

**HIT Standards Committee**  
**Draft Transcript**  
**April 18, 2012**

**Roll Call**

**Operator**

Ms. Deering, all lines are bridged.

**Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology**

Thank you very much operator. Good morning, this is Mary Jo Deering in the Office of the National Coordinator for Health IT and this is the 35<sup>th</sup> meeting of the HIT Standards Committee. It is a public meeting and there will be an opportunity for public comment at the end. I would ask members to identify themselves when speaking for the transcript and I will begin by taking roll. Jon Perlin? John Halamka? Dixie Baker?

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

I'm here.

**Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology**

Anne Castro?

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

I'm here, on the phone.

**Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology**

Chris Chute?

**Christopher Chute – Mayo Foundation for Medical Education and Research**

Present.

**Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology**

Tim Cromwell?

**Tim Cromwell – Veterans Health Administration – Director Standards & Interoperability**

I'm here on the phone.

**Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology**

John Derr?

**John Derr - Golden Living, LLC**

Here.

**Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology**

Carol Diamond? Lorraine Doo?

**Lorraine Doo – Senior Advisor – Centers for Medicare & Medicaid Services**

Present, on the phone.

**Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology**

Floyd Eisenberg? Jamie Ferguson?

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

Here.

**Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology**

Leslie Kelly Hall?

**Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

Here.

**Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology**

Martin Harris?

**C. Martin Harris - Cleveland Clinic Foundation**

Present by phone.

**Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology**

Stan Huff?

**Stanley M. Huff - Intermountain Healthcare**

Here.

**Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology**

Kevin Hutchinson? Liz Johnson?

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

Here.

**Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology**

Becky Kush? Arien Malec?

**Arien Malec – RelayHealth Clinical Solutions**

Hello.

**Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology**

David McCallie?

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

Here.

**Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology**

Nancy Orvis? Mark Overhage? I saw Marc here, I thought. All right, Wes Rishel? Charles Romine?

**Charles Romine – National Institute of Standards and Technology**

Here on the phone.

**Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Tech**

Cris Ross?

**Cris Ross – Executive Vice President & General Manager, Clinical Interoperability – SureScripts**

Here.

**Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology**

Walter Suarez?

**Walter Suarez – Kaiser Permanente**

I'm here.

**Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology**

Sharon Terry?

**Natasha Bonhomme – Vice President of Strategic Development – Genetic Alliance**

Natasha Bonhomme for Sharon Terry

**Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology**

Jim Walker?

**James Walker – Chief Information Officer - Geisinger Health System**

On the phone.

**Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology**

Okay. Thank you very much and I'll turn it back to you Jonathan, Jon.

**Jonathan Perlin – Hospital Corporation of America**

Thank you very much and good morning everybody. Thank you not only for being here or being on the phone, but my goodness, what a huge amount of work has occurred between the last meeting and this meeting as we move to our first pro forma activity, the minutes, it seems hardly fitting that we'll capture all of that interim work in the next set of minutes, but, appreciation from everybody to each of you for all of the hard work in reviewing the NPRM and providing commentary. Now we're going to have a good . . . great discussion today, indeed it is very exciting to realize that we've not only moved through Stage 1, but well into the work around Stage 2, and looking at it from all aspects from the perspective of building toward the ultimate goal of higher performance health care and higher performance information systems to support health and care and value, but also from really the nuts and bolts perspective of the experiences in learning of Stage 1 and with the that lens, that helps us think about how to help support a set of standards that really builds toward a logical progression to Stage 3, and so, I'm very appreciative of all the hard work in between.

As we begin, I want to make sure that everyone attaches a face with a name, an individual who has been present virtually on a number of activities, but a delight to welcome, joining Mary Jo as liaison from the Department for us as a FACA committee, MacKenzie Robertson. MacKenzie is well known to the Department and the FACA process. She came from ASPR, which I now understand is the Assistant Secretary for Preparedness and Readiness, did I get that right?

**MacKenzie Robertson – Office of the National Coordinator**

Response.

**Jonathan Perlin – Hospital Corporation of America**

And Response, sorry. And for those of you who recall the meetings, the building that monitors the country and the world's health risks, is the office from whence she came and really pleased to have you here. I know you worked in that office for four or five years and I look forward to the support you'll provide. It would be remiss not to recognize the continuing effort of Mary Jo, who, for the time, will tag-team with MacKenzie, but really I think it's quite remarkable that in the months that you've been with us, we have just continued with your support, to be hugely productive. I think we appreciate the around-the-clock emails, but, I know that the work has been around the clock and we're very grateful for your efforts.

I hope everyone has had a chance to take a look at the minutes, let's have a chance to look at the minutes now, if you will and if there're any amendments, modifications, corrections, please do mention. As you're doing that I would note that Dr. Mostashari is at the Senior Leadership meeting at HHS and will join us we understand at about 10:15 and look forward to his joining us then. Any amendments? Jamie.

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

Yes, this is Jamie. I found a couple of typographical errors that I will submit to Mary Jo.

**Jonathan Perlin – Hospital Corporation of America**

Terrific, thank you so much. Others? Notwithstanding those corrections then, let's assume a consensus on the minutes and we will move forward. As we approach today's work, it is, as actually I think it's Mary Jo or maybe it was you John, who said that we will approach today's activities chapter and verse and indeed, that is a good metaphor for the way that we will go through. It was apparent to us on the word call. . .word call or on the Chair's call a few days ago that trying to iterate without attention to Standards from other workgroups as we go through, would lead to an impossible way to pick. . . efficiently go through the material and so, the overall plan today is really possible, because of the hard work, really overnight work of. . .or many night work of the Office of the National Coordinator in creating a grid that will allow us to address the input simultaneously, from the multiple workgroups. We'll go through with the primary workgroup presenting and we'll seek first response from the other Chairs of the alternate workgroups. We know that there... it is inevitable there will be some sort of redundancy or coming back around, but, we hope that's the most efficient process.

I remind the group that of course our purview is the Standards to the extent that Policy effects the implementation of Standards with the expression of Standards that would be appropriate for discussion, but, for things that are Policy, unrelated directly to the Standards really, I would encourage all of us to exercise their Fifth Amendment Privileges and provide input elsewhere into the process. So, if you'll help me, recognizing that distinction. I want to really express particular thanks to an individual who has cross-threaded through absolutely every Standards activity, a really heroic amount of effort, for that reason, in my estimation, the Standardbearer and would ask then that Dr. Halamka not only provide some introductory comments, but lead us through the grid and the discussion for the next few hours. Great.

**John Halamka, MD, MS - Harvard Medical School**

Well, ahead of us we have a four hour marathon session. If you perform well, we will give you a break for lunch, going through chapter and verse. We had a debate at our last co-chairs or co-call, which was how shall we organize today's discussion, should we go and say, "Hey Jamie, tell us everything you think?" Well what Steve Posnack pointed out was that we are going to produce a recommendation letter at the end of this process and so it is best to go through the regulation subsection by subsection, looking at the comments that each workgroup has made in that particular subsection and then, as we finish both co-chairs that are named, ask if there are any other issues and then check off the section and hand it off to Steve one by one. You'll see that there's great internal consistency across the workgroups, which is quite impressive, and probably, little controversy. I think it was yesterday that you gave us eleven pages of correct... well, it wasn't you, but it was CMS who published 11 pages of corrections to the Meaningful Use NPRM for things like Stage 2 appeared in a few places as opposed to the 2014 edition, and so today, it's really about producing the ONC 11 pages of amendments that you can then incorporate.

So with that, again, our process will be, we'll go through these chapter and verse, at the end of the day, we will get the patient empowerment or patient engagement perspective, looking at some themes and some suggestions, because the patient engagement really is cross-cutting across all aspects of Meaningful Use, and they have both... and deep dive which we'll take a look at. So, let us begin at 130. ... 170.314-B-(iii)...

## **M**

(indiscernible)

### **John Halamka, MD, MS – Harvard Medical School**

Yes, there are a couple of areas where ONC has asked for comments for additional items that aren't currently covered in the grid relating to, for example, usability testing, price transparency and those kinds of things. Do we have a process... I worked with the Implementation Workgroup and I think we worked grid by grid, I'm not sure that we have a process for capturing comments to the ONC questions that weren't in the grid. Right, and so I would presumably go through the grid and then at the end of the grid, if there were additional issues that were not grid-based, we would make a comment on your behalf.

### **Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

We also have the, uh oh, a mute speaker we get an echo. The Certification Adoption Workgroup, HIT Policy Committee, we tasked them with taking on the Policy issues related to certification. So, the price transparency and other areas where we asked additional comment, they're essentially the lead on the Policy Committee, so we could funnel your thoughts over to them, if you'd like.

### **Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

This is Liz. We are working through eight of the questions, eight separate questions on it, I'll be glad to share that with you and then we can fix it.

### **Jonathan Perlin – Hospital Corporation of America**

I appreciate that clarification because, Arien, terrific point, and Liz I appreciate the Implementation Workgroup as contemplating those activities, Steve, appreciate the guidance, the best way practically and with due respect for the FACA Process is to channel it back through the Policy Committee. Again, you know, if there are things that do impact directly on the standard we'll certainly want to incorporate those around any of the grid items that come up. And John, before I turn back to you, I just would also want to express particular appreciation to Leslie Kelly Hall and the Patient Engagement Group who went 0 to 60 in about 4 seconds. Thank you. All right.

### **John Halamka, MD, MS – Harvard Medical School**

So, 170.314-B(iii), electronic prescribing, our proposed Standards are NCPDP Script, version 10.6 and RxNorm, the 2012 release, and note that these are the minimum versions of the Standards, of course as new versions come out, those would be adopted. So two general comments, one from Clinical Operations and one from Implementation. So, Jamie...

### **Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy**

We heard from a number of workgroup members the concern over HL7 not being mentioned and, obviously the NCPDP Script standard should be used when, and this was particularly in reference to discharge e-prescribing within a hospital when the hospital pharmacy fills the medication order. And, we heard from a number of organizations, including Academic Medical Centers, who are doing business as Organized Health Care arrangements under HIPAA, where they have a number of different legal entities in one building, under one roof, and so their reading of the regulation would be that they would have to switch to using NCPDP inside the hospital and previously, you may recall, we visited this issue, I think it was last year, we... in fact, the workgroup consulted with NIST and we went through certification testing analysis of HL7 version 2 and they found that it was easy to identify for testing purposes any valid e-prescribing message in HL7 version 2.X. So, in fact, it would be relatively easily testable to describe version 2.X, any version 2, the prescribing message for that purpose. So, I think that's the issue that

we're bringing up is that within a hospital, for discharge e-prescribing HL7 version 2.X should be allowed and should be therefore required in certification.

**John Halamka, MD, MS – Harvard Medical School**

We've had this discussion before, this is not really meant to cover the use case between a hospital and an external ambulatory pharmacy, where we all believe NCPDP is the right thing to do, it's just very constrained use case of how do you deal with an organized health care arrangement with coincidence of a pharmacy and a hospital in the same building and interconnection of existent systems where NCPDP isn't used in the transaction today. Any comment on that? Okay. Implementation Workgroup.

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

We concur with Jamie's point on the internal use of the HL7 2.X, we also though wanted to make a suggestion that we look at prescribing of controlled substances as a menu item for Stage 2, moving to Core for Stage 3. So, we'd like that to be considered as a recommendation going forward.

**John Halamka, MD, MS – Harvard Medical School**

Now, an interesting question you raised there which is, given that the DEA has specified options for Standards for two factor authentication, if we are going to declare it a menu set item, then do we have to also say, and you may use Biometrics, which are finger or retina, and here is the certain NIST level criteria that you must pass, or hard token, not soft token, not cell phone or whatever.

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

And I think the answer to that would be "yes" John, I think we do have to make, if we're going to make the recommendation, we have to recommend how. I think you are exactly correct. And so the question would be, in terms of the way we work this, do you want us to work this into this letter to ONC or do you want to do the work post-today.

**John Halamka, MD, MS – Harvard Medical School**

Well, let us ask Steve.

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

Steve?

**John Halamka, MD, MS – Harvard Medical School**

Has this discussion of e-prescribing of controlled substances and its relationship to the NPRM been discussed at ONC?

**Steve Posnack – Office of the National Coordinator for Health Information Technology – Policy Analyst**

CMS did include language in its preamble about controlled substance prescribing and some of the difficulties and challenges that still remain with respect to the overall environment and readiness to conduct electronic prescribing controlled substances. I am not here to pass Policy judgment today, so, I'm here to be lead staff, get you through the grid, get a letter out, that's my role today. So, you're welcome to make that comment, as part of your comment letter that would be submitted and then, we'll have to evaluate. The one thing to keep in mind though is that there is a regulatory structure already in place from DEA...

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

...right...

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

...and we, the Department along with DOJ and DEA would need to figure out the relationship between the two regulatory programs that are already established and how they would kind of cross-fertilize.

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

So, John and Jon, I would say based on that comment Steve, that we will make the recommendation and we'll waive the logistics to you – is that fair? Or... I see that smile...

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

Well, we've explored this to some degree with our DEA colleagues and our attorneys in kind of a brief discussion, but it is complicated from a Regulatory paradigm perspective to work out the...

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

So, we'll acknowledge the same...

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

Yes.

**John Halamka, MD, MS – Harvard Medical School**

So, this sounds like we're offering advice, not support. Okay, very good. Any other comments on electronic prescribing? Well, we've started off our day without controversy and there you have one completed chapter.

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

...I'd like to say one thing is that, you know, the e-prescribing, to Liz, the e-prescribing of controlled substances also requires two factor authentication and we explored the idea of maybe making the comment and decided not to, for exactly the reasons that have been pointed out here, just FYI.

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

Thank you.

**John Halamka, MD, MS – Harvard Medical School**

So, basically I guess, summarizing everything that has been said, that the CMS NPRM specifically notes that this will not be in Stage 2 for reasons of not ready for workflow and technology, so, we could certainly say it is directionally a good idea. 170.314A(iii) – Demographics. We have proposed certain code sets, the OMB Standards for race and ethnicity, ISO 639-1 for preferred language and ICD-10 for cause of death.

Quick comments on that. The US has used ICD-10 at the government level for the codification of cause of death since 1999, so, one of the things we want to be careful of as we go through this, is we know there has been a delay announced in ICD-10, so, you really want to be careful of where you use the words ICD-10 in a 2014 edition, given that those dates are changing. So, this one, first I... actually I should for clarification say ICD-10 CM is actually the CM designation correct for cause of death?

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

No, there appears to be a typographical error.

**John Halamka, MD, MS – Harvard Medical School**

Right, I believe it is just ICD-10 is used, and this is really different than the notion of using ICD-10 CM for encounter diagnosis. So, lest there be any question about its consistency. So, I'm doing these edits in real time...

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

...yes...

**John Halamka, MD, MS – Harvard Medical School**

So, should we get rid of the...

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

The CM is incorrect.

**M**

Okay, I had track changes running in the background.

**John Halamka, MD, MS – Harvard Medical School**

And so Jamie, Clinical Operations.

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

We heard from clinicians as well as quality folks that the country of birth or nationality of patients in the clinical use cases is frequently more valuable information than the crude ethnicity measures that are otherwise captured in demographics and so we suggest adding an additional data element for nationality of the patient, using the ISO 3166-2 Standard for country codes, just as an addition, not as a replacement for anything.

**John Halamka, MD, MS – Harvard Medical School**

Any commentary on that? Arien looks quizzical...

**Arien Malec – RelayHealth Clinical Solutions**

...work with multiple nationalities or mixed nationality, would that be a pick all that apply?

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

I don't know the answer to that. Chris, do you have any input on Arien's question?

**John Halamka, MD, MS – Harvard Medical School**

Don't use me as an example, but my mother is from Latvia, my father from Czech Republic, so am I a Latvian Czech Republican?? I...

**Arien Malec – RelayHealth Clinical Solutions**

They're really two separate questions. One is, how do we structure the information models associated with nationality? Do we have multiple slots, for example. The other is the coding system. I think we have to separate them. Clearly the coding system would work in either scenario, but to my knowledge, the vast majority of ADT demographic systems in the country have a single slot and the specter of post-coordinated nationalities has been raised, but I don't think gathers a lot of enthusiasm among medical records.

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

And just to add a little bit of color, so I think John in your particular case, your nationality would be American...

**John Halamka, MD, MS – Harvard Medical School**

...right...

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

And the intent from the clinician's perspective, what we heard is that they really care about what health system people have received treatment in, in terms of their personal history, so this is their country of origin, country of birth or nationality.

**John Halamka, MD, MS – Harvard Medical School**

Okay.

**James Walker – Chief Information Officer – Geisinger Health System**

John...

**John Halamka, MD, MS – Harvard Medical School**

Yes?

**James Walker – Chief Information Officer – Geisinger Health System**

Jim Walker.

**John Halamka, MD, MS – Harvard Medical School**

Yes, please go ahead.

**James Walker – Chief Information Officer – Geisinger Health System**

Just to comment on the clinical issue, it's a much deeper reality than what we're talking about here. I mean, you may not have been born somewhere, but you lived there thirty years, you may have been born there seventy years ago... so, I think if we wanted to address this, it would be a piece of work. It isn't at all simple, clinically or any other way.

**Jonathan Perlin – Hospital Corporation of America**

This is Jon Perlin. I want to just endorse Jim Walker. Let me give you a quick clinical scenario. I took care of a patient who was born in Costa Rica, which would be their nationality, actually had had treatment in Mexico for diabetes, came in with an acidosis and he was on metformin, a drug that's just seen in the United States. The relevant factor, in terms of the health care of this individual, is not his Costa Rican heritage, but in fact the fact that his health care, just as Jim Walker suggested, was provided in Mexico and the salient piece of information, the medication that's available in that particular health ecosystem. I make this point, not to get too far a field on this, but, this is really a Policy issue and I think the way to rein it for our purpose today is should the Policy Committee identify there are a set of Standards that would support nationality and with that as a proviso, I would offer that it sounds like a good recommendation to identify that that's a... if there is agreement... a Standard set, in terms of expressing that.

**John Halamka, MD, MS – Harvard Medical School**

Okay, in that clinical context, this field makes sense and probably would be singular rather than multiple.

**M**

In terms of making changes, so, is... are you saying that we shouldn't have this?

**Jonathan Perlin – Hospital Corporation of America**

I'm suggesting that this, I don't know, the format in which this might be entered is a note to the Policy Committee, should the Policy Committee identify that nationality provides additional clinical utility, we would identify this as an appropriate Standard to support that.

**M**

Okay, and I'm trying to work out the process as we go forward, it will help expedite things. So, right now I've suggested that it should be included in the rule as a comment. It sounds like the sense of the committee now is that it would be more of a... there are Standards that exist for nationality, if the Policy Committee determines that that is an important thing to include in the future, then it would be included.

**M**

Right.

**John Halamka, MD, MS – Harvard Medical School**

Correct.

**James Walker – Chief Information Officer – Geisinger Health System**

So, this is Jim Walker, so I'd recommend this as an offline recommendation to Policy Committee, not part of our comment on the NPRM.

**John Halamka, MD, MS – Harvard Medical School**

So, we have proposed a Standard that would be the Standard of choice, if the Policy Committee endorses the use of the nationality for the purposes that Jon Perlin and Jamie outlined.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

In terms of the final version of the letter, I'm just going to make a note here for myself that we'll clean that text out, because that won't be something that the Committee would comment on.

**Jonathan Perlin – Hospital Corporation of America**

And, looking at the body language around it if we have... go for it... John you've got two more...

**John Halamka, MD, MS – Harvard Medical School**

I'm sorry, Walter.

**Walter Suarez, MD, MPH – Kaiser Permanente**

Just a quick comment. I didn't hear any discussion about the difference between country of birth and nationality; they're two very different elements. They are complimentary in some respects, but, I'll give you a very personal example. I was born in Columbia, my nationality is dual nationality, I have a nationality of Columbian and a nationality of US citizen. So, there is that distinction. And, country of birth might be a more, perhaps, appropriate component of a medical record, nationality is more a political in the right, good sense I guess, a political distinction of your status as a citizen in a country.

**M**

But Walter's comments which are consistent with the other comments that have been made. The Policy Committee would elect what would be the appropriate policy field to add, country of birth for example might be the most appropriate to be clear, as opposed to a political designation, but we have a Standard recommendation should they have a Policy recommendation.

**John Halamka, MD, MS – Harvard Medical School**

Was there another card up? Oh, Floyd.

**Floyd Eisenberg – Senior Vice President of Health Information Technology - National Quality Forum**

Yes. I just wanted to make a comment. In the transmittal letter last September, that was recommended for Quality Measures being written for Meaningful Use, the Standard for preferred language in the wording of the transmittal letter was actually ISO-639-2 constrained to elements in 639.1 for patient preferred language, which is a little bit different than what's written here, which is just 639-1, so, there's inconsistency in what's being asked for in the Measures versus what's asked for in the record.

**M**

I think we found at that time, and that's correct, what Floyd says is correct, thinking back to the previous work of the working group and of the committee here. Essentially we found that the. . . I think it was the - 2, which is the three character designation of language, had more up-to-date curation and was essentially better maintained and so, that was why we felt that that was the more appropriate Standard. Also, I mean, although that is a much bigger set of codes, it has a lot of dead languages in it, for example, and a lot of variants, and so that's why we wanted to constrain it.

**John Halamka, MD, MS – Harvard Medical School**

And so the question is, from Steve's perspective, do we say the ISO 639-1 subset of 639-2 in the language that Floyd used, or do you say 639-1, 2002. Which do you think is more appropriate.

**M**

Personally my vote would be for what we'd said in the transmittal letter when we really considered it in detail.

**John Halamka, MD, MS – Harvard Medical School**

Okay, and just to – that language is the same as Floyd has said...

**M**

Yes. Exactly what Floyd just quoted.

**M**

There was another comment from the transmittal letter. I don't think it's specifically an implementation problem, but, for race and ethnicity, what was recommended back in September was the CDC value sets. The OMB standards are a very small subset of the CDC value set, so if that's what's implemented, the Measures will still work. But, it is a difference in what's being used for Measures and was recommended by this committee.

**John Halamka, MD, MS – Harvard Medical School**

And of course, that is a perfect segue to the Patient Engagement Workgroup comment on that topic.

**Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

This is Leslie and we agreed for the same reasons mentioned, and also that patients will self-identify in very different ways and we need to allow for that, rather than imposing a patients nationality, ethnicity and so forth. Also for future use for highlighting disparities and highlighting special needs, we felt that a more granular description was necessary and also endorse CDC codes or something very granular. This is an opportunity in the future we think for patient self-identification not only in person, but potentially when a patient might engage with patient-generated data. So, it's important for a patient to self-identify and as granular as it can be, meets that need.

**John Halamka, MD, MS – Harvard Medical School**

So, here's a question based on and Steve's need for a concrete statement. Are we saying the CDC codes are a more general set and today we're recommending the OMB Standards for race and ethnicity being a subset of the CDC or do we want to consider the actual wider CDC code set, of which I understand is something like 500 different possibilities. . .

**M**

...921.

**John Halamka, MD, MS – Harvard Medical School**

921, okay. So again, I can see both sides of this absolutely, but one of the worst data elements in my particular data set is the accuracy of race and ethnicity. I can't get people to decide whether they're Hispanic or not Hispanic, let alone, you know Haitian Creole and so... but, one wonders, again, is there directionality, I think we've heard in the past there is desire for additional granularity. You know, what do we recommend today? Chris.

**Christopher Chute – Mayo Foundation for Medical Education and Research**

Thank you. Chris Chute, Mayo Clinic. There's been, as everybody knows, substantial experience in the race and ethnicity space and I basically agree with John that the task typically assigns to a desk attendant that while the goal of self-identification is clearly desirable, as a practical matter, in most clinical implementations, it becomes extremely awkward.

**John Halamka, MD, MS – Harvard Medical School**

So, whatever meeting is going on outside, it's clearly much more fun than ours... They're cheering you on Chris. Okay, so it's very emotional here. So, Arien, a comment that you would add to that...

**Arien Malec – RelayHealth Clinical Solutions**

...having a conversation with Natasha related to diseases, genetic diseases with an ethnicity origin. And, just a question I guess for Steve in terms of is the OMB standard in this case considered a minimum set, if an EHR is able to capture a more granular definition, what are the requirements of that EHR relative to the OMB standard. So, for example, if you've got a patient whose Ashkenazi Jewish, do you have to record white and Ashkenazi Jewish, I mean, how does that actually work from a Meaningful Use perspective.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

Sure, so my understanding of the OMB standard is that it serves as the bucketing system. So, one can start with a more granular set of choices, however they so choose, to put them together for survey methodology, etcetera, and as long as the more granular choices can be cross-walked to those single OMB selections, conformance with the... compliance with OMB standard remains true. That's how OMB's standard for race and ethnicity is set up...

**Arien Malec – RelayHealth Clinical Solutions**

From a certification perspective, the EHR needs to be able to map whatever. . .

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

More granular...

**Arien Malec – RelayHealth Clinical Solutions**

...selected codes, more granular selected code to one of the categories in the OMB list.

**Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

So, the patient's management team would argue that race, ethnicity....which I can't say... is really a patient issue, it's them identifying who they are, not health care imposing what their interpretation is, and so the more granular is better. Now, we were saying, CDC is a recommendation or granular definitions and feel that there's work to be done here, but, it is important as a patient concept that this is how I am as a patient and who I am as a patient, and that definition needs to be of my own making. So, the team felt very strongly about granularity and self-expression.

**John Halamka, MD, MS – Harvard Medical School**

Right. So I think what we're hearing is, if an EHR implements more granular codes, that's fine and good, it's just for the moment, mapping to the OMB standard, so, in a sense, it's a bit like some of the other vocabularies that you've had in the past where there may be internal code sets that are mapping to external universal codes. I think, we've heard from the IOM in their report, that there's again, a sort of directionality that we want to be able to offer more granular choice in the future. So the challenge, I guess for the Committee today is for the 2014 edition, we can go one of two ways; one is to say EHRs may incorporate a level of granularity that is patient and family centered, as long as they map to the OMB as a bucketing system directionally, we hope to get more granular, but versus we will go immediately to the 921 today. And, yes...

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

This is Liz. From a just practical perspective, when you put "may" into the certification criteria it is, for the Vendor it is "will." That's fine, but I want to be real clear with everybody that if we say "may" then for a testing perspective, they will have to show it, they will have to show their ability, whether it is the 921 then mapped, I'm not disagreeing, I just want to be sure that we are clear what we are signing up for here.

