pick one today.

Betsy Humphreys – National Library of Medicine – Deputy Director
I'm just going – this is what Jim alluded to: Everything we went through it ended up being on the list of things for the vocabulary task force to take care of. But we have some good questions and issues to address these things around patient characteristics of different kinds, like gender, marital status, race, that sort of thing. Then we have a bunch of issues related to conditions, diagnosis, and problems, but those are the same real issues that we deal with for the problem list so we can fold those things together. Then there's the issue of non-laboratory diagnostic studies – radiology, etc. Then we had two categories around this notion of interactions and the recording of the same between patients and clinicians or other parts of the healthcare system, including face-to-face telemedicine, other communications like mail and email. We really need to tease this one out because we need to figure out what requirements we actually have the terminology versus what is really more about structure of the record and…Then we have a whole bunch of other things we didn't get to, although some of them, and I've listed a number of them here. Some of the things we didn't get to, I think there is no disagreement. What was being recommended by the group is the same as what would be recommended in general by our group. So we can move over this quickly, I think. But there are some little issues here and we're talking about things like family history, functional status, that component of the health record, lab test orders as opposed to results, which I think we have covered. Interventions of various kinds, physical exam, preferences of the patient and system resources, this has to do with what have you got in your system. How many doctors, I guess, resources you have in the hospital and provider. So we'll be moving along on those as rapidly as we can.

M
Just one comment for you guys: I was looking at schema.org yesterday as we're noodling through these micro data, micro formats, what's Google, Bing, Yahoo doing. What struck me was, on one page I found 200 different schemas that gave everything I possibly needed as the developer who understands code sets, vocabularies and structures for free. So Doug, where are we in getting these guys the same standardsthatyouneed.org?

Betsy Humphreys – National Library of Medicine – Deputy Director
You know, on that same – I'll let Doug answer that, but I wanted to comment that what NLM and others have been focused on is the identification of the actual subset of vocabulary. That is, the content of it that would be helpful to people, like the 2000 most frequently done this, or the most frequently seen problems. Where we're not there and where we could us input from anyone – all of you and anyone you talk to – is what are the most useful ways to – the format and ways, the things that would make these most useful to people. We had on our first slide that there's maybe a difference between a subset that allows and accreditor to say, yes you can read this thing and you understand it. What makes it easy for you to use in your system? I think one of the things that we find at NLM is the people say, "Just give me exactly the piece of SNOMED or this thing that will help me do my job." They extract it that way, and they throw away the free synonymy that UMLS provides. Which means, of course, from a functional point of view within their EHR they can't deliver what they could if they would just take the rest of it or make use of the rest of it.

M
And the other soft of thing that I'm talking about is exactly what you described: Give me the 5000 most commonly used SNOMED terms, record symptoms, conditions, complaints, etc. cross-walked to ICD-9 and -10 where it's relevant. And that's the CSV download, click here, it's free. The 2000 most common LOINC codes, the lab compendium for 98% of all orderables, click here, it's free. Marital status, ethnicity,

you know, on and on about 20 of these, and it's just one click in their CSV files and I can hand it off to my developers who are my commercial systems and they just import right in. We're just happy and interoperable, and it's going to be great. So, what do you think? So, Doug, it's not Summer Camp but more like back-to-school?

