

**HIT Standards Committee
Final Transcript
August 17, 2011**

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you, operator. Good morning, everybody, and welcome to the 28th meeting of the HIT Standards Committee. This is a Federal Advisory Meeting, so there will be opportunity at the end of the call for the public to make comment, and a summary of the meeting will be made available on the ONC website. Just a reminder, since this is virtual meeting, committee members, please remember to identify yourselves when speaking. And also, please keep your phones on mute, and don't put us on hold so we don't listen to the hold music. With that, I'll do a roll call. Jonathan Perlin?

Jonathan Perlin – Hospital Corporation of America – CMO & President

Morning.

Judy Sparrow – Office of the National Coordinator – Executive Director

John Halamka?

John Halamka – Harvard Medical School – Chief Information Officer

Present.

Judy Sparrow – Office of the National Coordinator – Executive Director

Dixie Baker?

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

I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Anne Castro?

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

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Steve Ondra?

Stephen Ondra – NeHC – Senior Policy Advisor

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

I know he's on, Floyd Eisenberg?

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant

Present.

Judy Sparrow – Office of the National Coordinator – Executive Director

John Derr?

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

Judy Sparrow – Office of the National Coordinator – Executive Director
Carol Diamond?

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

Judy Sparrow – Office of the National Coordinator – Executive Director
Jamie Ferguson?

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

Judy Sparrow – Office of the National Coordinator – Executive Director
Linda Fischetti?

Tim Cromwell – VHA – Director of Standards & Interoperability
Tim Cromwell for Linda Fischetti.

Judy Sparrow – Office of the National Coordinator – Executive Director
Alright, Tim. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director
B. J. Lide, NIST?

Kamie Roberts – NIST – IT Lab Grant Program Manager
This is Kamie Roberts from Cita.

Judy Sparrow – Office of the National Coordinator – Executive Director
Kamie, thank you. Stan Huff?

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

Judy Sparrow – Office of the National Coordinator – Executive Director
Liz Johnson?

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Rebecca Kush? David McCallie?

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

Judy Sparrow – Office of the National Coordinator – Executive Director
Judy Murphy?

Judy Murphy – Aurora Health Care – Vice President of Applications

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Nancy Orvis?

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Marc Overhage?

Marc Overhage – Siemens

Present.

Judy Sparrow – Office of the National Coordinator – Executive Director

Wes Rishel?

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

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Cris Ross?

Cris Ross – LabHub – CIO

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Sharon Terry?

Sharon Terry – Genetic Alliance – President & CEO

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Karen Trudel? And a number of members could not make it today, that's Martin Harris, Walter Suarez, Jim Walker and Kevin Hutchinson. With that, I'll turn it over to Dr. Perlin.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Good morning everybody, and thank you so much, Judy. Really, thanks this time, not just to the ONC staff, the Office of No Christmas, the Office, clearly, of No Summer, but to each of you. A huge amount of work has—let me just ask a question and anyone can answer. Are people getting a duplex echo?

M

Yes.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Is that better? Hello?

M

Yes, that's much better.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Okay, excellent. Well, again, good morning, and many thanks to everybody for your terrific work, as I mentioned, not only the extraordinary work at the Office of the National Coordinator but all of the Summer Camp activities are just extraordinary. As John Farzad and Judy and I and others have been in the crossfire of all of the commentary, we have a clear sense of the volume and the good thoughts that everybody is providing and to the items that require consideration for us to afford and support, not only of stage 2 of meaningful use, but to provide a coherent trajectory for improving interoperable health information. So, many, many thanks to everybody.

With that in mind, that there's been such extraordinary amount of work in between meetings, of course, it would be beyond our scope to try to recreate every last portion of the dialogue that's so thoughtfully been a part of the deliberations in between the meetings, but really appreciate the chairs of each of the activities and co-chairs bringing forward not only the recommendation but appreciate their help in articulating the basis of the recommendation, the pros, cons, understanding how the conclusion was made and why certain items will today be offered for our action.

In fact, two items outside of the usual approval of minutes for action need to come to consensus on the recommendations for code sets, and similarly, we need to come to consensus on the surveillance implementation guide standards. Doug will provide more detailed walkthrough of all of the activities of today's agenda, but at the outset with respect to a number if people ask what are our action items today, those are two of our action items today.

We are, it's fairly obvious, a call today a virtual meeting. In many ways, I think that requires more and closer attention than when we're together in a room, so really do ask for everyone's help in making sure that today's meeting is as effective as possible. Please do, if you want to signal in, just indicate to John or myself that you'd like to speak, but with respect to not only the committee members and ONC, but the public process, please identify yourself as you begin to speak.

Again, we are just so extraordinarily appreciative of the hard work that's gone on between meetings to really set a theme for today's activities. I'm going to stop there in the interest of parsimony and look forward to reflections on a personal ... approach to standards from John. But before I go to that, let me remove or dispense with one of the responsibilities of our committee. And that of course, is the acceptance of the minutes.

Are there any amendments or recommendations for changes to the minutes of our last meeting? Hearing none, let's agree to consensus on the minutes and move forward into the body of today's work. And with that, let me turn to John Halamka for some commentary on the items we'll consider, and I believe, really a challenge that we subscribe to the most parsimonious approach possible in our recommendations to ONC for standards. John?

John Halamka – Harvard Medical School – Chief Information Officer

Great. Well, thanks very much, Dr. Perlin. And so yesterday, Steve Ondra and I and Farzad were at a conference in Washington, and Farzad reflected on the fact that over the last two years, the Federal Advisory Committees helping ONC have met an average of every other day. And so, Jon Perlin, to the point, this is the hardest working Federal Advisory Committee in history. And today, in some ways, is our 28th meeting, is our actually most important meeting today that I actually regret, in retrospect, that it is telephonic because today, we actually have achieved something as you go through this agenda, that many of us have been working on for a decade. And that is, as we go through the agenda, you will see for the first time in history, we will be declaring true parsimony; single standards for each domain, one

implementation guide, and a clear path forward for all of the meaningful use stage one and stage two standards that are necessary.

And so, what do I mean by that? As we start the morning with discussion of vocabulary, one criticism of stage one, quality measures and the various places in which we have vocabulary standards, is there's choice. Do this or do that. Go this direction or that direction. And as we have said before, every time we say or we really mean and. And it actually creates a dizzying amount of ... because vendors need to support every possible variation.

So, what you'll see is that the Vocabulary Task Force and the Clinical Quality Workgroup have worked diligently for each domain have come up, in medications, laboratories, allergies, with a single recommendation of the best vocabulary to serve that particular need. In fact, even with singular vocabularies per domain, they have really tried for as few vocabularies overall. You'll see SNOMED-CT and LOINC being used as much as possible.

And they've also been very thoughtful. One the things that we've always tried to do as a team is engineer for the little guy and balance the need for standards with the difficulty in cost of implementation. So, where there are vocabulary standards that are emerging, but not yet proven, you'll see they've also said well we think this is the direction, but there's piloting that needs to be done before it's mandated, so again, an amazing body of work. I think back on the struggles that HITSP had five years ago, and today you will hear the presentation I dreamed about; one health domain, one standard, one vocabulary.

And then, as we move onto standards Summer Camp, and we are right on schedule, getting to September with complete recommendations in every area of Summer Camp, you'll hear from Marc Overhage on patient matching, an extraordinary body of work that isn't prescriptive saying that the country must use one approach to patient matching, but an extraordinarily thoughtful best practice guideline that shows you the kind of metadata that should be collected to empower patient matching with enough sensitivity and specificity information so that implementers can decide how best to approach the patient matching problem in a way that works for their local needs. So, it is prescriptive enough without being overly prescriptive. So, the issue that Deven had reflected on the HIT Policy Committee, felt there should be flexibility, yet best practices and education and Marc's achieved that balance.

On the surveillance implementation guide, this is really more of a surveillance. This is public health or at large. One the challenges with Meaningful Use stage one is optionality. We said you could use 2.3.1 or 2.5.1. You could use this implementation guide. There isn't an implementation guide for syndromic surveillance, do whatever you want. Well, you'll see coming out of this group, one implementation guide for surveillance, one implementation guide for immunizations, one implementation guide for reportable lab, elimination of optionality, one clear cookbook for each of the public health domains. I can tell you implementers will be overjoyed.

From Dixie, we're not getting the final recommendations, that's not to come until next month, but we're going to see an extraordinarily thoughtful construct for the evaluation of transport and security standards and their supporting components because one of the challenges we've all faced is although we have strong content and vocabulary standards, we don't yet have EHRs and PHRs that incorporate the functionality to transport data from place to place. Yes, we have the direct project and a variety of pilots. We have the pilot projects going on with New York and a number of states, but ideally, we will get, as a certification criteria, every EHR and every PHR implementing a set of components that will allow trivial transport from place to place, so that there isn't a massive amount of expense and time every time a simple data exchange between providers needs to take place.

So, I think you will really appreciate her evaluation construct that looks at maturity and adoption, that looks at the needs for the standards and reflects on the various building blocks that Direct and NwHIN has suggested thus far and identify that, in fact, some of those building blocks should not be pursued because need is low, and some of the building blocks should be reconsidered because the standards at this point are outdated, extraordinarily thoughtful.

Then, on the S&I Framework, some very important conclusions for your review. Remember that Dixie's team suggested certain certificate requirements and we asked questions to the S&I team to look at how might you do federal bridge, how are you going to build an ecosystem of trust. They've done that evaluation and come back with some suggestions; very helpful.

On transitions of care, again, our problem has been every time a doctor's office or hospital transitions a patient to the next provider of care, there are multiple ways to do it. Well, so not only do we not want multiple ways to do it because that creates dizzying complexity, but we also know that we're not going to ever create one standard that is precisely going to meet every transition of care need. So, how do we balance the need for diversity of content with parsimony of standards? And the answer is you'll see, in transitions of care, one set of building blocks that can be assembled to create a transition of care document to serve multiple purposes with one set of implementation guides that are easy for the big guy and the little guy for EHRs and PHRs. Again, a dream that five years ago, I never thought was going to be possible.

One of the great interesting aspects of HITSP was there were multiple lab standards competing. There was the simple ELINCS approach for simply returning a result to an EHR, and then there was a more complex and comprehensive standard that could meet other needs such as public health reporting or the ability to aggregate lab data for multiple purposes, and this was at odds. Do you want simplicity and lack of optionality or do you want something that was more ubiquitous that could be used for multiple purposes?

So once again, unbelievable work where the EOH folks and the folks from HL7 and HITSP all came together and came up with one standard that everyone agreed upon that could use templates to both suffice for the simple use case with little optionality and the more complex use cases that needed richer data; one implementation guide, one set of standards.

And on provider directories, we in our committee have had to ... debate. Do we look to DNS? Do we look to microdata? Do we look to LDAP or IHE standards? And you are going to see some fascinating work where, in fact, the S&I Framework have come to a brilliant conclusion. There isn't a standard yet that will meet the requirements of simplicity and parsimony that has been adopted and is clearly the solution. And so, in fact, there are a couple of approaches that should be piloted and then we can determine, after we see work in the field, where to go. And so in fact, sometimes in harmonization, the right answer is no answer. And I love the fact that they had the courage to come up with that conclusion.

So in summary, today, we are going to achieve what we've been working for for a decade, in multiple domains, finally declaring one set of standards, with one set of implementation guides, but in other areas, where there is work to do, declaring that there is work to do and suggesting that pilots be the next step. So again, regret we couldn't be together in person because this is truly a momentous event. If we are successful in achieving consensus on these recommendations, this will be a day where parsimony was finally achieved. So with that, Dr. Perlin, I turn it back to you.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Well, thank you John. That was just a terrific introduction indeed. It is a planned mark meeting in that regard. Let me—actually, let's continue in that thread, and the perfect start is to dive into the recommendations of the Clinical Quality and Vocabulary Task Force. And as we see up, Jamie Ferguson and his colleagues, Betsy Humphreys, Jim Walker and Karen Kmetik for both of these topics. Jon, let me come back to you for any threads you may want to weave from the terrific introduction into the set of activities that lead us to require a consensus on our disposition of code sets.

John Halamka – Harvard Medical School – Chief Information Officer

Sure, and one of the things that I always think about is the work that has gone before, and I examined carefully standards that had been recommended for stage one, in fact, standards that had been recommended previous to stage one, for various kinds of vocabularies around medications, etc., and I asked many questions of Jamie and Betsy and that team, and they have sufficiently reassured me that our previous historical recommendations have actually been incorporated into these future-looking recommendations because SNOMED, RxNorm, LOINC have achieved a level of maturity that they now have actually incorporated multiple previously suggested standards. So, I actually feel quite good about these recommendations and certainly look forward to their presentation.

Jonathan Perlin – Hospital Corporation of America – CMO & President

So with that, Jamie, are you online?

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

Yes, I'm here. Thanks, Perfect! Okay, so if we can go to the next slide, please. You can see this is the list of Vocabulary Taskforce members, not going to go through the list. We had a large number of these folks on many calls, and I believe the next page is the list of members of the Clinical Quality Measures Workgroup. These two teams met together over approximately the last two months. As I recall, it's probably at least ten times. We had a large number of meetings. We started with the quality data measures spreadsheet that was developed by the National Quality Forum, and it lists 23 domains of vocabulary and code set standards that are used in measure development and that are needed in measure development. We used that spreadsheet then to identify, in areas where there were measures that were used in Meaningful Use stage one or proposed for stage two, what are the code sets that are currently in use and what are their candidates.

So, can we go to the next slide please? So, the scope of this request was to establish and recommend vocabulary standards for this quality data model of the NQS, which is embodied in the spreadsheet I talked about, for use in EHR record data elements that are reported for quality measures.

Next slide please. I want to spend a minute on this page. So, we did look at the primary purpose of measured development. So, we looked at what was needed for the current set of measures, but we also looked forward at the needs for future measure development in areas that have been identified by the Policy Committee but where we may not yet have measures. And so, the idea is that the code sets that are used for measures, we did want to, as both John and Jon have mentioned, we wanted to have a parsimonious set of code sets, but also the code sets may be limited. So, in fact, where we're recommending SNOMED or RxNorm, it may not be all of SNOMED or all of RxNorm for particular purpose.

And a great example of this is the use of ISO 639-2 for preferred language. So, ISO 639-2 is a list of, I think, over 500 language variations including a number of dead languages. And ISO 639-1 is a more limited set of spoken languages. So, why didn't we pick ISO 639-1? Well, by picking this more expansive set, it does pick up some additional details, and it could be useful in measure development, but at the same time, the use of it can be limited. And in fact, our recommendation is to limit the use of 639-2 to

those languages that are spoken that are represented in 639-1 as the beginning set. But this is the more comprehensive set, and it's a three-digit code that's used in other places. So, it's familiar to measure developers, and it's already in use in other settings and in related ways.

So, what we're saying then, is that subsets may need to be specified, developed, and further development of subsets will be needed. So, this is not—this is sort of the beginning and not the end, in terms of these standards. We also limited the discussion to certification, and we wanted the certification process to be able to test for the processing of codes that would be used for these purposes. I apologize; on this slide it talks about Meaningful Use reimbursement. I think we all know it's an incentives problem, not a reimbursement problem. So, I apologize for that typo, but we did want to limit the use of these to those things that are required for Meaningful Use.

And then, point number four on the slide is really important because you'll see that in some cases, we've identified a long-term target where other code sets may be in use and where our transition plan needs to be developed. And so, we've agreed to continue to meet as a joint workgroup between clinical quality and vocabulary to develop those transition plan recommendations, and we anticipate coming back to the committee here, actually, next month with the initial set of those recommendations and our plan for continuing recommendations on the transition plans. So, what we're looking at today and what we're asking for approval on today is, in some cases, the long-term target so that we can set a direction and then have a transition plan that is developed on a case-by-case basis as needed.

Next slide please. So, I'm just going to dig right into the recommendations here then. So, for—and I believe these are just in alphabetical order, so for adverse drug effect, we're recommending RxNorm for medications, SNOMED for non-medication substances and also SNOMED for the adverse effect itself. And there was a question that came up about the use of NDFRT or drug class, and so we had a discussion that ended up saying that RxNorm being more detailed, really can represent all the drugs in the class, and that in many cases, from a measure developer standpoint, it's desirable to have particular drug exclusions. And so, really the detail of RxNorm is needed.

Next slide, please. In terms of patient characteristics, this is another one where we had extensive discussion, I mentioned already about the preferred language, the use of the more detailed set, but we will want to develop a code set subset that can be published for the use of preferred language. We're recommending the PHIN-VADs, the Public Health Information Network Vocabulary Service, standards for both administrative gender and for race and ethnicity. We did get some comments that the CDC's race and ethnicity hierarchies are very limited, and that's true. They are very shallow hierarchies that don't have a lot of detail, but at the same time, they're used for many other similar purposes, and for required reporting and for surveys. And so, we would certainly welcome CDC to further develop those standards, but this is what we're recommending for use at this time.

Now, the next one, in terms of LOINC for assessment instruments, you'll really see a pattern throughout the recommendations that LOINC is frequently recommended to identify the instrument, whether it's a survey or an assessment or the instrument that asks the questions, and then SNOMED being recommended for the specific answers to the questions with the particular values and observables for the answers to those questions that are in the instrument that's identified by a LOINC code.

We did have to refer socioeconomic status back to CMS for clarification of the request. We didn't really understand what was intended there. And then, to identify payers or the type or payer, there's a payer typology that came out of the Public Health Data Standards Consortium that's also used by X12 for administrative transaction purposes. And so, that's our recommendation there.

Next slide, please. On communication, this is an area where we are recommending SNOMED. Now, there are many different code sets that are currently in use, and so, so currently in 2010, measures we see both SNOMED, CPT, HCPCS, ICD-9 and moving to ICD-10, and so, this is one where a transition plan will be needed.

For condition, diagnosis and problem both active and inactive, we're recommending SNOMED-CT. Today in measures, SNOMED-CT and ICD are used.

Moving onto devices, now this is actually the area where our long-term recommendation is SNOMED. We previously had indicated that SNOMED would be an interim recommendation, and the reason why has to do with the negotiations that are currently going on, being conducted by the National Library of Medicine to include—that we anticipate will include the GMDN device identifier as part of SNOMED-CT. The GMDN, in turn, is expected to be used by the FDA in its unique device identifier. And so in fact, SNOMED, being the interim standard, really should end up being—we anticipate SNOMED will be the long-term standard that will incorporate all the details that'll be used by the FDA as well. So, this is another one where a transition plan will be needed because ICD is currently used, as well, in SNOMED.