**John Halamka, MD, MS – Harvard Medical School**

So again, other options include, as we look forward to our, and I don't want to call it Stage 3, the 2015 edition, 16 edition... that that may be the more appropriate place to get more granular. We're sort of weighing burden and...

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

Liz. So the question Steve is, is that given the NPRM comments, nothing like being on the hot spot, then will we have an opportunity then to revise the criteria, the certification criteria or is that your job?

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

That's going to be the final rule process.

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics ??**

(Indiscernible) argument...

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

So, it's a here and now type of judgment...

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

Right.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

And, trying not to come in conflict with my not passing Policy judgment questions... so, this has a corollary relationship to Meaningful Use and the collection of demographic information, that's the providers responsibility to demonstrate Meaningful Use and so, the selection of those... I mean, there are very different ways in which that could be implemented and operationalized and so the question is, to the OMB standard per Arien's question, you... it could be made available in a more granular list that would then cross-walk back for certification purposes, that would need to be shown. I'm not necessarily sure that if they just did what the Standard was required, they could get certified. I mean that's...

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

...right, you would not have to do the cross-walk as currently written to get certified. That's the point that we're making. Either way, whether the committee wants to do it, but, we just need to be clear what we're signing up for here...

**John Halamka, MD, MS – Harvard Medical School**

Right, what we said was, yes in 2014, you can use just OMB or, if you wish, you could offer something more granular and map it to OMB, that's your choice, you aren't forced as a Vendor to offer something more granular with directionality being the next edition, something more granular.

**James Walker – Chief Information Officer – Geisinger Health System**

This is Jim Walker...

**John Halamka, MD, MS – Harvard Medical School**

Yes.

**James Walker – Chief Information Officer – Geisinger Health System**

Is there any published study of, when you go out to a large population and ask them to self-identify, how many of the 921 get used?

**Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

I'm checking now Jim.

**James Walker – Chief Information Officer – Geisinger Health System**

I think a reasonable hypothesis would be that no more than 50 and I think us making a very large commitment in terms of work and potential adverse effects, it would be smart to know some kind of answer to that before we make a recommendation about increased granularity.

**John Halamka, MD, MS – Harvard Medical School**

It sounds like Jim has assigned some homework to our Patient Engagement Group to do a literature search, which I am certain, you are able to do...

**Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

I think though, this is Leslie, we can't, we also should determine how many times the field "other" is used.

**James Walker – Chief Information Officer – Geisinger Health System**

What I'm saying is that if you actually went out to people and said how do you define yourself ethnically? And let them pick their own language and then maybe... the point is, I don't know that anyone's done this research, I've never seen it and my sense of the discussions that we've had, and others have had so far, is that nobody actually has any rough idea what the answer would be.

**John Halamka, MD, MS – Harvard Medical School**

So, if you can bring us back anything that's been... so, generally from a recommendation standpoint, I mean, I've heard a lot of comment and I see some shaking of heads, the idea that OMB for 2014, you can go more granular if you so choose, don't have to, and then directionally, well, we will look at what evidence we might have that will allow us to make an evidence-based assertion for additional granularity. Now, I also have a friendly amendment from John Derr, it's very interesting. As we talked about clinically how important it is to know that a person received treatment in Mexico, he was suggesting, is there value of an indicator for treatment in a military or VA Health System? As both an indicator of where your records may be. . .

**Jonathan Perlin – Hospital Corporation of America**

This is Jon Perlin. Obviously I'd have a bias. There would be. But, I'd also adopt the Jim Walker role that, you know, that that be a notation to the Policy Committee, who, I suspect, would once pointed out, also identify that as a priority.

**John Halamka, MD, MS – Harvard Medical School**

So, this is not for the transmittal letter is a Policy Committee, is this. . .as we think of things that would add value for clinical care, like your country of origin, is treatment in a VA or Military Health System also.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

To close the loop on the race/ethnicity, I don't know if you guys can see it on that small screen, so, the consensus was OMB for 2014, more granular could be used to sum up your words? So, that would strike the Patient Engagement Workgroup comment?

**John Halamka, MD, MS – Harvard Medical School**

Well with an additional study that they're going to do and the consideration of requiring something more granular as a next edition, but for now, for 2014, it is not a mandatory addition.

**Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

I think that when the point comes that the patient is generating information about their own demographics, we have to be pre-emptive at that point, to make sure that we can respond appropriately to patient self-identification. So, this should be a strong signal for the future efforts.

**John Halamka, MD, MS – Harvard Medical School**

And we'll have a fair amount of discussion today about the bi-directionality of patient and family engagement and it actually does propose a whole variety of interesting Standards issues, so, how does a patient describe their problem list, or their race/ethnicity when they are using a layman's vocabulary.

**M**

John?

**John Halamka, MD, MS – Harvard Medical School**

Yes?

**James Walker – Chief Information Officer – Geisinger Health System**

Jim Walker. Just real quickly, I'm absolutely not arguing against increased granularity, I'm just arguing that in a world of finite resources, we ought to make some effort to make sure that the increased granularity is usable and useful.

**John Halamka, MD, MS – Harvard Medical School**

Right. Maybe as a process point, if we have instances like this where there is a refined comment, you can read it back, everyone can say this is good, we can move on, does that work?

**M**

Perfect.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

So, for this one, OMB for 2014, more granular, I'm just going to have the notes, we can make this prettier later. More granular code sets could be used that would cross-walk to them and then consideration of requiring more in the future and more work to be done by the Patient Engagement Workgroup. Sum it up?

**John Halamka, MD, MS – Harvard Medical School**

I think so.

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

May I?

**John Halamka, MD, MS – Harvard Medical School**

**Yes.**

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

The term granular has a lot of meanings, right? And I know that the CDC codes are granular from at least two perspectives. I don't have all of them memorized, but I know that they're granular in that they're intended to be worldwide, you know, to cover everything. I'm not sure OMB is intended to be worldwide. But secondly, they do incorporate the source of the assertion, they say whether it's apparent versus claimed race and both of those are ways to be granular. I think if we're referring this, we should be clearer what we mean by granular and ask, you know, whether it should be international, whether it should indicate whether it is a patient assertion versus apparent and those kinds of things. I think just saying "more granular" is not sufficiently descriptive to let the Policy Team know what we're asking for.

**Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

This is Leslie again and I think the group would agree with that comment about getting more specificity and understanding the words that we use and also the international aspect of race, ethnicity as a whole term here in the US, as that being a much more international focus to be relevant. So, I think those are two good comments.

**John Halamka, MD, MS – Harvard Medical School**

So, I think from your reading it back perspective, is to change the word granular to a higher degree of specificity and coincidence with international standards?

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

And source, and source...

**John Halamka, MD, MS – Harvard Medical School**

Well, I think we've wrestled this one, very good. Next we have 170.314-A(iv), vital signs, body mass index and growth charts. Now interestingly enough, this proposed standard's none. Jamie, just a quick question. For vital signs which have units of measure, did we make any statements like the use of UCUM as a millimeters of mercury or standard unit of measure associated with the vital signs?

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

No. I think we did previously recommend UCUM as the Standards for units of measure, but just within the context of clinical lab results.

**John Halamka, MD, MS – Harvard Medical School**

Vital signs could be recorded as alpha numeric, 140, 140/80, high. The reason I ask this, you'll find this sort of amusing, I generate a few million CCDs every year and the challenge is not the generation of the CCD, but the parsing of the CCD and so, we're running these CCDs from major vendors through the NIST validator and they are failing and it is often the case that the blood pressure is something like high, low, sitting, 140/, you know, normal. So, one wonders... I recognize this is bit late in the process, but, is there any comment that we can make on vital signs that would be helpful. Floyd.

**Floyd Eisenberg – Senior Vice President of Health Information Technology – National Quality Forum**

Yes. Just, I hate to keep bringing up the CQM issue, but, for the measures that are meant, some of them that are in the CMS NPRM, they do ask for blood pressure and I believe they are actually looking at some change in blood pressure over time as part of these measures, so, they really need numerical values with millimeters of mercury for systolic, separate from diastolic and so, to enhance your comment, yes, I think we do need that level of detail.

**M**

I agree with that. I was just going to ask that we think about broadening that and making that more of an overarching statement, referring to clinical observations in general, and not just vital signs.

**John Halamka, MD, MS – Harvard Medical School**

So, is there, for example, a LOINC code, is there a...any, for experts on Standards one could use for these kinds of clinical observations, is there something we should state?

**M**

I think they were... I think we recommended in the transmittal letter in September for handling vital signs.

**John Halamka, MD, MS – Harvard Medical School**

And do you recall that recommendation?

**M**

I did not write it down to have prepared here. I believe it was... it's LOINC or SNOMED, I apologize, I don't remember which one we... I think it was LOINC.

**M**

But I don't have it...

**M**

It was LOINC.

**John Halamka, MD, MS – Harvard Medical School**

Okay. So, we will, of course, check the transmittal letter, but, I wonder, do we want to go in this late time as bold as saying we actually believe that the vital signs should be reported in structured fashion using LOINC codes, and of course clinical observations in general. Okay, well hey, we have general nodding of heads. No more high, low or 140/, yay. I actually had a Vendor argue with me that they would not

change their data to a structured field and if their CCD was non-conformant, so be it... Well, great... Patient Engagement Workgroup has recommended the addition of a pain scale.

**Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

We have recommended an addition of a pain scale. We feel that that's an important... vital signs needs to be standardized and also looking forward to potentially patients being able to add to their record from HomeCare or NoteCare, being able to have that patient voice, which is pain, is an important part of standardization.

**M**

From a perspective of Policy, I guess that's a question of, as we have with some of these other recommendations, question for the Policy group unrelated to our transmittal letter, is the addition of a pain scale, something that especially as we think of bi-directionality, and is there a pain scale standard that. . .

**M**

Like HL7, there are many to choose from.

**John Halamka, MD, MS – Harvard Medical School**

Okay. Jon.

**Jonathan Perlin – Hospital Corporation of America**

The question I have would be, is that the most important next thing to add. It's a good thing, certainly, but, what about functional status, wouldn't that be a better... I'm not saying that is, but just as an example, something that would be at least as if not more valuable to say... certainly there are, again, Standards to choose from there. I guess this gives us a basic question of, how do you prioritize these pieces and is... while it's a good thing to do, is it the thing to do?

**James Walker – Chief Information Officer – Geisinger Health System**

This is Jim Walker.

**John Halamka, MD, MS – Harvard Medical School**

We have a couple of cards ahead of you Jim. So go ahead Leslie.

**Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

So, the team would say we did not spend a lot of time prioritizing what should be next. This seemed to be an obvious one that was shared both... that shared the patients voice inside the hospital setting, and not done just as an observation of a patient, but actually the patients voice. Also, the work team discussed in general the need to add many more fields that when the patient is the source of truth, that that should be aggressively standardized for future patient-generated data. So, there was huge discussion about this, we felt this was the most logical one for this particular comment.

**John Halamka, MD, MS – Harvard Medical School**

Hey Chris.

**Christopher Chute – Mayo Foundation for Medical Education and Research**

I'm sure that many of us support this idea in general and I think it's self-evident that it is desirable, the question is, which Standard to use and unless you are aware, AHRQ has been convening the PROMIS Groups Patient Reported Outcomes Measure Instrument something, something for many years now and the whole emphasis of the PROMIS Activities is precisely to consolidate into, not compromise, but into a consensus view what these kinds of patient reported outcomes should look like, what their Standards and Formats should be, what their value sets should be, that's all part of what PROMIS is doing, and I would urge that if we're going to look at that in the context of this kind of question, that work be carefully reviewed.

**John Halamka, MD, MS – Harvard Medical School**

So, with this one, we'll leave it as a Policy Committee question with some work to review from the PROMIS Group. Now Floyd, was there another comment.

**Floyd Eisenberg – Senior Vice President of Health Information Technology – National Quality Forum**

Yes. Actually, I'd like to make a kind of a compromise proposal based on something Mark had said, and I think, for vital signs, the question came up was, do you make pain scale a vital sign, but I might ask instead, should we ask that EHRs have the capability to manage a SmartForm, so that folks who wanted to use a validated pain scale or a PROMIS scale or Braden scale, should that be required for decision support, for measurement, that the SmartForm capability could handle it, but not specify which ones in the rule, just say it has to have the ability to capture information of a SmartForm that can calculate and be stored as an observation with a value. That was actually in the transmittal letter, there was some terminology suggested for that, using the Quality Data model concepts of risk evaluation and functional status, and they recommended LOINC for the instrument and numerical or SNOMED for the response.

**John Halamka, MD, MS – Harvard Medical School**

Right, in fact, thanks to Mary Jo, who's just sent me a copy of the transmittal letter, I have it in front of me and it is exactly as you say, so, work to be reviewed from the PROMIS Group, but the notion in the transmittal letter of being able to create instruments with arbitrary questions and structured responses using LOINC and SNOMED CT may be a more generalizable approach to this sort of thing.

**Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

And would also be scalable for future patient generated data, that would be wonderful.

**John Halamka, MD, MS – Harvard Medical School**

Jim please.

**James Walker – Chief Information Officer – Geisinger Health System**

You know, our job is Standards and if, you know, if we make a recommendation or an off-channel communication to Policy and say if you wanted to do pain scale, this would be the standard. If we don't do that, then we will have a situation where, in an accountable care arrangement or any other effort to care for patients to provide patient-centered care across the community, you'll have different standards for pain scales that won't be commensurate and people will find... patients and clinicians will find it hard to do any kind of comparisons across time or across venues. So, I think we ought to, not in the NPRM response obviously, we don't have time for that, we ought to provide a communication to Policy that says, if you wanted to do this, we would recommend this specific Standard.

**John Halamka, MD, MS – Harvard Medical School**

So, I think... good summary of the discussion that we've had. Thank you for that. Also, looking at the transmittal letter, we said for non-laboratory clinical observations, LOINC for the name of the thing being reported, SNOMED CT for findings and UCUM for units of measure. And so, because Steve just asked me this question, if you wanted to report the thing called systolic blood pressure, would that be a LOINC code for the thing, systolic blood pressure and UCUM for the millimeters of mercury. Okay...

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

So then the new comment would be, vital signs recorded in structured fashion with LOINC and UCUM?

**John Halamka, MD, MS – Harvard Medical School**

So, in fact we made this more general statement in the transmittal letter of LOINC for the specific name of the observation, SNOMED CT for findings and UCUM for units of measure. In the case of blood pressure, there is no finding, so it would just be the LOINC and the UCUM.

**James Walker – Chief Information Officer – Geisinger Health System**

This is Jim...

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

...general observation...

**John Halamka, MD, MS – Harvard Medical School**

Right, I mean, so...

**M**

Vital signs

**John Halamka, MD, MS – Harvard Medical School**

...do we want to go as far in our transmittal letter of simply reiterating the general observation structured data, non-laboratory, LOINC for specific study names, SNOMED CT for findings and UCUM for units of measure? I see general nodding of heads. Okay.

**James Walker – Chief Information Officer – Geisinger Health System**

John?

**John Halamka, MD, MS – Harvard Medical School**

Yes.

**James Walker – Chief Information Officer – Geisinger Health System**

Just real quickly. Jim Walker. As a general comment, in the Quality Tiger Team, we found that there have been several transmittals to ONC that have gotten lost in the midst of time that we have re-found. I think, whenever we can, if we refer back specifically and maybe just say, you know, just cite a section of a transmittal letter, it would help us all sort of remember what we've decided and reuse it, rather than reinventing it.

**John Halamka, MD, MS – Harvard Medical School**

And so specifically would cite the September 9, 2011, this was the letter of transmittal from the HIT Standards Committee regarding the Clinical Quality Measures Workgroup of Vocabulary Task Force jointly developed recommendations for code sets. And probably good, Mary Jo, to just circulate that to the group so they can see what we're referring to.

**M**

John?

**John Halamka, MD, MS – Harvard Medical School**

Yes.

**Christopher Chute – Mayo Foundation for Medical Education and Research**

Chris Chute. Briefly, while everybody loves UCUM, it was Stan who actually taught me that UCUM out of the box isn't helpful, that one actually needs units of measure that are composed of UCUM elements, and that's an important distinction.

**John Halamka, MD, MS – Harvard Medical School**

Sure. Understood. Okay. We are now moving on to the Problem List. Now, this is a simple recommendation, SNOMED CT. Okay, we're done. Next... go ahead Jamie, you have many comments.

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

Well, I think that for Problem List, we had asked... in the Workgroup we had asked the ONC staff whether the intent was really for the encounter diagnosis for administrative classification purposes or if it really was intended for clinical purposes. They pointed us to the preamble of the NPRM which indicated it really

was intended primarily for clinical purposes. And so, because that, we would recommend SNOMED for the encounter diagnosis for clinical purposes, but also feel that if there is a need to have a data element for essentially the billing classification, then ICD-10 CM would be our recommendation. But, since that wasn't the intent, we are just recommending SNOMED.

**John Halamka, MD, MS – Harvard Medical School**

And so, for those who have been on these calls, just recognize this same issue I had mentioned earlier of when do we use ICD-10 CM by name, especially exclusively ICD-10 CM and I think the answer would depend upon the need and if this is specifically looking at clinical observations, then SNOMED CT is a perfect need. Now, is it later in document that you describe about the billing, specific separate field...

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

...I think it is, sorry, I was mistaking this reference for that reference.

**John Halamka, MD, MS – Harvard Medical School**

Okay. Any other comments on the SNOMED CT?

**M**

Yes.

**John Halamka, MD, MS – Harvard Medical School**

Yes.

**M**

I agree with the recommendation. That being said, it would be regrettable if we lost sight of the opportunity of ICD to serve as an aggregating concept. We all recognize that SNOMED is intended to be more specific and it is evolving to be exactly that; however, I think for many use cases, there is advantage to having an aggregated parallel to patient problems and issues and I'm wondering if we could recommend that while SNOMED should be used, at some place in the record, summary categories of patient events and diagnoses, as rendered by ICD ideally, and we could quibble whether 10 CM actually does that or not, but certainly 9 did, in a way that gives a higher level grouping and higher level categorization which has many use cases in the record.

**John Halamka, MD, MS – Harvard Medical School**

Jamie, comments on that because you had recommended...

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

I wonder if this would be another comment to the Policy Committee to consider the need for an additional data element for that purpose. And if so, then we would recommend ICD-10 CM.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

Because that in fact, as the Workgroup discussed, the notion of, here's your problem list, oh but here's another data element that is sort of an aggregated summary billing category or other epidemiological report. We are going to have a transmittal letter to you and transmittal letter to the Policy Committee. .  
.Yes

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

David McCallie. My only concern is just overburdening the busy clinician with awful lot of list management for purposes that may not have as much to do with patient care as they probably should. It's already going to be something of a burden to capture an ICD SNOMED for the clinical and in ICD-10 for the billing, whether that's our purview or not, they're going to still have to do it, and then we can automate that to a certain degree. But, are you suggesting capturing a third category of information Chris?

**Christopher Chute – Mayo Foundation for Medical Education and Research**

No, I'm just trying to ensure that... first of all, I don't think the clinician should do it directly. I think this category should be algorithmically derived from other information. I'm arguing merely that the slot persist and that it not be discarded, so that we have no way of aggregating this kind of information. And second, you're correct in terms of immediate direct patient use, it may or may not be immediately obvious what its value is, but I submit in the context of secondary data use, which is an emerging important area of clinical information, in which I would include, incidentally, clinical decision support, the ability to have aggregate categories is becoming increasingly recognized and, not to put the burden on the clinician, it would be regrettable if the way of implementing this was to have the clinician code everything twice. But, I am anxious that we not throw the baby out with the bathwater.

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

Yes, this is David again, and that makes sense. I assume that behind the scenes aggregations and analytics could use whatever was the most appropriate tool, and ontologies may be self-developed, may be standard space, so, in terms of something that would be certified, unless there's a message passing back and forth, I'm not sure I hear a new requirement.

**Christopher Chute – Mayo Foundation for Medical Education and Research**

Just to keep the data field.

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

Keep the....but that's an internal data field...

**M**

No...

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

Is it as part of a CDA, CCD...

**Christopher Chute – Mayo Foundation for Medical Education and Resear**

I would hope it would be, yes.

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

Where does it go? I'm just... Are we adding a new field to the CDA, a new category?

**M**

I think what we've recommended is making this a comment to the Policy Committee to perhaps consider those questions.

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

Got it.

**John Halamka, MD, MS – Harvard Medical School**

That we're going to have the observations that are recorded by the clinician and then there may be a Policy reason to have a new field called, the billing diagnosis, for the purposes that Chris suggests, it is going to have an epidemiological or secondary use nature, without immediate intent that the clinician's going to be recording, it's probably going to be computed, but, today, you know, for the purposes of the transmittal letter, I think we're saying SNOMED CT for problem list...

**M**

And if I could just reiterate and recommend a minor change to what you just said. Instead of calling it the billing diagnosis, if we could call it the administrative classification, I think that would be preferable.

**John Halamka, MD, MS – Harvard Medical School**

Okay. And Marc, comment?

**Marc Overhage – Siemens Healthcare**

I guess I have a little anxiety because it seems like it's adding complexity that, as David I think was alluding to, as if you could do it algorithmically, then why include it in the transmission when you can derive it whenever you need it? That just seems like adding a lot of complexity... and if you can't derive it algorithmically, then...

**M**

Yes, sure.

**John Halamka, MD, MS – Harvard Medical School**

Any comments from either of the two of you at the moment. I mean, so, I think we can say that we're going to just refer this one to the Policy Committee without specifically adding the field today, but we've heard a couple of arguments why having such a field of an administrative classification would conceivably be helpful. So, SNOMED CT. Implementation Workgroup.

**Cris Ross – Executive Vice President & General Manager, Clinical Interoperability – SureScripts**

This is Cris Ross. I wanted our two recommendations. The first one had to deal with was a comment that came to us both from the Vendor comments as well as Clinical Components, which was that there needed to be a clear definition of longitudinal care, and the recommendation was that that be based on a definition from the Policy Committee, and with reference to the Proposed Rule Preamble. There was a further discussion that the definition ought to be patient-centric, which would reflect longitudinal care from multiple entities... multiple places of care as opposed to a single one. We would make the final comment that if that's so, that may require... affect the certification criteria for medication list and medication allergy, which would make those revised, rather than unchanged. So, essentially, you know, two components, one was to make it patient-centric and longitudinal across multiple points of care and then the second is just make sure that the definition is clear enough that the testing... certification criteria can follow easily, based on a common definition.

Second comment was around the, in order to meet Stage 1 Meaningful Use, there were instances in which a physician would need to enter into a chart explicitly that there was no new diagnosis, but didn't add any clinical value by doing so, and that may either be an artifact of the certification criteria that were applied or it could be part of the Standard itself. So, we're looking for clarification that a physician or other caregiver would not be required to add, no new diagnosis as a part of the calculation of Meaningful Use Criteria... or Meaningful Use numerator/denominator.

**M**

So for example, if I see my clinician for a wellness visit, and I have no acute complaint, my problem is, I'm well.

**M**

Yes, there's an example in here about an annual physical for a healthy 35-year-old, there is no addition to problem.

**John Halamka, MD, MS – Harvard Medical School**

Any comments?

**M**

Yes, just a comment on that, that last issue. Does the concept in the NPRM of clinical data reconciliation that includes problem list, make the need to the suggestion previously to enter nothing new go away, because if you've reconciled, you don't have to do anything. Of course, reconciliation also means checking a box I reconciled, there's always something that has to happen, but that's in the rule as well, or the proposed rule, just for discussion.

**John Halamka, MD, MS – Harvard Medical School**

So Steve, you've listened to these couple of comments, do you have. . .have you had any language to summarize?

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

Well, it didn't seem like there was anything necessarily suggested to change in the points that were being brought up...

**John Halamka, MD, MS – Harvard Medical School**

So a clear definition for longitudinal care, which is something that's a Policy Committee would offer...

**M**

I don't know, there's probably a number of comments that the Implementation Workgroup made that came from a bias of looking at certification and testing, to be quite honest about it. In many instances we erred on the side of bringing those forward for possible Standard or Policy consideration because there may be an embedded issue in those certification criteria that create an implied Standard or an implied Policy. This was a place primarily where there was a problem in practice.

**John Halamka, MD, MS – Harvard Medical School**

And really, I think the one concrete recommendation you had is that it be allowable to enter a problem of "no problem."

**M**

Um hmm.

**W**

(indiscernible)

**M**

...and not a requirement that you do enter a problem of no diagnosis. . .

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

...it's more of an interplay with our CMS colleagues.

**M**

Correct.

**W**

Correct.

**M**

Correct.

**John Halamka, MD, MS – Harvard Medical School**

Good. Okay. Well, let us move on now to clinical decision support where the one Standard that has been listed is the HL7 context to where knowledge retrieval or InfoButton standard as a means of getting customized decision support available to a clinician in the context of the EHR and Jamie, I know you had some comments on this.

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

Okay. Yes, our Workgroup also had comments on this, really two comments. One is that InfoButton is, we believe, misclassified as decision support and should, essentially, we like InfoButton, we're not saying that needs to be removed, information retrieval is important, InfoButton is a good standard for that

purpose, but we wanted to ensure that readers of the rule weren't confused by its inclusion in the section called Decision Support, when other things such as alerts or reminders would be more typically considered to be Decision Support. So, that's one comment. The other was a request for simple web links in essence, to also be allowed for information retrieval and we understand that there are benefits of using InfoButton in some cases, but in other cases simple web links may suffice, so we felt that both should be in Certification.

**John Halamka, MD, MS – Harvard Medical School**

Right, so this is analogous to Dixie's use of TLS, if it is a standard in practice to use TLS for communication of web pages, to say I'm not allowed to use a URL to retrieve a web page seems odd. So, certainly where I might license commercial software that, you know, I license Healthwise, I license Micromedex, I want to be able to use some standard to retrieve something that's context specific for the patient, but if I should author a whole variety of HTML pages, I would think a URL would be acceptable as well. That's the recommendation. Arien?

**Arien Malec – RelayHealth Clinical Solutions**

Yes, so I have a question about how InfoButton in this context, I understand InfoButton in a patient documentation context, how information retrieval in this context maps to a Policy goal. Is the, and I can invent one, but I'm just not sure what the Policy goal that InfoButton in this context actually maps to.

**John Halamka, MD, MS – Harvard Medical School**

And so the notion was, being able to in the context of an EHR, retrieve appropriate information of a reference nature, so the Policy goal would be that it would be good if you're in the middle of caring for a diabetes patient with hypertension, to pull an article that's salient about diabetes and hypertension.