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
Let me just have a comment and then I'll try to answer your question. I ran out of paper in terms of writing down my to-do list, so I'm going to have to start keeping track someplace else. The first thing is that I think the vocabulary area is one of those areas, and we talk about areas in which we want to have – kind of let innovation go forward. This is an area I think we have an opportunity to constrain, to identify those things that are going to be critical. Then also, as Betsy's alluded to, by identifying subsets and building tools around that will help people migrate from where they are to where they need to be. I think that's going to be a really important part of this particular workgroup's activities. We are working on trying to figure out ways that we can provide a – this team, actually, I think from the vocabulary group, there's notion of a one-stop shop. Where do we go to get a whole bunch of this sort of stuff? So I saw a brief demonstration of a prototype that we're working on right now. We pulled the slides from today just because as soon as I announce it publicly, everybody's going to want to go there and it's not ready for that just yet. I think by July we should have something that will begin to kind of collect all the pieces together. It'll be a draft, it'll be a little bit rough around the edges, but I think it's a way of getting there. I think long term and Betsy and I had conversations about this as well. If we can develop a way in which we can use standards such as CTS-2 and some of the other standards for exchanging vocabularies, it allows us to distribute that work and it allows us to have a one-stop shop, but still tap into the expertise that go with the NLM to try to pull in some of those vocabularies and terminologies as well. So we're working towards that. We need a little bit more time, given the other stuff that's going on, but we do recognize the need to have sort of a place to go to that will have implementation guides, links to where the standards might be located, and vocabulary value sets that might be helpful.

M
I just happened to notice – just for the public record, you may want to invest in this: www.codesteps.org is available at GoDaddy.com. It's unclaimed.

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
So good discussion there. Let's take a few cards up. …David McCallie, Jim Walker, close with Floyd Eisenberg on this section of the conversation.

M
So I have a quick question and then a time-bomb comment that I'm going to leave the room before the bomb goes off. The quick question – Jamie is so soft spoken that he doesn't ever trigger our irony detectors. Could you explain again why it is we want to use a code set GMDM that's not used in health care anywhere in the world?

M
Because it was picked by the FDA.

M
Okay, alright.

Betsy Humphreys – National Library of Medicine – Deputy Director
Good answer. I think if they proceed – if they do what they wish, and it's generally available, then at the moment the device has cleared all the standards will be with it at that time, which would be a good thing.

M
I think there's a lot of – if it's something that's starting from scratch anyways, then anything that you have to get FDA clearance on anyways, it makes great sense to do what they want. So I've been trying to find someone to renegotiate the 10 commandments – I'm trying to get the coveting fixed. But, I haven't been able to do that, so I'm going to try the next – (Thanks for clarifying). I tried to pick one that was pretty

neutral, anyway. I wondered if it's possible to renegotiate the ... for coding instead. The thing that's most troubling in the world that we've discovered in terms of ease of implementation of catching the wave, if you will, of implementers, is the notion that the code that identifies the concept should be deliberately free of any suggestive content. It makes perfect sense in many ways, but it also leads to things like noise and things like that that have created a noise-to-content ratio in messages that's very discouraging to developers. I wonder if there is any form anywhere to try to reopen that discussion.

Betsy Humphreys – National Library of Medicine – Deputy Director
You know, I think that I have, from my perspective, the really serious downside of that, in terms of if we ever get to any secondary analysis of data, if we ever get to real interoperability, is so bad that I guess I could – I would be interested in more creative ways of making it easier for people to implement these things than dropping that.

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
I was going to give a one-word answer, which is synonymy. So, without destroying what exists, it's possible to create synonymy in some new way that meets your criteria and have that also included in the world of vocabulary. But that would be sort of a non-destructive path, if you will.

…

M
As I say, I was just going to drop the time bomb and leave. So I dropped it.

M
We were prepared for more.

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
If you show them death, they'll accept pain and suffering.

M
So with that, just to colleagues out there, we strongly encourage your questions. They have very less work when we're sure we give adequate time to clinical notation, public comment.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Okay, thanks. This is David McCallie, and it's not so much – well, maybe it's a question but I don't know that there's a simple answer. Some of these domains in your joint discussion, like family history, physical exam, and so forth, is obviously a lot more than just the code values that have to be thought through. So what of the grammar, the way that you put these things together. Are they pre-coordinated, post-coordinated? Is there a process to address a broader construct? Maybe it's just more joint committee meetings, but I'm thinking of detailed clinical model where if it's underway it's going to be …Stan's work.