Betsy Humphreys – National Library of Medicine – Deputy Director

This is Betsy Humphreys. Jamie, just let me interrupt you to correct one thing. It is the International Health Terminology's Standards Development Organization that is negotiating with GMDN. NLM is participating but is not—

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

Okay, thank you for that clarification. Sorry, didn't mean to misrepresent that. Okay, so then moving on for the non-laboratory diagnostics. We're recommending again LOINC for the particular study name, SNOMED-CT for the findings, UCUM for units of measure. We did actually, and thank you, John Halamka, for your blog post that pointed out the commonly used UCUM codes, and I think that has actually been studied quite a bit and was very helpful in understanding, frankly, how little change was required from the common units of measure to adopt UCUM for a large number of purposes. And so, this is another area where a number of different standards are currently used, and a transition plan will be needed. So, those currently used standards include LOINC, SNOMED, CPT, HCPCS, ICD. So again, a number of different things are in use, and a transition plan will be needed.

Now finally on this page, we come to encounter—and so, here we're really talking about any interaction between the patient and professional caregiver. It's not restricted to billable events. And so, certainly today, we have CPT, ICD, SNOMED, HCPCS and other HL7 code tables that are used for this purpose. But we really feel that SNOMED-CT is able to cover any type of interaction between a clinician or a caregiver and a patient, and it's actually today, perhaps most used for those non-billable events, e-visits, telephone calls and so forth.

Next page, please. For the patient's experience, this is not used currently in 2010 measures, but we're recommending LOINC for the assessment instruments, SNOMED-CT for the responses. Similarly for family history, LOINC for the assessment instruments or the questions, SNOMED CT for the responses. Now, in family history, this is currently used in 2010, and it would have been the same as what's used for condition, diagnosis or problem being SNOMED and ICD. So, this is another one where a transition plan will be needed.

For functional status, we're recommending the international classification, ICF. For categories of function, the again, SNOMED for the assessment tools and survey instruments, and SNOMED-CT for the responses and for the particular items.

Next page, please. So, health record components is one that took a bit of discussion to understand what it is that is really intended to be captured here. And what we ended up understanding was that we're talking about naming components of health records that may be domain areas or functional areas. And so, we're recommending LOINC for naming of the components and the relationships between those components and HL7 for messaging among the systems.

For intervention, just a part of the spectrum of procedures, we're recommending LOINC for interactions that produce measurable results or an assessment, SNOMED-CT for results that do not produce, or rather, for interventions that do not produce measurable results, and counseling is a good example of that.

Then for—it's not in alphabetical order, for adverse effect other than allergy or intolerance, I guess, I like that the alphabetized, recommending again RxNorm for medications including inert ingredients, SNOMED-CT for the non-medication substances, as well as SNOMED-CT for the adverse effects themselves and the severity of those effects.

Moving onto the next page please. For laboratory tests, again, LOINC for the test name and its results, SNOMED-CT for appropriate results. And so, this is again consistent with using, for example, the Bethesda terminology for pap smear results, and then UCUM again for units of measure. And again, refer back to that blog post on, frankly, how little difference there is between UCUM, in some cases, the single punctuation mark or nothing, between the UCUM representation of the units and those that are commonly used.

Now for medications then, including vaccines, we're recommending RxNorm for medications, CVX for vaccinations. And so, as it explains here on the slide, in some cases, vaccinations are treated as medications and others they're treated separately. So, it can be either in the RxNorm as a medication or in a CVX as a vaccination.

And then, for physical exams—so here the items that are required for capture include vital signs and applauding and displaying growth charts and things of that nature, including calculation of BMI. And so again, here you see LOINC for the assessment instrument or the question and SNOMED-CT for the answer.

Going to the next slide, please. Then for patient preferences, again LOINC for the question and SNOMED for the answer.

Procedure, now this is—procedure certainly is one where a transition plan will be needed. We are recommending SNOMED-CT. Currently used in 2010 measures, we have SNOMED, CPT, CPT Modifiers, CVX, HCPCS, ICD-9 and ICD 10. And so, the transition plan on procedures will suggest narrowing that list a little bit to a subset. And then, but this is another area where we will have a transition plan that we'll have to come back and recommend. Long-term target, though, being SNOMED-CT.

Risk evaluation being another area, another pattern fitting the pattern, LOINC for the question, SNOMED for the answer. And then, for substances, SNOMED-CT.

So going on to the next page, please. Symptoms also SNOMED-CT. This is one where, currently in 2010 measures, we see ICD-9 and ICD-10 and SNOMED being used, but we do not think that a transition plan will be needed where it actually should be for measure development and reporting purposes. There should be able to be a direct adoption of SNOMED immediately.

And then, for system resources—so, here we're talking about device and system capabilities and facilities as EHR functions in HL7. LOINC for health care resources, such as staffing, and SNOMED for equipment.

And then finally, on transfer, essentially the way to describe a transfer from one location or service to another within a measure, rather than as an element of the measure, we're talking about SNOMED-CT, and this is one where actually NQS is considering deletion of the concept category, but we are recommending SNOMED-CT for this one.

And I believe that's the set of recommendations. So, we're requesting the committee to accept these code sets for meeting the needs of the quality data measure concepts for quality reporting. And I believe the next slide talks about next steps.

So, in terms of transition plans then, we anticipate, as I mentioned, that we will need to have transition plans for quite a number of these items. I think there were—it says here six. I thought it was ten, but—so there are a number of—I think six is probably correct, probably the count on the slide is most likely correct. So, a number of these will require transition plans. We do have meetings scheduled to development, basically, a plan for those transition plans, and some of them, we may be able to develop recommendations on, specific recommendations, before the next meeting. And so, you can see here the list of the kinds of things the transition time will be required for in terms of testing, for measure developers to incorporate them and to retool and new measures, particularly as one corporation, and to new certification criteria. And I believe that's it. I don't think there's another slide.

John Halamka – Harvard Medical School – Chief Information Officer

Well, great. Thanks so much, Jamie and Betsy and Jim and Karen and the whole group. Just again, reemphasize to the whole committee that I asked several questions, like where did MDFRT go, and where did UNI, the universal ingredient identifier, go. And what they reassured me was that RxNorm has now incorporated those concepts. So, by saying RxNorm and SNOMED-CT, we are actually inheriting all this previous work that has been done on naming non-medication ingredients or classes of allergens or those sorts of things. So, I hope what you get the sense of is these folks have tried to use SNOMED-CT, LOINC, RxNorm wherever possible, achieving the smallest number of vocabularies in general, but I hope you can also appreciate that you can see for every category of vocabulary, they have chosen one standard. So, it's not choose ICD-9 and ICD-10 and SNOMED and CPT and HCPCS. It's SNOMED-CT.

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

So, thank you John. So, one other thing, this is Jamie again. One other thing I'll mention is there has been some discussion and some questions about the scope and the intended purpose of the recommendations. So, we're making these recommendations for purposes of external quality reporting only in for incorporations into certification criteria that tests the ability to produce those quality reports. And so, I think there is a question, and I would love to get input from the committee on the degree to which the same vocabularies could or should be incorporated into certification criteria for other internal EHR functions in order to make it easier for hospitals and eligible professionals to adopt these code sets because I think one of the things that's being questioned is the degree to which you can take sort of any old thing that you have in your EMR and translate it accurately into what's needed for quality reporting purposes. And so, I'd just love to get discussion on that question.

John Halamka – Harvard Medical School – Chief Information Officer

Well, let's open it up to the committee for general comments on the body of work you've seen, which again, we're seeking approval on this body of work for quality measures only, and the secondary question that Jamie has asked. Well, what about extending its scope for future certification criteria more generally.

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

This is Wes.

John Halamka – Harvard Medical School – Chief Information Officer

Please Wes, go ahead.

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

Wes Rishel here. This is great body of work, Jamie, and I don't mean to be in anyway implying anything different. I have one or two concerns, and you could probably boil most of them down to say, when you say SNOMED-CT for appropriate responses to instruments, how would an implementer know which SNOMED-CT codes meet that predicate?

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

So, Wes, I'm going to ask—I think we have Floyd Eisenberg on the call, and Floyd, if I can put you on the spot to answer that from the NQF perspective, I'd appreciate your intellect.

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant

Sure, Jamie, thank you. This is Floyd Eisenberg. For each individual instance of use, the measure developer would identify the applicable instruments in a value set, but that value set would be restricted to using LOINC to instruments in LOINC.

Betsy Humphreys – National Library of Medicine – Deputy Director

This is Betsy Humphreys. So, also, Wes, there is the notion coming from the notion of direct collaboration or involvement between LOINC and SNOMED. So, when LOINC creates the concept, say for an assessment instrument, including information about each specific question and the order of the questions etc., then as appropriate, there would also be the development of here is either the range or in some cases, the specific values from SNOMED-CT that actually represents the possible answers to that particular question or the possible values for that instrument.

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

Okay, thank you. If I could follow up, the interpretation of a range or list of values is easier or harder to implement according to how well that information is in a unified and compatible format with the publication of the concepts and spells. Do we anticipate that—is there all of the mechanism and something in place to produce some appropriate format similar to the formats that are produced for concepts themselves, but that publish this as a concept network, rather than as a bunch of tables and PDF format?

Betsy Humphreys – National Library of Medicine – Deputy Director

Well, I don't know if Doug Fridsma is on the call, but the whole issue of how the value sets that are relevant to the measures will be made available in useful computable formats, is one that is under active discussions between ONC, NLM and others, and certainly, the intention is that these will be available in useful forms, and our intention, obviously, is to make proposals or put up testings and so forth so the community can respond as to whether that's happening or not. So, is it ready today? No. But will we be moving towards something that will be workable as soon as we can? That is definitely everyone's intention.

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

Okay, I think probably the critical task runs through NIST here in the sense that they have to compare certification criteria.

Betsy Humphreys – National Library of Medicine – Deputy Director

Absolutely true.

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

And I would hope that that process of working with NIST would be as public as most of our other work is because I think there will be at least 30 people in the country who are watching it with great attention to detail and great ability to provide good feedback.

Betsy Humphreys – National Library of Medicine – Deputy Director

I agree with you. I think there might even be 32 or 35.

John Halamka – Harvard Medical School – Chief Information Officer

And in fact, to amend or add on to Wes' comment, we need to think, of course, very practically. I neglected in my introduction to mention the very fine work of the implementation workgroup beginning to prepare certification criteria. And in fact, just a question for Betsy and for Jamie that follows on Wes' issue, which is recognizing that we look the next couple of years, we are making our final recommendations in September, we are going to see an NPRM come out in, say, December/January. By mid-2012, you'll see a final rule that then developers will have to implement, and the 2013 timeframe, assuming that there is that one-year delay of Meaningful Use stage two, so we're going to see the country, through certification criteria, widely using these standards in 2014. So, as you look at the body of work you're recommending today, do you think 100% of your recommendations are going to be 2012 final, 2013 vendor implementation, 2014 widely used or will we hear more about that in September as you reflect on a transition plan?

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

So, thank you John for the question because I think this is exactly why we feel that we do need transition plans for some of these items. So, and certainly there are a number of new and retooled measures that already exists that are using these recommended code sets, but in fact, because of other work that's already been done and the fact that some of these 2010 measures use alternative vocabularies, there will be some transition needed. So, no, not all measures—I don't anticipate that all measures for stage two would absolutely use the long-term target in every one of these cases. But having said that, if we've identified 6 out of the 23 domains where transition plans are needed, that means that a majority of them, a large majority of them, we feel do not need transition plans and that measures that use those concepts in those particular domains could be using these recommended vocabularies for 2013.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

This is Carol. I just want to jump in here and say that I would love to understand what the process will be getting from here to that requirement in 2012 where we are confident that what's necessary to implement these standards is available and that they are in fact, implementable. In other words, that they have survived some methodical and rigorous testing in a diverse set of environments. I just don't feel like I understand how that is going to be established before they are required. And I do think this is a ... issue for other things that we've been talking about over the last couple of months. So, I'd just love to understand what people have in mind or what people believe is necessary.

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

So, I think perhaps—again, let me turn to Floyd, if I could, to describe the implementation process for these quality measures. And then also, I'm not sure if we have Karen Trudel or someone else from CMS who can talk about it from that perspective of how these would be used for quality reporting.

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant

This is Floyd. As far as the implementation and testing mechanisms, I know that CMS and ONC have programs for projects either in currently active or in the plans. I have to defer to them.

John Halamka – Harvard Medical School – Chief Information Officer

Well certainly, one comment here is recognizing that we are going to—for Steve Posnack, I think you're on the line—regulatory purposes provide you with a set of those recommendations that we believe are ready for prime time, stand alone and those that are going to require more thoughtful transitions, so that as you craft those 2012 recommendations in combination with CMS and NIST and other stakeholders, there will be, I presume, a path for those that are known to be good enough and those that are thought to require more transition planning and timing. And I think it is the best work of this committee, which we'll hear more about next month to identify those that aren't quite ready to just simply stand alone as recommendations for 2012 Meaningful Use stage two.

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

And let me also add, if I may—this is Jamie again—that I think with the possible exception of the CDC's PHIN-VADS, there's nothing that we're recommending here that's not already in use in stage one quality measures. And so, it's not that it's not implementable but not already used because it is already used and in place, just used for different purposes and for suddenly and actually to excluding—

John Halamka – Harvard Medical School – Chief Information Officer

We have some background sound here, so if folks could mute their calls.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

This is David McCallie. Can you hear me?

John Halamka – Harvard Medical School – Chief Information Officer

Go ahead.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

This may be more for ... and it's a little bit of a follow on to Wes' question. In many of these questions, we see a fairly tie-coupling between LOINC and SNOMED, and I'm wondering if at the high level, how that relationship will be managed. Will those maintain themselves completely independent processes or is there some more close correlation or merger tracked between LOINC and SNOMED? That's a high-level question.

More detailed question is when we have the query from LOINC and the answer from SNOMED is the intent that the SNOMED answer will be a stand-alone answer that will be interpretable in absence of the query or does it require the coordination of the question and the answer to make an interpretation? So, for example, if the question is urine color, is the answer yellow or is the answer urine is yellow?

Betsy Humphreys – National Library of Medicine – Deputy Director

David, I'll answer the first part of the question and then address the second, or the first question and then the second one. This is Betsy. There are ongoing serious discussions between SNOMED-CT and LOINC or the IHTSDO and the Regenstrief Institute on establishment of specific relationships between them. I don't think that in terms of the expectations, that we're looking at any an immediate total merger of the two. I don't see that in the expectation in the short term. The short term might be a long term, might not happen, but a closer relationship, yes.

The—in terms of exactly what would be the case in the example that you mentioned, I would have to look at—be looking at a specific instrument and so forth. I think that the issue would be that—my sense would

be it would be interpretable. The meaning of the answer would be in the element for the answer, and that we would not have the case where the free-floating concept of yellow had 52,000 meanings within SNOMED-CT, but I would have to look at a particular instrument or get somebody who knows more about the specifics to address that question.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

I think—this is Stan Huff. I think in most situations to understand the meaning that's being expressed, you would need to understand the context of the question or the observable as well as the answer. Just think about, for instance, the name of a disease is the name of a disease, but if you want to know if that condition happened as an adverse reaction to a drug, you need to know the context that this is actually—it's in the adverse event message or transaction or structure in order to interpret and that meaning.

Betsy Humphreys – National Library of Medicine – Deputy Director

I'm sorry, I entirely agree with Stan about that. I would more in terms of having a concept defined in SNOMED that would be like one, and we wouldn't know one what.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

Yes. So, I agree with that.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

This is David. As you know, SNOMED has a mix of pre-coordinated and post-coordinated concepts, and all I guess I would ask for is that as these measures and their value sets get developed, that it be done in a consistent fashion, just to reduce the variation where sometimes the answer has both the answer and the question, and sometimes, it's just the answer.

John Halamka – Harvard Medical School – Chief Information Officer

So clearly, much of this has to do with the development of the instruments as Betsy has suggested. But in general, I think the question we're asking is do we have sufficient vocabularies in which to express questions and answers using these standards.

Betsy Humphreys – National Library of Medicine – Deputy Director

And we believe we do, and we believe that in the case of both LOINC and SNOMED that there will obviously always be something that is missing, but the assumption is that it can be added.

John Halamka – Harvard Medical School – Chief Information Officer

So, Jamie made a very important point that I just want to reiterate, that each one of the standards being recommended today is already incorporated into previous recommendations, with the exception of language, which has been expanded significantly. And that was a Policy Committee recommendation as well as an Institute of Medicine recommendation that ... field be expanded to be more

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So, please, other comments.

Steve Posnack – ONC – Policy Analyst

This is Steve Posnack, if I can pick up on, I think, what John Halamka mentioned a little earlier and Jamie's second question, which he put on the table for the committee as well. And so, I understand, I think with greater clarity than the meeting I was at last time, about the vocabularies being specifically recommended for quality measures, and I'd like to pick up on Jamie's second point, and maybe ask you, Jamie, or other people to chime in related to, for those areas where we have or have not adopted vocabularies or code sets, and this also will play into the work that you'll get presented a presentation on related to the Implementation Workgroup—I'm looking at some of our current certification criteria and the one related to problem list, we have that or situation where we permitted folks to get certified to ICD-9 or SNOMED or active medication list. We didn't adopt a vocabulary or code set. So, would that be an area

for Meaningful Use stage two that we would adopt RxNorm as a code set? Or recording demographics, obviously, we have the ONB standard right now, should we move to the PHIN-VADS race and ethnicity for active medication, allergy lists? We don't have a vocabulary or code set. So, those are the areas where I—it would be helpful to know where the committee would like to go because I think it would be truly informative to the work of the Implementation Workgroup that's currently underway.

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

Well, thank you Steve for bringing that up. This is Jamie, and I'll just sort of put the question I think back on the table list, and I think problem list, which you mentioned, is a good example. So, if, for quality measure purposes, you're required to represent the problem list elements in SNOMED-CT, how best should you be enabled to do that? What will make it easiest for implementers and doctors of HIT, the end users, to be able to meet that quality reporting requirement? So, should, in fact, certification be used to test the ability of a problem list to be captured using SNOMED-CT in the original documentation or not? I think that's a good question.

John Halamka – Harvard Medical School – Chief Information Officer

So, the interesting question, of course, for the group is this is for quality measures. There are other ways to think about these vocabularies as we've been talking about, and one is to say as data is transferred between systems, that these vocabularies be used not just for quality measures but for all data transfers. And then, of course, probably the most controversial, as Jamie has said, do we say in EHRs, PHRs, etc., these vocabularies should be used natively so that you can achieve the greatest levels of specificity.

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

Or should be able to be used datedly, not making it a mandate but requiring that the system have the capability.

John Halamka – Harvard Medical School – Chief Information Officer

And you know, Jamie, as a both standards guy and a developer, what I could say for my institution is I think I would be quite happy with using these four of the quality measures. I would be quite happy with using these vocabularies for all health information exchange, and it would be actually a bit of a struggle for me to convert existing internal code sets in all my applications to these vocabularies in the near term. And so, I would see a balanced approach. This is a direction where I would like to be able to support them natively, eventually, but in the short term, agree to quality and health care information exchange situations.