**Arien Malec – RelayHealth Clinical Solutions**

That's where I go in terms of inventing the use case, but the question is, does this map to a specific Policy Committee recommendation that clinicians must or must have the capability for accessing evidence based care guidelines or other kinds of reference information based on current information for the patient.

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

Clinical Decision Support, that's why it's grouped under Clinical Decision Support, which has consistently been a thread of Policy goal. In other words, being knowledgeable about the decision you're about to make is part of Decision Support.

**Arien Malec – RelayHealth Clinical Solutions**

So, what I guess I'm asking is, is this. . .are we creating Policy through Standard, is there a Policy Committee Recommendation that information retrieval and automated clinical decision support are both equal Policy goals and so we've got Standards recommendations that map to both of those. That's really the question that I'm asking. I'm not arguing that information retrieval in a clinical context is a good thing, I'm asking whether it maps to a specific Policy Committee goal or are we introducing a Policy need through the inclusion of a Standard.

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

You would need to see a policy statement that says you should be informed about the decision that you're about to make, so, I would expect it to be self-evident. I'm missing the...

**Arien Malec – RelayHealth Clinical Solutions**

I would expect this to be mapped to a Policy goal that clinicians should have access to evidence based guidelines or other kinds of documentation relative to the current problems, medications, etcetera. The context in which I've seen decision support has been much more in the context of automated decision support of a decision or rule that fires, at least, that's how I've interpreted the Policy Committee recommendations today. That's where I'm having a hard time with this one, is it... what if it mapped to... what Policy goal does it map to is the goal that EBM content should be available for the clinician and does

that create now certification or an EHR requirement to maintain, bill that and also... that's where I'm going.

**John Halamka, MD, MS – Harvard Medical School**

Clinical decision support can be comprised of an alert or reminder, something that is a rule firing in the middle of your workflow or access to evidence based medicine that would help you make a decision. So, I think... and is that an "or" can I achieve as an EHR, can I achieve it either or do I have to achieve both is it an "and."

**M**

Right.

**Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

So, I think the InfoButton standard was referenced because of the attribution capability, so, where it was authored, what the evidence was based upon and so that that was consistent with the information retrieval and the recording of that information that was used. So, the standard allows for both retrieval and a response back that says here are the attributes, here's the versioning, here's the authors and so, I believe that was the why it was mentioned specifically.

**M**

That isn't clear in how it's written.

**M**

So, what I would say Arden was that we... imagine this, so I have self-written an electronic health record that includes 2000 decision support rules. There are no standards inside my internal representation of those decision support rules, it is a function that I offer to the clinicians. So, as I read the certification criteria, you should be able to activate such a function that provides alerts, reminders, etcetera. The standard is the thing that we've just simply mentioned for evidence based medicine retrieval, because it's hard to specify a standard around the alerts and reminders, unless we want to go to Arden syntax or GLIF or some other representations. I think that's the issue.

**M**

It could be... I mean, so, to date, in the certification criteria, it's been a functional standard, that is...

**M**

Right.

**M**

...there is some workflow that triggers and there is an alert that triggers and that alert is available to the clinician, so as a functional standard, that's where this question is coming from people who are actually going to have to implement this and they don't know what to do.

**John Halamka, MD, MS – Harvard Medical School**

So I think 170-314A(viii) provides that functional standard under the certification criteria and then under the actual proposed standard, it's purely the one that we could specify that goes beyond function. Dixie, did you have a comment on this too?

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

I did. I debated whether... the InfoButton as a Standard, that is not widely implemented. You know, we always look for Standards that are widely implemented and, I actually did a little checking around in the systems that we've worked with and, it's not widely implemented at this point.

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

But, the capability to link out, to reference literature is widely implemented...

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

Right...

**M**

...and one of the hypotheses I think, that would be a Policy goal is that is that if you can put a Standard in place there, you will reduce the cost and complexity and barriers to creating those links between the activity data and the record and the reference data that is of interest to the clinician, and you can probably do a better job of that than we typically do with static URLs. So, I mean, I understand Arien's point that there may not be a clear mandate to go fix this problem, but I think there is a problem to be fixed.

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

I don't disagree with that at all, but, I thought that this Committee always looks for Standards that are widely implemented. . .

**M**

Yes.

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

...rather than introducing Standards that exist, but are hardly ever implemented. That's my...

**John Halamka, MD, MS – Harvard Medical School**

Over the years we've had some experience with the InfoButton standard.

**Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

We have had experience and I would argue that it's widely implemented for the maturity level that we have of selecting decision support content inside an EMR, they're proportional. The NLM uses this Standard to retrieve, we...

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

... which is not an EHR, I'm talking about...

**Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

Right, and inside an EHR, using the InfoButton to link out to referential material that could be free from the NLM, could be from a Vendor, I think that's underestimated. I know that of the billion uses that we've had over the last 35 years, in the last 3 years it's shifted to more InfoButton queries than queries directed by a person self-navigating. So, 35 years of history, a 2 year switch is a pretty dramatic change.

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

Hmm.

**John Halamka, MD, MS – Harvard Medical School**

Farzad?

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

Dixie, on this point, did you have any sense in terms not only of how widely it's been implemented, and there are some maybe fact finding we would do about that, but also in terms of its adoptability as it were, the simplicity of the Standard to adopt. Did you have any concerns about that?

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

No, actually, to give the context, I wish Wes were here. Wes asked me to check because this company I work for implements a lot of different EHRs and I checked with all our people that implement these various EHRs, across the board, and literally nobody had ever implemented. . .

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

Right, but in terms... but in terms of...

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

... but we have... I didn't ask them to (indiscernible) ...

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

... the adoptability, I think that's a key.

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

... yes, I did not ask them, right?

**John Halamka, MD, MS – Harvard Medical School**

But if we phrased it as, static URLs or InfoButton are enabled within the EHR to reach external resources, does that address your concern?

**M**

Map to a functional goal of looking up reference information, as opposed to map to the functional goal of clinical decision support. I think that would be... that would make a lot of sense.

**John Halamka, MD, MS – Harvard Medical School**

And this is the issue that Jamie was getting at is that it feels a little funny to call InfoButton a decision support Standard. It's decision support in the sense that you are looking up reference materials. Yes...

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

So, I just... I think that, whereas I agree that our traditional approach to decision support as we kind of would have defined it a couple of years ago, if you'd have asked somebody randomly, would have been "alerts and reminders," but I don't think. . . I think the overall level of dissatisfaction with alerts and reminders, because they're interruptive, leads us to scramble and try to figure out better ways to do decision support and one way to do that is to provide contextual information, you know, in a sidebar, in context that's guiding or reminding or hinting it to the clinician as the process evolves, not in the form of an interruptive alert necessarily, but in the form of a clickable entity that can take you to additional information which may involve just simple reference material, it may be just reference ranges, normal, it might not be evidence-based and so forth. So, I think we've got to keep a much broader notion of what decision support is and InfoButton may play a role as a way to remove barriers of integrating those kinds of external reference content.

**M**

I'm not arguing about the value of that, what I'm thinking, from an implementation perspective is, looking at a team that's thinking about building clinical decision support and thinking, "okay, what do I do with InfoButton, how does that... now what do I do," and if context for InfoButton is clearly specified for information retrieval of associated evidence based content, including NLM searches, I think that... there's a clear path for achievement of that.

**James Walker – Chief Information Officer – Geisinger Health System**

Jim Walker.

**John Halamka, MD, MS – Harvard Medical School**

Yes Jim.

**James Walker – Chief Information Officer – Geisinger Health System**

I guess from an organization... care delivery organization's standpoint, if a care delivery organization had a link URL in its EHR, that took users directly to high quality, evidence-based resource that was rapidly

searchable, and had enormous use of that URL by clinicians, would that meet the Policy intention here without using InfoButton?

**M**

That's what Jamie has proposed.

**James Walker – Chief Information Officer – Geisinger Health System**

Well, I'd strongly support that because that is actually our case. We, I don't know how many hundred thousand hits a year to a very high quality, evidence-based reference resource our clinicians use and find it very fast and very satisfactory.

**John Halamka, MD, MS – Harvard Medical School**

I think we have a few more comments on this topic. Marc, did you have a comment?

**Marc Overhage – Siemens Healthcare**

Yes, thank you. Marc Overhage. Just partly Arien to your question about is this clinical decision support and I think the answer is, it depends on what your server does, what your InfoButton server is set up to do, because in fact, an InfoButton link could look a whole a lot like what a pop-up clinical port rule delivered because you have the same context and it might come back and say, "Gee, you clicked the CT button, but you really ought to look at an ultrasound in this patient because their creatinine is lousy and a contrasted CT would be a bad choice." So, I don't think there's anything inherent that makes it different, in terms of is it decision support or not. Similarly you could have an alert or reminder that came up and said, "If the patient's creatinine is high, you should worry about it," is that any different. So, I think that distinction, I'm not sure I get the distinction there. I mean people traditionally have thought of InfoButtons as just getting you to some literature, but that's certainly not the only way it's used, nor is that a constraint of the Standard.

Um, on Dixie's point about utilization. I think that's a really good one actually, that I think there's only what about 5 or 6 commercial, including NLM, sources or InfoButton servers out there, BMJ, a handful of others that implement it, so, there aren't a lot of InfoButton servers to go to. And number 2, I don't think there are many real-world implementations of it in EHRs. We did implement it in my previous life at Regenstrief and to your point before about implementation, it's actually extremely tricky. It may sound trivial to embed, you know, a URL into your application as it is, but there's all kinds of implications. For example, the flow sheet application those URLs are massive, if you actually take the trivial implementation approach and just sort of stick the URL in with every value and say, "okay, the user can now click on it and get the value," you just destroyed performance because the browser and parsing and using those just dies. And so you have to. . .so, it's actually a non-trivial implementation effort, to actually make it work with performance and contemporary user interfaces. So, it sounds easy to put a URL in, and it is, but it has a lot of implications.

**M**

Comment back. The difference is, if I've got an existing decision support engine that I've built into my EHR and it works, and it meets the functional goal, I won't, if that's the interpretation of the Standards criteria, I will not be able to be certified. So, I'll meet the functional goal of providing clinical decision support for clinicians, but I will not meet the Standards goal and I will not have certified EHR technology.

**Marc Overhage – Siemens Healthcare**

But all it says is that you have to be able to have a InfoButton link, it doesn't say you have to use it as your way to deliver decision support.

**M**

And that's the clarity that I'm looking for.

**John Halamka, MD, MS – Harvard Medical School**

... modify a URL to a...

## **M**

... or URL.

## **M**

... high quality decision support reference would also be acceptable. Walter.

### **Walter Suarez, MD, MPH – Kaiser Permanente**

Yes thank you. This is Walter Suarez. This is a question about the description of the Standard. So, there is the Standard and then there is an implementation specification or implementation guide, and my concern, or I guess my question and maybe the concern, too, is that the reference is specific to the Standard, it doesn't make a notation about the implementation guide, HL7's implementation guide for implementing InfoButton, which might actually in some ways address the expectation that, yes, this is the Standard, but this is the way to implement it. So, normally in some of the definition of this, in Meaningful Use Stage 1 and in Meaningful Use Stage 2 I see it too, we reference the Standard and then whenever applicable, we reference an implementation specification. So, the question is, are we not referencing that, any particular reason or should it be referenced as well.

### **John Halamka, MD, MS – Harvard Medical School**

Marc, did you have some comment on that?

### **Marc Overhage – Siemens Healthcare**

I'm sorry, it sort of builds on that in the sense that the flip side of saying something about this Standard is the risk that. . . and I mean it's sort of obvious, you look at the list of data here and you say okay, now you're going to have two ways potentially, you're going to need another Standard down the road for other kinds of decision support and are you creating now two ways to do things and life is hard? Or is it good because you're creating two alternatives and people can choose the one that works well for them. So, maybe that gets to Arien's point about is it either or, or is it both, that becomes important.

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

And David. Which is my question as well, back to you know, Liz's comment a while ago that an "or" becomes an "and" for the Vendor if, what is our intent here, that everybody must be able to capable and certifying against the Standard or the implementation guide, but you don't have to use it? Or are we backing away from even saying that you should certify against it?

### **John Halamka, MD, MS – Harvard Medical School**

So, of course there are two other Workgroups commenting on this, but, what I wonder is, there are a couple ways we could go here, well Farzad before I summarize, let me, Farzad, did you have a comment?

### **Farzad Mostashari – Health and Human Services - Office of the National Coordinator for Health Information Technology**

Just, I don't know if it's been noted before, but, under A(xvi) the InfoButton is clearly proposed to be required for just patient-specific education resources already. So, in terms of ensuring that the capability to do what it is arguably best and is tightly fitted to do, retrieval of that information, it's already included in terms of requirements for electronic health records. I think Marc's point is a good one, about whether given, and particularly in the context of given that EHRs will all be capable of doing this, what is the added benefit of including it, particularly with an "or" under the decision support section.

### **John Halamka, MD, MS – Harvard Medical School**

So, based on all the discussion and Dixie's comments, one could say we will have a functional description of decision support without a Standard, because in fact, if you're implementing URLs and that's an "or," then what's the point of saying, "you know, you could do a URL or you could do InfoButton," if we're not going to require InfoButton versus requiring InfoButton. Now, for about patient education perspective, actually InfoButton probably makes great sense. I think the issue that Jamie's discussion was, in the context of CDS for clinician workflow requiring InfoButton may not make sense.

**Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

I guess I would add that the InfoButton allows for patient-specific context, so, before that is selected, whether it's for clinical decision support or patient education, I have at a minimum the age, the gender, the diagnosis or treatment, I have context with which to pull that information up, so it adds some safety features. If I'm going to pull up clinical decision support, shouldn't it be relevant to that patient that I'm reviewing in that chart at that moment. So, I understand that today there is the need to pull up self-authored content, perhaps on your own website with a URL, but that is not patient specific and does not allow for opportunity for future contextual additions to the Standard to further modify and specify clinical decision support or patient-specific education material. So, it's just. . .and the Standard also allows for reporting back into the record what has been used and referenced back with attribution. If we believe that's important and material to decisions being made for the patient, then the Standard should be adopted. If we believe that is not that material, and the convenience of a URL is a greater convenience, then that should be our recommendation.

**John Halamka, MD, MS – Harvard Medical School**

So...

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

The certification functional criteria specifies that it must be relevant to the patient context, so, that is an important, in a way protection, but, to make sure that decision support is not just generic, that it is specific and I think what we're discussing is the implementation of it, whether there are other emerging Standards for representing decision support and so forth.

**John Halamka, MD, MS – Harvard Medical School**

So, I'm actually hearing quite a lot of comments. . .I've got Stan.

**Stanley M. Huff – Intermountain Healthcare**

Just a couple of things that I think people have said and make sure I'm understanding and then maybe a comment. I mean, I think it is useful. . .you can argue whether it's decision support or not, but I think it's useful to make a distinction between something that retrieves something that I then read and decide whether it's applicable and make a decision, versus something that does logic and makes a suggestion that's very specific for this patient. I think that's a usual distinction of, you could call both of those decision support, but I think it's a useful distinction to think about in this conversation.

The second thing is really a kind of an extension from what Marc was saying, the thing about embedding URLs and one of the downsides of that, is you. . .it locks you to particular source of information and one of the real purposes and one of the goals of InfoButtons is so that at any given point in time, you can license or go to a different Vendor and not have to change all of your applications and change all of the pointers within your application to another. It creates that point of indirection, so that you can change your Vendor, change a source without having to re-engineer all of the content that you've embedded into your forms. So, I think that's one of the reasons to think. . .one of the reasons we would go with this as opposed to. . .I don't think we want to outlaw, if you will, the use of URLs, but there is a real advantage technically to using an InfoButton standard.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

So, I've heard both sides of this and, I could summarize it by it seems like many people have suggested the functional criteria are best, giving the implementation details some flexibility, where you could use InfoButton if you wished, you could use URLs if you wished and so, generally, as I ask everybody for everything you've heard for the last 20 minutes, does going with functional criteria without a specific requirement to use InfoButton make the most sense for this particular element? On patient, it may very well be different, we'll have that discussion in a moment. Oh, I see general nodding of heads, there does not seem to be overwhelming support for the mandate to use InfoButton. So, from a Posnack perspective, the recommendation would be go with the functional criteria that does of course highlight patient specificity and context and all the rest, but do not require the use of InfoButton.

**John Halamka, MD, MS – Harvard Medical School**

Okay, now, I know there are comments from Clinical Quality and Implementation on CDS in general. So, Clinical Quality, that's Floyd or whose the. . .or Jim.

**James Walker – Chief Information Officer – Geisinger Health System**

It's Jim. As you can see there, we had some sort of language recommendations. I think the one important one, that may be worth getting clear is how the SNOMED CT is strictly at the machine level or is also in a presentation level.

**M**

If everybody else on the phone can make sure they're on mute. . .

**James Walker – Chief Information Officer – Geisinger Health System**

. . .and I think that's the most pertinent recommendation there, that we had. You can see the others.

**M**

Sorry, again, you said SNOMED?

**James Walker – Chief Information Officer – Geisinger Health System**

Regarding SNOMED, the question was, is SNOMED in the representation level, the display level or is it strictly required at the machine level and then there could be a different display to clinicians that would be presumably more clinically relevant and. . .

**M**

Right, so, yes I think Jim, I think that one was further down in your stack. . .

**James Walker – Chief Information Officer – Geisinger Health System**

Oh, I'm sorry. . .

**John Halamka, MD, MS – Harvard Medical School**

Is this one, because we're just on clinical decision support; this was CDS for vaccinations, medication allergies, smoking, suicide risk – just looking at. . .this is page 5 of 33.

**James Walker – Chief Information Officer – Geisinger Health System**

Oh, I apologize. Umm, let's see. . .well, there are a number of issues that were raised. I think the most important one was that in each one in a combination of the following, and the question is vaccinations and medications, in some ways clinically and in terms of terminologies. Clinically, in some ways vaccinations are like medications but, because they have been treated differently and they are different in significant ways, there are questions about the vocabulary for them. And I'm sorry, I wasn't prepared for this one John. I think all the others are fairly self-explanatory.

**John Halamka, MD, MS – Harvard Medical School**

Floyd.

**Floyd Eisenberg – Senior Vice President of Health Information Technology – National Quality Forum**

Some clarification, Jim, maybe I can help here. . .

**James Walker – Chief Information Officer – Geisinger Health System**

. . .thank you.

**Floyd Eisenberg – Senior Vice President of Health Information Technology – National Quality Forum**

I think one of the issues was the wording, "in each one or any combination," led the group to think all of these had to be certified in order to meet the extent. . .or the intent, and did we really mean "each" one or

“any” one or “any combination,” and it was just a question. . .that was one of the questions the group brought up. Another question came up that since vaccination is not included, is that specifically to be excluded, because some don’t consider them part of the med list, they have a vaccine list. The other issue was that if we were to go with InfoButton, which I think things may have changed in our last discussion, the implementation guide should also be included. I think that’s the primary gist of what we were talking about, is there a “minimum bar” or a “must do all?”

**John Halamka, MD, MS – Harvard Medical School**

Refer back to the policy guidance that generated this one, which is, when you say an EHR is going to be certified as having decision support is it, it must have problem lists, medication list, allergy list, demographics, laboratory tests, vital signs and vaccination decision support or it must demonstrate that it has some elements of decision support in some. . .one or more of those categories.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

I don’t have the rule in front of me but, I believe, based on the intent of how it was written, A through F would need to be satisfied and then any combination. So, allowing something to be certified just to do based on problem list and saying “go ahead,” would not meet the Policy objective of the certification criterion to have clinical decision support to be based on the range of different data.

**John Halamka, MD, MS – Harvard Medical School**

So, I get CDS based on the fact that somebody has diabetes, a creatinine of 5, is on metformin, is 80 years old and has a blood pressure of 90/50. . .

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

If you wanted to set aside with one decision support rule, then you would have to create very complex, but a combination of decision supports that cumulative are. . .cumulatively cover the ground might be a more reasonable way to accomplish this.

**John Halamka, MD, MS – Harvard Medical School**

We did this in Stage 1 where we may have used 2 or 3 patients to demonstrate the spectrum of functionality. So, I think the answer is it’s “and.”

**Floyd Eisenberg – Senior Vice President of Health Information Technology – National Quality Forum**

What I’m suggesting is clarification of what that intent was, because there was concern about misinterpretation.

**John Halamka, MD, MS – Harvard Medical School**

Sure, to just make sure that it’s understood that it is “and,” not necessarily one patient, but the functionality exists across all those categories. And Implementation Workgroup.

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

This is Liz Johnson. So we, most of the comments have been covered, but there is one that we recognize as adding more specificity that may or may not be comfortable with the standards group, but, we have a concern that today, in looking at the certification criteria, it is not clear when a traditional sense of clinical decision support occurs does a secondary person get notified, and let’s just say it in English, if an RN is entering the order, an alert occurs, is there a requirement for a secondary alert of the physician who would actually be making the decision and we weren’t sure where to put that, but we think today, it is an area that is not covered and so Steve, we turn to you to say, is this the right place to put this, this is a real concern in the clinical world. It’s not covered in the functional standard, and we are talking about traditional clinical decision support.

**John Halamka, MD, MS – Harvard Medical School**

Interesting issue.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

Would that fall into the communication of the Policy Committee for additional discussion?

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

Potentially, I mean, I think we're, you know, obviously we were trying to look at not only the functional standards themselves, but the ability to actually implement them and what kind of ramifications went to the end users and this is one of them. So, what is the Standards stance on it?

**John Halamka, MD, MS – Harvard Medical School**

So when a rule fires, who is notified?

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

Correct.

**John Halamka, MD, MS – Harvard Medical School**

Arien?

**Arien Malec – RelayHealth Clinical Solutions**

This is in Jim Walker's, or in the Clinical Quality Workgroups, there's a comment that I'm not sure has adequately discussed by this group. Section 4 points out, I believe, the indirect reference is to the incorporate on transition of care, receive and incorporate on transition of care, and the requirement to fire clinical decision support on receive and incorporate. And there are, I think, three areas where I've heard that's problematic. One is a workflow consideration. I don't have any control over when a transition of care comes in to me, so what's the actual functional requirement, is it, it fires when I receive it, it fires when I open the referral or open the. . .maybe I'm misinterpreting Section 4. . .

**M**

Section 4 automatically. . .(indiscernible). . .

**Arien Malec – RelayHealth Clinical Solutions**

. . . maybe I've got the wrong one, there is one that requires clinical decision support to fire on receipt of a transition of care. . .

**M**

. . .I think maybe 5, at the bottom of page 5. . .

**Arien Malec – RelayHealth Clinical Solutions**

Roman numeral 3-B. . .

M

Top between. . .

**Arien Malec – RelayHealth Clinical Solutions**

thank you. . .3-B, thank you. So, now that I'm oriented to the right place, the three concerns are: A) Just a workflow concern of when does this trigger, does it trigger when I open the referral document or open the. . .does it trigger when it gets received, I think the definition of incorporate is a little fuzzy. The second concern that I've heard is a legal. . .so, there's a workflow concern and there's a legal liability concern and a potential conflict with reconcile workflow, where if I receive a transition of care, and am performing appropriate clinical judgment to update, reconcile the problem list, medication list, and other components of the patient's record, am I going to have the same alerts fire twice and am I. . .do I have legal liability

now for both the reconciled view of the chart and the received referral document. So, those were the three concerns that I've heard relative to that issue.

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

And I was going to say to John back. So those, as well, so as we address this, this is really real-time in a clinical setting, not a transition of care, but actually while giving care, I enter an order as a nurse, I am alerted because that is the appropriate thing to do, because it is real-time, you as the physician are not alerted, when do you get alerted, I think Arien's covered both, but we need to talk about real-time and again, I don't know if it's a policy decision, but if you look at the functional standard, it is not clear. It simply says it will fire at the time a transaction is entered, if the entry is by the non-ordering person then when does the alert occur. And then like you said, does it reoccur on transition of care?

**John Halamka, MD, MS – Harvard Medical School**

This a fascinating workflow question. Marc.

**Marc Overhage – Siemens Healthcare**

I think it's an important question to raise Liz, and I guess one of my concerns is, do we know the right answer, and I don't think we do at this point. . .

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

We don't know the answer. . .

**Marc Overhage – Siemens Healthcare**

. . .so I'd be nervous about dictating what should happen. . .

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

Right. . .

**Marc Overhage – Siemens Healthcare**

. . .other than to say this is an issue and down the road we might need to touch on it.

**Arien Malec – RelayHealth Clinical Solutions**

I think the cleanest point of view is one where the clinical decision support. . .easy for you to say. . . support rule fires against the post-reconciled view of the patient, because that's the view of the patient that I'm clinically managing.

**John Halamka, MD, MS – Harvard Medical School**

Right. The temporality of the decision support firing is the question, it seems. . .

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

Correct.

**John Halamka, MD, MS – Harvard Medical School**

. . .as you suggest, that once data is incorporated, that longitudinal view is what triggers the decision support rule.

**Jonathan Perlin – Hospital Corporation of America**

No, I think Arien you just said that perfectly in terms of the temporal aspect. The only other aspect I'd comment on is, I don't think we can anticipate, or that we should try to anticipate in this context, all the possible ways in which an order might be intermediated. The virtue of decision support is really that the person who's decisional, receives the information. I think what you're talking about is the reality that in an environment. . .this is not an endorsement, it's just an observation. . .where scribes or RNs or care teams for that matter, may share decisionality, in this instance you know, the nurse practitioner and a physician or otherwise, how do we make sure that all people who might be decisional or people who are entering but perhaps, you know, have some portion of decision, but not a full decisional capacity, are appropriately

alerted. It just strikes me that's something we need to take to the Policy Committee in terms of the contemplation of all the potential use cases, but I think we can provide the clarity around the temporal aspect.

**John Halamka, MD, MS – Harvard Medical School**

Floyd, do you have a comment?

**Floyd Eisenberg – Senior Vice President of Health Information Technology – National Quality Forum**

And I think the discussion we just had, if you look at comment 7 from the Clinical Quality Workgroup, #3, the issue of defining clinical workflow, this is in section 3-A(iii) of that statement in the rule, that since clinical workflow hasn't been defined, perhaps broadening it to care process is a way to handle some of the discussion we've just had. Just clarification.

**John Halamka, MD, MS – Harvard Medical School**

Chris, did you have a comment?