Betsy Humphreys – National Library of Medicine – Deputy Director
You know, Stan is on this group, and we never forget this issue.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
That's all I need to know.

…

M
Stan is on the group, and I think we're in agreement. It's not just these elements but the context and how it relates and the entire QDM model does address that. We were asked to just present the high-level concepts, but we will be presenting the whole thing for the group to look at, not just the concept. So it's in the model as it is.

M

The only two bits I would add to that is the model that has the most pure representation of what you want to capture and the process of capturing it from clinicians in a user-friendly way may not line up well. That is a huge struggle to capture structured information from clinicians in a free-flowing way that then maps to a pure model. You can't just stop with a pure model. There needs to be some thought about the surface manifestation of it. It's a really hard problem. We spent decades in industry not solving it.

M
I think it's pretty clear that there is a huge amount of work. This is a common pathway for so much of what was discussed today. Thanks for your very provocative introduction to this hearing. I want to make sure that we've been short-shifting our colleagues at the implementation workgroup, and also be respectful of public comment periods that occur within the anointed time as part of the federal advisory committee. So I appreciate Judy Murphy and Liz Johnson who've been reviewing the codes and providing preliminary review on the inputs of the blog on improving the certification criteria process. So, let's turn to Liz Johnson and Judy Murphy.

Judy Murphy – Aurora Health Care – Vice President of Applications
Thank you. So we have the requisite slides. The next slide lists our working group members. The only activity that's really happened since our last meeting was the blog was open for comment and it did close just on Friday. So, needless to say, we did not get a chance to summarize all the comments prior to today. So again, we'll be able to bring it home and help the committee end on time today, because our presentation will be very short. We will ask Judy to give us more time at the next meeting because we will have some preliminary results to discuss. So this is the same timeline we shared last month, and basically we're in this compile and summarize survey comments June 20 to July 15 timeframe.

A quick summary of the comments that we received: There was a total – now our math isn't adding up – Anyway, there were 19 comments total. Of the 19 comments, some were submitted through the website, I forget the numbers totally, and some were submitted directly to Judy. The majority of them were relatively lengthy and folks got into some pretty good specifics in terms of what they thought was really positive about the certification process and what they were really suggesting that we should change. We are going to be summarizing our comments in really two categories, and that was at Doug's suggestion initially. They really are falling out that way. What are some really short-term things that we should worry about? Informing the current process – right now, that's going to give us enough benefit that we should do them immediately, the current existing process, and there will be just a few of those, but there will be some of those. Secondarily, how should we change the certification process for the stage two certification? I know Doug's already addressed this who issue of being really clear on the mapping, if you will, between the meaningful use measure, the standard, the implementation guide, and the certification criteria and literally laying them out on the grid so that everybody can see them very clearly. I think, again, there was confusion in the past and that's …found in the comments between certification for vendors to get certified as compared to using that criteria when you're actually attesting the meaningful use. So I think laying this out on the grid is going to really help everybody understand it better in terms of a go-forward with the general public as well.

We did get one really good slide deck. It's 32 slides – great amount of detail – through a consortium that was the American Hospital Association HIMs Chime: The Electronic Health Record Association and the Federation of American Hospitals. We were aware of this work, both Liz and I, and we actually participated on a few of their conference calls so we could stay up with what they were going to be looking at and recommending. So they called this slide deck "Certification Experiences and Observations from the Field." That not only was submitted to us, but it was also submitted to Secretary Sebelius, Dr. Berwick and Dr. Mostashari. So there's a lot there as well in terms of informing us about some of the struggles and some of the things that were going real well.

Liz, any –

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

I think the points are clear. We've gotten the information, now we need to do the analysis, come back to the committee, particularly around, we thing, certification criteria is probably one of the most critical pieces. So, we're good.

M
Any comments or questions for Liz or Judy? Okay, well thank you very much for your work. We await your analysis, look forward to the input on that process. Let's turn to Judy Sparrow to invite public comment.