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

This is Wes. I'd like to say that if the ... EHR that was certified first in the country says it's a bit of a struggle, that would be excessively diplomatic when compared to the rest of the industry. I think it's very important to recognize that—just to congratulate ourselves on how far we've come. One of the lessons that all standard development efforts there is that everything is complicated, and you don't even know how complicated it is until you try to make it simple. And if you compare where we are as an industry with regards to having implementable standards measures between now and two years and one quarter ago when the ARRA Bill was passed, it's enormous progress that we have. And the outcome, by any pass, will really help the ability to aggregate information about health care throughout the country.

At the same time, I'm mindful of the lessons we've learned with regards to implementing LOINC, specifically that the balancing of the need for precision with simplicity was both a barrier to the acceptance of LOINC and a cause of error in implementing LOINC. And I don't know exactly how that lesson transfers here, but I want to echo Carol's concern that, and maybe restate it in my own words, certification is step one towards getting these quality measures implemented. Step two is using them in order to meet Meaningful Use criteria.

Step two is a much bigger step than step one. And I know we have our own needs to balance progress versus the doctrine that don't do anything until you've tried it first, and I see us as working right on the edge. I think it was one of the racecar racers who said if you think everything's under control, you're not going fast enough. The proscription I'd like to make, with regards to this concern about our being on the

edge of what can be implemented widely, is that throughout the process of development, we make it public. We look for continued feedback on the implementation that has happened in stage one during the time of, particularly the time, when people are actually reporting quality measures as opposed to simply attesting that they have met the quality measures. Thanks.

John Halamka – Harvard Medical School – Chief Information Officer

Thanks very much for that. So, other comments on, remember today, really all we're doing is seeking the approval of the committee for these to be used in the quality measures exclusively. I think what we're hearing feedback for you initially, Jamie, is that extending it beyond that domain seems premature.

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

Yes. And I don't disagree with that. Let me explain, perhaps a little better or differently the context of that question, where it came up from. The question really is a question actually for CMS to ask, I think, which is how do you ensure that the accuracy of what's represented in the quality measures is adequate for CMS purposes. So, how do you make it easier for implementers to ensure that they're actually using these target vocabularies correctly for quality measures?

John Halamka – Harvard Medical School – Chief Information Officer

I believe Karen had to drop off, but I think Marjorie has joined from CMS. Judy, do you know if she has the ability to comment?

Marjorie Rallins – AMA – Director, CPT Clinical Informatics

Yes. This is Marjorie. I'm here.

John Halamka – Harvard Medical School – Chief Information Officer

Any comments you would make on this general topic of quality measurement accuracy and the CMS view of how these standards for quality measures should be incorporated over time?

Marjorie Rallins – AMA – Director, CPT Clinical Informatics

I certainly can't speak for the CMS view, but I can speak for the—you say how they should be incorporated over time; I'm not sure what you mean by that.

John Halamka – Harvard Medical School – Chief Information Officer

So, what we've been talking about is really a continuum here where we recognize that in the short term, most EHRs won't natively incorporate these vocabularies. What they'll do is have code sets that are proprietary and historical and then are mapped to these particular quality measures, which will be expressed in RxNorm and SNOMED and the vocabularies we've talked about today. And that actually will work fine except for the fact that we'll—some vocabularies have greater specificity and others have less. So, they'll be some loss of information's fidelity that takes place with this step-wise process, but Wes and Carol have made very wise comments that we can only move as fast as the industry can implement. And so, I think the recognition will be should we move forward with these recommendations today, we will have well-specified quality measures, and it will take time for EHRs and PHRs to be able to express that level of richness internally that will ensure as accurate numerators and denominators as possible.

Marjorie Rallins – AMA – Director, CPT Clinical Informatics

We would agree with that, and we would also support the use of maps. We've had that discussion internally here at the AMA. We believe that maps are absolutely necessary in making the transition, and we certainly acknowledge the challenges that are foreseen, with respect to implementing these standards.

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

This is Dixie. I have a question very closely related to that, John. Obviously, there will be mappings, and they're already doing exactly that for their transition to ICD-10. Will there be some effort at CMS or elsewhere to align this transition and these mappings with those that will be required for the transition to ICD-10?

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

So, Dixie, this is Jamie. I think that Betsy Humphreys may actually be in the best position to answer that because the NLM is publishing, I believe, a number of useful cross maps.

Betsy Humphreys – National Library of Medicine – Deputy Director

All I can say, Dixie, is that we are—our main goal in all of this mapping work is to ensure that we all—that there are not duplicate mappings created because it's very hard work to do this properly, so we're trying to align all these different groups to ensure that if they are in the process of mapping A to B that we corral the good work of everyone who's working on A to B maps. It's not—this is not necessarily easy to do, but a question is exactly what has to be mapped for a particular purpose, and a major issue with mapping SNOMED-CT to ICD-10 CM, and we are attempting to have a unified approach and involve different groups, including, for example the Kaiser, with other groups on that one. So, yes, we would like to coordinate this, and we certainly wouldn't like to hear that resources are being expended in more than one place to produce something that either duplicates or contradicts something else.

John Halamka – Harvard Medical School – Chief Information Officer

And so, ideally, as we've talked about in the context of this committee, that there will be a website, by which anyone in the United States could download the vocabularies and code sets and cross maps, and those would be maintained, and of course, as you say that did incorporate the wonderful intellectual property that Kaiser has donated to the country and all the fine work at the NLM, so that as we see this stage two and stage three pass forward that the code sets that support stage two and stage three are not reinvented by multiple organizations.

Betsy Humphreys – National Library of Medicine – Deputy Director

That is certainly the goal, and obviously, NLM is working closely with Doug Fridsma and the ONC to ensure that these things marry up with the work being done there to package the standards in more computable and appropriate format.

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

This is Wes. I'd just like to add to what has been said so far that one of the Dixie's questions really started us talking about mappings, and of course, that's not an unrelated question to the question of using standard code sets internally. I think that—I'm not aware in most cases that there are alternatives that are also standard to map between. We talked about the ICD-9 and ICD-10 transition or SNOMED to ICD-10. Those are cases where we could at least conceive of a mapping, even if the specifics of ICD-9 and ICD-10 code sets make that difficult. But the mapping problem that most implementers will have between an ADHOC system of codes that they have been using and building over some period of years, and the standard system of codes.

There, I would say there's no potential for making a standard mapping available because no one except the particular site knows what they're idiosyncratic codes are. One would expect that this is an opportunity for industry to create tools or to further develop tools that are already there for creating mappings. I think it would be an interesting agenda item at some time to examine where the industry is in that regard and what if anything can be done in the public policy sphere to ensure the availability of those tools.

Betsy Humphreys – National Library of Medicine – Deputy Director

Wes, this is Betsy. I agree that obviously, with everything you said, and I think there are obviously a number of people working in this space, and of course, there are publicly available tools, freely available tools, including some that derive from the NLMS and related programs that industry and individual organizations can and do use to help with this, but it is obviously a case-by-case mapping if you've got your own idiosyncratic vocabulary inside your system.

John Halamka – Harvard Medical School – Chief Information Officer

And so, just to give you a real-world example, Wes, the kind of mappings I was talking about, internally to all the systems that I've developed, we've used a commercially available product for And so, we need

to ensure there are maps between what is a standard proprietary data set and RxNorm or that we may use ICD-9 for say diagnosis and that we need to map ICD-9 to 10 and SNOMED-CT, and therefore, we would derive that mapping from the Kaiser work or the NLM work. So, it's a combination of those that are self-developed code sets and those that are proprietary commercial or historical code sets.

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

Good point. Thanks, John.

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

This is Dixie, once again. Beyond the mapping, to give you an example, if CMS requires that they use ICD-10 and transitions ICD-10 for reporting a diagnosis, would they—is there any effort for CMS to align their requirements such that they require SNOMED-CT for diagnosis across the board?

John Halamka – Harvard Medical School – Chief Information Officer

And of course, this is a fascinating question that Jamie and I and many others have talked about that wouldn't it be an actually wonderful future state if clinicians could actually never have to see ICD-10 and recognize they would record all clinical observations in SNOMED-CT or tools that were natural language that then allowed SNOMED-CT results and those clinically specific vocabularies on the back end could be mapped to codes for billing. It's a beautiful idea. It's what Kaiser's doing. It just—it's going to take multiple years for the industry to catch up to that, I think.

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

But until that day, I think, this is one of the reasons why we've been working with both on the Vocabulary Task Force and separately in other committees with IHTSDO and NLM to get the standard ... published so that there can be a standardized way of moving from one to the other until it becomes a more unified environment.

John Halamka – Harvard Medical School – Chief Information Officer

So, other comments with the question on the table of adopting these suggested vocabularies for purely the quality measures going forward with the notion that there will also be transition plans for any vocabularies that have been previously stated differently or with additional optionality for stage one?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

John, this is Carol. I really want to go back to this implementation issue, and I think Wes clarified that the step two of this is a much more difficult step. I want to press, again, that we cannot rely on a small handful of entities who may be well adept at implementing more complex standards to give us the kind of feedback we need before this becomes a requirement and a certification requirement and implementation requirement for reporting.

I want to suggest, and I actually felt this way looking at some of the other recommendations that we're going to hear later in this meeting, that we are going to have to have a proactive process, and it potentially will need to be funded where there is some testing in the—that steps out to test implementation in a diverse set of environments, same with input on proposed standards. It is always true that when you have these open volunteer efforts, it's a sample of convenience, but I think the stakes are too high here to rely on those before a federally mandated requirement is out there for a standard. And I just really want to press on the committee and on ONC to really think carefully about a glide path for putting forth requirements that have not yet endured the kind of implementation validation and testing that need to be endured before they can be mandated.

John Halamka – Harvard Medical School – Chief Information Officer

So, fair point, which is, so Carol, to try to phrase that as a specific recommendation, recognizing that the great majority of what is being discussed for quality measures are already in place, but that there are those transitions that will reduce some optionality and that those transition plans need to be fairly crisp so that it doesn't create an undue burden, and going beyond the quality measures, to use these vocabularies natively would require a substantial additional experience.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Hey John, this is John Perlin. Maybe I'll weight in on that point. I really appreciate the discussion and Carol and Wes' point. Wes, the attribution for that quote if you don't feel slightly out of control, you're not going fast enough, was Mario Andretti, and I think the counter of that is that if you don't know where you're going, you may not get there. And I think the counsel that Carol just offered provides some guardrails so that, indeed, one is not out of control, but thinking about the various entities that have to weigh in and be engaged and adoption of standards and development and implementation of technology that incorporates these standards, it takes me back, John Halamka, to one of the points that you made earlier is that in the absence of parsimony or means and. And that's really much more challenging for everybody that optionality of implied and or having to cover a number of standards as opposed to a clear direction.

And in this context, it certainly seems helpful to have the guidance that is parsimonious and—or as a result of that really helps to channel the activities productively, not down rabbit trails or false paths. These are standards that really have, as has been discussed, substantial implementation in a number of independent ideas and bringing them together in this context seems like a rational and parsimonious and productive approach. So, I think with the counsel that you've provided, we really should move forward on this. John, let me turn back to you.

John Halamka – Harvard Medical School – Chief Information Officer

Okay, so any other comments folks would add before I ask for objections to moving forward with these as quality measures and the caveat that transitions for any optionality being reduced will be presented next month?

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

John, I wonder if it might be reasonable to add a second caveat that is essentially Jonathon's guide rails statement dressed up in \$0.50 words, that it's critical to monitor the—to get—to actively seek experience in the industry implementing these standards as we're developing the transition plans?

John Halamka – Harvard Medical School – Chief Information Officer

And certainly, it is very reasonable, and Judy and Liz, as you have been the keepers of the examination of certification criteria and experience, it would seem natural that our Implementation Workgroup would do that monitoring.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I would support that addendum to this recommendation.

John Halamka – Harvard Medical School – Chief Information Officer

Very good. Well, so with that, our two caveats being transition plans for existent standards that may be eliminated over time and for the need for ongoing monitoring of implementation challenges in many settings, any objections to moving forward with Jamie's recommendations?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I just want to say again that Wes used the word active, and I think that's very important. There has to be a real process here to seek implementation experience as active and not passive.

John Halamka – Harvard Medical School – Chief Information Officer

Well, I think as we'll hear at the end of our meeting today, the Implementation Workgroup see this rule as extraordinarily active, and it's keeping us honest and giving us feedback especially where there is burden created that is unexpected or unduly causing cost or implementation difficulties for some stakeholders.

Judy Murphy – Aurora Health Care – Vice President of Applications

This is Judy Murphy. So, certainly the Implementation Workgroup will take that challenge, and I think one of the things that Carol is hinting at that probably we could do better at is ongoing tracking, if you will, of implementation experiences. I think that what we've been doing in the past has been a bit more episodic.

We wait for a period of time to pass and then we ask. And maybe what Carol is suggesting is that we have a more iterative or ongoing open ability to give comments, like all the time.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Yes. I'm suggesting a proactive process even before these become mandatory requirements where we seek out purposefully experience from the field in the implementation realm so that the recommendations can become more solid.

Judy Murphy – Aurora Health Care – Vice President of Applications

Got it. Yes, that makes sense.

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

This is Wes, and I would just add to that that we look at the full-trip experience, which is to say not only the experience of getting products certified but getting the implied outputs created, and I think a lot of the issues that come up in implementation relate to two things; one, what seems obvious in a concept network, can be hard to explain to users; and two, there are things in code sets that are more tested and things that are in there, as a sense, to cover all the bases. And so, we know that in some areas, we may be saying that, for example RxNorm, is the lingua franca for medicines, but in fact, it has been difficult to keep it up to date with certain medications that tend to have a lot of product announcements, like Metformin. And so, I think all of those issues can be uncovered by an examination of the full loop as opposed to just the implementation process.

John Halamka – Harvard Medical School – Chief Information Officer

Well said.

Betsy Humphreys – National Library of Medicine – Deputy Director

This is Betsy Humphreys. There is absolutely no doubt that broad use of any of these standards will, as we envision at any stage of Meaningful Use, will yield feedback that will be necessary to improve the standards to make them more fit for purpose, inevitable.

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

This is Wes. I'm glad to hear that that's recognized as an important part of the process. My concern is that we tend to take all that progress and freeze it up in two-year chunks in our statements of requirements, and we need to make the chunk not too big in stage two.

W

Very reasonable.

John Halamka – Harvard Medical School – Chief Information Officer

So, any objections then to moving forward with the recommendations that caveat it by these two treads of discussions? Recognizing again, Jamie, to your point, this is limited to quality measures for now with ongoing discussion of expanding it to scope. We are not voting on an expansion of scope today.

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

Right. Exactly, but I do want to thank everyone for that discussion. I think that that question did actually come from CMS, and so, I'm very glad we were able to have the discussion on that point. But as it says here that the recommendation is for uses in quality reporting only.

John Halamka – Harvard Medical School – Chief Information Officer

With no objections being heard, then Judy if you can record. Of course, I presume we will do a transmittal letter to you that will identify these caveats, but I think we have a set of recommendations for you.

Judy Sparrow – Office of the National Coordinator – Executive Director

Great. Thank you all.

John Halamka – Harvard Medical School – Chief Information Officer

Now, is Doug Fridsma on the call?

Judy Sparrow – Office of the National Coordinator – Executive Director

No, he is not.

John Halamka – Harvard Medical School – Chief Information Officer

So, as we then move to Standards Summer Camp and again, thanks so much, Jamie and the entire team, Karen, Jim and Betsy. Standards Summer Camp, we outlined a whole set of activities starting in April, and we are marching through those activities exactly as planned with two sets of recommendations being finalized today; patient matching and surveillance and then preliminary recommendations on the Power Team on the Nationwide Health Information Network component tree. And so, Marc, recognizing your group has done extraordinary work and you have drafted a set of recommendations that has incorporated marvelously some of the concerns of the Policy Committee, and look forward to your presentation.

Marc Overhage – Siemens

Thank you very much, John, and I want to acknowledge the tremendous work that folks have done to help putting this forward. If folks will remember from previous meetings, we've walked through in a Power Point deck, a series of recommendations, as proposed, as we're working through this. And we've had some very good and helpful feedback and discussions that's been reviewed and attempted to incorporate into this document that John kindly suggested might start to thread the needle.

Rather than walk through the document point by point, because I think it's easier for you to do that simply reading it, I wanted to highlight and perhaps open up for discussion, the two areas that I think were both the most contentious, if you will, and where we could use the most input or were the least ill formed in the last version that you saw as a Power Point.

So, I think the first area that has been difficult is really centered around our recommendation number one, which as it currently is stated—is that obviously as we acknowledged previously, a policy decision to be made is the level of sensitivity and specificity that would serve as a floor for patient matching. What we tried to lay out in this recommendation is that based on some arguably reasonable assumptions about the minimal level of sensitivity and specificity that we might expect a policy to be based around, that using simply the patient's first name or given name, last name, date of birth and do not achieve those minimal levels, even when the data are perfect, and that's clearly an emphasis here as I was trying to make the data as good as possible.

And so, it seemed to us, and there was some, disagreement's too strong a word, but some feeling in the committee that we maybe didn't even go far enough here, but that there needs to be, depending on the levels, it was decided that there needs to be a base set of attributes that allow us to achieve that level, and that it will go beyond the given name, last name, date of birth, level of specificity, and that zip code doesn't add enough to get us there based on the available literature and experience. So, it is probably something other than just adding zip code, that we were trying not to be proscriptive and rather provide the available guidance about what some of those tradeoffs are in terms of achieving what we expect the levels of sensitivity and specificity would be appropriate for a patient care use case, that as we've talked about previously, we've decided to focus on. So, that was one key thing.

And the second, I think, important thing to highlight is our last recommendation where we spent a fair amount of time trying to come up with a really peppy, good way to characterize the matching process that you could tell the requestor, here's some information that will give you faith and confidence in the matching process. And after a lot of review and discussion, we, frankly, didn't come up with very good potential metrics there. And so, in this recommendation, it seemed the best we can do at this point and time is to suggest that the provider of the matching service should expose at least a textual description, should expose a contact person who would be accountable for being able to answer questions and describe the matching process. And after this document went out, ..., who's traveling in Africa sent back a suggestion that we may want to add to that as well, some of the basic, sort of a checklist of the quality

approaches that are applied to the data, although I think there are some challenges in doing that in large distributed environments because they may be quite diverse across the environments.

So, we punted, essentially, on the fourth recommendation saying we don't know exactly what would be useful, but we think there's a role for exposing some useful information and some contact information that would allow the requestor to get better informed. So, those were the two things, I think, I wanted to highlight. The other recommendations, I think, have not been terribly controversial, and I think are fairly well aligned with recommendations that the committee has made over the past month, but of course, those are up for discussion as well. So, let me stop there and see if there are questions, comments or additions and corrections from my Power Teammates.

M

Well, ..., a real quick verification of the process. Sometimes the HIT Standards Committee makes formal recommendations to ONC. Sometimes we provide input to the S&I Framework. Today, this particular agenda item is listed as an update, and we have a letter that contains some recommendations. How is ONC viewing the particular patient matching team deliverable and what are you really looking for today?

W

I think today is an update, and I think Marc Overhage would agree with me on that.

Marc Overhage – Siemens

Absolutely.