**M**

Yes, not to completely pile on this question, but Arien's comment I think helps illuminate what we ought to have said perhaps in the Implementation Workgroup, which is not just this temporal issue, but also the issue of what's event-driven as opposed to user-driven. But, there's places where it's clear here that when the clinician interacts with the technology, a decision support must be available to them. I think our question. . .our discussion was around there may be events that drive intervention necessity and we ought to be talking not just about being a temporal issue, but also where the appropriate events ought to trigger CDS outside the clinician going to the record to do something.

**John Halamka, MD, MS – Harvard Medical School**

David, did you have a comment on this?

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

Yes. Just to pile on the general notion that we should avoid being overly specific about what we think these workflows look like, because, we know they're going to evolve and with this increasing amount of duplicity of external data, now that we've created a case for interoperability, that the way alerts work, it's going to have to be really rethought, otherwise you're going to be seeing the same alert over and over and over again, every time you connect to your HIE and you know, three CCDs show up with the same information in it. So, we have to avoid being overly specific. I would say from a certification point of view, demonstrate that you can, in fact, fire an appropriate alert, but not be too much more specific than that. As to Liz's question about notifying secondary actors that aren't present, that's a broader and more difficult question, but again, let's not over specify it.

**Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

This is Leslie and I would agree with David's comments and also add that the nature of data being added by new participants or new roles that is added asynchronously in the future, also then, will illuminate the ability that Christopher just mentioned of "boy, something might happen in the background that's new," so, if I have a patient entered preference that indicates "no blood byproducts," for instance that's not added until a later time in that care process, that's informative and material, but, might not be available at the very right moment in time. So, we have issues about reconciliation and we have issues about role timing, asynchronicity of data, that all apply. So, I do think that being prescriptive will actually curb innovation and may prohibit advanced workflow.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

And so, from a Posnack perspective, what we have recommended is that there be changes so that it is clear to go to 3-B that it isn't when a summary record is incorporated, it is the fact that decision support rules fire based on the sum total of patient information. There's no. . .we're not specifying the workflow or its temporality at the moment.

**John Halamka, MD, MS – Harvard Medical School**

Okay, and also, Wes has joined us. Wes, are you there? At least somebody from the 510 area code just IM'd me. . .well, somebody has just joined. . .

**M**

Yes John, I'm here. . .

**John Halamka, MD, MS – Harvard Medical School**

We were feeling lonely, thank you. So, I think. . .

**M**

John, I have a question. . .

**John Halamka, MD, MS – Harvard Medical School**

Yes. . .

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

. . .about that. There's interaction with the CPOE requirements obviously. . .and as part of the discussion of the justification in the CPOE section, the conversations the Policy Committee's having around who enters the order, one of the discussion points there has been that the person who enters the orders would be the person who can receive decision support and be able to change the order, based on the decision support information that's been given to them. I don't know if that has any relevance for this conversation. I mean, I think that the point of not limiting and not overly specifying, that it must be only in response to an order, right, really good one and particularly when you want to have passive approaches, etcetera, but if a prime justification for CPOE being done by the provider is that it provides a CDS opportunity, is that something that has relevance to this conversation.

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

As we all nod our heads, I think it absolutely has relevance, I think we're also dealing with practicality of who is entering and so we're grappling with, when the physician is not consistently entering, Farzad, then what are we doing with those alerts. I mean, I think you're. . .where is the ultimate, what you've talked about, physician enters, gets the alert and acts appropriately. Is that what you're saying?

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

I just want to urge the group to consider the connections and linkages. . .

**W**

Right. . .

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

. . .so that they, if we're requiring something for one reason on one part. . .

**W**

. . .what do we do on the other side?

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

. . .that the other part supports the requirement on the other part.

**W**

Right.

**M**

Can I just (indiscernible). . .Farzad, I thought I heard you say something further, maybe I misheard, but that orders are one thing, but there's many, many events in the patient's care process that maybe should trigger decision support, and that we shouldn't constrain our thinking to decision support from orders.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

I was supporting David's observation that there can be many forms in which decision support. . .

**M**

Yes.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

. . .can take, some more usable than others and we want to. . .don't want to overly constrain what the options are. . .

**M**

But that's a different question from what triggers.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

That's right. And the question is, I think the question for this group is, is there a minimum bar in terms of workflow, places where there should be a trigger opportunity for decision support. . .and so is. . .

**John Halamka, MD, MS – Harvard Medical School**

. . .and certainly. . .

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

. . .I'm sorry, and there's another thing, so not. . . is do we specify exactly all the places in which decision support must, or is there a minimum association with CPOE that should be preserved functionally.

**John Halamka, MD, MS – Harvard Medical School**

So, ordering meaning one great opportunity for CDS, but, there will be other alerts and reminders based on, oh, you are 50 years old today, here's your colonoscopy appointment, etcetera., which, by the way, I'll be 50 years old in about two weeks, so, I'm worried about this. . .

**Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

I would just also add that scope of practice can tell us that there are a lot of different orders and different ordering people that could have clinical decision support. So, scope of practice has to be taken into consideration. . .which my scope of

**W**

. . .question or. . .

**Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

I think that scope of practice could also indicate that you're working on behalf of that physician under the auspices and direction of that physician, so, where there is appropriate scope of practice, isn't it handled through that?

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

I guess, Leslie, in answer to your question, yes, there are certainly instances where acting within the scope of practice of the practitioner at the computer, the answer is yes. But there are others, when that is not true, so we go back to Farzad's question of when I'm making a decision about the medications to be

given to the patient, and I'm getting an alert, frankly I'll just use my own scope of practice as a Registered Nurse, I am not. . .it is not within my scope of practice to make that decision. And so I think we have to leave it open like I clearly said, but, I think we need to recognize as we move forward, what are we supporting Policy wise long-term.

**Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

Thank you.

**John Halamka, MD, MS – Harvard Medical School**

Steve, I'm sure the last half an hour has given you the clarity that you need, but did you have anything to read back to us??

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

Sure. So, in terms of summary of the new comments that have been added here, I didn't hear anything taking away from what was produced by the workgroups, discussing the temporal aspect of the incorporation of summary care record, is it post reconciled view, what interventions are event-driven versus user-driven, then the comment for the Policy Committee on other actors or roles as part of that process and then again, not specifying the workflow or temporality of that one piece there, in terms of decision. . .incorporating the summary record.

**James Walker – Chief Information Officer – Geisinger Health System**

John this is Jim.

**John Halamka, MD, MS – Harvard Medical School**

Yes Jim.

**James Walker – Chief Information Officer – Geisinger Health System**

On the post reconciled, I guess I'm concerned that that might be overspecification. I think that's one of, maybe the primary place in the process, but it seems to me that when patients are transferred emergently for instance, there may be a role for decision support while the patient's still in the helicopter and orders are being made to rev up the cath lab or the OR or whatever it is, so, I wouldn't want us to overspecify it and say, that's always where it occurs and never before that.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

What I understood Arien's suggestion was not that that is a trigger point that post reconciliation is the trigger point, but rather, that it is the information content that is at issue here. In other words, the goal of the transition of care requirement is that if you. . .to ensure that it's actually computable, that the information that's incorporated is actually structured and computable and can be compared to the other data that's there, so, not that post-reconciliation is a trigger point in the workflow, but rather that the information, whenever the CDS triggers, it is based on the totality of information that's been incorporated from internal as well as external sources.

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

That's the minimum direction, there's no interpretation that you can't do anything. . .

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

You can't do it at whatever point.

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

That's right.

**John Halamka, MD, MS – Harvard Medical School**

Great. Very good. Well, I think we're almost now a third of the way through, but halfway through our time. But, the rest is going to be far less controversial, I promise you. So, onto eMAR, no controversy there. So, what we've said with the inpatient medication administration record is exactly analogous to the conversation we've just had. We are not going to over specify, oh, the five rights. You know, whether you use bar codes or RSIDs or photographic recognition, you know, up to you what technology you're going to use, the one thing that we have specified is that clocks be synchronized, so when you say I gave the medication at noon, it wasn't 12:30 and your clock got buried on your mobile device, for example. So, that was the only Standard, but the Implementation Workgroup had comments.

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

. . .that's where you exactly, you've done a great job John, of describing exactly what our concern was, is that we not be too prescriptive and that the assistive technology component of it be very careful, what we put in there, because we should leave open a variety as John has just told us, specify what we might want to be able to do to this. It's the right thing to do, but we could go on for, like you said, several hours and discuss for example how are you going to do this, and there are certain, for example, right route, that cannot be specified electronically. Frankly, except for the IV pump, and I don't want to go into the specific operational ramifications, but as a group, that's exactly what we talked about. So, Steve if you can capture that then I think we are on the same page.

**John Halamka, MD, MS – Harvard Medical School**

And then there was a Patient Engagement Workgroup comment about the patient acknowledging who they are, where able. . .

**Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

Yes, generally because the team felt that the patient is a great source of self-safety and this would be a good opportunity.

**M**

And so the workflow when my wife received chemotherapy is scan the wrist band, now let me validate, twice, that you are who we think you are, because the wrist band could be wrong.

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

Right, just recognizing again that in terms of an operational world, that the patient is not always able to do that, so, I don't want specification in the rules that prohibits care.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

Just as a clarifying question for context, transcript, etcetera, we're talking about the capability that the EHR technology would need to be able to provide, so would that be an indication that the patient had been asked the question and acknowledged if they were able to do so?

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

Yes.

**M**

And so, that would be novel functionality added to the EHR to record that the patient had said they were who they said they were. . .

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

It would be novel because today, for example, we do that, but regardless of that. . .but we don't necessarily document verbal acknowledgement. The second thing is if you bar code, there again, I mean obviously. . .I don't want to go into all the scenarios where that wouldn't work, we have to be careful though, because. . .I want you to repeat what you just said. You're saying we would make it a requirement?

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

So, I'm asking how this would be implemented to. . .

**W**

(Indiscernible).

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

. . .how you would certify EHR technologies capability to do this.

**John Halamka, MD, MS – Harvard Medical School**

There's really two issues. There is the "we're able," because you're doing this with a neonatal patient, it's unlikely they are going to identify themselves, or a non-responsive patient, they're not going to identify themselves, but the key issue is, making this a certification criteria would now require the EHR screens to be modified to acknowledge that you had asked the patient to validate their identity. . .

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

. . .Correct. . .

**John Halamka, MD, MS – Harvard Medical School**

. . .and you'd specifically date time stamp and all the rest, and that has workflow implications.

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

It does, which sort of. . .go ahead, Farzad.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

And potentially also...you didn't, whether they had a condition that you know. . .

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

. . .exactly. . .

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

. . .you couldn't do it, getting into a lot of the data collection, but also, a lot of the goal I think here is around automation of some of these processes and so, if there are technologies that, again in terms of over-specifying how it's done, if there are technologies that enable that patient matching to occur without needing the manual reconciliation, and I don't know if there are, but this could potentially be overly specifying to talk about this.

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

Which kind of goes with. . .getting back to clinical scenarios and what we talked about last time which was, one of the next jobs of the Clinical Implementation Team is to create clinical scenarios for testing, which then answers the question without over-specifying.

**John Halamka, MD, MS – Harvard Medical School**

So, I think the answer is, we all concur that this is a good practice, it's just from an EHR certification perspective, it's probably overly specified.

**M**

This would be struck from. . .

**M**

. . .yes. . .Two other comments.

**M**

I agree with what you just said John, that was my comment.

**John Halamka, MD, MS – Harvard Medical School**

Floyd.

**Floyd Eisenberg – Senior Vice President of Health Information Technology – National Quality Forum**

I agree with what you said. I think the challenge in implementation is how to avoid. . .what I've heard well can happen, is all of the bar codes for each patient can be put on the med card so they can be easily scanned and all the electronic data is there, but they actually didn't do it at the patient's bedside, and I think that's where the question came from. I just don't know that there's a way to handle it in the Standard. But, it wouldn't be a recommended practice I don't think.

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

That's true. That's a good point.

**John Halamka, MD, MS – Harvard Medical School**

Well, that was easier than I thought, so, very good. So on to 170.314-E(ii), clinical summaries where we recommended the consolidated CDA for content, the OMB standards for race and ethnicity for a code set, preferred language, I presume Jamie it is the 639-1, subsetted from 639-2, the same thing we'd said earlier today, as code set, smoking status types, SNOMED CT, ICD-10CM, HCPCS, CPT-4 procedure codes, LOINC and RxNorm and Jamie, comment.

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

Yes. One of the things that we have had workgroup discussion on, which is our comment number one is about RxNorm, and particularly the use of RxNorm for medication related terminology. So, previously we had recommended the use of UNII for the ingredient identifiers and NDF-RT for the drug class identifiers. Now those are both in RxNorm, so we now recommend the use of the RXCUI, the RxNorm identifier for the same thing in RxNorm. We had actually earlier this week, a long workgroup conversation about allergies, specifically contaminants in vaccines and so, these are some things we had also previously recommended the use of SNOMED for non-medication allergies, which would include, for example, food allergies, but, vaccines are identified in RxNorm, yet the allergies, for example to egg or yeast contaminants in the vaccine currently are not in RxNorm.

So, on our call earlier this week, the NLM representatives have agreed to add all the common. . .all of the known contaminant allergy concepts into RxNorm, so that we can fully recommend now the use of the RXCUI identifiers for all drug related allergies, including contaminants, and specifically, I think in our comment letter we would want to call out specifically including contaminants in vaccines, where known.

**John Halamka, MD, MS – Harvard Medical School**

Did you feel a rush of power Jamie?

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

No.

**M**

You should have. (laughter)

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

So, but it was an interesting. . .I mean the. . .so some of the discussion was about you know, whether it's the same thing if its ingested orally versus injected and so forth. But anyway, so that's our recommendation on RxNorm.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

Clarifying question, to the second sentence, for this point number one, should it be medication allergy vocabulary because that's the focus at the present with no vocabulary.

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

Yes, the second sentence should say medication allergy, but I would amend the first sentence just to say at the end, including contaminants or unintended ingredients, where known.

**M**

So, is there a comment on this one Jim?

**James Walker – Chief Information Officer – Geisinger Health System**

No, it's just on the broad point, a question about how something that's late breaking enhancements to RxNorm gets captured in the statute when it specifically seems to refer to a particular dated release. I mean, this is a problem that just keeps coming up over and over again, but how do we. . .

**John Halamka, MD, MS – Harvard Medical School**

It's because the language states this is the standard provided at a minimum, with the understanding that, as new versions are introduced, they surpass the minimum.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

That was a proposal we had built in, prior rulemaking of setting the baseline standard for its certification would be required and then as part of this rulemaking as well, I don't know if you recall, I came by I think last June to talk about minimum standard code set adoption, we've actually made the process be more proactive, so as these code sets get updated for purposes like this, someone would have the flexibility to bring forward EHR technology with that newest version to get certified, as long as it's above the baseline in the rule.

**M**

Okay, as long as we're comfortable that we're not locking ourselves in and Jamie's enhancements are lost. . .

**John Halamka, MD, MS – Harvard Medical School**

Jamie, you also had the SNOMED CT comment. . .

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

Yes, so, the SNOMED CT is actually the same comment as before, that the encounter diagnosis should adopt SNOMED CT because the intended use is for clinical purposes and not for purposes of administrative classification.

**John Halamka, MD, MS – Harvard Medical School**

So schematically we are effectively removing ICD-10 from the entire Standards NPRM, except certificate of death or cause of death, which ICD-10 is used. . .

**M**

Something else that is actually in this list of proposed standards is ICD-10 PCS, which is, of course, not really ICD-10, it's. . . I mean, as you know, it doesn't have a relationship to ICD-10, the international ICD-10, but, I would like to entertain some discussion about whether the Committee should recommend the use of SNOMED CT instead of PCS, again with the understanding that the intended purpose there is for clinical specificity of the procedure and not for the administrative classification of the procedure.

**John Halamka, MD, MS – Harvard Medical School**

Comments on that one? Yes Floyd?

**Floyd Eisenberg – Senior Vice President of Health Information Technology – National Quality Forum**

I'd actually like to comment on that. I think that if you go back to the September transmittal letter, thinking about procedures in the broad context, where they don't only represent procedures for which you might be able to bill, but other interventions that occur for a patient that are important in clinical care and important for decision support triggers or clinical quality measures, that SNOMED was the recommended terminology for that, so, it would be helpful to be consistent for that for encounter based procedures.

**John Halamka, MD, MS – Harvard Medical School**

Other comments? Yes, Walter?

**Walter Suarez, MD, MPH – Kaiser Permanente**

So, would this recommendation mean not just replacing ICD-10 PCS, but also HCPCS and CPT-4?

**M**

Because as we currently list some options for procedures, CPT-4, HCPCS, and. . .

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

I think that our particular recommendation that we had discussed previously was about replacing PCS with SNOMED CT, but still allowing CPT and HCPCS also has other uses for identifying some devices, for example.

**M**

So the language that has been suggested is to simply replace ICD-10 PCS with SNOMED CT.

**M**

**Any other comments on that?**

**Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

I have a question. The Patient Engagement Team asked about this. . .we talked about allergies and medication allergies, but not patient intolerances as being passed, so there are intolerances to certain procedures and that's not accounted for in this list of recommendations and is that something that needs to be accommodated and is it also understood under the SNOMED that you recommend or is this a new classification, because an allergy might not be the only patient intolerance that needs to be communicated.

**M**

So, of interest, I am reading the September transmittal letter here, where this was addressed called "Adverse effect other than allergy – Intolerance," and specifically recommended SNOMED CT for adverse effects.

**Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

So, I guess now we would like to add that for the patient, it was discussed as a relevant and necessary item. It's not reflected here.

**M**

Any comments on that?

**M**

So that would be a new data element that would be captured?

**John Halamka, MD, MS – Harvard Medical School**

No, in other words, so that as one thinks of adverse effects, allergy is one kind of adverse effect, so one could document that there is an adverse experience in MRI, you know, claustrophobia. SNOMED CT would be used to codify that.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

Just part of the clinical summary, where would that. . .are you picking up on that?

**Arien Malec – RelayHealth Clinical Solutions**

No I wouldn't argue with desirability of the standard, what I would note is that we're creating Policy through Standards and, we should be following what the Policy Committee or kicking that one back to the Policy Committee.

**M**

So, perhaps this is another opportunity to make a comment to the Policy Committee that should they desire to have that included in the clinical summary, then this would be the appropriate standard.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

Shouldn't it already be included under problems, if there's a SNOMED CT code for intolerance to claustrophobia potentially. . .I'm thinking about logical outgrowth Steve, in terms of if there's. . .if it's not already in the list of data elements, adding something without giving people an opportunity to respond to it in the comment period is not problematic.

**John Halamka, MD, MS – Harvard Medical School**

Right. So, in our September letter we termed this adverse effect other than allergy, so you think the problem was to document such a thing using SNOMED CT would be a logical thing to do. We have a compromise, and it doesn't require any statutory change. Okay, very good. Ah, Doug. Sorry, the tables are so long and narrow this time, that as your cards sort of at an angle to me, all I see is a sliver.

**Doug Fridsma, MD, PhD, FACMI – Office of the National Coordinator - Director Office of Standards & Interoperability**

I just wanted to ask a real quick question to follow up on Jamie's comment. We just had the conversation about changing SNOMED from the problem list and adding an administrative code to sort of separate those two. Is there a similar issue as you're talking about procedure codes, in the sense that the clinical care summary is supposed to capture clinical information whereas the PCS is used as a billing code? I wondered if you. . .and then I guess the follow up question would be, to what degree in your experience or maybe people around the table, do people make that distinction between. . .you know, maybe it's a shorthand to use the billing code for the clinical code, but, in the previous discussion it sounded like we would get higher quality problem lists using a clinical vocabulary. So, I just wondered if you could just kind of elaborate why that recommendation and how that fits.

**M**

Well, I think, again, just pointing back to the preamble, we saw that the intended purpose was really for clinical use and so that was the genesis of our recommendation to use SNOMED CT instead of ICD, which really exists as an administrative classification system instead of a clinical documentation system. But, I think to your point about the desirability of adding an administrative classification for procedures and devices, you know, maybe that's a question back to the Policy Committee of whether that's intended to be added. I think for this purpose, what we saw was the intended use was in clinical care, for clinical purposes, for clinical documentation, so we didn't really consider that question exactly.

**James Walker – Chief Information Officer – Geisinger Health System**

This is Jim. Part of the discussion in the Joint Vocabulary Workgroup, Clinical Quality Workgroup I guess last year, was that an increasing number of procedures don't have an ICD code because they aren't billable and our concern was that going forward, it seems likely that there will be a substantial number of interventions that are procedures or could reasonably be called procedures, that don't have any billing implication and so, the other part of it was the need to capture all of those interventions provided to the patient, some of which just don't have any administrative billing significance or aren't likely to have any code.

**M**

Very good. So, I think we have that recommendation. Anything else, I think you had one other item.

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

The other thing on here is, actually it would not be a part of our transmittal letter on the NPRM, but it was a strong recommendation of the workgroup was that there are a number of resources available for cross-maps and subsets and so forth, and query tools related to the use of both SNOMED and the administrative coding systems together, that really there should be a program of education and outreach to inform both the Vendors, the implementers and the users of these systems, of the availability of those resources, specifically those that are available from NLM and the IHTSDO.

**M**

So purely a friendly comment.

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

And so, whereas I totally agree with the spirit of what we're trying to do here to capture this information with the clinical coding vocabulary as opposed to administrative coding vocabulary, it's not possible to fully automate the mapping from SNOMED to ICD-10, because of the weird granularity of ICD-10. So, the clinician will have extra work to do, or you'll have to invoke some kind of decision. . . automated tool to help him with that process, and it's just a laterality question alone, you'll have to pick that knowledge out of the note or something else and the clinician will have to confirm it. So, there is extra work for the clinician, because like it or not, most sites do require the clinician to actually come up with the administrative codes as well as the clinical codes. So, as long as we're comfortable that we know that's the consequence of this, fine. And I agree, most of it can be automated, but not all of it, not given the way ICD-10 is structured today.

**John Halamka, MD, MS – Harvard Medical School**

So, the fascinating workflow issue all of us are dealing with, do you use computer-assisted coding to transform codified clinical observations into ICD-10 codes, CM or PCS, do you have an army of professional coders that are turning clinical observations into structured codes, or do you teach the clinicians both SNOMED and ICD-10 or, in Jamie's case, do you use some mapping that is going to provide a clinician friendly vocabulary at the front end that results in appropriate codes in the back end.

**M**

Mapping and coders and NLB and. . .

**John Halamka, MD, MS – Harvard Medical School**

And in fact, we are doing exactly that, which is why at BIDMC , it's a 25 million dollar project as opposed to what the Federal Register claimed a 450 thousand dollar project. So, whoever wrote that regulation, their math was off by a factor of 10. . .not you. . .

**M**

Good for bidding, but may not be good for clinicians.

**John Halamka, MD, MS – Harvard Medical School**

Well next we have patient lists and this was the functional criteria, rather than a standard, but Jamie I know you did have a comment that there is an implication for the desirability of transmitting patient lists.

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

Right. The actual requirement for transmission relates to immunization registries, but I'll just mention here that there was a desire on the part of the workgroup to seek an implementation guide for the use of the immunization registry update standard, which I believe is HL7-2.5.1 to update groups or panels or lists of patients as opposed to individual transactions, essentially that an implementation guide would be desirable for how to use that for batch updates in instances that have single patient updates to the registry.

**John Halamka, MD, MS – Harvard Medical School**

And so, this is not a specific NPRM related issue at the moment. I mean, it's a desirability. . .

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

We don't. . .yeah, I don't think we have a standard, an implementation guide to recommend.

**John Halamka, MD, MS – Harvard Medical School**

Okay. Then, patient-specific education resources. This is the same InfoButton. . .

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

Sorry, can I ask a question on this one, around the specificity question. . .and we're often walking a balance between not wanting to overspecify particular implementations and yet, not wanting to leave it so vague that implementation approaches that really don't get at. . .that it's clear what we want to be implemented functionally. And so my question is whether functionally this captures the concept of a provider being able to do population health management? Make a list of patients who need. . .who have care gaps, who need to be reminded, who need to be reached out to, those who have all of the functions that we are increasingly associating with the need to provide coordinated, comprehensive population based care, do these currently capture that or could this be implemented or is there lack of clarity around what this means, in terms of here's a list of your patients. . .

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

I think it's a good list, but we heard from providers, from registries and from health plans that the lack of a standard for transmitting lists of patients is a problem. But, we don't have one right now. . .

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

Yes, I guess. . .

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

. . .that's all I'm saying.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

I'm saying first on the functional side, does this functionally get at the concept of a dynamic. . . kind of, something that supports registry function and population health management. Is this sufficient level of specificity without being overly specified or not.

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

I'd say yes. Jamie, that would be yes for us. What about you Jamie at Kaiser, yes?

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

I think so, yes.

**John Halamka, MD, MS – Harvard Medical School**

I know you're asked to do things like identify patients who've been on Vioxx so that you can recall, oh okay, that's in there, you know, identify patients who have specific demographics that make them an acceptable population for a care intervention. . .it seems like a very, very reasonable list.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology ?**

In terms of timeliness issue, similar to this trigger issue, you know, I was visiting MetroHealth Plus in Cleveland, where they had the diabetes registry that's automatically updated whenever someone is diagnosed with diabetes, you're not enrolling them in the registry manually, is that part of the. . .you know, so when you incorporate information, right, from somewhere else that says here's a patient with diabetes,

does that automatically update a list, right? That is in a sense, right or can this concept as written be met by something more static and less dynamic than that.

**John Halamka, MD, MS – Harvard Medical School**

This is the issue that Jamie is raising, is that, as written, it is a good functional criteria that enables us to use our EHRs to identify patient lists; however, if we were to populate registries, we would need a standard by which I could then say, here's a thousand individuals I wish to enroll in the registry, and we don't have such a standard at the moment.

**M**

That's interesting. I mean, this. . .

**M**

That's actually. . .

**M**

Or is this the registry?

**John Halamka, MD, MS – Harvard Medical School**

In fact it's using the EHR as a query tool as opposed to an enrollment transmission. . .

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

Actually, I think what we believe is needed is an implementation guide for how to use the HL7-2.5.1 standard for that purpose, sorry.

**John Halamka, MD, MS – Harvard Medical School**

Right, but. . .so, defining diabetes turns out to be a rather hard thing to do, so, once I've identified a diabetic patient, you're right, there are separate registries I maintain and transmitting the list of those identified patients from the EHR to the to the registry would be helpful and we lack an implementation guide to do that at the moment, which is why we haven't specified.