Judy Sparrow – Office of the National Coordinator – Executive Director
Yes, please. Anybody in the room who wishes to make public comment, please queue up at this microphone on the table. If you're on the telephone, just press *1 to speak, and if you are on the computer you will need to dial… Please identify yourself, your name, and your organization for the record, please.

Carol Bickford – ANA – Senior Policy Fellow
Carol Bickford, American Nurses Association. This is a comment in relation to the last slide presented by the vocabulary task force. They've identified characteristics, diagnosis, problems, and so on, but they've not encompassed the concept of outcomes and goals, which is where we want to go for the evaluation piece. It seems like we've lost that component in that discussion. We encourage the inclusion of that content.

Richard Singerman – TrustNetMD – Chief Innovation Officer
Hi, Dr. Richard Singerman, Co-Founder and Chief Innovation Officer for TrustNetMD. We're a social media for hospital/physician collaboration. Two comments: One, regarding that slide deck that was just referred to by Judy Murphy, it would be great if there was access to that deck before having to wait let's say whatever the next policy meeting is and that kind of thing. So, more interactive to those public comments. Vehicles would be great if that's not already accessible. That's one, and two, I think that the comment Stan Huffs made was really on point from the times that I used to be with discussion help and running innovation there and this balance between what are you doing in terms of discreet processes versus how are you achieving the clinical outcomes. Or, from the point of view of a knowledge management chain going from acquiring data to storing data, to actually analyzing it and using it for value. I think that it would really be interesting to maybe expand on some of those certification experiences and combine with what we're hearing over here, so we really see how are different organizations really approaching meaningful use from the point of view are they really doing the teaching to the exam? Are they having to change their workloads, like John referred to, to hit that checkbox for the quality measures? Are they somehow able to manage with their current workloads? You always hear how difficult it is to change work flow, but what really is going at ground zero? Maybe there are three or four different paradigms. Maybe a VA and Kaiser work one way, versus and HGA or smaller community systems work different ways. It would be really interesting to get that compare and contrast and how folks at the end of the day are really using this to achieve the policy objectives, to connect some of those dots.

M
Thank you very much

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you Richard. Robin Raiford?

Robin Raiford – Allscripts – Executive Director, Federal Affairs
Hi, Robin Raiford from Allscripts. Just a couple of comments specifically related to John, what you had said and Floyd as well. Sometimes when there's multiple EHRs in place and when you come forward and you take it all the way through the certification that you also give thought, or at least make a reference, to perhaps that quality measure is perhaps coming from two EHRs, or if and how the certification things are bundled. Currently, all hospital certifications to do quality measures is bundled, which left ER vendors kind of out there if they added stuff that would happen in the future and the length of stay to their products

in order to do the quality measures. Or, they didn't do the quality measures at all, which then left ED products with this valuable stuff for the ED visit, specifically the time of the order to admit, and how are you going to get that into the system to go ahead and calculate that. So if you can give some thought to the idea of bundling? Or, do mention it, bundling it and perhaps multiple EHRs are involved with ED and surgeries. The other issue was when a certification is done and requirements specifically – I think it's 173-02-N, automated calculation – that even if they only do three pieces to the EHR for modular that they actually have to produce that report. Because that's another issue of an ED system having functionality doing all this stuff and no way to get that data without duplicate data entry which is certainly something that people don't want to do. The other issue I wanted to just bring up is the issue of the CCD and advanced directives. Knowing that's going forward, my developers tell me there's a single place to put the code value for the advanced directive and the CCD. So you either have IVs or you have intubation, or you have antibiotics, or you have fluids. There needs to be more space to be able to put that, realizing in stage one it's just yes/no do you have it and you want to scan it. But if you want to get it discreetly, that field needs to be looked at by standards development to make it bigger to accommodate multiple choices the way – How involved do you want to get in prolonging life, because that could turn into several choices. In fact, it could be looked at as well. Thank you very much.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you Robin. Gary?