W

Great, thank you.

M

And so, would you see, then, us giving a final transmittal letter in next month or—

W

Yes, that's correct. September was always the month.

M

Well, I just assumed Marc was above average, that he was just doing it faster.

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

So okay, so that then the committee recognizes we are not seeking your approval on these recommendations today. We are seeking your comment on the update, and Marc, I will just, again, congratulate you and thank you because I told the committee before, I have had to invent patient matching algorithms for health care information exchange, and I have not previously had guidance as to best practices, sensitivity or specificity, metadata characteristics and those elements that might be considered core or menu set, and therefore, I have actually had to run into problems and revise on my own, probably Marc, recapitulating everything you've learned in Indiana over the 20 years you were there. So, thank you for that. Comments that folks on the committee would make about the update today?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

So, this is David, and I'm on Marc's committee, and I'll represent maybe some of the discussion that we haven't, I think, necessarily reached complete consensus on on the workgroup and now that we have an extension before our final report is due, maybe surface some of these questions for other discussion. And as Marc pointed out, the basic attributes of first and last name, date of birth, administrative gender, accomplish a fair amount of problem of specificity that we like to see, but it's easily demonstrable in any real world data set that the addition of other identifiers can drastically improve the accuracy to reduce the false positive rate, which is the one that we're most concerned about.

And so, the question that we are debating as a committee is should we—is it possible to specify an additional recommended identifier or that should be a part of everyone's core consideration because of

the fact that we know we can do better than just those four current members? And obviously, the debate that, in the real world, centers around the use of either social security number or these days, much more commonly, the last four digits of the social security number, and there's numbers of studies to show the additional value in specificity that can be gained by the addition of, say, let's just focus on the last four digits of the social security number. In the committee meetings, obviously, we've had a lot of discussion, or the workgroup meeting, I should say, we've had a lot of discussion about the risk of using last four digits. In particular, Deven, who I don't think is on our call today, pointed out that the issue isn't really that the last four digits is particularly revealing, but if you use the last four digits, then you require the system to maintain a social security number, or at least part of a social security number, in their database, which increases the risk of loss of privacy due to the ability to join that number to other databases outside of health care.

So, we were uncomfortable with the recommendation for last four, but we didn't really reach any consensus on what's the next best choice. We had a fair amount of debate about the use of phone numbers, in particular now that number portability is more available to people, the use of the notion that most people have at least one phone number that is relatively stable, but of course, it's not always stable. So, we weren't able to reach any conclusion there, which makes me uncomfortable that we end up doing a lot of work and not necessarily being much better off than we were before we started to do the work. And that's unsatisfying at minimum, and maybe incomplete. So, I'll stop rambling and just let Marc, maybe you want to pick up and elaborate on anything I missed there.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

This is Carol. I just want to make a comment about that. I don't think we can optimize a matching algorithm at the national central level. There are always going to be ... in the data. There are always things that are unique to the population or the use of the information that are going to affect the algorithm. I think our job is, I hope, to say there's a level of sensitivity and specificity that's required for trust across the network. And by the way, we can provide a set of standards recommendations for a whole set of fields, including the ones that you just mentioned, David, because we think people will need to use several different fields in order to achieve that sensitivity and specificity, and I guess I'm wondering why we just won't recommend standards for any of the fields we might could use to optimize matching.

John Halamka – Harvard Medical School – Chief Information Officer

Carol, you're exactly correct, and Steve Posnack, one of the questions I was asked is if ONC crashed the advance notice of proposed rulemaking and that leads to a notice of proposed rulemaking on metadata, that actually won the most valuable services of Marc's committee, is to ensure we incorporate their recommendations on the metadata elements to be captured to empower patient matching into the metadata standards. So to Carol's point, as local variation occurs, at least we will have the various data elements formatted appropriately to implement a matching algorithm that works for you.

Marc Overhage – Siemens

Sounds great.

John Halamka – Harvard Medical School – Chief Information Officer

So, hey, all we've got to do is converge, Marc and David, your work with the metadata NPRM work, and Carol, I think we've achieved what we need to do.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

This is David. So, the thought is we would just supply a standard for the formats but not have any expectation about what the core would be. I'm not sure that's a terrific advancement.

John Halamka – Harvard Medical School – Chief Information Officer

Say this, what would help me, as an implementer, is to know what contributions these various data elements make to sensitivity and specificity, to enumerate the kinds of data elements that you have found to be useful in matching, and therefore, I can then take such a document and then be able to, based on my local needs and my requirements for sensitivity and specificity, implement the algorithm of my choice, picking those elements from a core set and an other set that is going to meet my local needs.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Right. So, the more you specify, the more accuracy you can attain, that's going to be a curve that has a ... to it. The tradeoff is when do we feel we have crossed, and this is really a policy question, when do we feel we have crossed into specifying too much information, in other words, put privacy at risk? And again, we can leave that to be local decision, but if we have some vision that in the future, someone's medical record could follow them as they move and as they live their life, then local decisions do have national implications. If you can't reach the data in a remote location because they don't use identifiers that are necessary for proper specificity, then you've essentially defeated the purpose of building that network in the first place. I just wonder if we've gone far enough in specifying the tradeoffs between increased accuracy and any perceived risk of loss of privacy.

John Halamka – Harvard Medical School – Chief Information Officer

Go ahead, Wes.

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

If you add to providing the standards for formatting this metadata and compiling the contribution that it makes to sensitivity, then I'm going to argue we have gone as far as we can go. I think that the discussion that you reiterated, David, about adding the last four digits of the social security account number, creating the potential for joining with outside data, is going to be true for virtually every piece of metadata that we can think of that the decision's based on sensitivity. Sensitivity's good when you're matching patients and bad when you're matching patients to something else. Fundamentally, we're in a situation where the balance between those things will continue to be a policy issue for a long time, and the best we can do is being sure that whatever is decided for policy in a specific place can be implemented interoperably and that those that are making these decisions have the best information available on the effectiveness of this piece of metadata versus fact.

John Halamka – Harvard Medical School – Chief Information Officer

So, Wes, this is exactly the point. I have felt the contributions, David and Marc, of your work is I really didn't know what pieces of metadata were likely to change over time versus which are more stable, which contribute to matching and what fashion. And so, you have tried to put together a set of best practices and guidelines that now enable me to make a more wise choice, and it also would enable us, as we think about the metadata standards to describe those elements that should be incorporated into metadata to support various matching approaches.

Marc Overhage – Siemens

And I think, this is Marc, to follow up on David's comment, and he's been a consistent and reasonable voice on this since the first day, the one, if you put sort of your pragmatic have-ons, and say given what we know today and the experience that we have today, is there an alternative to some variance of social security number that would achieve the kinds of levels of sensitivity and specificity that we think a policy recommendation would result in? The answer is there is no good alternative to get you there today. And the in particular, when you look at the need to look historically at patient data, it's not like you can just start over Monday and have everybody have the same things. You have laboratory results and immunization records and things like that that, that for many years are not going to have whatever these other, maybe it's a more stable phone number. I find it very difficult to know that this is any alternative, and if there's no alternative, and if the privacy risks are too great, then that's obviously a policy decision to be made, then the recommendation might be that patient matching at this stage, given the current tradeoffs willing to be made between privacy, and would preclude patient matching at the levels of sensitivity and specificity we talked about. That could be a stronger version of what we said.

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

This is Dixie. Did you consider—and I know this is just beginning to get more popular, but the voluntary health identifier?

Marc Overhage – Siemens

We, if you will, allowed for that. The realities are, though, it doesn't exist. So, you can't match anybody based on it today. And certainly, it would add to and be, if it were to happen, it would allow going forward again over some after some period of time of people opting into that, you would begin to be able to actually take care of patients using it, but none of the historical data is going to have it. And you're not going to, in the penetration of, it's going to take considerable time.

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

Well, maybe I don't quite understand. Is the intent of this work to specify certification criteria for fields that should be included? Where is this—if that's really the intent, I think it would be good to at least consider requiring that field to be there. But my question is, is that the intent.

Marc Overhage – Siemens

And so, perhaps I should let John or Judy answer that.

M

So, from an ONC perspective, basically my belief is that this team was charged with doing a survey of best practices in patient matching and coming up with a set of recommendations as to how to think about patient matching, what fields could be used in patient matching, the value of using certain fields, the tradeoffs, without enumerating a precise set of activities for matching but effectively giving the country the guidance to implement locally what works for them.

John Halamka – Harvard Medical School – Chief Information Officer

And Steve, Judy, others, any comments you'd make on their charge?

Stephen Ondra – NeHC – Senior Policy Advisor

This is Steve. I think that the other, not as a different direction, but I think what you have just been describing, John, has been, and I don't want to commit to maybe Doug's staff to this or others, that it may be helpful if we were to make available for public comment, a more formal—say we get these recommendations from Marc's group through the committee in September, and we were to be able to process them and package them into this best practices document that everyone across the country could reference and look to, to give them some guidance, some type of guidance document that we would be able to develop and get public comments on, etc. I don't think you've added a realm of possibility.

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

This is Chris Chute, if I might, I think Dixie makes a very compelling point, and I understand that we're discussing the guidance and the scope of this, but if the intent, more or less, is to provide guidance so that implementers can know what metadata fields they need to start managing or at least curating, then an anticipatory field for the kind of voluntary identifier variable that Dixie was referring to, I think would be logically a very important piece of that guidance.

John Halamka – Harvard Medical School – Chief Information Officer

And I certainly appreciate Dixie and Chris' recommendation, whether that is a state originally issued numeric identifier, a direct e-mail address that is used for the patient centered electronic medical home or a health URL that might be issued to an individual to track their information over a lifetime, there are those identifiers that may be voluntary opt-in additional data, that would make matching much more specific. So, I concur that that is anticipatory desire that seems very reasonable.

Marc Overhage – Siemens

So, perhaps folks could give us some guidance on we included voluntary identifiers as a potential patient attribute to be used in matching, and others may correct me here, but I believe that the CDAR2 header formats accommodate a variety of specific identifiers with a way to label them, if you will, whether this is for example, a driver's license number or whatever might turn out to be a voluntary identifier. I'm not saying a driver's license isn't, but there's a way to do that. So, what else would we say in this document or add to this document to accommodate that possibility?

John Halamka – Harvard Medical School – Chief Information Officer

Recognizing that a place holder in the CDAR2 metadata for a patient opt-in health care identifier, whether again, it could take many forms, but in effect, it's not—saying that the metadata has the capacity to transmit such fields.

Marc Overhage – Siemens

Which it does.

John Halamka – Harvard Medical School – Chief Information Officer

Yes. And so, I'm thinking your analysis just recognizing that it is very early, but over time, recognizing that SSN or four digits of SSN is extraordinarily helpful, there may be other like identifiers that evolve that are an opt-in health care ID that will provide extra layers of specificity, that say, a phone number or an address doesn't get today.

Marc Overhage – Siemens

Great. And if we have language here that folks can suggest, we were not trying in any way to be proscriptive about which of these fields could be included, but there's language here that folks can help us with that imply some specificity, that would be helpful.

John Halamka – Harvard Medical School – Chief Information Officer

Well, very helpful guidance, and I know we have three agenda items that we're covering in this particular Summer Camp section, but I think what we've heard is that Marc's team would welcome your feedback and guidance on additional language, recognizing that it is next month that they will present their final recommendations to us.

So certainly, Marc, thanks so much for all of your work thus far, and I encourage the committee to provide feedback to Marc to add to these items that we discussed. So, why don't we move on to Chris and the Surveillance Implementation Guide Power Team, which is seeking consensus on three public health transactions standard recommendations?

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

Thank you very much, John, and I do want to commend the group of people who worked very intensely over the past three months. The list is in the report, and they've been shown, I think, on previous slides. Like Marc, I'm not going to march through the slides. We've done that before, and simply present the conclusions of our activities.

They focus on three recommendations. One, surrounding electronic laboratory reporting, which is essentially, if I'm to be honest, a status quo, in that right now, the recommendation is to use HL7 Version 2.5.1, and we're recommending that that be continued along with the specific interoperability of framework implementation guide that accompanies it.

The second recommendation surrounds immunization reporting. This one was a bit more interesting because the reality is that most immunization is done by proprietary interfaces or idiosyncratic interfaces. There are some implementations of 2.3.1, but given that we are trying to have a simplified view of what the public health reporting interface might be, and pertinently that there is metadata and information associated with 2.5.1 that is not in 2.3.1, I think there was strong consensus that the recommendation should be restricted to for immunization reporting HL7 2.5.1 and the associated implementation guide that goes with that.

Finally, in syndromic surveillance, there was, from a technical perspective, less compelling reasons to pick 2.5.1 over 2.3.1, but again, we did want to have the elegance of consistency for public health reporting and simplification for both implementers and receivers. We definitely wanted to avoid having a mixed set of recommendations, so given the functional characteristics being equivalent, we opted for 2.5.1 as the recommendation for syndromic surveillance to maintain consistency with other public health reporting infrastructures and initiatives.

Now, there is a caveat on this one. There will be an implementation guide for hospitals published imminently and with the opportunity for timely review. However, eligible providers are unlikely to have an implementation guide developed in time for phase two recommendation, so our caveat is that consideration of syndromic surveillance as a core element for eligible providers, in the absence of an implementation guide, should be given very careful consideration and conceivably not recommended.

I would close by saying that we did, and were mindful of, a strategic direction here. It's very clear that the scope of public health reporting on surveillance in terms of disease reporting, cancer reporting, case reporting and the like, may transcend the capabilities of the 2.5.1 infrastructure that presently exists for many of these reportings, and in future, the embracing of a clinical document architecture mechanism, which is I think consistent with the capabilities of most providers who are going to deploy Meaningful use infrastructures, CCD is, after all, a kind of CDA. However, the inertia is going to rest with the recipients since the public health infrastructure, by and large, does not yet have a capability for meaningful reception of clinical document architecture messages, with possible exception of cancer reporting, where there is experimentation.

We're not making a recommendation in that space other than for the HIT Standards Committee and others to be mindful that this could be a graceful evolution over time with the consolidation, at some point in the future, of public health reporting standards around a CDA type of mechanism, but for the immediate purposes, I think we were quite clear on our three use cases of laboratory reporting, syndromic surveillance and vaccination reporting that 2.5.1 would be the single preferred standard for public health surveillance.

John Halamka – Harvard Medical School – Chief Information Officer

Well, Chris, let me thank you for that fine work, and say that having worked closely with the Massachusetts Department of Public Health and Boston Public Health Commission, each has a virtual gateway capable of parsing HL7 Version two messages and would certainly applaud the notion of a single HL7 Version two implementation guide for all three of the public health portable standards. They are not yet able to parse a version three or CDA construct. So, your recommendations seem to hit the sweet spot of parsimony but also implementability and I welcome comments from others on the committee.

Wow, is this to say, Chris, you have achieved such incredible harmony that there are no comments?

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

I think we have harmony parsimony.

John Halamka – Harvard Medical School – Chief Information Officer

Oh, my God, come on Wes, you've got to have a comment at least.

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

Actually, I don't. I think we've been around this—chased around this push enough.

John Halamka – Harvard Medical School – Chief Information Officer

So, the fact that we have now reduced HL7 2.3.1 and 2.5.1 optionalities with single implementation guide with the guidance that we know syndromic surveillance does not yet have an implementation guide for eligible providers but will 2012-2013; therefore, we need to take that into account. Seems to me to be a very logical set of recommendations, and if there's no additional comments, does anyone have objections to moving forward with final recommendations to ONC on these three public health standards?

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

Just to be clear, this is about reporting from a lab to public health. It is also about reporting from an EHR to public health.

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

Well, that would be the eligible providers and when it comes to syndromic surveillance, that's the one case, Wes, where we're suggesting that there is no implementation guide in place. However, for electronic lab reporting, obviously, most of that would come from labs, but there are providers that have their own labs, and therefore, yes, it would include that, and there is implementation guiding for that.

Similarly, for immunizations, clearly, most providers are the one who deliver immunizations, although, we are aware of what we call the big box stores, the major pharmacy outlets and even grocery stores that do immunization. We're confronting that in our own area. That being said, we're still recommending a single consistent standard for those who report immunizations with infrastructure and vended software that would support that single standard.

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

Okay, and this specifically does not impinge on the standard for delivering lab results to EHRs. That's a different—

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

That's a completely different unit.

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

No, I think we've talked this one to the ideal point for consensus, which is exhaustion.

John Halamka – Harvard Medical School – Chief Information Officer

Okay, any objections to moving forward then? Wonderful. Well, thanks very, very much, Chris, to you and your team, as I introduce today, the fact that we could come out of a meeting with harmony and parsimony with single implementation guidance is a real achievement.

Well, now let's move onto Dixie. Dixie's presentation is not to specifically seek approval. It is to present to you a set of constructs for evaluation of the building blocks of the standards used for transmission and supporting standards above direct in the Nationwide Health Information Network. So, Dixie, look forward to your comments.

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

Alright. Thank you, John. This is an update of the work of the Nationwide Health Information Network Power Team. You see the Power Team members, and I really appreciate the support of all these individuals on this work, and I particularly want to thank Avinash Shanbhag of the ONC and his excellent team for their support on this. It's just been wonderful working with him.

I wanted to remind you of what the Power Team's charge was. We were asked to use the NwHIN exchange specifications and the Direct Project specifications as the primary initial inputs. And using those as these primary initial inputs, to recommend a modular set of transport, security and content components, sort of a portfolio of building blocks, if you will, that could be selectively combined and integrated to enable to trust that exchange of content in support of meaningful use of EHR technology. As we reported at the last meeting, this month we are reporting to you our preliminary recommendations, to the point that we've gotten at this stage, and next month, we expect to report our final recommendations.

But I do want to emphasize that this is an ongoing review, and in fact, we've already identified some standards that need to be further discussed, even beyond what's reported here. And also, as you'll hear from me, we still need to consider alternatives for some of the specs that we believe should be replaced.

Here you see a list of the specs that have been considered to this point. All of these can be downloaded from the NwHIN exchange specifications webpage. The Direct Project comprises two specifications. One is the core direct specification. It's called applicability statement for secure health transport, but basically, that is proscribed the use of SMTP and S/MIME standards to do secure email between two entities.

The XDR and XDM is an implementation guide that also is available from the Direct Project website. It's a single specification that describes how one could use XDR and XDM to really provide a transition between a direct exchange and someone using the more robust NwHIN exchange specifications, the SOAP-based specifications.

The selection process that we've laid out starts with evaluating the exchange and direct specs with respect to the functions that they provide and to eliminate those from further consideration. The specifications that provide functions that there really isn't a need for. The obvious logic here is that if there's no need for them, why name them as building blocks.

And then, the second step is to take the remaining specs and to identify those specifications on this grid that I've shown on the slide, that the X axis shows the technology maturity. This is technology maturity within the life cycle. The life cycle being from merging to maturing to mature and into declining phases when you're just sort of losing ... within the industry.