**W**

(Indiscernible)

**M**

Right.

**M**

Can I put my card up?

**John Halamka, MD, MS – Harvard Medical School**

Sure.

**M**

Just a question. The way I read this, it doesn't imply that this is a clinician at the bedside producing this list, this. . .

**W**

. . no. . .

**M**

Right, are comfortable that this could be you know, a non-patient care function that drives. . .

**M**

. . .a systems analyst, a quality improvement person. . .

**M**

Okay, I just wanted to make sure its. . .

**M**

I think Farzad actually asked the key question, does this wording enable the systematic creation of lists via automated mechanisms, and I'm not sure that it does.

**Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

It could actually stifle innovation that might add for very flexible systems interoperability where it defines that a list has to be created rather than a function of transmitting patients that meet a specific criteria, that have proper consents to be forwarded to a separate system.

**M**

I would suggest that's a completely separate function. . .

**Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

Well, if we mandate lists, is that an "only" or is it an "and."

**M**

It's different.

**Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

Okay.

**M**

Chris, I think this is all begging the question about whether a patient registry is a thing that is independent from an EHR. It seems like it certainly could be within an EHR, but often times might not be. I don't know that we've ever really talked about the idea of a patient registry for population management purposes, at least from a standards perspective. I don't know about from a Policy perspective, but it certainly sounds like that's something that's at least a MU3, excuse me, 2015 edition, whatever, consideration about do we want to be specific around what are the attributes of a patient registry and where may they reside, and are their standards required for putting data in and pulling data out and otherwise triggering activities of that registry. I may have. . .my registry might be in an HIE or I might be an unaffiliated physician that participates in two health systems and I want to look at my patients to find out, are they part of a registry someplace to be managed in some fashion. Are they in an ACO where I'm not financially part of that ACO, but I'm managing the care for the patient who is. All those questions.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

I think that's the key question from a Policy Committee point of view, is, is the intent here that there be integrated poor mans registries. . .

**M**

...exactly. . .

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

. . .within electronic health records, right? And separate and apart from whether you feed information to more sophisticated registries, but, if this. . .make a list is meant to be a poor man's registry, is that the intent and does this, as written, meet that?

**M**

But in some instances the EHR could be the rich man's registry. . .It could be the foundation. . .

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

. . .but what's missing?

**John Halamka, MD, MS – Harvard Medical School**

Actually, what Steve has just shown me is the Meaningful Use CMS statement, and this does tie to a Meaningful Use requirement, so, you can imagine multiple architectures, so, it could be Cerner has decided to have a rich registry in the context of a complete EHR, turns out, the way I've structured it, is I have a separate registry and I use a CCD export from the EHR to a modular rich registry that provides lists of patients and analytics, but, we aren't going to specify which is right at this moment, and I think Jamie's point is, is that the best we can do is a functional criteria of some variety, because we lack a standard and we don't want to over specify architecture and limit innovation.

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

. . .CMS. . .missed, what Steve showed you, what does that say Steve? What specifically was the goal.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

This is Stage 1, because I only have the Stage 1 stuff right in front of me. So, the objective is to generate lists of patients by specific conditions for use for, you know, a variety of different things. The measure is that the provider generates at least one report listing of patients with a specific condition, it's pretty simple, functional.

**M**

That's a . . .

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

That's a report. . .

**M**

. . .report and not a registry.

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

. . .that's a long way from what is being suggested here. . .

**M**

So, I think. . .

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

. . .around population health.

**M**

The thing we ought to look at is, you know, perhaps CCDA is perfectly sufficient, perhaps transport mechanisms we've already described are sufficient, but there ought to be at least some thought about, if you can identify a thing that looks like a patient registry, how do you have to interact with it.

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

I would state that, I mean we're not anywhere close as you, I think made clear Chris, to defining what a registry is, and this is a narrowly scoped thing that says the system has to be at least capable of producing lists of patients based on criteria from, at a minimum these data sets, for whatever purpose you need to put it to.

**M**

Which is a step in the right direction. . .

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

Which is a step in the right direction. . .

**M**

. . .and by the time we get to 2015 or 2016 edition, we ought to be thinking about how to identify something, and we've stretched the boundary of what is certified electronic health record technology in general anyway, and a lot of what we're trying to do, I think, is dependent on technology that isn't CEHRT.

**John Halamka, MD, MS – Harvard Medical School**

Why don't we do Dixie and then Floyd and then Walter and then Leslie. . .and I promise we're going to get through at least the clinical summaries before lunch. That's our goal. Dixie?

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

First of all, I agree with exactly what David just said. But secondly, this is a question for Steve, does the regulation define user and provider in your case, when you read from Stage 1, you actually used the term provider versus user, I know they do define provider. But here we have enabled a user, is a user sufficiently defined such that it could be a service within the EHR?

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

We responded to comment in our final rule, for the 2011 edition, that we had a very broad view of what a user could be, not necessarily a carbon-based life form, and so, just to be specific here, I just used. . .I should have said, more specific, that the EP eligible hospital critical access hospital, is the one that's responsible for generating the patient list, so, however they satisfy that generally for other Meaningful Use requirements.

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

Okay, it doesn't have to be a. . .

**M**

I appreciate all the discussion about what was the intent and is this a first step, and I like the general concept, I just want to put on the table, will the fact that this is functional and without a standard described about how, will that encourage many different ways to do this, that might actually become cumbersome to clinical users and then by 2016, when Query Health work is more complete and there's a standard recommendation, it's going to be reworked, I just question whether we're potentially adding additional hardwiring, because of the functional requirement without identifying a standard.

**John Halamka, MD, MS – Harvard Medical School**

I think the response to that is, what I'm hearing from around the room is, this is a direction we all want to go in and we want greater specificity, we just don't at the moment have well adopted implementation guide that we could specify today.

**Walter Suarez, MD, MPH – Kaiser Permanente**

All right. Walter Suarez here. I think the discussion about registries is certainly an important one. I think looking at this comment about the transmission of list of patients, I think there is transmitting simple list of patients just with some basic demographic about the patient, but there is a very different aspect of transmitting a list of patients for a particular purpose, for example, immunization registries transmitting a group of patients that includes not just the demographics, but a whole host of other elements about the immunization. So, there is in the Public Health arena, of course, there are a number of registries that exist around the country, cancer registries, immunization registries, asthma registries, you know, the C-specific registries, event registries like trauma registries and things like that. But, in order to submit data to those registries is not basically just a simple list of names or simple list of patients, it's really a much more structured message to provide. . .just like pulling out data from those wouldn't necessarily be a simple list of names, it would be a message that we send back. . .for example, from an immunization

registry that includes demographics as well as some clinical information. So, I think while there is certainly a significant value and it's a very good, as Floyd mentioned, a very good first step to point to the ability to pull out and transmit lists of patients, I think we shouldn't confuse perhaps, or mix the basic element of a list of patients with a more complex message for registries for specific purposes.

## M

Jim, did you guys look at the. . .I don't have any update on it, but the QRDA category 2?

### James Walker – Chief Information Officer – Geisinger Health System

No, I don't remember looking at that, sorry.

### John Halamka, MD, MS – Harvard Medical School ?

The same lessons learned in popHealth evaluation and that is, the nature of what it is you need to transmit so that one can compute a quality metric, an immunization. . .I mean, it is more than just a list of patients, dependent upon the use case.

### Leslie Kelly Hall – Senior Vice President for Policy – Healthwise

John, the question is on the syndromic surveillance work that went on there, I think, 22 required fields and 17 optional fields. Is there opportunity for harmonization between that work and this patient lists, generating patient lists based on these criteria? Is there a possibility there?

### Walter Suarez, MD, MPH – Kaiser Permanente

Well, this is Walter Suarez again. I think again, the syndromic surveillance standard message is specific for syndromic surveillance, so it contains specific data elements that support the function of a syndromic surveillance program. For immunization, it will be 10 common demographic data elements and then 15 specific immunization type data. For cancer, it will be 10 common demographic data elements and then 35 cancer specific. . .

### Leslie Kelly Hall – Senior Vice President for Policy – Healthwise

I was just wondering if there's the opportunity to build upon that, since these four are definitely in that list.

### John Halamka, MD, MS – Harvard Medical School

Let me summarize all this discussion. As we recognize that there's work being done on Query Health being able to send questions to data and get lists back, on popHealth of exporting data from EHRs that can be used for a registry like analyses, for conceivably just lists of patients that would be put into a registry, but, for the 2014 edition, since all these are in-flight and not yet done, it seems like we have this, among all of us, the desire to separate and modularize the EHR and the registry functions, but for today, it seems like the best we're going to do is a functional list of the sorts of things that a human, or non-human, may be able to run, and it may be in the EHR or separate from the EHR, but we aren't going to overly specify for now. But all these are very consistent with where we all want to go. Let us move on the patient-specific education resources; this is the InfoButton question all over again.

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

InfoButton Part 2. So, the Clinical Operations Workgroup again would recommend here adding to certification and allowing the use of a simple URL web link, in addition to InfoButton. So again, InfoButton certainly has the benefits that were described earlier of being able to ensure context awareness and tracking of its use and so forth, but at the same time, URLs as simple web links can also be used in an equally context aware way within the EHR to fulfill the intended purpose here, so we would recommend adding that.

### John Halamka, MD, MS – Harvard Medical School

Okay. Comment?

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

Yes, this is David McCallie. So I was puzzled by the assumption about workflow here. Is this targeted at the clinician being able to pick something to give to the patient? So, in this case I would go the other direction than I went in before and say that maybe that's. . .we should be much less specific about how that process works. So for example, that could be an interactive process where you're navigating with the patient an application on a web site, I mean on a web page there in the office, focusing down, narrowing to what you think is relevant, getting patient consent that they understand these are the parts that are important and then pushing a button and printing and giving it to them. It might have nothing to do with links at all. . .

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

Well, we talked about that as being actually a use case for the URL. .

**Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

Right. They're not mutually exclusive.

**John Halamka, MD, MS – Harvard Medical School**

So, as an example, on the workflow that I have today, I have sort of this information prescription kind of model where a clinician can write for what is effectively a URL to patient specific information. There are other ways in which we use. . .you know, other commercial products with the patient to find something that's of use to them and print it. And so, here's the interesting question for us all, which is, if we're going to go to optionality, which, you know, "or" means "and" I mean, I see all the advantages of InfoButton and I've received some emails from folks highlighting where InfoButton is cool and specific is good, but yet, we are seeing that it's not going to meet every workflow use case, so we're saying URL is okay, and if we say InfoButton or URL, then you get back to the same question, do you have to say InfoButton at all, it it's an "or?"

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

Or even URL at all, I mean, it may be a menu item on your EHR where you click the menu item and it launches this interactive application and that menu item isn't technically a URL. I think the spirit of the goal here is that you have a way to create a customized patient education handout or customize information to provide to the patient, however its provided. And I'm not sure that technically narrowing it to InfoButton or URL is wise.

**John Halamka, MD, MS – Harvard Medical School**

Dixie, Chris, then Leslie.

**James Walker – Chief Information Officer – Geisinger Health System**

And Jim afterwards.

**John Halamka, MD, MS – Harvard Medical School**

Okay.

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

I agree with what David said and I also. . .I was thinking about this before, but I'll add it here. . .you know, semantic search is one of the most active areas of technology development right now so I think, especially now, it doesn't make sense to lock into specific solutions in this kind of an area.

**John Halamka, MD, MS – Harvard Medical School**

Okay. Cris?

**Cris Ross – Executive Vice President & General Manager, Clinical Interoperability – SureScripts**

So, while we were discussing InfoButton before, I went out to go look at the HL7 spec for it and it looks like it includes the ability to do web service lookup against an API service that could be equivalent to a URL. So, you know, I'm not expert in it, but I'm really wondering if whether we ought to just simply press

the InfoButton spec to include the alternative pathway of URL if that isn't sufficient. I'm trying to understand what the. . .

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

. . .it can't include every alternative as fast as this area is developing.

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

The level of indirection that we're adding for technical reasons, could get in the way of the goal here, which is a more well informed patient. I'm envisioning this as being much more interactive than something that is required to go through a link to satisfy a technical requirement, should there be a link.

**M**

Good point, you may have patient educator who may want to just use. . .URL.

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

I might have a stand-alone device in the room, or maybe something I have them download to their iPad and navigate with them on their iPad and say, take this home with you. I mean, there's so many ways to give that information to the patient that don't go through a link.

**Cris Ross – Executive Vice President & General Manager, Clinical Interoperability – SureScripts**

That makes total sense.

**John Halamka, MD, MS – Harvard Medical School**

Farzad put up his card, so that trumps everybody else.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

I just wanted to highlight, from a context perspective, not necessarily a context, a where perspective. This is in the 2011 edition certification criteria, without any reference to a standard. And so, as part of the rule making process, what we did, in looking forward for what 2014 could look like, was to include a standard that could advance the capability of EHR technology to provide at a minimum, some form of more interactive education resources. And so, I don't want to redirect the question here, we could go back to what we had previously in 2011 and not specify a standard or, at a minimum, what comes with folks 2014 edition EHR technology is the ability to find patient education materials using this standard.

**Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

So, I would like to talk a little bit about this because it is actually widely used by us, used inside some EMRs in their native look, for JAMA articles, for instance, outside and it doesn't preclude the ability to have navigation, it says here are the top five, we need to discuss this with the patient. It actually allows you to get a top five, that's both based on prevalence or relevance on that context. So, this is not mutually exclusive and it accommodates web links, so, it's not also prescribing something that doesn't accommodate more of an open architecture. There's also future use cases that I think should be considered, apart from the two we've mentioned today. This is the only standard we have that allows for bolt-on of modular technology. It allows for common contextual sharing with other applications from an EHR, so fast-forwarding that, there could be other additional use cases.

But, for patient specific education materials, we find it important because we get age, gender on all of the context that's appropriate and the ability to report back what the patient has actually seen, which is an important loop to close, what has the patient received, what are the attributes of that document, is it based on medical evidence and so forth. So, I strongly say that we've been saying all along that we need to use standards where applicable, this is a great example of starting out with something that's optional on a menu with no standard specified, a market actually starting to adopt a standard, then why would that not be then adopted overall?

**John Halamka, MD, MS – Harvard Medical School**

And Jim Walker.

**James Walker – Chief Information Officer – Geisinger Health System**

Yes, I want to push the patient education aspect of this a little bit. Part of the genius of InfoButton is that it automates a search and is context aware. When you're working with a patient, very often you want to help them learn how to find their own stuff about the next thing, the next question they have and so, maybe what you need to do is to say, you know, Medline's a great place, it's usable and it's got great information, so, let's go there and see if you can find something that looks useful to you. It just. . .the automation of InfoButton, while valuable, cuts against patient education for 30 or 40 or 60% of patients who can learn how to do this themselves, find something for their 8 year old, not just specific to their personal context.

**John Halamka, MD, MS – Harvard Medical School**

And so what we have is. . .again,, just as before, questions of innovation, questions of architecture, questions of desiring specificity and as less optionality as possible. What I'm sort of hearing is "boy, it would be great if products did develop around InfoButton;" however, at the moment there are semantic search technologies, there are unique products that may be apps that sit on a mobile device, so to constrain patient educational material with anything beyond a functional criteria at the moment, is probably going to stifle innovation and constrain architectures and possibilities. But yet, at the same time we'd like to see an ecosystem develop for the reasons that Leslie has highlighted.

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

So that sounds like we do not make a proposed standard.

**John Halamka, MD, MS – Harvard Medical School**

So, you know this is, we have the wise Farzad and since he's here, listening to what we were talking about, was here's our challenge. What if an app for patient education comes out on this, that isn't InfoButton-based, or isn't URL-based, is that something that is not permitted, so where do we go functional versus where do we go specific standards because we want as many novel products to enter into the marketplace that are specific to the patient as possible. So, Leslie makes the good comment and Jim makes the comment that InfoButton provides a context of age and problem or other things and it's nice, but yet, it seems like the marketplace is still exploring new technologies and other more generalizable solutions.

**James Walker – Chief Information Officer – Geisinger Health System**

I'm sorry John, this is Jim, I was arguing that InfoButton is too automated, too capable for a lot of patient education that needs to go on.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

I think that, Jim, the question as is so often the case, is are we raising the floor by requiring a minimum capability on the part of electronic health records, that may or may not be the sole way, right, in which this Meaningful Use requirement is met, if you include multiple means, options, right, then a provider could meet the requirement for Meaningful Use using either browsing a web if its simplest approach or having URLs or the InfoButton, but, it functionally raises the floor, in terms of making sure and, to Leslie's point, creating an ecosystem where there are more InfoButton service providers because they know that electronic health records will be capable of using the InfoButton standard to retrieve information. So on the one hand, you know, raising the floor, right, without limiting additional approaches. On the other hand, Dixie points out the risk of freezing technology if it's not what's going to be the more flexible, the more future-looking approach. . .

**Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

. . . a minimum standard I think.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

So I think that's the Standards Policy question for you to consider and something that obviously we are looking for your recommendations to us on. . .

**John Halamka, MD, MS – Harvard Medical School**

. . .of course. . .

**M**

. . .more information on that, my understanding is that when the certification criteria are specific and specifically associated with a Meaningful Use attainment measure, that only use of the certified standard qualifies for attainment, unless CMS explicitly provides for optionality.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

That's why I said, if there's an "or" there, so if the certification requirement includes an "or," then they could use either of the certification criteria to functionally meet Meaningful Use. . .you're correct. . .

**M**

If there's a functional standard and then at a minimum InfoButton, that would be a vehicle for getting that kind of outcome.

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics?**

So the vendor would have to have it but the provider would only have to show that they actually do this, whether they use the InfoButton or not. It raises the standard for the vendor, gives us options. Is that the correct interpretation?

**M**

As it is currently written, my interpretation is the only way to get Meaningful Use attestation is by use of InfoButton.

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

Me, too.

**M**

And I think we're all saying that's not a good idea. . .

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

. . .so broaden the options.

**John Halamka, MD, MS – Harvard Medical School**

I recognize we don't have complete consensus on this, but it seems like that we are more going toward a functional desire rather than a single constrained standard to give people options with. . .therefore. . .you know, the way to do this is to do what Stage 1 says, which is, functional criteria without a specific named standard which otherwise we force the implementation of that single named standard, and if we did "ors" then the question is, or what? InfoButton or URL or mobile app or semantic search. . .

**Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

. . .earlier. . .

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

. . . it's just or patients . . .education at a minimum based on those criteria.

## **M**

Optionality for areas that require interoperability is a bad idea, because you don't get interoperability, but optionality for systems that are internal to the EHR it's really the EHR Vendors decision about whether they want to use InfoButton so they've got flexibility in swapping out their content vendor, so there is a very different policy reason to include no optionality for an interoperability case versus what truly is a functional case.

### **Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

Just to pick up on that in terms of your regulatory tools, there's required. . .and this all goes without saying, right, so there's required in the certification criterion, which is if it's there and it's not designated anything else then it's required. In some cases you've probably seen as you've read through them, we have a specific designation, you know, pre-labeled in front of a requirement, where it says optional, or I should say a certification criterion element, so it says optional and then there's not requiring anything at all. So, here, as part of this certification criterion, if you look at it specifically, the Roman numeral at II we could put the designation optional in front of it, which would, to piggyback right on what Arien is saying, would make it optional for certification for EHR technology developers to say "we think our clientele would benefit from having this in our product," and there's a mechanism for them to get certified to it, but it's not required to be part of certified EHR technology necessarily.

### **John Halamka, MD, MS – Harvard Medical School**

Well this sounds like a Solomonic approach, which is. . . we allow the diversity of technologies but we signal to the industry that we think that this is useful and so, now Doug, did you have a comment as well?

### **Doug Fridsma, MD, PhD, FACMI – Office of the National Coordinator – Director Office of Standards & Interoperability**

Yes, I just wanted to put on my standards hat and just. . .we want innovation in how people exchange information, we don't want innovation in standards. So we need to be careful, I mean, if what we have is a standard like InfoButtons that provide flexibility to use URLs or maybe to be modified to HL7 to include semantic search or other things like that. There is a single standard that will likely lead to a host of innovations around that. If we take a look at the internet, if there were multiple ways to send TCP/IP packets, we wouldn't have the web. If every browser had a different way of interpreting this, yes we would stifle innovation around those browsers but we would impair our ability to exchange information.

So I think it's very important as we kind of parse this through, is to ask ourselves the question is, "if there was a consistent way for external vendors and external content providers to interact with an electronic health record, even if it might be rudimentary to begin with but could over time evolve as the market drives that, if there was that singular way to do that?" Would we see a decrease in the cost to get access to patient material? Would we see a decrease in cost to get provider information? Are we going to start to again, put that lower bar in there that would allow that other innovation to occur, so, I don't think we should characterize standards as being constraining of innovation, but in fact most of the time standards, when well thought out, can actually promote innovation and new uses that we otherwise wouldn't have seen.

### **Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

I would echo that, this is Leslie again, and also add that the cost of implementation for a little non-profit, as we have, went from about 3 years with an EMR without a standard to the last one was 1 week, So, the implementation costs have dramatically decreased so that a non-profit can actually compete. So, I would add that it actually added innovation and any work that the vendor did can also require or actually seek out multiple content providers with the same work and so, there's much more diversity for that EMR vendor and that provider.

### **John Halamka, MD, MS – Harvard Medical School**

David?

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

No argument, this is David McCallie. No argument against the value of the standard for that purpose, I just again come back to the notion that in this space, particularly given that the presence of mobile devices and emerging technology around the way patients manage their own health that constraining it to something that is based on browser notions would be as ill-advised as outlawing the apps store because it wasn't based on HTTP. I mean, it's just not going to do it. . .

**Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

It's still using an EHR to retrieve it, the EHR is the URL. . .

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

. . .It doesn't. . .it wouldn't have to. There are ways to do it without a link as an intermediary. So, I think the "optional" I think makes great sense, and it will be the common way people do it. . .

**John Halamka, MD, MS – Harvard Medical School**

I think we have a proposal that sort of addresses everyone's concerns, which is, there are many advantages to InfoButton, the standardization, to Arien's point about what you constrain and what you don't constrain, by stating it as, "optional," it signals to the industry that this is something that we think is going to lead an ecosystem of functionality, but it doesn't make it a certification criteria that must be done and how about that? Okay, we have no objections and Wes, I lied, because I said we were going get to your stuff before lunch, I thought this was going to be not so controversial, so, what we will do is do your stuff right after lunch. It is noon and we have a rich discussion with several controversial items coming up. So what I might suggest is we do a 45 minute lunch break, we return and, you know, Leslie will give you as much time as we possibly can. This has not been a controversial morning, it has been a rich discussion by thoughtful people and I hate to constrain the amount of discussion. So, 45 minutes and we'll get at it again. Jon, anything to add?

**Jonathan Perlin – Hospital Corporation of America**

No, great effect, if you're back earlier maybe we can start before that, I think we've got a robust afternoon ahead of us.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

Okay.

**John Halamka, MD, MS – Harvard Medical School**

There's a food court to the left.

**Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology**

Yes, if everyone would take their seats, we're going to open the lines and start the meeting. So, if everybody would please be seated. Are the lines open operator?

**Operator**

Lines are open Ms. Deering.

**Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology**

Thank you very much, back to you.

**John Halamka, MD, MS – Harvard Medical School**

Okay, well let us continue. Now remember, we have two hours left to go through the remaining 22 pages, but I am convinced that if we go through this next section, we will actually have addressed quite a lot of the more complex issues. So, this next section is transitions of care and the notion of incorporating a summary care record into an EHR and the standards are very similar to those that we saw for other

summary transmission, consolidated CDA, the various vocabularies that we've discussed. We also include some comments about transport and so, although content and transport are quite different, they're both incorporated in the recommendations that Jamie and his team have made. So Jamie, go ahead.

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

Thanks. So, as you can see, we're on page 11 of 33. We have a number of recommendations; however, I'm going to edit some of them in my comments, because of subsequent conversations that have happened. The first one is just an acknowledgement, it's not a recommendation, it's an acknowledgement that the workgroup really likes consolidated CDA, and we think that that was really great work and we've actually pointed out a couple of additional places where we think it should be used. Then I'm going to skip to number 3, which says that in the proposed rule it requires SMIME/SMTP and makes SOAP optional and the workgroup feels that both of these should be equally required; that essentially they should both be required in certification, but then the main point of number 2 is that providers, in the care process, should choose among those standards, which one best fits their situation in terms of their community, their referral patterns and so forth.

And so what I would do is actually, as a result of the more recent conversations, I would strike the last two sentences of number 2, which talk about non-standard approaches, but just to say that because the different protocols best fit the communities, providers, patients and transfer of care scenarios, we would recommend allowing either of the two standards that we propose should be required to be used, which is essentially either direct or exchange. And then the point of our point number 4, is that the reference to the standard seemed really obscure, I mean, it was just hard to understand if SOAP really meant exchange or not, but we heard that it was supposed to, and so we recommend just being explicit, to say that both direct and exchange should be required in certification and the use of either one should be allowed as the transport protocol.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

In terms of deletions, as you suggested for number 2, it would start at the instead would be deleted?

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

Start at instead and I'll give you. . .I have a couple of other word changes, but yes.

**M**

So, in exchange do you mean the, I forget what exactly the exchange standard is called, but the one that points to XDR or do you mean all of the NwHIN exchange specifications, because there are. . .

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

Well, you know again, that's not clear, it depends on the intended scope, but I think probably it would be the base, what I think the exchange calls their messaging protocol, which is fundamentally the IHC, IHE XEA in addition to the XDM and the XDR and the SMTP. So we would say, all of those.

**M**

Can I reframe what I think you're saying and just see if I'm understanding what you're saying? Um, with respect to a transition of care which is at least presumed to be, in most cases, a directed event from X to Y, then the SMTP/SMIME and XDR specifications in your proposal, would be both required for certification and you would also say that any use of another NwHIN exchange standard for meeting the requirement should also count for Meaningful Use achievement, but not be required as a certification criteria.

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

I think we would say. . .we would add the exchange specifications as a certification requirement and allow them to be used to meet the measure.

**M**

All of the exchange specifications. . .so XCA, XCPD. . .

**M**

. . .XTSP. . .

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

. . .the XTSP actually isn't an exchange specification, the public health. . .what's that one called. . .

**M**

So, I mean, it is problematic because so many things have been added to the exchange specifications, including X12 and ESMD and so forth. So, I mean, I think that we'd have to pick the ones that actually are relevant to the scenario, but we didn't actually have that detailed discussion in the workgroup.