Gary Dickinson – CentriHealth – Consultant
Gary Dickinson, I'm a consultant representing CentriHealth. Back to the issue of providence and metadata, we've done a fair amount of work in HL-7 and also ISO in the area of metadata. We have three documents that are actually standards in various forms. ISO-21-089, which is trusted end-to-end information flows, we also have the EHR from the HL-7 side and then we have the HL-7 EHR life cycle model. We also have the records management and evidentiary support functional profile, which are valid as daters in HL-7. Now those are requirements documents. Some time ago, a year or so ago, we spent a fair amount of time looking at, okay, how do we move this from, or how do we recognize that there's not only requirements but actually a way to implement against those requirements. CDA release two as the obvious candidate in that regard. We found the CDA release two was a very good fit for many of the metadata requirements we had identified in those three standards. Though, we did find that there were some gaps. So I think it might be worth this committee or task force to take a look at some of that work as a way to inform, at least, the effort going on here in the standards committee.

Judy Sparrow – Office of the National Coordinator – Executive Director
We have two callers on the phone. Is it Karen Whiting?

Karen Whitting – IBM
Yes, this is Karen Whitting from IBM and I'm going back to the discussion on patient matching. I was involved in a long discussion on this when we created the patient discovery spec, which is the NHIN specification that's been in use for several years now. In that specification it talked about many of the things that you're also talking about, and I think it would be wise to look at that spec and consider the discussion we had at that time in light of your work right now.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, and finally we have Mark Segal.

Mark Segal – GE Healthcare – Director Government & Industry Affairs
Yes, hi, thank you. Mark Segal from GE Healthcare speaking today for the EHR Association. I wanted to make a quick but important clarification on one aspect of the meaningful use recommendations that were so well presented. There was reference on the clinical physician support item to attributes for certification. The attributes that were actually listed in the PowerPoint today, and I believe in the letter that was sent by the policy committee, really are a shorthand of what was actually, I believe, adopted by the committee. There was reference today to the fact that what was finally adopted did largely reflect recommendations from the EHR Association. So I would just reference you and your work on certification here to look at the actual items that I believe per the slide deck are in the comment summary that the

policy committee meaningful use workgroup recommended. I think there are nuances in those items that will be very important in terms of applying certification criteria to clinical decision support. I thank you very much.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you Mr. Segal, and thank you to all members of the public. I'll turn it over to Jon Perlin.

M
Thank you very much Judy, thanks to you Doug, Dr. Mostashari, all the ONC staff. We particularly appreciate the public comment today. Input is very much appreciated as part of the ongoing process of this committee. John, is there anything you'd like to?

Jonathan Perlin – Hospital Corporation of America – CMO & President?
This committee meeting today achieved everything that I expected it would, which is it dealt with some of the extraordinarily challenging foundational issues and came up with very thoughtful recommendation and I look forward to moving forward on patient matching, e-prescribing, discharge medications, adromic surveillance and quality measurements. That's that.

M
So take the rest of the afternoon off.

M
It was really, I thought, one of the more provocative agendas and very thoughtful and impassioned discussion and very well supported by a variety of perspectives. I hope that it seemed helpful to ONC as support really was the overwhelming attempt to improve the healthcare possibilities in our country. So many thanks to each of you. Again, thanks to the public and ONC staff.

M
We stand adjourned.

Public Comment Received During the Meeting

1. Regarding Patient Matching: the specification is XCPD not XCDP and is adopted by NwHIN in their Patient Discovery specification which should be reviewed by this group since all the issues the group is discussion were considered in creating that specification. Also, the reference to PDQ is from 2004 and has been significantly updated since then, and the XCPD supplement has also been updated in 2010 and will have many fixes in the 2011 version.

2. Please don't reinvent Data Classification - http://t.co/eNGM8Yq

3. Please don't reinvent Content Packaging -- XDS is agnostic of document type, yet maturely built off of CDA knowledge