And then, on the Y axis, we have the maturity of the specification itself. So, the second step is to identify those specs that are in early or moderate stages of development because they're not even fully developed, but they use technologies that are in the declining phases of a life cycle. But as we noted in step one, these specs still have a need. The need still exists. So, we don't just cut these specs out. Instead, we set them aside for further consideration of alternatives to these specifications.

The third step, it uses the grid shown here, that compares industry adoption and deployment and operational complexity. And industry adoption is relative to the industry it's developed for. And on this grid, we would recommend as building blocks those that fall into the areas circled in green there. We would recommend as building blocks those specs that have a moderate or low complexity and moderate to high industry adoption, judged against the industry's it says that they were designed for.

We would recommend alternatives for those that fall in the block I've outlined in red. And then, we would consider the remaining specs that don't fall into either of these, on a case-by-case basis, relative within the context of the need for that, the functions that they provide, as well as the architectural compatibility with the other building blocks that had been selected to that point.

And I wanted to say a little bit about deployment of operational complexity. This was judged on a low, moderate, high scale. And it considers both the ease of the implementation itself and the maintenance of the technology throughout ongoing operations. And low was—it was given a low score if it can be handled with ease by IT support, in other words, low complexity. Medium complexity, or moderate complexity, if it needed moderate administrative support for deployment or maintenance. And then, it was given a high score if it needed substantial ongoing IT investments both to implement and to support it over time.

And then, as I mentioned, that industry adoption is assessed relative to the market segments. In other words, if the specification or standard is removed ... is developed for the broad industry, including but not limited to health, then the industry adoption would have a broader scope of applicability than if it really were a specific health standard like an HL7 2.5.1 that we just discussed.

The fourth step was to consider alternatives. In other words, the ones that we set aside in the last two steps, we would look for alternatives to them. And we have already done, within the Power Team, we've done an exercise where we identified a number of non NwHIN or direct specifications that had been broadly adopted by health care. And we also have already identified a number of other industry standards beyond health care that—so, those will be our two primary sources as we move forward into considering the alternatives. And in considering the suitability of alternatives, we'll use the same criteria that I've just outlined.

And then, the final step is to subjectively assess whether there are any gaps that we think we should recommend as specifications either be selected or developed. If we see other things that we think might

should be—might be considered for this suite of building blocks, that's where we would identify them and recommend them.

Okay, I'll show you the results so far. The scores that were assigned were assigned first by the ONC team, the S&I Framework Team and reviewed by our Power Team. And I won't go through each of these scores, but I would also stress that these scores are still—I'm still getting some comments in about them. So, if you want to make some statements about any of these scores, I would welcome any comments that you might have.

And as you can see, we've specified them in terms of secure transport specs so there are two here from the exchange specs and two from the direct specs. And this is a good example, for example, obviously, they—a comment from David just two days ago about questioning whether XDM and XDR is most appropriately considered a transport or content exchange. And so, we're continuing to have discussions around that.

The discovery specs have to do with finding resources, finding capability, finding people and finding documents. And then, ... the final category is content exchange specifications. This is to really exchange content between two entities. So, walking through our process that I outlined before, the first step was to eliminate from further consideration those specs for which the need is low, and we eliminated two; the Exchange Access Consent Policy. This has to do with privacy policies. It's not a very mature specification, and the other one is the Health Information Event Management specification, so the need was judged low for both of those.

The second step is the—looking at the maturity of the specification itself, and the maturity of the technology, again for life cycle, and we set aside only one at this step. And so, at these points, these are actually, we found only one that we set aside for further consideration. This is where the need still exists, we have to consider alternatives. And that one is Web Service Registry, which uses UDDI.

And then, the third step is to evaluate the remaining specifications on the complexity versus across an industry adoption. And here you see a number of specs that, at least at this point, we're seriously considering recommending these building blocks, and you'll see that there are three that we've identified—one that we've identified at this point that we need to consider alternatives. And then the others, we will be considering on a case-by-case basis in administrative distribution, document submission and authorization framework.

Okay, so the preliminary results are summarized. At this point, those that we have identified as potential building blocks from the exchange ... of specifications, are the messaging platform, patient discovery, query and retrieve. And patient discovery, query and retrieve are standards that are almost always used together. They're almost always implemented together and used together, so we will be considering those as potentially a single building block rather than three.

The direct-based architecture, there is one that in this list, that we will probably recommend, and that is the basic, the core, what I described really was the core specification, SMTP and S/MIME, secure emails. And then, there's the building block that's XDR/XDM. Although it's a direct specification, it really is a bridge between the direct-based architecture in the exchange-based architecture. So, and it too, has been identified as a potential building block at this point.

Let's see. And then, the one that we're considering alternatives for is the Web Service Registry, which the S&I Framework already is considering alternatives to this specification, so this exercise almost proved to validate that decision by the S&I Framework Team. And then, the next step is to consider these remaining steps that are outliers. They're neither accepted nor identified to be replaced, and we need to look at them on a case-by-case basis to see whether we want to recommend them as building blocks or recommend that they be replaced. One is the authorization framework, Exchange Authorization Framework, where there was a high need identified and it is exchange architecture, the administrative distribution, the moderate need and the exchange architecture and the document submission is the moderate need, and it sits within that exchange architecture.

A couple of notes, the first one I've already mentioned. The second I wanted to mention is we initially considered the reason we published CMS, esMD specification, but we concluded that it was really not really an exchange specification but really was an application of the exchange specification and not a core respect, so we really eliminated that from consideration, even as consideration as an alternative, even though it was on an earlier slide. But we do want to recommend to the CMS team that they consider additional transport building blocks for that specification, as right now, it just uses exchange, and we believe that the ability to use esMD across direct would also be of value to the industry.

So at this point, the next steps are to decide whether to recommend these three sets of building blocks or to suggest alternatives, to recommend alternatives for the Web Services Registry and any of the other three above after we've decided what to do with them. And then, to subjectively assess that to see if there are any others that we might want to consider that aren't part of the exchange or part of direct but might be good for this suite of building blocks. One that has been mentioned to me is, for example, the Blue Button. It's really between a provider and a consumer, might be a candidate that we might consider. And then, we will be presenting our final recommendations at the next meeting.

After that, you'll see in your handout, or in the ... that was distributed, that there's a glossary that defines each of the specifications more completely so that you can see what the standards that really make that the specifications that we're dependent upon.

John Halamka – Harvard Medical School – Chief Information Officer

Well, thank you so much, Dixie; a comment and a question. So, yesterday in this conference where Steve Ondra and Farzad and I were presenting, it's interesting that ONC actually does describe that it really has three transport standards or constructs in its portfolio; direct for push, exchange for pull, and Blue Button, the notion of simply delivering a view of data. And so, your point is interesting. I often think of transport as you have outlined it; direct and exchange, push and pull, but there really is that third. In fact, in many of my implementations, I am not sending files, I am providing data views for remote users both patients and providers. So, that may be very interesting to consider in your ongoing work.

John Halamka – Harvard Medical School – Chief Information Officer

John, this is Marc; just a clarification, though, is that the connect protocols do include push as well. It's not exclusively a pull protocol. And in fact, the CDC is using that today.

John Halamka – Harvard Medical School – Chief Information Officer

And then, with regards to looking at the life cycle of standards, which I really appreciate your construct, looking at maturity and complexity and life cycle, it's often in our committee that we talk about ebXML metadata as being incorporated into certain aspects of the exchange standards. And did ebXML come up as something that is really not widely adopted or declining life-cycle item?

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

Well, actually we have identified ebXML as one of the alternatives, but we haven't yet assigned the scores to them. We preliminarily assigned them scores, but it certainly is one of the transports that's used, for example, ... uses ebXML, and it was identified in our study of other transports that are used within the health industry. So, it's on the table for future consideration.

John Halamka – Harvard Medical School – Chief Information Officer

And of course, if our criteria for industry adoption and those modern nature of standards is if Facebook had to do something tomorrow, would it use ebXML? Probably not.

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

Probably not.

John Halamka – Harvard Medical School – Chief Information Officer

But might it use a restful approach? Probably would.

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

Probably yes.

John Halamka – Harvard Medical School – Chief Information Officer

So, certainly welcome the comments of others on the committee about Dixie's constructs in the work so far.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

This is David. I'll make a comment from the team itself, one of the debates that we've had in our calls has been around sort of the question that we were being asked, and maybe importantly, the questions that we weren't being asked. So, what I think we've got here is a list of building blocks that to make a metaphor that might be dangerous because sometimes metaphors can go too far, it's not sufficient to just have building blocks. You need an architecture to weave those building blocks together, and for certain scale of architectures, certain building blocks might work fine, but for other scale of a different architecture, those building blocks would be inappropriate. So, to revert to metaphor space, wood and brick are perfectly fine building blocks unless you're trying to build a skyscraper, in which case, they're not very appropriate, and you need a different building block.

So, what I don't think we've addressed yet is really what are the architectures that are most appropriate. Well, let me put it the other way around. For a given architecture, which of these building blocks fit best? So, that's really outside our scope, but I think it's an important question, and to, John, to your Facebook question, ebXML may be a perfectly suitable building block for certain scale, but for Facebook scale, it's not. And we haven't really addressed that yet.

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

Well, we did in fact, in response to your concern about that. We did create the architectural break out that's shown on the slide that I'm showing right now. And that slide was created exactly responding to that concern that you expressed. Because clearly you don't use SMTP in an exchange architecture. So, and that also is what we mean by, in considering the building blocks alternatives moving forward, we look at both the need, as well as the architectural compatibility, so we did consider that, and it's a very, very valid point, and that's why we changed the slides and changed the presentation in response.

John Halamka – Harvard Medical School – Chief Information Officer

And so, just to answer your question, the scope, to me, I have always thought of transport and the surrounding standards as one of the most key enablers of health care information exchange. Coming out of today's meeting, I think we have some very crisp transaction and content standards. We'll hear more from the S&I Framework about transfers of care. We will have very crisp vocabulary standards, certainly for quality but also for other domains, but on transport, we're still seeing evolution. And does every EHR and PHR in America have a direct connector that makes it trivial for EHR to send summaries to PHR? It doesn't. And so, I hope coming out of Dixie's recommendations next month, will be a set of building blocks that can be incorporated into certification criteria so that EHRs and PHRs will, inside their products, have the necessary connectors to allow transport for various purposes.

So, other comments from the committee?

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

John, this is Wes. That's the clearest statement I've ever heard of the purpose of this committee. In that regard, I'm trying to think back of what I've heard. Is the implication here is that if committee may—a consequence of a recommendation of this committee may be that certifications standards for EHRs include the suite of protocols necessary to use connect?

John Halamka – Harvard Medical School – Chief Information Officer

Well, let me play it out this way. And of course, I can't presuppose what the committee will decide nor what ONC will write. But if we suggest that it is very important to engage our patients, and yet, we don't specify as a certification criterion a mechanism by which an EHR can send data to a PHR, it seems that we will not have achieved adoption or interoperability in this country. And I would love to see every EHR

have a capacity for a direct address to be entered for every patient such that upon a transition of care, a summary of that care is sent to the desired location of the patient be it a PHR or the primary caregiver's EHR. And so, this would provide a set of building blocks that says should you need to do a transmission, a push of data, from one place to the other, that's S/MIME, SMTP, as written in direct specifications, is the way to do that, and hence, a certification criterion could be written.

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

Yes. I guess to try to belabor David's metaphor in more of a glorious way, what we have here is a set of building blocks that could be used to address certain use cases that might be requirements for achieving incentive payments for Meaningful use of an EHR. And we can, for a specific use case, such as sending data to a PHR or, and I'm going to fall short of sending data out of EHRs for a minute because that's pretty confusing, but sending data to a PHR, could be that we—that ONC, with our support as requested, comes up with a specific set of building blocks and makes it a requirement for certification, thus, making it easier for hospitals or providers to achieve their Meaningful use goals because there's something presumably pretested that they can begin to implement. Is that the direction we're going with this? Is that right?

John Halamka – Harvard Medical School – Chief Information Officer

And so, Dixie and Judy and Steve, certainly appreciate your thoughts on this. My sense is, Dixie, you were trying to do the foundational work to screen all of the existent recommended standards for particular purposes to come up with some sort of read as to which are capable and which are mature and where in the life cycle and which are adopted, so that certification criteria in the future could be developed.

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

Well, I recall, it's too bad Doug isn't on the line, because I'm about to paraphrase him, but I remember at the end of the last meeting, we probably—the fairest statement I've heard as to what the ONC plans to do with this work, and at the end of that meeting, he said that this work would help inform the ONC's decisions on where they would invest in pilots and pilot testing versus where they would invest in further standards development. And that was the clearest articulation of the purpose that I've heard today.

John Halamka – Harvard Medical School – Chief Information Officer

And that certainly would be extraordinarily useful because as we constrain the field of standards, we'll have a sense of what needs to be piloted based on industry adoption and maturity and what doesn't exist. We'll hear from the S&I Framework on provider directories, and, Dixie, you know so well that we have this real challenge with provider directories of what we need either doesn't exist or hasn't been widely deployed.

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

Right, right. And some of those standards are among the alternatives that we've identified as well.

John Halamka – Harvard Medical School – Chief Information Officer

But we say, Wes, on the call today, these are simply—we're looking at the process that Dixie's going through. We don't have conclusions, and I don't have a precise answer to your question, but I would hope, to Dixie's comment, that ONC would use these to direct future pilots, future investments, and as is appropriate for architecture and policy in the future, use them as guidance for certification criteria.

Avinash Shanbhag – ONC – Director, NwHIN

This is Avinash from ONC and channeling that a little bit more, I think that's precisely the intention. The intent, at least also in addition to looking at pilots, was to look at all the existing pilots and trial implementations that they're experienced with using direct and exchange and examples but not just those ones, and see if there are elements of building blocks within the architectural framework that are now ready, for not only being nationally deployed but could then be used subsequently for testing. I know certification, I think, is the ultimate goal. I think right now, I think, as a starting point, again, in that ... would be to come up with crisp certifications that are implementable and testable for wide reference implementations and then subsequently come up a plan and see if those could be then incorporated into the certification criteria in the future. Does that help? ... that we've been marching on.

M

Makes very good sense to me.

John Halamka – Harvard Medical School – Chief Information Officer

While I don't ... to move on to the S&I Framework discussion, but I think Dixie, your next steps are to continue with the evaluation, as you say, you have many additional items still in progress, and then, to report back to us in September based on these criteria you've developed of maturity and adoption and life cycle, and that hopefully the committee could endorse your work as providing input to pilots, future investments and potentially the development of certification criteria.

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

Yes.

John Halamka – Harvard Medical School – Chief Information Officer

Well, thanks everybody for your thoughtful comments. And I know we do have a significant agenda item next of looking at the S&I Framework and how they have worked on provider directories and certificates and lab and transfers of care. And again, they are coming to us today with an update, not specifically seeking an approval, and let me turn it over to that team because I know you've got a lot of folks on the phone to present to us.

Jitin Asnaani – ONC – Coordinator S&I Framework

Thanks this is Jitin Asnaani, coordinator S&I Framework. Thanks, John, for that segment to this. Good morning to one and all. We do have an hour today and a lot of ground to cover. So, I'm going to set the context of this presentation in one slide. And then, we're going to jump right into each of the S&I Initiative readouts and updates for this committee.

So, let's go to the next slide. So as a remember, really for all listening, the S&I Framework tries to create a collaborative incremental standards process, which is guided by the ONC and in particular the Office of Standards and Interoperability. And of course, ONC and ... receives input and recommendations from our proper committees. Critically, the work that's accomplished by the S&I Framework is led by an open community, right now consisting of some 300 committed people representing 200 organizations and is focused on real-world interoperability problems. In the spirit of incrementalism, each S&I initiative focuses on a narrowly scoped but broadly useful interoperability challenge, tackled through a rigorous development cycle that ideally results in clinical implementation guidance and real-world implementations at the end of it all.

Today's presentation, this discussion today, is a reflection about consensus findings as opposed to formal recommendations. These are the consensus findings of S&I purpose been so far. At the ONC, we are very, very grateful to our community. They're showing tremendous effort and broad expertise and resourcefulness to these initiatives, and we're hoping that, today, our findings will serve as valuable input into this HIT Standards Committee process for recommending standards to ONC for Meaningful use.

Now, given our really tight timeline today, myself and selected leaders from each of the S&I Initiative communities will read out the initiative findings. At the end of the readouts, I will summarize the findings and suggest some logical actions that may help the Standards Committee to meet its goals. So without further adieu, let's dive straight into the first initiative readout today around certificate interoperability.

Next slide, thank you. The work conducted by this particular initiative, the Certificate Interoperability Initiative is best framed by the recommendation made by the Standards Committee to ONC, which was essentially to investigate the alternatives for cross certifying HISPs with the FBCA, the Federal Bridge Certificate Authority, including an examination of potential implications for cost, market dynamics and complexity.

Next slide, this is gives a little bit of the background. In the current environment, the FBCA cross certifies multiple certificate authorities as meeting the requirements of the Federal Bridge. They also certify

bridges that take on the responsibility of certifying certificate authorities and ensure compliance with the Federal Bridge policies.

Next slide. As such, the red dotted box, on the left of this diagram, illustrates options for addressing the requirements of the direct projects, and the requirements are just mainly in—the first option is that this can be directly cross certified by the FBCA. Option B, another bridge such as a Direct Project or health care bridge could be established to manage cross certification of certificate authorities in the healthcare domain.

So, to analyze these options, and let's go to the next slide, we followed a fairly meticulous process. We reviewed all the existing documentation around certificate requirements for Federal Bridge, Web-Trust, ETSI, etc. and conducted a number of industry interviews, incorporated public comments so that we could get the best thinking we could from the broader public, and then conducted additional research to address that feedback and today actually is more-or-less our final report out on the certificate of interoperability initiative to give to the Standards Committee.

Let's go to the next slide. What this initiative uncovered, first of all, and of significance, was that the current FBCA policy, in fact, does not issue organizational level certificates as required by the Direct Project, nor does it address policies and procedures to verify organizational entities. To address this, ONC has already met with GSA and found that development of such a policy will take six to nine months, and so is being currently conducted. But even while ONC coordinates with GSA on this, the Direct Project Rules of the Road Group is developing guidance to ensure certificates used in the interim align with anticipated FBCA policy and comply with commercial best practice.

Next slide. So, in light of this gap in the FBCA and the work being done to mitigate this gap and to get to a happy end point, we investigated options for ONC to provide support and came up with, essentially, four major options. First one is continuing the status quo, which leaves it to the Direct Project participants to identify and assess cross-certified certificate authorities.

The second one is in the case in which ONC issue guidance that goes beyond the FACA requirements—I'm sorry, goes beyond the FBCA requirements for certificates and identifies vendors that comply with certificate guidance and are cross certified with the FBCA. So, the ONC will play a much more active role there.

The third option is that ONC can directly or contractually establish a bridge that is chartered by the Federal Bridge, and the fourth option is that ONC would issue an RFP to select one or more vendors that are cross certified and meet any additional requirements. So, that would be directly working with vendors to get discounted certificates.