**John Halamka, MD, MS – Harvard Medical School**

So here's the question is that given that we have Direct as written was SMTP/SMIME with the option of XDR on-ramps and off-ramps and we have NwHIN exchange which is both a pull and a push, there are elements of exchange that are push and that are appropriate for this. So here's the challenge that we have, is that, and we talked a little bit about this at lunch, do you say that an EHR must speak SMIME/SMTP and optionally supports XDR or you say, it must do SMTP/SMIME "and" XDR "and," if there. . .I don't recall in the NwHIN Exchange if the push model is anything beyond XDR. . .

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

I don't think it is. . .

**M**

I don't think the XDR. . .

**John Halamka, MD, MS – Harvard Medical School**

So, since we can be explicit by saying, you know, instead of the SMTP or optionally XDR, it's SMTP "and" XDR as covering these two transport mechanisms, and then of course, we get into the question of what about the future implementations of REST and there isn't an implementation guide, so what do we do. . .

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

I think, if I can just add, so the gist of the workgroup comment is that by requiring both SOAP and SMTP in certification, the provider then has the choice of what best fits their situation, and so the actual. . . actually the way we drafted the comment didn't say Direct and Exchange, it said SMIME, SMTP and. . . I guess, there are two different comments, one says Direct and Exchange and the other just says SOAP and SMTP. So, one way of doing it is just to name the actual transport standards, which are SMIME/SMTP and SOAP period, and not provide essentially the implementation guide as the certification standard. I guess another one would be to name both the Direct and Exchange protocols. . .

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

You're going to have to be pretty specific if you're going to test, right?

**John Halamka, MD, MS – Harvard Medical School**

Okay, and so I'm sure there are several comments, so, if we go around the table here. . .

**Cris Ross – Executive Vice President & General Manager, Clinical Interoperability – SureScripts**

Excuse me, just really quickly, just a process standpoint. Implementation Workgroup has got some similar comments that fit in, so I don't want to take time away from Jamie. We had two conversations on InfoButton and I'm hoping maybe we could have one conversation on standards.

**John Halamka, MD, MS – Harvard Medical School**

Sure, why don't we go ahead with your comments and then we'll go around the room in a consolidated fashion. . .

Three people talking. . .

**Cris Ross – Executive Vice President & General Manager, Clinical Interoperability – SureScripts**

If you wouldn't mind, just from a process perspective, I think we'd be more efficient.

**M**

Sure, go ahead.

**Cris Ross – Executive Vice President & General Manager, Clinical Interoperability – SureScripts**

So, were you done Jamie? So, Implementation Workgroup we really had, I think, had three buckets of comments. I'm going to do the first two and Wes is going to do the third. So, our comments one and two, we noted that there needs to be this further definition of care plan which is a place where CMS had requested some comments and frankly we just ran out of time. Implementation Workgroup was looking at testing criteria in addition to comments on NPRM and we did not yet require that, but we noted that it's a need. Um, and someone else will probably have to speak to that, other than the Implementation Workgroup. Then we also had the other comments around additional known care team members, more or less a testing requirement Steve, around what, you know, that shouldn't be required unless there's a further definition of what constitutes a known care team, so, somehow that has to be resolved before it comes to testing. Then our comment number 3 is probably the place where we connect mostly with the Clinical Operations Workgroup piece.

You can read the bullet points, but what we were looking for was clarification around which transport standard applied to which domain, and we think that we got guidance based on the conversation, as listed here, and this language was directed kind of jointly by Liz and I and with Mike Lipinski, around transport standards required around transition of care, that for other forms of Meaningful Use transmit to third party requirement that any transport standard could be used, that it's non-specific. Comments made with respect to incorporate lab results certification out of the S&I Lab Results interface would use that set of criteria and we were looking for, in the end, essentially as the rule was written, a clarification of the relationship of certified standards, with the Meaningful Use objective and measure. So, if there's both Meaningful Use CMS and then the ONC certification criteria and that those two were not conflated. We didn't discuss or have an opinion about the issue about the optionality or non-optionality of SOAP, so, no comment other than what Jamie has already said, except I think that the spirit of our conversation would say, whatever we do, be clear about it. And then Wes, do you want to talk about point number 4.

**Wes Rishel – Gartner, Incorporated**

Okay, I don't have the piece of paper that 4 is. . .

**Cris Ross – Executive Vice President & General Manager, Clinical Interoperability – SureScripts**

It's just the bilateral asynchronous. . . yup, you're on. . .

**Wes Rishel – Gartner, Incorporated**

You just have to speak my language. The problem is that I can't get my computer to show me the slides. All right, so, I'm concerned about what happens when we change the standard. We had a discussion at lunch today that some people may actually believe that once the standard is written, its self-sufficient and never changes. I doubt if anybody in this room subscribes to that. We have basically two approaches to changing standards for a large group of participants. If it's just you and the hospital down the street, you know, you get together at Starbucks and you decide when you're going to do it and you make sure your contractors are done and you do it. Starbucks isn't that big for the country and, no one has ever really gotten a vendor to deliver any product on time, much less two vendors working for two different clients.

So, if one hospital is using software that is on version A of a standard, and then you communicate with another hospital, maybe across the country, that's using version B of the standard, neither can go until

the other has proceeded and that is a . . .that would be a bilaterally synchronous cut-over. There have been situations where we have seen major changes to networks go on, like that. In healthcare, in the US, the change from the 4010 to the 5010 X12 standards recently occurred, it was a big effort with lots of megabucks being spent to do it, even though the changes were rather minor. It actually happened almost ten years after the 4010 became mandatory, and it was fixing problems that were known in the 4010 at the time it went mandatory. It probably wouldn't have happened then, except that it was needed as a readiness for ICD-10. The way it worked was on September 30<sup>th</sup>, or on claims with the service date of September 30<sup>th</sup>, you send using the old standard. On claims with the service date of October 1<sup>st</sup>, you send it using the new standard and so, everybody had to be ready and everybody had to cut over on exactly the same day.

Well, one major payer, whose name we shall not mention, except that they provide probably most of the funding for senior care in United States, had an error in their cutover and it caused a large slip in deliverables due to false rejections. It was corrected fairly quickly, then we got down to what I call the collateral damage, individual practices that had not . . .weren't fully tested, whatever, and individual practices that just decided to ignore all this baloney about 5010, you know, they would send their bills or continue to send their bills. I call that collateral damage, I mean, that's going to happen, there's not much you can do about that, but, it didn't have to go through this huge spike in expenses and testing, it didn't have to wait 8 or 9 years, except that it was driven on the notion of a cutover day and so, my goal, is to find a way that as we move standards forward in healthcare, clinical healthcare, we have a way to cutover from a new standard to an old standard bilaterally, not at the same time.

Now it turns out there's good evidence on how to do that from the internet. So, we have gone from a time that maybe some of us older people can remember, when all email messages were plain text and then we got to a point where if you wanted to send somebody a picture, you could send it as an attachment to the point now where I have to avert my eyes when some email messages pop up, because of all the multimedia graphics that's going on in them, and no one ever had to take down a client and start a new one to do it, or virtually no one, right? The way it happened was that the framers of the interface accounted for bilaterally synchronous cutover in their interface definition. Basically what they said, which is pretty clever, is if you want to send a multimedia message that's fine, you can send it, but you have to send the plain text message, too. So if you take any, you know, you're email from your nephew with the pictures of his baseball game, and you look inside the package that came to your email client you're going to find all of the stuff he wrote in plain text, all of the attachments and then another version, probably in HTML that has all of his upper case and fancy fonts and all that sort of stuff, literally sending messages twice so that old receivers could continue to use the old approach while new receivers. . .and we're still doing that 15 years later, the overhead is rather nominal and everybody's doing it.

So, send it twice is one approach. There's the secure socket layer or transparent layer security implementations that have been steadily getting more rigorous to protect information across the line, and yet, you don't have to synchronously agree with who you're communicating with, on which of the four or five levels of this and three levels of that, that you're going to use, because there is a negotiation at the start, during the start of the conversation, here's the things I can do, here's the things I want to do; between the two we find what's the minimum level. . .what's the maximum level of security we can support, and then either end can say, well that's not enough, I won't go, but, most of the time people that are different levels of security find a common match. So, we know that the work has been done to support bilaterally synchronous cutover. . .if I can't say it, how can I get you to say it. . .and we just need to talk about how it applies in healthcare.

The fundamental thing that has to happen is that receiver receiving an old version, a message according to the older version of the standard, needs to know how to process it. So, what does that mean? Well, ideally. . .it looks mostly like it did before, but there's probably some data missing or there's possibly some data that was in one place in the old message and now it's in a different place because it's part of a repeating group or something like that. The receiver of the new message has to have a defined behavior for receiving the old message. This was built into HL7 version 2, if you go back and read the original stuff that I wrote, it's right in there, exactly what they should do. It wasn't always implemented by people who use HL7, but I get another chance at it now. The fundamental rules are, if you find some. . .this is the

new receiver receiving the old. . .if you're looking for some data and it's not there, then you assume its null and you have a defined behavior for null.

The defined behavior could be, reject the message if without that datum, I just can't do anything for this transaction; but more likely it's okay, so there were no allergies recorded and no reason given why they weren't recorded. You know, typically for clinical data we have a lot of different ways. . .we have all the flavors of null for different situations and this is one of them. If you're looking for a data item under the new standard , and it happened to be the one that moved, you have to go look in the old place and maybe that means, in the case I said, what turned into repeating group, maybe that means . . .say there's only one in the group this time, but you can find it. So, there's a defined behavior for receiving an older message, most of which can be done with the syntax. I mean, really, it's not that complex to do.

Turn it around, you have a system still operating on the old standard, receiving the new message, it has to be written so that unexpected data, it's not expected because I'm not working on this version of the standard, unexpected data is not an error. You don't invalidate the whole message because there was some unexpected data in it. People who are careful testers like to do the other thing, they like to say, well, you know, if we don't understand anything, that represents a danger if we try to interpret the rest, but, there are specific rules for where unacceptable data is allowed that say it should be ignored. Now if data was moved in creating the new standard, then it actually. . .if that particular data element has to be sent redundantly, it has to be sent both where it used to be and where it is, and that creates a modicum of redundancy, and people usually say, well, after so many versions, I can declare that we're going to drop the old version of the data item. And it comes up every once in a while, like in the situation I said.

If we put those standards in place, if we write certification criteria that actively enforce the behaviors that we're describing; if we don't write certification criteria that disallow the behaviors we're describing, then we can be in a position where when we release a new edition of standards, or when it is discovered a year into implementing that one important use case involving post-acute care wasn't exactly understood properly in the standards and we want at least the active people to start sending it right, we can create that addition , whatever the regulatory process is, out of cycle knowing that we're not forcing anyone into an implementation cycle in order to do it, that doesn't directly care. So, my concern is that we find ways, we adopt the ways that are known, for making bisynchronous, bilateral asynchronous cutover a way of doing business for healthcare standards in the United States.

#### **John Halamka, MD, MS – Harvard Medical School**

Dixie?

#### **Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

Oh, I got it. . .I was going to respond to Jamie's comment about the SOAP. We did look up the Privacy and Security Workgroup made a comment about the transport in a different spot, but we did look up the reference that's in the specification is not to the entire set of exchange standards, it's really to the NwHIN SOAP based secure transport RTM version 1.0 which is really the. . .that's the standards in interoperability framework modular version of the exchange platform standard, right? So, it doesn't include HIEM and all the other Exchange standards. We did make the same comment as you did about consistency, it should be either one and two. . .at one place it requires Direct and doesn't even mention the other option and in the other place it requires all three. The second point I wanted to. . .so we've got they should be consistent.

The second point I wanted to make is that if we required everybody. . .the reason the Direct standards were brought about was to make it easy for the little guy to exchange information with everybody. If we also now impose SOAP on the little guy, and everybody has to do both, then it kind of becomes, why are we doing this? You know, the XDR XDM was supposed to be the on-ramp, off-ramp between the two and it just seems kind of senseless to me to have everybody required to do both.

#### **Cris Ross – Executive Vice President & General Manager, Clinical Interoperability – SureScripts**

That's not our recommendation. Our recommendation is both messaging platform specifications should be required for EHR certification, so vendors would have to support both. . .

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

Right. . .if every product needs to support both. . .

**Cris Ross – Executive Vice President & General Manager, Clinical Interoperability – SureScripts**

Right. Oh, I thought by the little guy you meant the provider.

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

No, it's the guy whose using. . .well, actually they would be using an HIE. . .it still doesn't make sense to require both, because they really are two options and an on-ramp and off-ramp between them is XDM XDR.

**Arien Malec – RelayHealth Clinical Solutions**

It might be worthwhile for me to just talk about the justification for how the Direct Project made its recommendations. The intent was to supply. . .so I'd first of all say that SMTP and SMIME gives the capability that XDR alone doesn't, which is universality of transport, it gives a way to. . .via the DNS, gives a way to send a message to somebody else without having to negotiate all of the SOAP hops that you would need to do via XDR. You've got, if everyone is connected to exchange under a single trust network and there's unified addressing, you can get it that way. But the intent was to decouple the single trust network and still allow for SMTP/SMIME to be kind of a universal transport in between HIOs or universal transport between HISPs or EHRs.

The recommendation that we made in the Direct project was that SMTP/SMIME was required and that because many EHRs support the XDR standard, that there be a well-defined way for those EHRs to plug into a module, generally a HISP that would be under BAA, to plug into a capability that does the upgrade downgrade, right. So, the intent was to support EHRs at their given level of understanding, inclusive of EHRs that want to do just the simple stuff and EHRs that have the full implementation of XDR. So, that was, I just want to give some of the justification for why SMTP/SMIME required, with a well-defined upgrade downgrade path, was the recommendation from the Direct Project.

**John Halamka, MD, MS – Harvard Medical School**

We've heard from Jamie and we've heard from Wes and Dixie and Arien and they've raised all these issues, which is, how do we ensure we don't have an impedance mismatch of protocols and versions and that we can get data from any point A to any point B, and you can hear all the options that are on the table and that's every sender and every receiver has to support multiple protocols, there is a single required protocol, but there are adapters along the way, should the sender and the receiver not have the same protocol. The challenge, of course, we don't want to necessarily constrain architecture and that is some communities may have a HISP, others may not have a HISP, there could be EHR and a PHR, there could be EHR to EHR, there's all kinds of possibilities. So, come on Steve, we need another Solomonic pull-it-out of your hat rabbit here. And so, I think in something like this, the Direct Project said you must have SMTP/SMIME and you might have XDR and here's the way to support it should you. And, I think the concern, Jamie, that the group had was that statement may not work in every communities implementation because of architectural differences, compatibility, the things that Wes has talked about. So, let me just get the last couple of comments and then we'll see if we can get this one to a final conclusion. So David, Marc and Floyd.

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

Yes, David here. So, to echo Arien's point, one of the goals of Direct was to enable this notion of universality, to define kind of a minimum secure trust model so that it was quite likely and easy for any provider to be able to communicate with any other provider and eventually with any patient through a PHR via direct, without requiring additional negotiations other than membership in a trust community and I think it would be a shame if we lost that goal as an inadvertent side effect. On the other hand, I certainly think that anyone who's capable already of using XDR or a more complicated transport to achieve the Meaningful Use goals of transition of care should get credit for using whatever protocol they get. So, I think maybe like the InfoButton debate, you know, certify to the minimum, but give credit for something that goes above the minimum in terms of your incentive. Then we kind of get the goal of everybody at least can speak a simple protocol and if they can support something more complicated, they certainly

could get credit for it if they're achieving the incentive goal, which is transition of care with a structured message.

## **M**

David, does the current rule support that?

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

It's not clear, it's ambiguous. I think, first off, there's confusion about reference to the wrong standard for XDR, SOAP is not XDR, SOAP by itself is like saying TCP, it's not very much, so you actually have to refer to one of the Exchange documents. The one they refer to is the wrong one, so, but that's just standards clean-up, I think the spirit is, there's XDR as defined by IHE, which is a fairly complicated standard to implement to deploy because of the community that needs to agree on a bunch of details. The SMTP standard is a little bit less complicated to deploy, it's a little bit tighter spec and the only agreement is which trust tokens do you accept, which if we get a governance ruling that makes that easy to settle, then hopefully that's applicable across the country, so. . .

### **John Halamka, MD, MS – Harvard Medical School**

Jamie, did you have a clarification?

### **Jamie Ferguson - Kaiser Permanente – Executive Director HIT Strategy & Policy**

Yes, just to part of that point. Our understanding was that essentially the measure has to use the standard it the standard's named. And so, if you have a minimum standard, if you have, for example, SMTP named, then the use of an alternative to SMTP can't count for the measure. So calling it a minimum standard, I don't know, perhaps that applies in the case where the minimum is truly a subset of what is used, but in this case, it would just be an alternative.

### **Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

Steve, if SOAP were an optional, as is proposed, where optional certification criteria, could two vendors who have both implemented the optional certification criteria use SOAP and the XDR XDM to communicate with each other and the provider get credit for that.

### **Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

I'll do the short answer first, so yes. Because today, as proposed Meaningful Use Stage 2 transitions of care electronic 10%, it says you have to use certified EHR technology and would only count for the measure as proposed are the transport standards that certified EHR technology includes and so, the way that we support that from an EHR technology perspective was to require the direct specifications and then allow for EHR vendors, depending on the market and customers that they serve, to also get certified to SOAP option, so that if they did have customers that wanted to both speak SOAP, and that got certified as part of their EHR technology, then they could use their certified EHR technology to continue to demonstrate Meaningful Use.

### **Cris Ross – Executive Vice President & General Manager, Clinical Interoperability**

On that subject, I think part of what we were trying to accomplish in our discussion in the Implementation Workgroup was to understand what was the domain to which this needs applied; so, this whole thing about directing SOAP is applying only to transition of care for summary care record, for which Direct seems perfectly sufficient. The issue is, that there are other domains that include transport, that are number 1, probably better targets or put better, the reason why the complexity of an exchange was developed was to handle those other additional, more sophisticated kinds of things. So, presumably Steve's answer plus the desire of vendors to do additional things, would lead them to implement SOAP for that purpose.

The other piece is, you know, the NPRM included also the idea that there should be opportunities for development of new, RESTful-based standards for exchange, and NwHIN Power Team last summer, we spent a lot of time looking at the relevant maturity and goodness of fit for both direct and exchange and

found that they both fit domains nicely, but they were not, either of them, an across the board solution and so we encouraged. . .so, long story short, I think our way to try to slice this was to say, look, let's focus direct on the stuff that direct was invented to do, Direct plus XDR, and allow the use of SOAP, no not SOAP, and an Exchange for the places where it was really intended more to have power as needed and to be silent for those channels where there is legacy interfaces, like the many, many lab interfaces and other things that exist, and where we want to have other standards develop, where it's less crucial. I mean, this is the one really core interoperability standard. . .

## **M**

Cris, where would you put the transmit to third party?

### **Cris Ross – Executive Vice President & General Manager, Clinical Interoperability – SureScripts**

Yes, I'm sorry, I should have spoken about that, that's also called out here, exactly the same thing. The transmit to third party and summary of care/transition of care are the two places where we understand, based on going back and forth with Mike on drafting this, that they apply. So, hopefully that solves at least some of that concern Jamie.

### **John Halamka, MD, MS – Harvard Medical School**

So, let me summarize all the discussion so far and I just threw out a straw man, and I know Wes you want to make a comment, there's a couple of others. But if what we said is, we're going to constrain the use case to the push transactions that go from point A to point B or the transmission that occurs after a package is received by somebody, and that Direct, as written, says SMTP/SMIME plus adaptors for XDR. So, if you say, hmmm, we will require Direct which implies you will be able to be a sender or receiver with SMIME/SMTP and if you use XDR, you can be a sender or receiver there, too; and for these two kinds of use cases, that is point A to point B and the transmission subsequently, direct with SMTP/SMIME and XDR, would seemingly be a reasonable solution. Do we need to even state SOAP generically, I mean, I wonder. . . . .does that create even more murkiness? I mean, so again, so maybe this is cleanup in the way that it's been written and when Exchange, you know, what is it's role in NwHIN Exchange.

### **Jonathan Perlin – Hospital Corporation of America**

. . .SOAP. I think we've all agreed we should take out SOAP because it doesn't mean anything in this context.

### **John Halamka, MD, MS – Harvard Medical School**

(Indiscernible) that.

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

It's a question of what you accept on the wire. To say SOAP or, more properly XDR as specified by IHE, that's talking about a wire protocol. The Direct adaptor actually takes the XDM content out of the XDR and puts it on top of SMTP so that it's SMTP on the wire. So, it does matter what we say, because what's on the wire is where the interconnect actually happens.

### **John Halamka, MD, MS – Harvard Medical School**

All right, so given that this domain has a lot of Privacy and Security Workgroup. So Dixie, your comments here?

### **Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

Yes. The NPRM actually specifies NwHIN SOAP-based secure transport RTM version 1.0, which is the document that the standards and interoperability framework developed a modularized version of the NwHIN messaging platform specification. That's not the entire Exchange stack. . .

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

But that's not. . .it doesn't include XDR, that's just SOAP. . .

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

. . .I know, but it's not the exchange, it's the entire Exchange stack. . .

**M**

I know, but it's not. . .

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

. . .and I think it's really clear. . .it's important for us to make it clear that we're talking about the transport, not the entire stack.

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

But that spec by itself would not enable clinical data to flow.

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

Well, we add XDR. . .

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

That's just the spec. . .that's just. . .

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

. . .but what I'm saying is, I don't think we. . .I think we should be careful that we not specify either SOAP alone or the entire Exchange stack. . .

**John Halamka, MD, MS – Harvard Medical School**

Fair. And David's made an important point, which Arien can clarify, in your direct work, did you ever envision where XDR being a SOAP specification, would be used over the wire?

**Arien Malec – RelayHealth Clinical Solutions**

Sure, yes, we were just having this conversation. . . the way that the specification is written, it notes that people who have negotiated to a higher level of service, for example XDR to XDR, are perfectly free to negotiate to that level of service, and in fact, one of the things we wanted to make sure was that somebody using NwHIN Exchange for this purpose wasn't non-Direct compliant, because these are two organizations that have negotiated via the DURSA and via their participation to use the XDR protocol as their transport. So, it was never intended to exclude people who had negotiated XDR to XDR, what it was intended to do was to say, look, if I'm sending to somebody and I don't know that they support XDR at the other end, that I've got a well-defined way of converting that to. . .converting the packaging and converting the transport to this universal transport format that everybody supports. . .

**M**

Right.

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

So that fourth quadrant of both sides already speak XDR and are happy to do that is a policy statement, it's not really part of the standard in a sense, it says that if you can do that, of course you should be able to do that, and what we're debating now, I think, is should you be required to do that. . .

**M**

That's right. . .

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

And I think the other three quadrants of that 4 x 4, you are required to do, no one's arguing, it's that fourth quadrant, are you required to support XDR? In which case, the matrix kind of goes away. . .

**Cris Ross – Executive Vice President & General Manager, Clinical Interoperability – SureScripts**

I think Wes' point may be to send twice, to send that payload as a . . . I think that's the point, right? That you would send a CCDA, but you could also send it in an XDM cont. . . I'm just asking?

**John Halamka, MD, MS – Harvard Medical School**

So again we get to this question, if the certification criteria is that EHRs will be certified to Direct, does that allow us an ecosystem where XDR to XDR could be appropriate and supported, SMTP/SMIME could be supported, but is there anything wrong with saying, EHRs will be certified to Direct, don't specifically call out SOAP or a SOAP variant or the S&I framework transport subset of NwHIN Exchange, just simply certify to direct. Is that suitable?

**M**

That's the policy.

**John Halamka, MD, MS – Harvard Medical School**

Okay. . .

**M**

And I think it's a problem for. . . not because of direct itself, but because if we're going to say that you must use this certified approach and get to some functional outcome with it, there are too many, my opinion, unanswered questions about how to use that standard, the lack of existence of ways to manage the certificates and I know all the work that's been done, we're not there yet and yet we're saying you must be able to do this. . .

**M**

. . . yes, but we're close, I agree, but we ain't there. . .

**M**

. . . closer than anywhere else. . .

**M**

. . . I mean it's demonstrably (indiscernible) . . .

**M**

I think that we're making a terrible mistake to say, in a certification requirement, that you must do something that frankly is still only 7/8 –

**M**

. . . 2014 version, so we've got some time. . .

**M**

What Jamie's proposing when. . .

**M**

Not enough.

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

. . . you say two requirements that are 7<sup>th</sup>, 8<sup>th</sup> – by your definitions. . . perfect. . .

**M**

And so, I mean, if you want go and say, we shouldn't constrain for the goal of achieving some high likelihood of universal interchange, then let's not say anything about it and we're back where we were in Stage 1, we just didn't say anything about it, except CDs handed out in the ED, which didn't go very far. So, I think the goal is to step up one level, the whole direct effort was to try to make that step as simple and straightforward and universal as possible. You could argue that we haven't got great proof yet. . .

**M**

...we don't have the string across the canyon. . .

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

Well, we do, depends which canyon you're in and there are other canyons that have XDR across the canyon. Do we require everybody to finish both of those or do we focus on one, which is arguably the simpler, arguable, there's always argument about everything in this case, and then allow. . .but allow for the other, if you've already got it or for emergent technologies like you know RESTful technologies. So, do we certify to a minimum bar and then give credit for use of more sophisticated technologies if you already have them. That seems to make. . .kind of have our cake and eat it too, right, we get everybody at the minimum but we allow people who've gone beyond that to get credit for it. . .

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

Just as an observation, what I've seen in both the Standards Committee, but also the Policy Committee deliberations, sometimes we begin to re-litigate the conversations that we had months and months ago and what has been helpful, at least on the Policy Committee side, has been to say, look at the DMS and ONC, lay the marker down. Having heard all the discussions, having heard all the points that were made, lay the marker down in the NPRM and what we're really looking at in this stage, what is different now than it was when we were having this conversation last time is, there's a marker down in the NPRM that we need to comment on. So, that may help a little bit, not have the same conversations, but say, in view of the marker that's down now, what are there. . .is there consensus about making a recommendation that says, do something different than what's in the NPRM.

**Wes Rishel – Gartner, Incorporated**

Can we get clarity on what the marker is that's down now?

**John Halamka, MD, MS – Harvard Medical School ??**

On the top of page 11, the exchange will occur with the standards specified in § 170.202(a)(1) and (2) and optional § 170.202(a)(3). Now. . .