So, each approach has both pros and cons, which we have detailed in the final report, and we provide a link to that final report after this presentation. But let me summarize them over here. To stay with the current states, by definition is very rapid, to the point, and requires low overhead for ONC, but as we know, it fails to create a health care root and also puts a higher burden on purchasers to do the due diligence on certificate authorities.

The second option enables some choice of roots, lifts the burden of vetting vendors off of the purchasers and also allows ONC to specify policies that go beyond those specified in the FBCA. So, it has a good set of positives. The clear trade of reports is that the burden of vetting falls squarely on the shoulders of ONC.

In similar being, the third option can enable tighter policies and lower the burden of purchasing of certificates while creating health care roots. On the other side though, it also creates a burden on ONC, and it's also slightly unclear what impact on certificate costs will be our priority before I change

The final option, when ONC negotiates discounts with one or more CAs, has much of the benefits of the last two options, the previous two options, with the added benefit of lower costs for purchasers by

definition. In this scenario, ONC will be responsible for contract management and procurement, and so that's the burden that ONC bears, and it's most likely that you'll also review these choices in the markets.

Let's go to the next slide. So, with these sets of findings in mind of both the gap and the FBCA policies and the various options that we've simply outlined that can be pursued, the findings really suggest that ONC can pursue a few options. One is to work with the GSA, which is exactly what we're doing right now, what ONC is doing right now, I should say. Ensure that in the interim, the Nationwide Health Information Network, including the Direct Project, participants acquire and use certificates that align to the maximum extent possible to the Federal PKI policies, and as I mentioned, the Rules of the Road Workgroup is trying to specify a set of policies to get us there.

And once federal policies for authentication of organizational identity are in place, there needs to be a migration process, transition process from the solution that is discovered ... now to that set of policies in the future. And of course, none of this precludes that we need to create a longer-term strategy to establish a health bridge that is cross certified with the Federal Bridge.

Now again, this is a summary of the final report that we created, and the link is over here on the slide, and of course, ... through the ... on the slide deck on the website. And I will recap these findings again toward the end and be spared of being able to move quickly through our other presentations, we're going to go ahead and move into the next initiative; Transition of Care initiative. And for now, I invite John Donnelly and Russell Leftwich from the Transition of Care Initiative community to come and provide us updates on the community's consensus findings. John and Russell.

John Donnelly – Transition of Care Initiative

Thank you, Jitin. This is John Donnelly. I just want to introduce myself as being one of the volunteer leads of this initiative of having served as the, or serving, as the lead for the Standards Analysis Workgroup and also some work with the Use Case for Certification sub-workgroup for data elements.

As you see on the screen here, our perch is going to be for this initiative to present our objectives and then our summary of findings and then to drill down a little bit on our approaches and our findings and how we got to there. So, as you can see here, coming out of our use case for Transitions of Care, our objectives are to provide clear guidance in terms of the information to be exchanged in the Transition of Care. And not only to look at specifically at that transaction, but to also to look at the vehicles by which they can be deployed and promoting uptake in the industry.

So, we needed to look at tooling and with the implementation support to ensure that there would be adopted by both vendors and vendor-care providers that are using those HIT systems. And not only do we need to look from an IT perspective, but also from a clinical perspective, and I'm going to talk a little bit about the IT Standards side, and then Russell will talk more about the clinical perspective. There you see at the bottom, the mission statement for us is an underpinning of this initiative, as well as that that comes from Meaningful use.

Next slide, please. So, in summary, we basically have two main consensus that have been reached. One is that the HL7 CDA Release 2, and specifically, the CDA consolidation ballot results is the best standard to use in support of the meaningful use requirements as it relates Transitions of Care.

The second area we feel that the Transitions of Care clinical information model, which has been worked on as part of this initiative, is good guidance. It is the best guidance to provide a clinical perspective for these care transitions, and this has been mapped to the HL7 CDA Release 1 and will be in reference implementation. The meaningful use, specific meaningful use requirement there is listed. I'm sure it's not new to any of you that we're trying to facilitate a human readable and either unstructured text or preferably a fully interoperable structured data at the end of the day.

Next slide, please. So, a brief moment to the path of transition of what we took here. We started out with a couple of different standards that could address this, and what we did to simplify the process and to be equitable in our analysis, we defined our requirements of data in something that we call data element

sets, and it was a way to somewhat generically describe aggregations of data that came out of our use case discussions that let us then look at the appropriate standards that could then be applied in the use of those data element sets in their transition. So, we did this looking at how these data element sets related to the CDA R2 data standards. We looked at the CCR, and then, we've actually even looked at the HL7 Version two elements for use in the ... project.

So, we're trying to establish this underlying process of using a data element set to define the data requirements and then associate that to the appropriate standards in a consensus manner. So, as a result of this path, we have then come together with some findings that have led to that summary of finding about the CDA R2 being the best choice.

Next slide, please. So, a synopsis of our findings is that the CDA R2 seems to be the best selection as reached by our community. It covers not only the specific exchanges that we have, but basically any exchange that could also be entertained and done or accomplished via the CCR. So, we felt that it was a good selection here.

But independent of the actual data module definitions and the template ... and things like that, we felt that it had also a support infrastructure, which was quite robust. So, it has a substantial library of CDA R2 templates that we can leverage, and these are all being harmonized across CDA initiatives by the CDA consolidation ballot work, and we also feel though, that in order to actually promote this in the industry because we have the CCR as an accepted format of exchange, that in the—that we should have the transition guide or a transformation service that is included as part of the reference implementation guide, so that those systems that have not yet embraced the CDA standard, have a clear path for transforming their CCR-based information into a CCD-based information.

And lastly, we feel that at this point, we have quite a community of individuals in the industry that are now collaborating to develop tooling and testing as well as education resources to enable both the executive guidance and the implementation support for the HL7 CDA R2 deployment. Bottom line here is that we have felt as a community here, that by utilizing the single standards that we would minimize potential misinterpretations from different formats and data structures. We can streamline the patient transition process, and we can increase the overall care coordination responsiveness to provide better patient care. Next slide.

Okay, with that, I'd like to hand off the baton to Russ who can talk a little bit more about the clinical information model. Russ?

Russell Leftwich – Transition of Care Initiative

Good morning. This is Russ Leftwich. I've served as a co-lead of the Clinical Information Model of Vocabulary Workgroup and the Plan of Care sub-workgroup, and I thank you for the opportunity to present these findings of the Transitions of Care Workgroup.

First, the clinical information model workgroup, based on the use cases developed for this effort and building on work elsewhere, has specified, what we refer to, as a core or priority A data element. It was the consensus of the CIM Workgroup that the priority data elements should be included with the clinical summary for every transition of care, including the summary sent to the patient's PHR. That core clinical information would include ... data, demographics, the active medication list, including an indication of when it was last reconciled and by whom, the active problem list, also with an indication about last reconciliation, and the list of intolerances including allergies.

It's been shown by many analyses that the failure to communicate this information compromises patient's safety, attributes prioritized to poor patient outcomes and precedes the cost of care. The CIMS Workgroup has catalogued and prioritized and put B, C and D categories.

The additional data elements recognized as information that might be included in clinical summaries for transitions of care, including those data elements for care planning. The B elements considered frequently important and frequently included in summary documents are optional but still considered

high priority. They would include the data elements referenced in the proposed stage two meaningful use.

While it was felt that the core data elements should be automatically uploaded to the clinical summary by the EHR system, it was also consensus that the B, C and D data elements should be included only as selected by the creator of the document, not automatic. This is consistent with us at clinical practice and with a patient-centered approach where only relevant data is communicated and with information overload recognized as contributing negatively to outcomes and patient safety.

The output of phase one of the Transitions of Care Initiative is available for review on the S&I Wiki, and I could have the next slide, including the Transitions of Care clinical information model, its current state and the current version of the implementation guidance. The continuation of phase two will focus on further development of greenCDA schema for those CDA sections that are to be reused across multiple care transitions and the focus of the clinical information model work will be to further define and finalize the identification of standards and the vocabularies for data elements as needed and as cited by the ongoing development of future phases of Meaningful use criteria and as it implies depth around the data need for Transitions of Care. Thank you.

Jitin Asnaani – ONC – Coordinator S&I Framework

This is Jitin Asnaani again. I'd like to first thank John and Russ for this update, and I'd like to invite Hans Buitendijk and Ken McCaslin to come and to describe the findings of the Lab Results Interface Initiative, and Hans, as always, I apologize if I butchered your last name.

Hans Buitendijk – Siemens Medical Solutions – Senior Product Manager, Healthcare IT Division

That's where the mountain bikes come in handy. Thank you, Jitin, for this chance and the committee. Want to first describe a little bit more what the value of the ideas, how we went about it, and then Ken will delve a little bit deeper into some of the vocabulary topics. I'm a co-lead of one of the workgroups, the implementation guide of about four or five different workgroups that we have within the initiative.

The key objective that we were striving to achieve is we embodied in the mission statement that are on the slide, where we are trying to establish a guide that can further provide guidance and a direction on how to implement lab results that need to be sent to ambulatory EHR, so that they would enable primary care physicians to receive meaningful, structured, standardized lab results. So, that's the main focus that we have, with quite a perspective of stakeholders, LIS members, EHR vendors, providers, labs, etc., and where we are trying to ensure is that, by having consistency, that we can send a message that does not require a lot, if any, transformations in between that middle men might provide.

And then, as a result, we can really adopt EHRs more widely with consistency of interpreting, including and utilizing lab data. So, as we went through that, we determined that we needed to establish a base line that supports the ambulatory report requirements, but not only that, that we can also grow into the future with that, so that we have opportunity to enhance and expand that capability. We looked at work that was already in place from an HL7 perspective with a number of different implementation guides that addressed different angles, different philosophies, different perspectives there, so we were looking at those to help strengthen our use case, understand those, use those assumptions and some of the ... and use the best of all those guides that have been developed to date and see what would work best. Could we use one of them? Did we need to create a new guide in order to take advantage of that?

We had active participation from ACLA, EHR vendors, SDOs, government agencies, etc. to help pull the decisions together. And as indicated, we wanted to look in the future as well, and particularly as it relates to public health, so that there is a growth opportunity from reporting between labs to primary care physicians, and then be able to report to the public health as well.

Next slide, please. So, as we went through that, the conclusion that the group reached is that we want to propose a new implementation guide, based on version 2.5.1 as the foundation, but also, pre-adopting some capabilities out of 2.7.1, possibly 2.8.1, and as I'll review in a moment, there's some 2.7.1. And in new guides was the conclusion that neither one of the existing guides was seen as being able to set

aside a use case and the current understandings of what we're trying to achieve; that if we took one, we would miss out on other capabilities. So by taking the best of the respective guides and pulling it together, we felt that we have a better opportunity and a better guidance, more or less, ambiguous, I should say, and improvements that went well beyond the individual guides, that also may have required us to turn to HL7 and ask for some enhancements to the base standard to support that.

So, there are some requirements to have additional fields, and there were some requirements to have improved conformance and usage guidance that would reduce ambiguity in the interpretation of an implementation guide to get more clarity to the implementer to work with that. So, we asked HL7 to consider a new version, similar as what happened a couple of years ago with some of the HITSP work, and currently, as a result of that, there is an out-of-cycle ballot in HL7 that is lined up for both version 2.7.1 to address those missing pieces, as well as the implementation guide to run through the HL7 ballot process.

So, in early September is when we're looking at that out-of-cycle HL7 7 ballot for both version 2.7.1 and the implementation guide, while at the same point and time, work is in progress to identify pilots so that we can get practical experience with the proposed implementation guide, its contents and that the combination of the ballot, as well as the pilot experience, can be used to get to a final implementation guide that satisfies the use case at hand and can grow into the future.

With that next slide, and I'll hand it over to Ken.

Ken McCaslin – Lab Results Interface Initiative

Hello, I'm Ken McCaslin. I one of the co-leads of the Laboratory Results Initiative Implementation Guide Workgroup, and I'm reporting from the Lab Vocabulary Workgroup, and that was led by Cindy Johns with LabCorp who unfortunately couldn't be with us today because she is out of the country presenting a paper to her peers. This group did a tremendous amount of work to get us to where we are today. They looked at the standard vocabularies, as well as vocabularies that existed in HL7 tables. Cindy and her team recommended that the community observe the appropriate data types for the data elements, and this is in recognition that some in the community have not always complied with the structure of the data types.

Now, in regards to vocabulary, they were looking at the impact on the annual certification of the laboratory, so the pilot of vocabulary is viewed as a crucial part of next steps. LOINC has had some use, not only in the public sector, but also in the broader community as well, so the community proposes LOINC for the observation identifiers.

The same can be said for SNOMED for appropriate laboratory results. However, the community has recommended a pilot for SNOMED as specimen information. The community did determine that UCUM is viable for reporting for many units of measure but recommends a pilot to help transition the community to the use of this vocabulary.

The pilots that they're proposing over the next 12 to 24 months will help transition the community. In addition, this will give the CLIA inspectors opportunities to review this as the transition occurs and help the laboratory understand how these vocabularies will be evaluated by those inspectors. In addition, there will be a review of the proposed pilot of vocabulary by the Clinical Laboratory Improvement Advisory committee, which meets later this month. The expectation is that they will review that and help put some guidance around how that pilot should be developed and what kinds of things we should be looking at. As you are well aware of, labs are inspected every two years. And so, the how things are going to be evaluated is quite critical to the laboratories making sure things can be moved forward. And with that, I'll turn it back over to Jitin.

Jitin Asnaani – ONC – Coordinator S&I Framework

Thanks, Ken,

Bob Dieterle – Provider Directories Initiative

Yes, I'm here

Jitin Asnaani – ONC – Coordinator S&I Framework

on the Lab Results Interface Initiative, I now would actually like to turn it to Bob Dieterle who is going to give us the update on the Provider Directories Initiative. Bob?

Bob Dieterle – Provider Directories Initiative

Yes, I'm here. Thank you very much, Jitin, and I'd like to thank the HIT Standards Committee for the opportunity to present the work that we have been doing over the past couple months on the Provider Directory Initiative of the S&I Framework group. We've had a fairly significant group of individuals representing roughly 118 individuals, of which 63 are committed and ... members participating in this process. The goal of which was to help to identify process for technologies for the ability to query and discover the information necessary to identify electronic imprints and the ... information for the various artifacts necessary to ensure secure communications between those end points.

We looked at two specific use cases; one, the discovery of digital certificates given in electronic address, something that is infinitely important to the current opinion of the Direct Project; and secondly, to discover electronic service information which we'll describe in one of the later slides, along with direct electronic address getting certain known provide information. The first use case is, as we said, infinitely important to the Direct Project right now, and the second use cases focuses on the needs of EHRs, HIEs, and provider directories, vendors and developers to have standards for the data sets that they can use for their development process.

Next slide, please. Specifically, on the first use case, the immediate need of the Direct Project community to have identified standards for the discovery of digital certificates was the driving force and present and immediate need and challenge for the industry. We developed the use case around that, and then proceeded to look at new specific technologies, DNS and LDAP/x.500 as vehicles for storing certificates and providing paths for retrieval, given the direct address.

Broadly, we went through both of these standards. The information on the review was on the Wiki. What we have here are some very high-level summaries of the relevant information that we thought drove our decision. First, there'd be an ... effectively being utilized currently by the direct Project and its efforts, limited efforts, to store and discover digital certificates.

Second is that DNS provides an easy and highly deployed method for federation replication of certificate data. One of the drawbacks of the ... is that a significant number of deployed DNS servers do not support the cert record, and therefore, cannot be repositories for digital certificates. While they've been participating in the discovery process, they can't participate in the repository process.

On the LDAP side, LDAP is broadly deployed and used for certificate discovery in a number of organizations, internal primarily. LDAP has well-established tools to enable organizations, large organizations, to manage large number of records, so we have significant and strong management capability of the data. However, LDAP does not have demonstrated federation of universal accessibility outside of organizations as currently deployed. So, we ... should talk to on the LDAP site.

Next slide, please. What we have recommended through consensus in this S&I Framework Provider Directory Group by specific use case is a hybrid DNS/LDAP approach, which was shown on the next slide, to take advantage of the known strengths of each of the two technologies and to use those strengths to cover the identified weaknesses in the other technology. We also believe that a hybrid approach will provide the ability for more developers to get involved in the process of creating repositories for digital certificates and making them assessable for the community as a whole.

We explored with the Direct Project Reference Implementation Team exactly what it would take to implement a hybrid approach like this, and the response coming back was actually trivial since most of the implementation of access to both DNS and LDAP is currently interrupted ... as it is deployed. And we

have several EHR/HIE organizations that are willing to volunteer time, effort to develop the ... reference implementations to support the hardwired approach, and we have two of the current and direct pilot communities that are interested in deploying that implementation once it is developed. As such, we are suggesting to the HIT Standards Committee that they consider a hybrid approach for this particular use case involving the discovery of digital certificates with a known Direct Project electronic address.

Next slide, please. The process would be to use the current DNS resolver to look for a cert record containing the digital certificate for a specific Direct Project electronic address. If that fails, then they would change to the LDAP resolver, which would look for an SRV record on DNS, pointing to an LDAP service that would contain digital certificates for this specific domain. A standard LDAP query using an anonymous bind would then be used to go out and retrieve the certificate from the LDAP store.

On the right, you'll see that the current reference implementation supports the DNS, supports multiple resolvers. It supports the DNS certificate discovery, and it also supports LDAP anonymous bind and certificate discovery. The work that's necessary to complete the hybrid approach is to rate the implementation guidelines for publishing and discovering the LDAP services using an SRV record that work is underway. The implementation guideline for the LDAP query and response ... for digital certificate using the anonymous bind, that work is underway. And then, to update the reference implementation code to look for the SRV record to point to the LDAP service and to update the reference implementation code to specifically go out and use the new ... schema to retrieve the digital certificate.

So, that is the overview of the recommendations of the consensus opinion of the S&I Framework Group related to provider directory use case As far as use case two goes, this is now talking about the discovery of electronic service information and electronic service information we're describing as the information that's reasonably necessary to define an electronic destination and this ability to receive and consume specific payloads, such as discharge summaries, patient summaries, laboratory reports. It would include the destination electronic address, its messaging framework that it supports or one of your messaging frameworks, the payload specifications and the required security effects. In the case of direct, this would be primarily an electronic, Direct Project component or electronic address, and it would be the certificate or the electronic address could be used to retrieve the certificate from a store that was declined by use case one.

Broadly, we have communities of interest around provider directories that are currently in the process of specifying or developing or deploying provider directories. They need guidance on the data set that is to be supported and the various vocabularies related to the data set for the query, process and inquiry of the information to be returned from the query. This is also necessary for the HIEs and EHRs and provider directory vendors to work on their development process in a way that is consistent across the industry. Unfortunately, at this moment, as the HIT Standards Committee has also observed, there are no good—I shouldn't say good. There are no broadly deployed standards for the provider directory. And so, it's important at this point, to allow the market to evolve some of these alternatives, and we can come back in the future and visit and see if the market has decided on which of these particular alternatives are viable both commercially and from a practical standpoint in providing access to the information that we need.

Next slide. So, the effort was focused primarily on the data sets for query and response for the electronic service information. We utilized the information that was developed to give It was developed by the provider directory to the practice, which was an effort among a number of states sponsored by ONC, to define development process for provider directories. This data set was reviewed, evaluated and updated by the members of the S&I Committee, and cast a consensus vote, and we're in the process now of mapping that data set to a series of technologies, which include microdata, LDAP or x.500, HPD and the ASC X12 standard.

We're looking for community-driven focused efforts to take these mappings and these data sets and deploy them over the next year or so, so that we can come back and evaluate the success of, and the market interest, in these various technologies. The diagram on the lower right can show you how this potentially will help those vendors. They can have a standard query and response set that they can use various interfaces to the technologies to query and retrieve the electronic service info.

Next slide, please. So, broadly and the details are on the Wiki and are current to the details in this slide, rather, that to be exemplary. We have defined in the query information sets that we recommend, including the return of the identifier, ... directory, return the information in the event in the future there is a federation among provider directories or its a gateway to provider directories. And then, a highlight of information that I give to the individual in the organization and the relationship between the individual and the organization as indicated here.

The response side is bringing back more detailed information, again, this is defined on the Wiki, related to the provider directory that returned the information, the individual's information, the organization's information, relationship information, and obviously, electronic service information. The return of the information is intended to be adjustable based on query parameters. So, the one ... return anything for a specific organizations and ... organization to a general parameter to return this to our positions in the geographic area.

The next steps, as we said, are to map it, to report technologies and from that, to determine events between real specific ... and the core data set and what if standard extensions, or extensions of those standards, and we accommodate over the first set or the most critical elements of the defined query and response data set. And then, to also identify any known incompatibilities between those specific technologies and the specific data sets that have been developed. That is the end of the report on the S&I Framework Provider Directory Initiative.

Jitin Asnaani – ONC – Coordinator S&I Framework

This is Jitin. Thank you very much, Bob, really appreciate that update for the committee. So, I wanted to—as we have reached this point, one thing's obvious, we have quite a lot of information, quite a lot of great findings over here, and even though it took us probably about just under 45 minutes to call out those finding, that's still a distillation of 7 and ½ months of work by 300 people to come up with a set of findings in aggregate. So, what I'd like to do is two things. One is I'm going to go through a couple of slides just to set up a sort of framed discussion, and I'm going to request our chairs just to help us to conduct a discussion and make sure we don't far overstay our already slightly delayed timeline over here.

John Halamka – Harvard Medical School – Chief Information Officer

Let me just quickly introduce your summaries. So, recognize that this has been a fire hose of information to try to give you some grounding in what the findings are. We have four slides left, and we're going to take those slides one at a time in each of the four domain areas and ask the committee for some commentary. And, Judy, there's going to be some questions of process here, as to how the committee can be most helpful with next steps in each domain. So, let's go to our next slide and discuss how we can be most helpful with regard to the certificates.

Jitin Asnaani – ONC – Coordinator S&I Framework

Okay. Terrific. Let's go to back one slide. So, just to give you as quick a recap as we can, what the readout of the Certificate Interoperability Initiative found out that there is currently a gap in federal PKI policy to address identity validation for organizations, and that gap is being addressed through ONC's work with GSA. And in light of that gap, the initiative evaluated options for ONC and outlined them to provide support for the industry. So with that in mind, I'll actually borrow what John just said over here and say, what are some of the actions that the Standards Committee could be providing—could be acting on, or should be acting on to take the next steps and help fulfill their goals? I'd like to turn it back over to the committee to discuss.

John Halamka – Harvard Medical School – Chief Information Officer

Sure. So, recognizing, Judy, the Standards Committee has provided many things to ONC, generally recommendations and advice, sometimes evaluation of implementations. So, here we have, from the S&I Framework coming back to us, a suggestion, followed up on our question that came from Dixie's committee about how certificates should have appropriate trust frameworks. There's a gap that has been identified and a set now of monitoring and observations that take place. And so, therefore, does the

Standards Committee, through Dixie's workgroup take on an action item of monitoring progress and offering additional advice on that progress to ONC?

Judy Murphy – Aurora Health Care – Vice President of Applications

I just think, John, Dixie's going to address that. Go ahead, Dixie.

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

Yes. Since it was our workgroup that recommended this task, I wanted to just respond to it and first to commend the S&I Framework for the excellent job they've done on this. I personally concur with all of their findings. I did want to add one note. They are already working with the GSA to resolve this issue of the fact that the federal government has no policies for governing the authentication of organizational identity, and as was Jitin, pretty thoroughly of that, said a six to eight-month effort, we recently learned that the federal government is a bit behind in its enforcement of requiring certificates be issued from certificate authorities that are cross certified. So, I believe my understanding of the timeline is that that six to eight-month gap should work out fine.

And also, noted the Direct Project Rules of the Road is already specifying the policy that they recommended, and we would like to suggest that that be expanded to apply to the entire Nationwide Health Information Network and not just Direct. And other than that, I think that what they've made out is very good.

John Halamka – Harvard Medical School – Chief Information Officer

Other comments folks would have on the topic of certificates? Dixie, it sounds like you gave them a question. They have examined the possibilities. They have identified gaps, and now they suggest we monitor the ongoing work of the GSA and notes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

This is David. I'll weigh in on this a little bit and agree with Dixie. I'm actively involved in the Rules of the Road Group developing the certificate policy for Direct, and I think everything I've seen on these slides is consistent with the assumptions that we've been operating under. I want to reread them more carefully when I have a little bit more time, but I think it's quite consistent. Developing a certificate policy that is essentially a minimal modification of the Federal Bridge certificate policy so that when it comes—when the time is available for us to reconcile the two, when this GSA process is completed, the changes will be minimal. But I would also caution, as Dixie just noted, that operationalizing a bridge is a step that goes far beyond the mere issuance of bridge certificates. And we need to be cautious that that may take longer than six to nine months. And in the interim, what most agencies appear to be doing is using multiple routes that adhere to a common policy, which someday will be enforced through bridge mechanisms but which today are just enforced through policy. And that's the direction that we're headed and I think it's consistent with what Jitin recommended.

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

Yes. David, thank you for mentioning the multiple routes that are cross-certified. That's a good point to add as well. I agree with you.

John Halamka – Harvard Medical School – Chief Information Officer

Any other comments on this particular topic? Very good. Okay, well let us then move on to the Transfers of Care.

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

John, I'm sorry. I was trying speaking into a muted microphone here.

John Halamka – Harvard Medical School – Chief Information Officer

Oh, please go ahead, Wes.

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

Dixie made a comment that she would recommend that the approach being adopted by the Direct Rules of the Road be applied to connect as well. I don't have the vaguest idea how that might happen. I just wonder do we want to somehow wrap it up in our—if we're going to have a period where we either accept this or don't. Are we going to include that in our list of our action on this regard?

John Halamka – Harvard Medical School – Chief Information Officer

Dixie, any comments on that?

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

Yes. I was really referring to Jitin's slide where he said that ensure that in the interim, the Nationwide Health Information Network, including Direct Project participated and acquire use and use certificates that align with the Federal PKI policies. And I wholeheartedly agree with that recommendation, but as that recommendation says, it's including the Direct Project, and I don't honestly know what the exchange community has in place to assure that they too are aligned with the Federal PKI policies. But as we're trying to move toward a single nationwide health information network, that is a step beyond these individual projects, I think it would be worthwhile to have a single body that looks at policy for both.

Avinash Shanbhag – ONC – Director, NwHIN

This is Avinash. Just to kind of add on to it in terms of what exchange is doing. Currently, exchange does provide certificate, which is certified on the Federal Bridge, and it's to a common group that's maintained by ONC, and a single root that provides the certified certificates.

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

So, we do know, for a fact, that the policy that is used for—I did know that they had a certificate CA that was cross certified with Federal Bridge. Do we know for a fact that their policy is consistent with the direction Rules of the Road is going?

Avinash Shanbhag – ONC – Director, NwHIN

Let me check on that. I'm not very familiar with the direction the Rules of the Road Project I may have to read on that.

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

That's why I think we need some alignment.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

And this is David. We got some inconsistent information on exchanges use of a CA that's bridge. We were told, at least by one person at ONC, that that was not the case. So, I think we have some homework to do to reconcile all of these issues.

John Halamka – Harvard Medical School – Chief Information Officer

So, I think the answer is, Wes, this is an action item to investigate further and obviously if there is a possibility of aligning the approaches, that would be good, but Transitions of Care Initiative.

Jitin Asnaani – ONC – Coordinator S&I Framework

Okay, great. The Transitions of Care Initiative, this is Jitin speaking again, so of course, the biggest findings here, the most—the key findings here was that after evaluation of standards, the community feels that the CDA consolidation ballot results, which based on HL7 CDA Release 2, are the best standards to use and support meaningful use requirements getting both—limiting both optionality and ambiguous definitions while also involving a templated approach that allows extension.

The tooling, testing and educational resources will be key to this as it will enable easier implementation, and that's an important part of the work that the initiative is doing. And lastly, but not least by any means, the fact that there's a Transition of Care Clinical Information Model that will provide clinical perspective for care of transitions and maps to this standard, should be the thoughts over here for suggested actions for the HIT Standards Committee is that this should feed into a standard for care transitions for meaningful use to be declared for Meaningful Use stage two in light of existing hospital standards that have

previously been declared. And it should also most likely impact an EHR certification criterion for the incorporation and usage of this structured data appropriately beyond just being able to accept it. And so, what does the committee think about those comments?

John Halamka – Harvard Medical School – Chief Information Officer

And so, let me just introduce this notion that it would seem, Judy and probably Jamie, that as we now get back from S&I a set of recommendations on Transitions of Care, that as we usually do examine those in terms of their market maturity, implementability, appropriateness for inclusion in stage two criteria, and I presume that ONC is going to want us to recommend some stage two certification criteria around the potential incorporation of data into EHRs and not just to display. So, there would be a body of work that we would then have to engage in to respond to their recommendations. So, Judy, any process comments there?

W

I think would have to go to either Judy Murphy's Implementation Workgroup or as you said, maybe Jamie's clinical operations for that decision. And as you stated the outset, this is just a conclusion, basically for your review of suggestions.

John Halamka – Harvard Medical School – Chief Information Officer

So, comments from Jamie, comments from others about how we might get this handoff and then examine it?

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

Well, I guess I have a question first. And that is, in our previous discussion, so I think, Russ, this is for you, Russ Leftwich, in the Transitions of Care as you described the A-list priorities, the problems, meds and allergies or more generally intolerances, we've just had a large discussion on standardizing vocabularies for exactly those things for external reporting for quality measures. And so, all of the same external reporting requirements for those items have to be in standardized vocabularies for quality reporting, and I know you and I have discussed previously that for example, med list reconciliation and problem list reconciliation is easier if the drugs and conditions are described consistently. And so, I'm wondering if the group has discussed using the same set of standards for this external exchange format as is used for the external quality reporting format?

M

We have to accept that. That was not something that we attempted to reach a consensus on, but I think we work with the concept that that would make sense to have the same vocabularies used in all aspects of data exchange.

John Donnelly – Transition of Care Initiative

Jamie, this is John Donnelly. I can add a little bit to Russ' response because it's kind of like a collaborative effort between the CIM modeling work and the standards work, and I can agree that the work that you presented earlier in this meeting for these different sections of data, were equivalent or also reflected in the templates of the CDA consolidation ballot work. I didn't see any disconnects there. So, as Russ said, although we haven't taken this on as a specific charge, to harmonize the two needs of the data. At this point, I do not see any conflicts between the vocabularies and terminologies recommended by your work and the work that we've been doing inside the standards analysis work.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

This is Stan. I'm very interested in the Clinical Information Model. My question really relates to the future of this as well as maybe more details of what we were just talking about. There's a national and international initiative around clinical information modeling that is just getting underway, which would overlap with these kind of—and it's not ready to use and I'm not proposing that be a solution here, but if that national and international work evolves and is useful, what are our opportunities in the future to use that work rather than having all of the work being done inside of the S&I Framework specific to just U.S. emphasis opposed to coordination internationally on these kind of models?

And then, secondly, I think very specifically, what's needed is what HL7 folks would say would be the terminology binding for these models. And I haven't had a chance to look at these models so I don't know to what extent for instance. As you look at the model for allergies, that the exact value sets have been specified for severity of the reaction, the reaction types, all of those kinds of bindings to exact value sets for each attribute in the model. So, I guess two questions. The summary of my two questions; what's the opportunity in the future to evolve this to use national/international standards that are evolving and parallel?. And then number two, how much of the binding work has actually been done to each coded element in these models?

M

Jitin, if you don't mind, I can respond, at least take a first shot at the response. And if others want to add. Stan, to your first question, I'm not sure which initiative you're talking about in terms of the national/international modeling, but I do know that the work from the CDA consolidation initiative had looked at the vocabulary definitions underpinning the templates of both the HL7 work, the health story work, as well as IHEs implementation guides related to CDA profiles, as well as then work that HITSP did that was built on top yet of those core standards. And I know both HL7 and IHE have international participants in their formation of their implementation guidance. So, there might be some overlap or some harmonization already underway from those organizations into the modeling tools that you're talking about. So, I'm not sure which ones they were, but I do think we have a decent representation of the committee members that have an international participation level at the international level as well.

To your second question, in terms of the specific, down to the specific value sets and the elements there, there is quite a granular specification done through the templates that are published and available from HL7 and now from the CDA consolidation ballot results. That does drill down to very specific attributes and elements underneath the specific data concept or data elements. So, that is all that I have available on the S&I documents set, the Wiki and/or the HL7 ballot results that so certainly we can look at that and field any questions that you might have in that regard.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

Thank you.

John Halamka – Harvard Medical School – Chief Information Officer

This one seems to have quite a lot of moving parts. And what I wonder is given a time that we have remaining for the meeting, when we get the handoff back from the folks in the S&I Framework, probably assigning this work to multiple parties. But I heard—was there another comment?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

This is Carol.

John Halamka – Harvard Medical School – Chief Information Officer

Please go ahead, Carol.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Yes. I just wanted to raise a process issue on the Transfers of Care work that was done. I tried to look back at the Wiki to understand how the recommendation was made, and it seems like there was an acknowledgement that there weren't enough volunteers who might support the use of a different standard, and I just want to make sure that in our interest, in our best interest, in accepting these recommendations "as consensus of the community" if there are less than ten participants or if the participants acknowledge that they didn't get to volunteer support that might have been required to have a more robust recommendation or discussion, that that would be good to acknowledge. We can always go back and try to get that in, rather than taking a recommendation that may not have enjoyed that kind of discourse.

John Halamka – Harvard Medical School – Chief Information Officer

So, Wes, I think you made the comment as the community changes so does the consensus.

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

As the consensus group changes, so does the consensus. I agree. I think that—I think what we need to do is not reopen the question from the start, but at least, if there is—at least give some form for people to attempt to make the case that it's worth reopening the question. And at some point, we have—one of the great things about the ARRA law was that it set deadlines, and deadlines mean you often have to make a decision in a certain timeframe rather than make the optimal decision. What we want to do is not give everyone who just didn't want to go to those meetings a chance to come up again and start over, but somehow, make sure there's not a major miscarriage going on here. I have a couple of comments of my own, John, if that's okay.

John Halamka – Harvard Medical School – Chief Information Officer

Please go ahead. I know, Jon Perlin, we are short on time, and so we do want to get to the Implementation Workgroup. So, if you could make some brief comments, Wes, and I'm going to try to summarize the action items on the other two very briefly so we can give Judy and Liz their time. So, please go ahead.

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

So, slides 13 and 15. My comments are basically along the lines that optional is a four-letter word. The slide 13 talks about human readable unstructured text or fully interoperable structure of data. And without a clear statement of what that means as a requirement for those sending information or receiving information, I just don't know how to interpret it. Now, this is the Meaningful Use requirement, but I don't see anything in the summary that's responsive to it.

Slide 15 talks about a library of harmonized templates. And again, what are implications on a product developer and on an organization that using a product? Do they have to be prepared to receive all of the templates? Do they have to be prepared to send all of the templates? Or is it only in the circumstance when someone chooses a specific template that someone else likes that any operation occurs? Some clarity on that point is needed.

And overall, I think that all of the efforts that we've seen, the pilot efforts and the earlier adopter efforts, around accepting CDAs into an electronic health record, have shown that it's a very, very difficult process to implement. And it's true for everything, but it's particularly true for the problem list and allergies, and I would be very careful that we have taken into account the actual real workflow that's necessary at the point of acceptance. I think there were those of us, and I might have been one of them three or four years ago, who believed that there was going to be this background exchange of CCDs that was going to create an extended common record for the patient and what I've learned in watching other people work is I think so.

John Halamka – Harvard Medical School – Chief Information Officer

Well very well said, and I will tell you that my own experience is if a doctor is in the middle of caring for a patient and receives an incoming CCD that has a problem list, a medication and an allergy list, one has to ask, by what workflow is that data incorporated in structured form into the native record or could be attached as an unstructured document for reference. And this is a big question So, let me suggest—go ahead.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

This is David. One other comment, which is the focus on CDA Release 2 makes sense given today's state of the art, but I think there's a lot of churn in the CDA world about simplifying with green and other approaches, and I would just caution that we not prematurely close on CDA R2.

John Halamka – Harvard Medical School – Chief Information Officer

Obviously, the greenCDA activity has been pretty robust, but I don't think this particular S&I Framework activity has had much participation. The greenCDA folks elected not to join, for whatever reason. So, I think the comments that folks have made are significant that as we receive this, we should ensure that appropriate party's interests have been represented, and we should consider this thoughtfully in the context of likely our clinical operations and implementation workgroups. But also, I think, Judy, if you look

at the other two, lab results, there's a clinical operations set of activities to review, and provider directories, well, Dixie, you had initially recommended LDAP, then revised that to other approaches, DNS, microdata, and now, you're seeing that they have done some ... reviewing. There's a hybrid approach suggested. It would seem that that would go to the folks who initially had reviewed these materials. And so, Judy, therefore our process would be we will receive these back from S&I. We will assign them, and then we will make these part of our future deliberations.

Jitin Asnaani – ONC – Coordinator S&I Framework

John, this is Jitin speaking. Just to emphasize one point, if I may, about the S&I Framework. We've done our utmost best to keep the community as open as possible and where we have not received or had participation from specific groups, we have gone out of our way to try to bring in that information. So, it's not to, in any way, to refute the next steps that are being suggested here by committee members. In fact, they make perfect sense to me. But I do want to ... that this was as open a process as could possibly be to this point. And certainly, there's a way to improve the products such that the community and the country benefits, and we're always open to it, but not to think that this was done by anything less than the 150 people who participate in the Transitions of Care Initiative.

John Halamka – Harvard Medical School – Chief Information Officer

Understood.