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

Can I break in?

**John Halamka, MD, MS – Harvard Medical School**

Yes.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

So, the (a)(1) is the secure transport, applicability statement for secure transport and (a)(2) is the XDR XDM Direct, the other specification is part of Direct and then (a)(3) is the NwHIN Exchange SOAP RTM modular specification.

**Wes Rishel – Gartner, Incorporated**

Now, can we get clarified on what portion of NwHIN is specified there, is it simply. . .I mean, one of the characteristics of NwHIN that could be important in play here is that it allows looking up data for a patient as opposed to knowing to send it. In. . .

**John Halamka, MD, MS – Harvard Medical School**

...So we're constraining it to just to the push portion. . .and the subset that is referred to is just the transport for push. . .

**M**

So the marker that's down is push and push.

**M**

Right, no. . .all right. . . okay.

**John Halamka, MD, MS – Harvard Medical School**

And so as stated, the standards SMTP/SMIME and XDR and optionally, and we heard the definition of optional earlier, if you happen to have that constrained NwHIN Exchange push capability, as specified in the modular subset of the S&I framework activity, that could be an additional higher bar, not required.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

The other part of this that's in the Meaningful Use section is that it also counts, it's also okay if you are a member of or use a member of the Nationwide Health Information Network.

**M**

Chris, I know you've been waiting to comment.

**Christopher Chute – Mayo Foundation for Medical Education and Research**

At the, Chris Chute, at the risk of relitigating the question, I am. . .this is the third or fourth time you've said John, that we've constrained the use case to push. I guess the question in my mind, and maybe if you just say, well Chris, you didn't read carefully enough, that might work, but the question in my mind is what about pull, because we've certainly recognized in the Continuity of Care Consortium, we've certainly recognize in Southeast Minnesota Beacon, we certainly recognize in a number of these use cases where we have used NwHIN Connect, or whatever it's called this week, pull is a useful use case, and I'm just curious if that's. . .why that's completely off the table.

**John Halamka, MD, MS – Harvard Medical School**

It's my understanding, and you guys please comment, that a pull model is something you could choose to do, but specifically the minimum, the bar, is referring to a transition of care that is pushed from one provider to the next provider of care.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

It's a good question. If you have two organizations. . .well first off, the members of the Nationwide Health Information network, then that would be covered actually. So, Mayo, for example, or other members of the CCC who happen to be part of the Nationwide Health Information Network Exchange group, or who are part of a new governance process that would be established, presumably there would be, that would count, first. And second, if they're using that part of the Exchange stack, and also using other parts of the Exchange stack, right, I think it's a minimum bar, it's not constraining or limiting. The issue would be around whose criteria is it satisfying, and on the. . .on a pull transaction, the responsibility around Meaningful Use is on the giver, not on the receiver. So, if you are participating in a pull transaction where someone queried and you give them, for a transition of care, that information using the XDR and the portion. . .and including a portion of the IHE specifications, I think it would be covered. So, I think we have to look both at Meaningful Use and at certification in this instance, but, that's my interpretation. Steve, am I?

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

I think I followed that.

**M**

So, in this case. . .

**Wes Rishel – Gartner, Incorporated**

Differently. . .if you. . .10% of your transitions of care, the information was transferred by someone receiving pulling documents from you, you would have satisfied the Meaningful Use requirement.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

As long as either they were a member of the Nationwide Health Information Network or you used certified EHR technology and the technology within either the optional or the . . .

**Wes Rishel – Gartner, Incorporated**

Right, but in using certified EHR technology, you could use the basis that came from the S&I group and then add other layers that support pull on top of that.

**M**

Right. Okay.

**M**

But this is place where some form of schematic would be incredibly useful, because, we're talking about multiple forms of ways that EHR systems can interact with each other, and there are a vast number of those interactions where the regulation is essentially silent. And people are going to do what they need to do, as long as that, where it's relevant, it counts in the Meaningful Use numerator and denominator, and as long as you're using technology that is otherwise certified, but is using a plug that the regulations don't speak to, I think we can meet many of these missions.

Then that one slice that we're talking about specifically transition of care for summary of care records plus the transmit portion of view, download and transport, those are the ones where there's specificity to say you must do this, and, oh by the way, if you built this infrastructure to do those other missions, that allows you to accomplish that, that works too, but, you're going to have to have a trading partner with whom it works. And I think what we're seeing in the market to Marc's 7/8 issue, I think that's legitimate, but, I think it's a fair statement to say that the marker, whatever it is, that CMS and ONC have put down, has catalyzed the market, and I think we are seeing smaller vendors mostly focus around SMTP/SMIME, some larger ones are there, and we're seeing larger ones typically thinking about how they might leverage their XDR interface that they have for other purposes that could be used for this. So, this feels like one where yes, the work is not complete, but clarity on this, specificity about its constraint so that people can do other things in addition. I think I'm with David, I think it's sufficient to get the market moved. I was skeptical about that frankly 6 months ago, I'm not so much. . .

**Wes Rishel – Gartner, Incorporated**

John, can I. . .

**John Halamka, MD, MS – Harvard Medical School**

Sure.

**Wes Rishel – Gartner, Incorporated**

I think the area that Marc, appropriately raised our concern about was the process of getting certificates that mean enough to be sufficient to trust sending data to the holder of the certificate. And, frankly, I don't see anything in the 2014 edition that even provides the base level for doing that. However, I take great faith in the 10% number and in the fact that most institutions I think can meet the 10% number working with other institutions that they know and do business with regularly, in which case, the process for getting and trading certificates is handled with indirect at this point. I think that bar can't be raised until we have some of the other work that's in plan become. . .go further down the path, or we can get it further down the path by raising the bar, one or the other. But, I share Marc's concern, but I feel like the 10% is a good way to kind of get the block out under the wheel and get it to start to roll.

**John Halamka, MD, MS – Harvard Medical School**

Arien?

**Arien Malec – RelayHealth Clinical Solutions**

I wanted to follow up on that because that was very similar to the comment that I was going to make. The addition that I would add to that is that none of the standards that have been mentioned or discussed, including anything that we're considering in terms of a REST specification, magically solves the trust and identity problem, and so the need to have a local community that, as Wes notes, the need for a local community to define sufficient trust for directed exchange is going to be a prerequisite for achieving the 10% number, the standards alone don't get there. And, regardless of what transport we use, we're always going to be facing exactly the same problem. So, the governance work and the long awaited unicorn- horned ANPRM, is a really critical part of this ecosystem and, also to Wes' point, we're going to be forcing the problem on local communities to solve this definition of trust and definition of identity and left to their own devices, they're going to solve it poorly, insufficiently or incompatibly and so, that. . .I just want to set the appropriate expectation of the standards don't create magic, none of the standards create magic and the need to have well defined policy, particularly for identity, is foundational to anyone achieving a 10% threshold.

**John Halamka, MD, MS – Harvard Medical School**

Let's try to get to a consensus statement, because we do have 22 pages to go through in the next hour, so, Jon Perlin has suggested actually a different format for going through those next 22 pages, which I think is reasonable. . .

**Jonathan Perlin – Hospital Corporation of America**

Faster.

**John Halamka, MD, MS – Harvard Medical School**

This was the hard one. . .

**M**

(Indiscernible) that's very easy.

**John Halamka, MD, MS – Harvard Medical School**

So, what I'm kind of hearing in general is, a bit like InfoButton, we don't want to overly constrain every possible use case in architecture, so we will be mute on some things. We set the bar at some place to get us started and offer credit for those who go beyond the bar. Now, so, just reflecting on what Farzad has said, the line in the sand, that was written by ONC and CMS basically says, you will implement Direct as specified in the two specifications and artifacts associated with Direct, but you do get credit if you are part of the NwHIN Exchange activities. And so, yes, I recognize that there still are issues as we roll out Direct and provider directories and certificate management at a community level, but, 2014 is when this takes effect and I do think the market is moving pretty quickly. So, if that's the proposal on the table of those two Direct specifications as listed as required and the optional credit for the constrained NwHIN just push transport or, if you're a participant in NwHIN larger, what do we think. Tim?

**Tim Cromwell – Veterans Health Administration – Director Standards & Interoperability**

Thank you. Tim Cromwell. So what is credit? What does that credit mean? Does that mean if you're an NwHIN participant then you don't have to comply with Direct or you get an extra credit or additional points or what does that credit actually mean?

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

It's about counting in numerator for the objective.

**Tim Cromwell – Veterans Health Administration – Director Standards & Interoperability**

Okay.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

So if the transaction or transmission takes place using any of the standards that certified EHR technology includes or Exchange participant that transmission counts in the numerator for the measure. That's how you get the 10%.

**Tim Cromwell – Veterans Health Administration – Director Standards & Interoperability**

Okay.

**John Halamka, MD, MS – Harvard Medical School**

So, let's actually ask a question very specific to Tim. So what if you don't support SMIME/SMTP or XDR, but you do actually do the whole NwHIN transport as specified by the S&I framework. . .

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

Wait. Meaningful Use's a requirement on the provider, certification is a requirement on the vendor. The vendor has to support, according to the marker that we've laid in the NPRM, the vendor has to support direct and the XDR and optional for the IHE transport portion of the stack. A provider could meet the Meaningful Use 10% requirement by using. . .by being a member of the Nationwide Health Information Network or by using the optional certification criteria. . .

**M**

(Indiscernible). . .I just

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

Well, I sure hope so.

**Tim Cromwell – Veterans Health Administration – Director Standards & Interoperability**

I want to be clear, all of our participants in the NHIN are also pursuing direct, so that's a good thing. I don't think that will be an issue, but I like the message that I'm starting to form in my mind about an encouragement to keep at it with us in the exchange and the conversation that it is going to matter to Meaningful Use 2014 edition, when we're doing the NwHIN exchange with them.

**John Halamka, MD, MS – Harvard Medical School**

So the proposal would be, if there is vagueness, that is the word SOAP appearing as a stand-alone term, we remove the vagueness so it's understood that what we meant when we said SOAP was the extra-credit around this particular part of NwHIN exchange or participation in NwHIN exchange, but otherwise as written, it seems that the spirit of what you intended was an EHR will support the two specifications that were indirect, the SMIME/SMTP specification and the XDR specification, with the potential that it would be allowable for XDR over the wire to be a certifiable bit of functionality.

**M**

That's a key question. . .

**M**

Right. . .

**Arien Malec – RelayHealth Clinical Solutions**

So when you wrote in SMIME required and XDR with the interchange optional, so I get credit for doing it, I can do mutual and bilateral XDR, or are both required, in which case as an EHR vendor, I've got to implement. . . So, the first case allows if I support just XDR right now, one of those EHRs that supports XDAR, then I can achieve certification in conjunction with another certified EHR module that does the interchange for me, right? So, that would be my package for achieving certification.

**John Halamka, MD, MS – Harvard Medical School**

Because Steve, as this was written, it does have the word “and” . . .

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

. . .right.

**John Halamka, MD, MS – Harvard Medical School**

. . .which would imply that an EHR does need to support both.

**Arien Malec – RelayHealth Clinical Solutions**

Arien. Is the modification you’re suggesting or the question you’re asking that under our proposed approach. . .accepting the approach, right, whether the XDR XDM should be with the required direct portion or with the optional IHE direction. . .with the option. That’s right, so it’s my recommendation it would be with the optional IHE SOAP section, that’s where it logically belongs because it’s part of that interchange bit.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

That’s what you had recommended when I presented last time. . .

**Arien Malec – RelayHealth Clinical Solutions**

That’s right.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

So, it would be. . .

**Arien Malec – RelayHealth Clinical Solutions**

I’m at least consistent.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

So, translating the Reg speak it would be required for (a)(1), which is the applicability statement for secure health transport and then optional would be both (a)(2), the XDR XDM direct messaging specification and the SOAP-based secure transport RTM, because those would be packaged.

**M**

Can you also provide the same guidance on what’s required for the EP and EH. . .

**W**

Yes please. . .

**M**

Because what you just said applies to the vendor, totally get it. What applies to EP and EH?

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

As proposed, they would need to use the transport standards that come as part of their certified EHR technology. So, if a vendor only gets certified to direct the applicability for secure health transport, because the other two are designated optional, then that’s all they would have to select from, unless they participate as part of exchange Capital E or if their EHR technology developer wants to give them both options, then they could get certified, you know, to this additional capability.

**M**

So for purposes of transition of care and the transmit section, that's the place where both the EP and EH and the vendor both need to pay attention to the technology that's being used to push the message.

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

That's right.

**M**

Just for clarity.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

I don't think I came across clearly enough. . .

**M**

Just to reiterate. . .

**John Halamka, MD, MS – Harvard Medical School**

See, I knew this was going to be the hardest thing, but, what's been suggested around the table is we're going to call it the Arien Proposal, which was, what he had said. . .months ago. . .is that you will simply change on 11 of 33, the top line to read, "the standard specified in § 170.202(a)(1), that is the requirement, that is the direct specification and optionally we will support § 170.202(a)(2) and § 170.202(a)(3), that is XDR and the specific transport push in NwHIN that takes care of the Cris and the VA issue.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

Would they need to be done together, so it would be (a)(2) and (a)(3) or each. . .

**Arien Malec – RelayHealth Clinical Solutions**

They would have logically to be done together so that you can get the interchange done correctly. So, if I'm sending XDR but my receiver only receives SMTP, then, I can. . .

**M**

Mechanically it would just be moving. . .

**Arien Malec – RelayHealth Clinical Solutions**

No you're right. . .it does. . .it's right. . .so this is really an implementation detail, not a certification detail so, as an implementation detail, I might choose to support XDR with a certified EHR module that does the interchange for me, but the functional result is I can send both XDR and SMTP and SMIME. So, I withdraw that point. The certification approach is I support both and I don't even need to worry about the interchange bit, that's an implementation detail about how I get there.

**M**

And it's if the vendor implements 1, plus either 2 or 3. . .

**Arien Malec – RelayHealth Clinical Solutions**

Yes.

**MI**

. . .and then the eligible hospital provider ends up sending their 10% across 2 or 3, that still counts?

**Arien Malec – RelayHealth Clinical Solutions**

That counts.

**M**

I just want to be absolutely clear. . .

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

And for clarity for me, this is taking notes, the 2 would be made optional, and it would be independent of 3.

**M**

Yes.

**M**

That's right.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

Okay.

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

It is, because you've put the XDM wrapper in SMTP and satisfied 2, without needing 3.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

So 1 required, 2 and 3 optional.

**Arien Malec – RelayHealth Clinical Solutions**

And you might even. . .you could even in that approach, you even just strike 2 and still get outcome, because that's an implementation detail for how somebody could implement just XDR and still satisfy both measures with the appropriate EHR module.

**John Halamka, MD, MS – Harvard Medical School**

But as we did with InfoButton and as I think Jamie's group suggests, we really want to signal the industry that using SOAP or eventually REST is really where we want to try to head, so leaving it in that optional category sends that signal. So, what we have done, but doing this, is we have actually created this parsimony of actually requiring one transport standard for the country and then offering some additional, beyond that, should you so choose. And actually, although it's not going to make everybody completely happy in all circumstances, that's a remarkable achievement if we can do it.

**M**

Leave it also opportunity for innovation, by allowing 2 and 3 to exist and to count. I think that's really huge.

**M**

Okay. . .

**John Halamka, MD, MS – Harvard Medical School**

And 4 that the . . .reserve 4. Exactly. Okay, well, yes Jamie?

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

That's good. I wanted to say that there was one other comment that our workgroup had on this, and that is in the nature of more of a typographical thing, that the standard citation for XDR and XDM should read IHE XDR and IHE XDM.

**John Halamka, MD, MS – Harvard Medical School**

And that is there.

**M**

That would derive from the document that was produced from the direct project, so, the attribution that we need to assign to the documents that we adopt are the title that is on the document itself.

**M**

Well. . .okay, so it. . .

**M**

. . .could be the NLM profiles of XDR, so that's different. . .so there are three things. There's (a)(1), (a)(2) and (a)(3), right, so you've got that right? So (a)(1) is the applicability statement that's the direct specification; (a)(2) is titled use of XDR and XDM for directed exchange or something like that. . .

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

For direct messaging.

**M**

For direct messaging, right. And it was another specification of the direct project that was created with the active support from a number of people who also participated in IHE, and it referenced. . .that specification clearly references the IHE specifications for XDR and XDM, which if you spell them out, are something completely different. So. . .

**John Halamka, MD, MS – Harvard Medical School**

Okay, so I think the answer to this, is just use the appropriate full title of whatever that full title is, just so there's no ambiguity.

**M**

That's right.

**John Halamka, MD, MS – Harvard Medical School**

Okay. So I think let's move on from this one, we have got one single standard, direct and we have two optional and you will clarify to make sure they are titled correctly and we will redact the plain word SOAP so that there's no question of that being yet another option. Okay. Here is the Perlin Proposal. We have about 45 minutes to go through the remainder of this document and we will do a consent agenda, and that is, just go through these and we will just say "ya know, that looks pretty good to me and only speak if you have a very significant objection." Is that a. . .

**Jonathan Perlin – Hospital Corporation of America**

That is, so, we've talked about a number of, I realize not all of the most foundational issues. The last discussion was very robust. So, let's assume that these have been, if you will, litigated in each of the workgroups, if they're cross-cutting issues that you'd like to extract, then we'll pull those out and address them, and I think it would be useful also to hear from the Patient Engagement Workgroup to the extent that we can do this expeditiously. If we need to, we'll schedule a call to complete, so. . .

**John Halamka, MD, MS – Harvard Medical School**

. . .and we've been doing a lot of good patient engagement discussion along the way. . .

**Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

We have. I do want to clarify this. . .our comment here, based upon the further discussion, is not trying to be too prescriptive. Our point here on two types of care teams is that there really is fluid care teams and the care team definitions in the standard should include the patient and their designee and also assume both participants in the immediate care and also in more of a community care construct. So, we don't know if it's two or if it's iterative, but it has to accommodate a more fluid idea of care team and care team specificity.

**John Halamka, MD, MS – Harvard Medical School**

So as we go to clinical information reconciliation. . .you see there are some comments from the Clinical Quality Workgroup, basically suggesting as you do that reconciliation that we include not only medication allergies, but other substances, you know, sort of friendly, reasonable thing. And that comment from you, the ability to perform actions based on role configured CDS. Jim?

**James Walker – Chief Information Officer – Geisinger Health System**

John, this is Jim. Frankly I don't remember that that one means, I apologize.

**John Halamka, MD, MS – Harvard Medical School**

I just wasn't sure what that meant. So, if you could clarify that, that would be great.

**James Walker – Chief Information Officer – Geisinger Health System**

Will do.

**M**

Well, I do have a comment related to it. We mentioned early about non-medication allergies and that the earlier transmittal letter we talked about indicated SNOMED for those and would that apply here? Is, how would they be expected to be represented in the EHR, what standard? So, if the Clinical Quality Workgroup is saying and other allergies to medication, it was non-med allergies they were referring to and to identify.

**Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

Intolerances, for instance.

**John Halamka, MD, MS – Harvard Medical School**

And so Jamie, to refresh my memory, we've said RxNorm for everything class and product and contaminant and SNOMED for non-medication allergies. . .

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

Right. So, this is a functional certification criterion at this point with no standards associated with it, so.

**John Halamka, MD, MS – Harvard Medical School**

Now, there was a brief discussion at our last meeting of an oversight that their allergy vocabularies had not been specified anywhere in the NPRM and do you know if that's something that you plan on specifying somewhere?

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

I think we take our lead from the Meaningful Use Policy side, so that's not a component, that's specifically called out in Meaningful Use.

**John Halamka, MD, MS – Harvard Medical School**

It's just we had. . .

**M**

Medication allergy?

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

Medication allergy is, yes, and there's an objective associated with recording medication allergies, but not all allergies.

**James Walker – Chief Information Officer – Geisinger Health System**

But, this is Jim. In the transmittal letter, we did address non-allergy medication contraindications. For those who aren't clinical, the problem here is that the word allergy can be used precisely as one mechanism of patient having an adverse effect because of medication, and then there are lots of other

causes of the patient having an adverse effect that do not match that specific mechanism, but can be equally problematic, or more. And so, what we have been. . .back to that earlier discussion, it's a question of including all of the things about a medicine that might make a patient sick and, there is no clear language for that in healthcare.

**John Halamka, MD, MS – Harvard Medical School**

So again, we just want to make sure that in the NPRM there is the statement that medication allergy vocabulary RxNorm for all substances is desirable and if it is a policy question as to whether non-medication substances, such as food, environmental allergens are included, then we have suggested that SNOMED is appropriate.

**Jonathan Perlin – Hospital Corporation of America**

And those were included in the transmittal letter. I think if we referred to that, that would be clear and complete.

**John Halamka, MD, MS – Harvard Medical School**

Right. So next we have the transmission of electronic laboratory tests. . .

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

Sorry John, I had a question. . .

**John Halamka, MD, MS – Harvard Medical School**

Oh, I'm sorry. . .

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

In this section we also asked about for comment on whether there should be reconciliation of identity, and the question I, I don't know if it's been adequately discussed already, is around the demographic variables used to link individuals. So, if we want. . .and the rationale is around the patient's safety, you don't want to have the wrong patient. . .matched to the wrong patient. So, if you're going to be comparing this patient to this patient based on their name, I don't know, their address, their date of birth or their Social or whatever, do we have. . .is there, in our process a place to talk about that question that we asked in the NPRM.

**John Halamka, MD, MS – Harvard Medical School**

And so certainly we did have work that came out of the Marc Overhage Power Team that recommended a set of demographic elements to be included in Medidata. We confirmed I think, Dixie, that the consolidated CDA header included Medidata, wasn't that your group. . .I thought. . .

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

I looked at it.

**John Halamka, MD, MS – Harvard Medical School**

Yeah, so. . .

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

It includes the providence and identity.

**John Halamka, MD, MS – Harvard Medical School**

The Privacy and Security Tiger Team is also looking at that particular topic, I know, because Paul and Deven reached out to us. . .

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

Yeah, that's when I looked it up, when she said to look it up, and it included the identity part and it included providence and then, this is the CCDA I'm talking about, and then it includes a pointer to a

privacy policy, but. . .I think, you know, I know that neither the Tiger Team nor our workgroup thought that the standards for codifying policy is at a sufficient level to. . .

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

Right, right. I'm not talking about the policy, I'm just talking about the, I don't know, 5 or whatever it is, data elements commonly used for patient matching. . .

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

. . .for identity, they are in. . .

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

. . .an identity, whether we have articulated standards, Steve?

**John Halamka, MD, MS – Harvard Medical School**

We have validated that they are in the CCDA.

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

Yes.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

To put a finer point on the question, in the preamble associated with this certification criterion, there was an additional question that I'm not sure the groups got to scope-wise. So, would encourage you in in your individual capacity to think about it, with respect to the EHR technology being able to, before reconciliation were to take place, make sure that it's the same patient whose information is about to reconciled.

**M**

. . .Tiger Team, the Privacy and Security Tiger Team has that charge, and they're on the case.

**M**

. . . can touch base . . .

**Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

And then the Patient Engagement Team was just also considering that the roles of the individual also be included, time date stamped and that the patient, for adherence purposes and reconciliation, might also be considered in the design.

**John Halamka, MD, MS – Harvard Medical School**

So, on the lab transmission of electronic laboratory results, was there anything the Implementation Workgroup wanted to specifically highlight?

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

No, I think we are just saying this is not in the measures and so we went ahead and recognizing that, still gave you parameters for denominators, numerators in the standard. So, if policy then eventually perceives this, do you have the rest of the work done. We are in favor of this, we don't have a measure on the CMS side. Okay?

**Arien Malec – RelayHealth Clinical Solutions**

The only comment I would have here, I know that the Information Exchange Workgroup and the Policy Committee as a whole are relooking at this one as a policy recommendation. The only question I have relative to achievement of this, as a sender it is easy for me to receive LOINC in all cases where it's provided. . .sorry. . .as a receiver, it's easy for me to receive LOINC in all cases where it's provided for

me. As a sender, um, if any transmission that doesn't include a LOINC term is not counted as being part of the certification criteria, that's problematic in the sense that I may have appropriate LOINC coding for the most frequently sent lab codes and LOINC codes, test codes and LOINC codes, but there may be some particular tests that I have not yet mapped to LOINC and so, I think it would be important from a certification to Meaningful Use attainment perspective to think about those cases and \_\_\_make for this flexibility.

**John Halamka, MD, MS – Harvard Medical School**

Well, looking at the major themes as we do through the next couple of pages, view, download and transmit to a third party, is one of those major themes that we could probably spend a fair amount of time on, and Jamie, I know there were a couple of things you wanted to call out, that is, the notion of being able to view or download should be something other than free text and that we be specific. So, the method that we had suggested in getting through this quite quickly is to try to cull out those things that will have sort of major discussion. . .

**M**

This is on the bottom half of page 16 of 33, and so, the comment that John is referring to was developed by the Clinical Operations Workgroup suggesting that patient download capability should be required to use the consolidated CDA format and the argument put forward was that this format can meet all of the objectives of individual empowerment for view, print, download, re-uploading using. . .storing your own data, but also has benefits of being able to then reuse those data by integrating them into other systems in a way that simple free text doesn't have the value for.

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

We agree.

**John Halamka, MD, MS – Harvard Medical School**

Any comments on that?

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

Yes. My only comment, this is David, would be that it not necessarily be required to use it, but that it be made available and my concern is, that there may be content in the record that's downloadable that doesn't yet fall into the CDA specification that may valuable to the patient nonetheless. I mean, an image that's standalone image, DICOM image, isn't technically CCDAs.

**M**

Well so I think we had a question as we've talked about a floor, so, at minimum a consolidated CDA is available, if there's more, fine. . .

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

I'm happy with that.

**John Halamka, MD, MS – Harvard Medical School**

Now Dixie, I know you wanted to highlight the TLS issue.

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

Well actually we didn't, that was a Clinical Operations Workgroup recommendation. We actually, in our initial recommendations, the Privacy and Security Workgroup did, in fact, recommend TLS as a standard, but once we saw that what had really been required in the NPRM, is mutual authentication at the endpoints, integrity protection, encryption and, as explained in the preamble, TLS is what's generally used, but they didn't want to constrain it to that forever and ever, so we did not make a comment about TLS.

**John Halamka, MD, MS – Harvard Medical School**

So do we then agree that for transmit, as Cris talked about, it seems like this direct approach to transmitting pushing data, but for viewing and downloading, TLS or like-standard that appropriately authenticates the end points is what you're suggesting.