M

John, I know you're trying to move on and I just need to get something in for the minutes. I strongly support the clinical information modeling work that Stan is referring to. I believe that and greenCDA are both in a stage where they're not appropriate for consideration for stage two certification, but clinical information—but they each have a reservoir of intellectual property that could make them move faster than what we've seen in the past. And I think the most important thing is just to somehow not avoid the well it's done and it's done and even though there's something better. It can't replace what's done. Anyway we can. And I just wanted to make sure that that comment was in there.

John Halamka – Harvard Medical School – Chief Information Officer

Absolutely. Well, again, I want to thank everybody, the S&I Framework, hundreds of people working very hard in an attempt to bring clarity and constraint, and we will take your recommendations and put them through our thoughtful review ensuring we keep in mind maturity, implementation, begging for the little guy and come up with a consensus as we have so successfully done in the past. And so, Jon Perlin, we'd like to turn the meeting back to you, slightly delayed, for the Implementation Workgroup discussions and public comment.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thanks, John. Brilliant discussion, much accomplished. We've essentially been setting up the discussion of the Implementation Workgroup through our last few meetings. As you know, Liz Johnson and Judy Murphy have worked with ONC staff to create a survey. And just as it's our aspiration to support a learning health system, we want to support really learning health policy, and lot of good feedback has been obtained through the survey process. And in the interest of time and having discussed the intent of these activities at prior meetings, let me turn immediately to Judy Murphy and Liz Johnson to summarize the results of the survey and implications for the Standards Committee and thus for ONC.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

Great. This is Liz Johnson, and I'll start. And again, thanks to all the persons who are in the workgroup. And so, certainly not to take away from the work that we recognize as to say, the work plan and the timeline are outlined on this slide, and as you can see, we're moving through our work plan as we've been coming, and as John said, going forward. And today, we'll talk about specific survey results.

I want to predicate that discussion with two comments. First of all, recognizing from earlier discussion today that practicality and usability above the criteria and the standards is critical, and I think you'll see that as the work comes forward, both today and in the future, that we're taking that into consideration. And the other thing is that, we had over 100 pages that we shared with the group of survey results. So,

we have taken that to a high level today to talk about basic concepts, but you can rest assured that all of the comments specific to both the test criteria, the criteria themselves will be given to consideration for adjustments for the future.

Go to the next slide, please. So, here is a just overview of the types of persons that responded to the survey. So, you can see we had a wide arrange of respondents and also a wide range of group sizes that did respond.

So, let's talk on the next slide about specific results. So first, from the global perspective, the things that the survey indicated worked with the last set of criteria were that the accrediting bodies were very helpful, that they want the choices in both testing the certification bodies to continue, that using remote testing works, that there was consistency in the NIST testing procedures, certainly, that we needed to—that the addition of modular certification was important but needed further clarification, that the ability to seek as, they have referred to it, a slight certification needed to continue, and then, it was very important to distribute the information using web blogs and frequently asked questions. So, that was the global comments on what worked.

Going to the next slide. There were also suggestions, obviously, for improvement. And one of them was that the guidance to the certifying bodies needed to be more consistent and from the certifying bodies. Also, that the criteria themselves needed to be clear, more clear, and the details were not sufficient. And you'll see some work coming forward to address that deficiency as identified, that the criteria do not address clinical specialties or ancillaries, particularly in the eligible provider population. Certainly, we saw over and over that the FAQs were occasionally issued late and most importantly, we're not cross referenced, and I think ... a recommendation around that. We've talked about, in our committee, and certainly in the workgroup, that the modular versus complete EHR requirements were very confusing, although clarity came out as time went forward. It needs to be further refined. There's really a debate over how the criteria should be focused. Should it be interdisciplinary in nature and should the testing procedures follow that protocol as well? Should we use workflow centric, meaning should we use workflows that are meaningful in the clinical arena to test the way that we use the software or not? And then, should we align results and that comes with meaningful use objectives?

There was no stated plan for new releases of EHRs. So if there is a minor change to an EHR do they have to go through the entire certification process again or would there be an incremental certification process required? And then, it's very difficult, according to the survey, to discern which products you combine together to achieve a complete EHR. The version certification numbers were mentioned in terms of being able to, as we always say human readable, can we take that and determine what should we be certifying against? And then, the lack of assurance of interoperability between certified products was not addressed. So, those were some of the global findings, and let me talk to you specifically about a subdivision of each one of those findings.

If you'll move to the next slide, please. So, we got comments and these are, again, are certainly not all inclusive, but we got very specific comments we thought we'd bring forward. On the public health surveillance, they want further clarification of what constitutes a test. As we know, there was a debate about whether or not since a receiving entity could not receive the tests, did that constitute a test or not. And then, there was comment related to cap and clear requirements and were they taken into consideration related to lab.

In the exchange of information, there was comment around the ... being unclear. And desire for consensual definitions of what transmit meant and was inconsistent. They want a clear definition. We've heard today from several groups that clarity, and that's the way John and Jon opened to meeting, clarity and specificity is what the constituents were asking for. The vital signs, body mass and so on, those are required but don't apply to all settings. Is that appropriate? In the summary of care portion, there are less data requirements than what is required by Meaningful Use. And then, what kind of copy is required? Is there going to be more specificity in the future as to how we might provide that output. In security and privacy, there were several suggestions. One was for authentication and access to be put together because it required ... testing. Security audit laws, would they be allowed to test independently? So,

you'll see a flavor of different opinions on how we might move forward, and then again, meeting the HR modular and site certification needed for the refinement.

Continue please to the next slide. On the temporary certification process, there was a request that our scripts begin to get version control and that no script should be released without prior acknowledgement in time for the testing entities to have time to put it in place and those who are being tested would be aware of the changes. Again, aligning real clinical workflow and context in the care settings for testing purposes.

And then, certainly deletion of obsolete drugs and other clinical references was critical. In specific testing scenarios, and then again I gave you, and we gave you, specific examples, and I don't want to prolong this discussion but really looking at how many tests to look at a specific requirement, combining types of processes so the testing would be more relevant. Looking at the calculations and for the quality measures and how could that be clarified, so what the inclusion in the denominator and the numerator would be very clear, tightening up the correlation between security risks assessments and then testing for accounting of disclosures needed further description.

Next. And then finally, on the test procedures, again, high level of findings. Version control is on the test; alignments were real workflow. This is a repeat of the previous one. So, tightening the correlation and so on. And with that, I think we're going to move to Judy to talk about recommendations.

Judy Murphy – Aurora Health Care – Vice President of Applications

Thanks, Liz. That was great. So, one of the things I do want to draw your attention to is that we did give you all of the information related to the survey as attachments that Judy sent out yesterday, Judy Sparrow. And so, there were two different summaries of the information. ONC was very helpful for us, and they did take all the comments from the survey and summarize them first by question. So, we had a series of questions and you can see the summary that was done by question, and that was summary number one.

And then, secondly, the other summary labeled number two, was summaries by certification criteria. So, it actually pulled the information together from the multiple questions if it related to the same certification criteria. And then, there were two additional documents. We got a very helpful letter from a cross-industry consortium that had pulled their thoughts together in a letter that was sent actually to the honorable Kathleen Sebelius with copies to Dr. Farzad Mostashari and to Liz and I as the Implementation Workgroup co-chairs, and as an adjunct to that, the last attachment was a Power Point slide deck that also outlined their recommendations. They did represent, I think, it was ten different organizations and a lot of different kinds of experiences from both the ETCBs as well as from the vendors who went through certification. So, we found that adjunct of information particularly helpful as well.

So, if we move then to the recommendations that are on the screen; the first is something that we had already talked about in previous meetings that we believe it's going to be particularly helpful, and that's really to harmonize the information around each of the stage two meaningful use measures and the quality measures that on a grid across a row would show the applicable standards, certification criteria testing methods and implementation guidance for each of the measures. And that actually, that work is in process already right now. We have actually just begun it, and we made some assignments to the workgroup. So, you'll be seeing some iterations of that grid. What we've done thus far, related to that, was made the assignments and then also talked about each of the criteria and whether the certification criteria that had been used are sufficient or whether they need additional clarification or whether they need to be created. And we've got a timeline of a couple of weeks to make a first cut at that with our next meeting on August 25th.

So, the second recommendation then is to launch a unified HHS website that serves as the single source of truth for both CMS' meaningful use and ONC's certification programs. There was a lot of consternation voiced about the fact that it is very difficult to track and trace the different pieces of information that come out to clarify the measures and to clarify the certification process. And so, there was, again, a lot of discussion and recommendation that this be unified in a more simplistic fashion. So, that is something we

will need to be pursuing with CMS and ONC. And I think it's something that they have identified already as well.

Along that same line, the third recommendation talks about establishing a clear process to manage updates that specifications for the meaningful use measures and the quality measures. And here there was discussion about the past that when something got updated, you actually didn't know what in that document got updated. So for example, if an FAQ was published a month ago and then it was updated yesterday, you would have to print out the old and the new and compare it yourself to know what had actually changed. And so, a better way of managing change control and using version numbering was recommended, and again, in conjunction with our second recommendation, if those were put together in a way that you could easily track and trace these things across the measures and across time, that would be a lot easier to identify what had changed, then what was required. There was also a discussion about indicating whether the updates are additional clarity that are optional or whether it is a specific requirement that is now considered mandatory.

And if you go to the next slide, fourth recommendation. I think our group did have conversations in the past about this possession idea. And specifically, that was in reference to an individual organization's need to own all of the technology or ... all of the technology for all of the menu set items even if they were only attesting to a subset of them. And so, this was a recommendation to clarify and simplify the requirements for possession. And the third bullet down, talks about consider requiring providers to only possess the EHR technology certified against those measures which they are using for meaningful use. So, it's actually a requested change. The clarification, that came out at stage one.

The next bullet talks about listing the products included in the certified system by name and indicate the meaningful use measure supported by each named product. So again, that's that same idea of simplifying things similar to what we talked about with the grid on the first slide where you'd be able to see this product meets this criteria and do more of the ability to match it up at that vendor and product name level.

And then lastly, and this was specifically addressed by the cross-industry group in those slides that we provided to you, looking at puzzle pieces, but it really describes the inability to totally understand which different options you have when you are attempting to pass and put together your set of certified products. So, the idea here is that we make it overtly clear that an individual provider has the flexibility to pursue either a complete certified EHR or an all modular EHR complies the certified modules or a complete certified EHR plus some number of certified modules or pieces of a complete certified EHR plus certified modules. And that was, I think, got really confusion for people how to pull that all together.

Okay, fifth recommendation is to build realistic software development and implementation timelines right into the regulatory requirements. In other words, aligning the certification requirements with the stage of meaningful use and establishing a minimum of an 18-month effective date for newly adoptive criteria. And the 18 months, specifically, is the approximate amount of time that would be required for a vendor to understand the criteria, integrate it into their product, release their product, or actually get it certified first, release their product, have it be adopted or used by an individual organization and then that organization's ability to actually achieve the meaningful use criteria using it, and that as we condense that and make it shorter, it literally makes it impossible as we talked about with the stage two criteria.

The sixth recommendation is around publishing the process for conducting meaningful use and certification compliance audits. There's a little bit of consternation about how that's going to come down. And this goes back somewhat to when the FAQs were posted. Are those recommendations? Are those mandatory items? Are those things you have to do or just clarity that you could choose to use? So, definitely clarifying how those would be used. And then, identifying the type of documentation that the provider will need to provide during an audit so that when they're attesting or preparing to attest, that they could actually be preparing that documentation in advance. And many of the compliance departments were talking about the need to understand that better.

Seventh recommendation is to publish the timeline for the publication of the Meaningful Use stage two measures. Again, a fair amount of consternation about when those are going to be coming out, as well as for the associated proposed and file regulations and certification test methods, so actually getting that timeline locked and loaded.

So, if we go to the eighth recommendation, revising individual certification criteria and tough procedures based on specific comments. So, Liz, in several of her slides, went through some very particular things that were either unclear or were in a few cases, almost incorrect clinically that were incorporated into the certification criteria and test procedures, and we need to go methodically back through all of those that were pointed out and make sure those all get corrected for round two. There was mixed reaction to creating scripts with combined test procedures that permits a better set of satisfied multiple criteria at once. That was one of the questions that we actually asked on the survey, if people thought if we created more of a use case script that would combine different criteria and test procedures into one, and there was definitely a very mixed reaction to that, almost 50/50, and a general consensus that more input analysis would be required. And although it made sense for certain scenarios, like the medications process, it made a lot less sense in other circumstances.

And the last but not least is to publish more guidance for providers in order to clarify the difference between the certification criteria and the meaningful use incentive requirements. In other words, again, people got a little bit confused if they were attesting for meaningful use, the meaningful use measures. What part of the certification criteria or testing methods did they have to incorporate? And there was particular confusion around privacy and security requirements.

So then if we go to our wrap up slide, before we ask for comment, this is one that we've used with the group before. And again, this is the old Christmas past, Christmas present, Christmas future, that factored that ... formulated, but we're really in the first bullet here where we're talking about what did the survey tell us. We know that one of our big action items is to harmonize all the information by creating this grid, and that is again what we're working on right now, and then we'll moving forward in thinking about the future certification strategy with NIST. So with that, I will close our comments and turn it back to Jon Perlin.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Well, thank you very much both Liz and Judy, what a tour de force of analysis, clearly many themes that were resonate with today's discussion about improvements for future and certainly sets a framework for us to contemplate our core process. Let's take—I want to be sure that we have time for public comments, but looking to get any reaction to what Liz and Judy and the Implementation Workgroup so ... put forward.

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

Jon, this is Dixie. I had two comments, if you don't mind.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Please.

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

First of all, I want to commend them for this excellent work. It certainly is very useful to us, and I'm sure it will be useful to the vendors as well. The first question relates to slide eleven, where it says clarify and simplify requirements for possession. My understanding is that there's no requirement for possession. The requirement is that they adopt certified EHRs technology. And in particular, I recall early on, this committee having a lengthy discussion about how the small providers may most likely adopt software as a service option and choose not to possess a computer in their office. So, I don't know where this possession came from. So, that's my first question.

And my second question is on slide 12, where to publish a timeline, I keep asking for a timeline, and I'm asking it again, a timeline for when ONC requires input for standards and criteria for stage two. The Privacy and Security Workgroups started this early on looking at new standards and criteria that were driven by some of the Tiger Team recommendations, and I'm afraid that one day Judy's going to send me

an email and say we need all of your standards and certification criteria by close of business tomorrow. So, I'm requesting that ONC provide that guidance.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Okay, good. To ... I don't know if Judy Sparrow and—we'll work on trying to be more transparent on the timeline so much as possible, but I think ONC, obviously, hears the charge both from you and from the Implementation Workgroup. And Liz or Judy, any comments on Dixie's first point?

Judy Murphy – Aurora Health Care – Vice President of Applications

Sure. The possession was clarified in a FAQ, and I couldn't give you the number and date right now, but it was a requirement that in order to attest to meaningful use, you would need to own the capability of executing on all of the menu set measures not just those you were using for attestation.

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

That's not my question. If you own the capability—if I subscribe to the software the service is offering, I own that capability.

Judy Murphy – Aurora Health Care – Vice President of Applications

Absolutely, so—

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

I don't possess a machine.

Judy Murphy – Aurora Health Care – Vice President of Applications

Possession was the word that they used in that FAQ, and I probably could have put in quotes here, which would have maybe resolved it. You are correct. You do not have to own it. You just have to have possess the capability of using it.

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

Okay. Thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Just terrific. Any other comments that people would like to offer at this time?

Okay, well I think that was a stunning synthesis of a huge amount of data, a number of topics. I'm very concordant with many of the major themes that have been brought forward in today's discussions and prior discussions. So, terrific work. No good deed goes unpunished, and the implications are both a set of tasks to be able to really support these articulated needs, as well as an accountability to the charges you've set forth. So, I think we have a set of improved requirements, clarified requirements that will be helpful to all of those for whom we work. Great work.

Let's then stop at this time, and I want to turn back to Judy Murphy with great thanks to each of you who've presented, each of you have been part of this call today with a great deal of attention, but especially to each and every one of you who members of the committee, all of the task forces, workgroups. Tiger Teams, etc., that have done work between meetings. All that work was reflected and synthesized in today's activities; just terrific contributions. With that, let's turn to Judy Murphy to ask members of the public for any comment.

John Halamka – Harvard Medical School – Chief Information Officer

Or Judy Sparrow, as the case may be.

Judy Sparrow – Office of the National Coordinator – Executive Director

I'll take that. Alright, we'd like to invite comments from the public at this time. Please state your name, organization, and there is a three-minute time limit. Is there anyone on the line who wishes to make a public comment? Let's just wait a moment.

Operator

Ms. Bickford, your line is live.

Judy Sparrow – Office of the National Coordinator – Executive Director

Okay, Carol, go ahead, Carol Bickford. Carol? Carol Bickford, are you on the line? Do we have any other comments? We might have lost her.

Operator

No other comments at this moment. Yes, we have Ms. Carol Bickford.

Carol Bickford – ANA – Senior Policy Fellow

This is Carol Bickford, can you hear me this time.

Judy Sparrow – Office of the National Coordinator – Executive Director

Yes, we can. Thank you, Carol.

Carol Bickford – ANA – Senior Policy Fellow

I want to make two comments. I'm from an American Nurses' Association. The first one is in relation to the matching discussion. We strongly encourage being proactive and including the additional fields that would allow the inclusion of a unique health identifier, whatever that might constitute in the future.

And the second point is in relation to the vocabulary discussion. For those of us who are supporters of the nursing terminology, which are patient centric in nature, would be very helpful if there could be identified resources or a central office or entity that is going to be available to consult with us on moving forward on the mapping strategies.

Judy Sparrow – Office of the National Coordinator – Executive Director

Great. Thank you, Carol. Do we have any other public comments?

Operator

No other comments.

Judy Sparrow – Office of the National Coordinator – Executive Director

Okay, well thank you all. Thank you all to the public, and I'll turn it back over to Dr. Perlin.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thank you very much, Judy Sparrow, and again, as always, many thanks for your terrific support and all the hard work in ONC. John Halamka, any closing comments on your end?

John Halamka – Harvard Medical School – Chief Information Officer

Okay, just an amazing amount of work today, and I hope folks have a feeling that our Summer Camp has been extraordinarily successful as we draw to that final September meeting, where we will review all of the accomplishments over the summer, and I think we have done as best we can to take every issue and take a balanced view, taking a look at the big guy and the little guy, the mature and the developing standards and come up with a set of wise guidance. And I've said this publicly, I have never worked with a team as high powered and functional as you. So, I thank you all.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Well said, Dr. Halamka, and many thanks for your leadership, and on that terrific note, I think we will stand adjourned. See you all in September and thanks for the work in between.

M

Thank you.

Public Comment Received During the Meeting

1. Note the last 4 digits of the SSN are the ONLY sensitive part. The first 6 can be derived by knowing where the individual was born.
2. At what point do you see the ability to manually abstract clinical quality measures into certified software change to requiring the data be electronic?