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

Well, what we explicitly addressed suggested for viewing and downloading is that they have another criterion that specifically addresses the need to create a secure channel for viewing and downloading, that is very similar to the transmit to third party, but that is specifically related to viewing and downloading. Because transmit to third party uses direct and we didn't think view. . .direct is not appropriate for viewing and downloading, but TLS is, so you really need to specify authenticate the end point, encrypt the channel, integrity protect the channel.

**John Halamka, MD, MS – Harvard Medical School**

Cris?

**Cris Ross – Executive Vice President & General Manager, Clinical Interoperability – SureScripts**

Question friendly amendment. I understand, I think, what you're trying to say about TLS, but TLS is not a transport protocol, right, it's a security protocol that could be used for. . .

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

It's at the transport level, security protocol at the transport level, yes. "T" is for transport.

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

(indiscernible) consistent with the way we've been using the word transport.

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

Yeah, it's not really. . .it doesn't send anything, it just creates a secure channel.

**Cris Ross – Executive Vice President & General Manager, Clinical Interoperability – SureScripts**

Understood, it's just a couple of different protocols could use TLS.

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

Oh yes, so. . .

**Cris Ross – Executive Vice President & General Manager, Clinical Interoperability – SureScripts**

Right, so that's my only point. . .

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

Secure SOAP uses TLS, yes.

**Cris Ross – Executive Vice President & General Manager, Clinical Interoperability – SureScripts**

So that's my only point. That's my point is that I think to be precise about the language, we ought to say, a series of protocols, e.g. and you can fill in the blanks with whatever you want, all of which are secured by TLS is I think what we want to say.

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

Well actually, what we are recommending is that we specify this requirement and call it the secure channel. . .

**Cris Ross – Executive Vice President & General Manager, Clinical Interoperability – SureScripts**

Perfect.

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

. . .and then the transport goes through the channel.

**M**

Perfect. Perfect.

**John Halamka, MD, MS – Harvard Medical School**

Are there any Implementation Workgroup items to highlight on the transmit. . .

**Cris Ross – Executive Vice President & General Manager, Clinical Interoperability – SureScripts**

If I could just, on that last point. . .

**John Halamka, MD, MS – Harvard Medical School**

Sure. . .

**M**

This may be an opportunity to make TLS optional as an example of how that secure channel could be created.

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

I have. . .we've started specifying the. . . I think this is appropriate. . .we've started specifying the test procedures at this point, and you know, not specifying TLS creates real challenges in coming up with test procedures that. . .yeah, that sounds fine.

**John Halamka, MD, MS – Harvard Medical School**

. . .the technique you've suggested. . .

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

I've added that in to that first bullet under the Privacy and Security Workgroup heading, which suggested that TLS be used. So, I just put in that you'd make optional suggestion. . .

**John Halamka, MD, MS – Harvard Medical School**

Steve you had a question on Dixie's point two, the intent of the transport standard. . .

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

Oh no, it was on number 1, because it mentioned TLS.

**John Halamka, MD, MS – Harvard Medical School**

Okay. Dixie, any other items on that you wanted to highlight?

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

Um, let me see. . .no, I think. . .the point number 3 had to do with transmission to third party and the patient accessible log and we've had exchanges with Steve on that topic and I think we've clarified our concern there, right Steve?

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

I think so, and Mike as well, in my stead.

**John Halamka, MD, MS – Harvard Medical School**

And then, again, just looking through where there are going to be items that our groups would specifically like to highlight. As we go to page 19, auditable events and tamper-resistance. I believe Dixie you had a couple of issues there that you wanted to highlight, about page 20, number 1 and 2. The audit logs. . .

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

Oh, yes. You'd had a requirement there that . . . it's a negative requirement, which are always problematic, but it says that the audit log must not be capable of being changed, overwritten or deleted and our workgroup pointed out that there. . . regulations do require the archival and destruction of audit logs after a period of time, so, the systems do need to be able to delete, so that you don't have to always destroy the media. So, that was our one comment. And also, the second thing is that we have a requirement, and you picture an EHR submitted for certification and we have one requirement that says that it's impossible to change, overwrite or delete audit records, and then we have another requirement to detect the alteration of audit logs, and it seems like that's a little redundant. If it's impossible to modify the audit records, then why should a vendor have to also implement the capability to detect something that's never going to happen?

**John Halamka, MD, MS – Harvard Medical School**

Right. And also related to this Dixie, you recommended. . .

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

That's really secure.

**John Halamka, MD, MS – Harvard Medical School**

. . . you recommended the use of ASTM E2147.

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

Yes, we did and, we made a general recommendation that as a general rule, an SDO standard, if an appropriate SDO standard exists, that that should be. . . and it has appropriate requirements, that that should be preferred over making up new requirements and regulation, because the SDO standard has been vetted more widely, its maintained by a group over time, it's widely implemented and so that it's more likely to have a common interpretation of it, so, we recommended that the section of the ASTM standard be. . . that specifically addresses auditable events and the data elements that are collected for each event be incorporated, instead of the list of specific auditable events. We still would want the network time protocol there though.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

In terms of logical outgrowth, if that segment includes more data elements than we proposed in the NPRM, then that would be problematic from an AP perspective. You know if it exactly maps onto the data elements that we said, does it go beyond it or is it a subset of it?

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

I don't know, we could check on that. Do you know?

**Walter Suarez, MD, MPH – Kaiser Permanente**

Yes, I think it does cover a few more data elements beyond the ones that are listed, but, one way to phrase it could be to reference the ASTM standard and explain that at the minimum, or at a minimum, these data elements of the standard should be supported. So that way, it's referencing the standard and referencing a minimum set of those.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

Can I? Quick follow up on the. . . so recognizing them may be a little semantics in the alteration of the audit logs. How would you classify an attempt to alter it, recognizing that you want the capability that the audit log be immutable. . .

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

Well, audit, you know, commonly detects attempts to do things they're not supposed to do. So, if you put the attempts to modify an audit log, that's. . .

**John Halamka, MD, MS – Harvard Medical School**

Now, page 26, HL7 pedigree, family history. . .

**Arien Malec – RelayHealth Clinical Solutions**

Comment relative to disabled or enabled by default, here's another one that has an enabled by default criterion that says must only be a limited set of identified users. I want to make sure that isn't implying the capability to disable it. So, it may be, if permitted, may only be permitted to be disabled by certain sets of users. You can imagine interpretation of the must only be permitted to be disabled by a limited set of identified users in a testing. . .or in a test method, to require that somebody show us that you can disable it, that would be a bad thing.

**John Halamka, MD, MS – Harvard Medical School**

Why would you want such a function?

**M**

That's right.

**John Halamka, MD, MS – Harvard Medical School**

I mean, if you have a certification criteria that shows that you can create a flawed audit trail . .

**Arien Malec – RelayHealth Clinical Solutions**

My understanding is that during upgrades and other system testing, that audit logs are sometimes disabled has been discussed. So, I guess what I would recommend is either strike that whole thing or just say, if may be disabled, then may only be disabled by only a certain set of users.

**M**

We audit everything during testing as well, because what if somebody uses Ben Affleck as the test patient, you know. . .

**John Halamka, MD, MS – Harvard Medical School**

So, family history, pedigree. . .

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

Yes, what we were doing, this is Liz Johnson, we were looking at a potential standard, this is a menu item but people expressed concern about how would we capture this? There were two concerns, one was the HL7 pedigree and the second one was we can't. . .we capture familial history or relationship, excuse me, in two areas, one is administrative and the other is clinical and we need to be careful that those are two separate and have separate reasons and so, we were also asking back to the Standards Committee, is there a different pedigree or HL7 standard that potentially could be applied and this is all we could come up with.

**John Halamka, MD, MS – Harvard Medical School**

Because of course, there is the Surgeon General's implementation of the XML format. . .

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

. . .I mean, we're up for options. We weren't trying to legislate this, we were actually trying to. . .people were asking implementation questions about it and we were looking for options for them.

**John Halamka, MD, MS – Harvard Medical School**

I had thought that you had actually. . .I mean, Doug, didn't you at some point see a comprehensive. . . your office look at a comprehensive review of all the family history representations and found that the one that was most widely implemented was actually not the HL7 ballot, but the XLM and the Surgeon General's website, or something like that.

**Doug Fridsma, MD, PhD, FACMI – Office of the National Coordinator – Director Office of Standards & Interoperability**

I think we looked at it, but. . .I don't think that we've got a formal report. Jacob, Jacob come to the table.

**John Halamka, MD, MS – Harvard Medical School**

We're going to hear from Jacob, then Jim.

**Jacob Reider, MD – Senior Policy Advisor – The Office of the National Coordinator for Health Information Technology**

Yes. And so, that if one had to cite a specific standard, that would be one, but this particular criteria does not currently cite a standard.

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

No, it does not. And so the question was, if a menu item, how would people capture it, should we do anything in this area was the discussion we had.

**John Halamka, MD, MS – Harvard Medical School**

Should we say optional Surgeon General's XML. . .

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

Give em options, give em some information.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

Yes, we requested comment on whether or not a standard should be applied and I think cited the HL7 pedigree one to see if the industry thought it was mature. . .

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

And didn't we mention the Surgeon General's . . .Yes, as well. . .and when we looked at the Surgeon General's stuff, we found people who were using it, including the Federal Government. So, it's out there and in use.

**M**

We surveyed some members of the Clinical Operations Workgroup on their use, on how they capture family history and, John did mention the Surgeon General's XML, but we didn't have any agreement among the workgroup members on any standard that was widely used.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

Just a point of process. I believe that this and a couple of other areas where new criteria were added to Meaningful Use that have not been recommended from the Policy Committee, the Policy Committee in their deliberations about whether the measures should be kept or not, one of the factors that they stated as being relevant to them, is whether standards. . .widely adoptable standards for them exist. So, in that, there's a handshake that has to happen between the standard side and the policy side here, and is some ways, there's an interdependency, whether or not this is collected may depend in some part on whether or not you advise the Policy Committee that there is or is not an appropriate standard for it. So, I just want you to be aware of that. . .

**John Halamka, MD, MS – Harvard Medical School**

The answer is, there is not consensus, there is not wide adoption of any standard, although there is some adoption of the XML from the Surgeon General.

**Wes Rishel – Gartner, Incorporated**

And is this about collection or transmission? The standards. . .I mean, the standard's about defining the data elements to be collected or about. . .

**John Halamka, MD, MS – Harvard Medical School**

It's the content standard. Right, so it's the collection of those data elements.

**M**

Okay.

**John Halamka, MD, MS – Harvard Medical School**

Now also I believe the Implementation Workgroup had comments on cancer registry.

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

Same kind of comments.

**James Walker – Chief Information Officer – Geisinger Health System**

John. . .

**John Halamka, MD, MS – Harvard Medical School**

Oh, sorry Jim.

**James Walker – Chief Information Officer – Geisinger Health System**

A comment on the standards. You know, taking one step back. The standards are to enable Meaningful Use of electronic information systems. There are elements of family history that are parts of validated clinical prediction rules, clinically validated in testing with patients, that could be used meaningfully to identify patient's risks for having BRCA 1 and 2 or for having coronary disease and so forth. Those family history elements are extremely precise, first degree relative with history of coronary disease age less than 55 and if they aren't captured with that precision, then the clinical prediction rule isn't valid. And so, this is probably a Policy Committee issue, but I think, I would recommend that we invite the Policy Committee to consider, as they think about what we're going to do with family history, or redesigning criteria that would identify, you know, what would a standard be that could actually be used meaningfully as opposed to what has achieved a large amount of use or acceptance, but actually can't be translated into anything that benefits the patient.

**John Halamka, MD, MS – Harvard Medical School**

Great, thank you. Now, one item that I want to make sure we get to is the clinical quality measures, capture and export and this is on page 28, and I know there were several comments. . .Floyd was still. . .

**Floyd Eisenberg – Senior Vice President of Health Information Technology – National Quality Forum**

I have to learn how to hold this higher because you can't see it. You missed mine on the last one, too.

**John Halamka, MD, MS – Harvard Medical School**

Sorry.

**Floyd Eisenberg – Senior Vice President of Health Information Technology – National Quality Forum**

The question. . .just to respond to Jim's comment. I know that clinical quality measures are something Policy Committee asked for and one of the elements in measures can refer to family history and as such, I hate to keep repeating this transmittal letter issue, but, one of the reasons it includes family history could include a LOINC specified validation instrument is to accommodate what he just talked about, which was my reason for suggesting that for at least. . .you could potentially get it in for the purpose of measures, that if the EHRs were required to handle a SmartForm that is validated, that might be a method to get what Jim is looking for in family history. Just a thought.

**James Walker – Chief Information Officer – Geisinger Health System**

Well, that's fine Floyd, but it wouldn't change the fact that what are called family history standards are not capable of use that's meaningful to the patient.

**Floyd Eisenberg – Senior Vice President of Health Information Technology – National Quality Forum**

Correct.

**James Walker – Chief Information Officer – Geisinger Health System**

I think what you're talking about makes considerable sense.

**John Halamka, MD, MS – Harvard Medical School**

So, the clinical quality measures on page 28, I know there's many comments from the Clinical Quality Workgroup, but Jim and Floyd, anything that you would want to highlight?

**Floyd Eisenberg – Senior Vice President of Health Information Technology – National Quality Forum**

Jim is Chair, I'll let him start.

**James Walker – Chief Information Officer – Geisinger Health System**

I'm not sure there were any that achieved strong consensus Floyd, but you check me on that.

**Floyd Eisenberg – Senior Vice President of Health Information Technology – National Quality Forum**

So, what I can state is there were some discussions about looking at. . .there's a lot of discussion in the NPRM about the quality data model and I will indicate my bias, since it was created and it's maintained by the National Quality Forum, so I'll bring that out right up front. I think the issues around the QDM is they were developed since 2007 based on needs of information for quality measures, thinking of not just measures then, but measures in the future. In the process that occurred in retooling of measures as is, there were many areas of Medidata that had to be expressed, some of which aren't in Meaningful Use certification requirements. And so, there's not a direct one for one match to that.

So, there are a few mechanisms that can be managed and I think some of these were discussed in the Clinical Quality Workgroup. One is use of the term constrain the QDM so that only certain components of it could be used for MU Stage 2 for certification, but that's the floor, it doesn't mean it would keep from quality measures via other options, it would mean they'd need a hybrid methodology to get the data or look in other sources, not just the EHR. Another mechanism would be to just make sure the key requirements for measures are spread throughout certification requirements, so EHRs are required to capture those kinds of data and not discuss the QDM at all, just discuss the components needed to express a measure. The challenge with either is by using measures that are being retooled as is, does raise a risk of some content in them, very granular content, that won't be available based on certification requirements. So, those are the options. I can't really make a direct recommendation but I just want to provide the information to the group. Well, I can make a recommendation, but I'm sure it would be seen as biased.

**John Halamka, MD, MS – Harvard Medical School**

And also the issue of the PQRS XML versus QRDA, is that something you want to highlight?

**Floyd Eisenberg – Senior Vice President of Health Information Technology – National Quality Forum**

Yes. So QRDA category 1 was balloted a few years ago. There is a ballot now open for public comment looking at categories 1, 2 and 3 and it will be reviewed by the HL7 committee in Vancouver in May, and hopefully will succeed as a ballot that describes the patient level data in category 1, the population data multiple patients in category 2 and so maybe leading to the list question that came up earlier, and category 3, the summary results. It's in ballot right now for categories 2 and 3. I have heard concerns

that the PQRS XML may work for ambulatory practices, but not hospitals and I think that led to some modifications in reporting for the 2011 approach, so, I don't think it would apply for hospitals, but I again leave it to the committee to discuss.

**John Halamka, MD, MS – Harvard Medical School**

Any other comments on the quality measures? This has been a lightning round and lots we're going through very briefly.

**M**

Can you go to the cancer registry comments?

**John Halamka, MD, MS – Harvard Medical School**

The comments which we made was. . .

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

It's premature is what. . .that's what. . .

**M**

My understanding of this one, I just want to clarify, my understanding of this one is based on the way that certification is based, you would only need to certify to this requirement if you intended your EHR to be useful for the menu set option for cancer registries, and likely, that would be, if I was building an oncology system, I might certify to this, if I was building an internal medicine system, I probably wouldn't.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

That's an important point. That's a really important point in the new approach to certification, have only, you know, because that's only what you need for Meaningful Use, when there are menu items, and there are a few of them in Meaningful Use, that makes the bar a little bit lower in terms of including certification requirements, because we're not talking about a thousand eight hundred products needing to get certified, so it would only be those that choose for that relatively, probably smaller set of providers who really care about cancer registries to do that, so, that's a very valid point. . .

**Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics**

. . .from a modular perspective, that is a legitimate comment, that you could add from our behalf.

**John Halamka, MD, MS – Harvard Medical School**

Well, I recognize that we didn't comprehensively go through every single comment, we did it close to chapter and verse as we possibly could, and I hope we really highlighted where those hot button issues that the workgroups spent a lot of time on, and hopefully we'll get good guidance that will lead to that polished NPRM into a final rule that we can all be proud of.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

So, in terms of process and formulating a comment letter that would be submitted by the Standards Committee, we'll go back and the elves will do their magic on the tables and reconciling cleaning up some of the notes that we've made in areas where things need to be deleted and then ship it out to you all to confirm, just like you would with minutes, etcetera, for that it reflects the final intent of the committee. Sound good?

**Jonathan Perlin – Hospital Corporation of America**

That would be perfect but just lets complete this here. I think we've gone through many of the foundational elements in great depth, in fact, obviously we've spent more time on those that we had collectively intended and I appreciate tremendously robust discussion. The remainder of the agenda we dove a little deeper on a few of the items, the rest handled by consent. Is there anyone who, let me not

phrase it in the negative, but, can I assume consensus on the discussion today, that assuming that the elves and Steve faithfully. . .

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

... Included as a gnome. . .

**Jonathan Perlin – Hospital Corporation of America**

.. .that this is obviously our intent to transmit as a recommendation?

**M**

Process question, are we going to have in that elf magic work, are we going to have an opportunity to send, because this is probably one of the more critical documents, are we going to have an opportunity to send that recommendation letter to the full committee with an exclusion date for comment?

**Jonathan Perlin – Hospital Corporation of America**

I would like to suggest that we have that opportunity, but, I want to be really clear, one it's not practical to relitigate. . .so it's really to –

**M**

We're not opening cans. . .

**Jonathan Perlin – Hospital Corporation of America ??**

.. .that's right. It's really to assure that the discussion was accurately captured in terms of the recommendation. So, Wes?

**Wes Rishel – Gartner, Incorporated**

In my discussion on bilateral asynchronous cutover, I have available specific recommendations that I didn't present here as part of the talk today. I could present them now or I could do it to the group by email, however you'd prefer.

**John Halamka, MD, MS – Harvard Medical School**

Presumably by email. Although we do want to get a couple of minutes of the patient. . .

**Jonathan Perlin – Hospital Corporation of America**

Yes.

**M**

Yeah.

**Wes Rishel – Gartner, Incorporated**

I'd like to have the opportunity by, you know of failure if they're becoming controversial. . .you know, if they do fail to become controversial, I'd like to have them included in the letter, if that's possible.

**Jonathan Perlin – Hospital Corporation of America**

Okay. I just want to make sure that we give. . .the Patient Engagement Workgroup has done just heroic work and I want to make sure that we attend to that. Okay, with the proviso that we'll have some continuing delay, I think Steve you did capture some fairly specific language, to the extent that they're not controversial and parsimonious with that. . .

**M**

Okay.

### **Jonathan Perlin – Hospital Corporation of America**

Okay. So what we'll process then is that Steve and team will get the letter out, but perhaps before that Wes, if we can ask you to get the information out so that it at least circulates and we can get some consolidated guidance to go into that letter, hopefully with, so, with that as a proviso, is everybody comfortable with that as a process. And notwithstanding that singular item, the consensus on the recommendations that will be transmitted. Good. Well, I appreciate the hard work on that. I think it's quite an accomplishment. A very robust discussion today, much appreciated. I thought a very effective discussion. I also thought the discussion was influenced in the most positive way by the input that Leslie represented on behalf of the Patient Engagement Workgroup. John, I want to thank you for just leading a very thoughtful and effective discussion, I can't imagine that it could have been more accommodating in terms of really seeking input and to each of you for really very, very thoughtful points that were raised. So, Leslie. . .

### **Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

Yes. Thank you. All right, I will try to be brief so we have plenty of time, and I guess I have control of the slides. Wrong way. So, we had a very significant charge that we took quite seriously, to really look at the standards in terms of patient engagement. Our goal was to ensure that the standards meet current opportunities for engaging patients and their family in care. As we reviewed this, we had a great team of people from this committee, people who are very active in the S&I framework, who have been working diligently for the past year on the transitions of care under S&I framework, Dr. Leftwich and Dr. Miller. We had great representation from patients themselves, who were very enlightening to the group as to concerns, conditions, overarching themes that we'll talk about, that we should consider as we went forward. So, in trying to determine how standards might meet patient engagement, we first had to determine what are things that mean patient engagement, so we came up with some overarching themes which I'll talk about, then some rationale for changes, comments and some directional sign posts for the future.

So what we found as we did the review is where policy exists and standards don't, we would like to see active efforts that the patient engagement and EHR standards are developed consistently, that there is potentially for most EHR action, a reaction in a patient-facing system. So let's look at two first, when we look at standards, that where there are gaps in policy and standards exist, how can we harmonize those, now or in the future. And where both policy and standards exist, let's make sure they also include patient-facing systems. So our overarching principles were really important as we reviewed each one of these objectives. "Nothing about me without me," we've heard before and it really means that I should be informed about my care, I'm a contributing care team member, what I say, my voice has value, its important and material to care. Many EHR systems have a patient-facing reaction to an action done in an EHR and let's be innovative here, patient-facing systems are not limited by legacy systems, this is a green field largely, so let's take that opportunity and then although we were not asked to look at clinical quality measures specifically, we felt there was a great question to ask as we develop standards for CQM, which is, how does my care compare? So patient specific dashboards that might be included, so that we're always using quality with the patient in mind and not necessarily just institutional quality.

Some of the themes that came under these overarching goals were, make things understandable to me, in plain language and in my language, CC me or my designee, not just as a view, download and transmit, but actually on-demand requests for information; give me a copy of that note, I'd like to see what that says, not only from a provider to a patient, but provider to provider. We felt this is very meaningful and everything about me. I am a health information exchange of one. Often times the patient is the participant in that health data exchange, that means the data that the patient receives should be computable and interactive and raw data for use by me, in the way I believe is important. I am a necessary and important safety check point and should not be ignored or trivialized. I am a credible source of information and generate meaningful and material data for my care. Clinical information reconciliation needs to include the patient as a participation and view, download and transmit needs to be computable, transferrable and moveable in any way I see fit. Those were just some of the examples and we encourage you to look at the complete list, it's approximately 37 different themes underneath these overarching objectives.

Our comments, as you saw, we've already been through the grid, where we saw logical outgrowth. We really started with the big picture in mind, given these themes, and we believe the documents that we've created can be a good bellwether for future patient engagement opportunities in both standards and policy. Some of the frontier issues that we saw, that were just borderline between I guess 2014 and 2015, that patient action should be flexible and bidirectional; the things going to the patient, CC me. For instance, a record of a CPOE, I might be the one who has been ordered to go get a lab test, I should know what I'm getting, where I'm going, how to get it. E-prescribing, making sure that I know what's being sent or expected of me with regard to medication or my designated proxy, computable and human readable on demand and available as populated. So, rather than looking for a timeline, having the patient participate in the decisions about when that information is available.

Additionally, from the patient, a current medication list, my family history, my smoking status, medication adherence, my experience of medication, my experience of care, specific questionnaires that might be asked of me, where I respond back with information, particularly relevant to an episode of care and computable inside the electronic medical record, patient intolerances, patient initiated data. So we thought that from the patient was just as important going forward as information to the patient. We also felt that clinical decision support should include patients in shared decision making in the future, because so much of the care that we provide today is preference-sensitive care where my values and my opinions, my biases have as much opportunity to create great outcomes as does the medical evidence. We also felt that the quality of life decisions to be very, very important in all consideration of shared decision making.

Patient communication should include relevant education, so even if I view or download information, I have the ability to understand what is being sent to me. So, the Infobutton question that I feel so passionately about, always gets back to the patient. Do I have information that explains that lab result or that med? Could I understand my care, because being informed is not enough, it's being educated that is important. The data should be computable and discrete raw data, so any patient data, so I can do with it what I may and that also the care team roster in the future needs to consider the idea of both institutional teams as well as community-wide teams. So, this group really talked a lot about collaborative care of the future and felt that really our future of health care is not just transitioning a patient from point A to point B and making sure that transaction is complete, but making sure that the community of care that revolves around the patient is collaborative, that the nature of care makes sure that the patient is a co-producer of their own health, with their own equal say and value in the team.

We also. . . here's some examples of the overarching principles and how we got to individual criteria. "Nothing about me without me, cc me. I am a contributing care team member. I can generate data as well as receive data." Many EHR actions have a patient-facing system reaction, just as I generate orders for laboratories, I generate orders for patient's to participate in. And that patient-facing systems are not limited by legacy systems. Why not a patient-facing API that sits on top of a standard of other systems, and again, how does my care compare for patient report cards. Some of the take-aways; the energy and enthusiasm of this team was amazing. We had three sub-teams that each met that provided information and significant detail. We actually went through every single objective and looked at patient engagement in that objective, whether or not that could be commented on today as a logical outgrowth, we felt that it informed the future and felt very, very strongly about making this a complete body of work. The ability to have a brand new group including patients to coalesce and to convene this cannot be overstated; it worked, we got great contributions and participation, and I've only touched on some of the comments from this group. I invite you to look at the documents that we've attached, which I'll go into in a minute.

We also believe that policy helps innovate standards, but standards can help innovate policy and this idea of throwing it over the fence can be quite narrow-minded, especially where there's green field opportunity and technology, that exists with patient-facing systems and collaborative care models using technology. We believe and recommend strongly, that we extend this team effort across those committees, jointly or in collaboration, as a long term team to make sure that patient engagement is viewed equally and ongoing throughout our efforts in Meaningful Use. To support the recommendations you'll find attached a sheet that reflects both in writing and on the website, it reflects our overarching themes and the individual items underneath, as well as our dialogue about every single objective and these are not complete, time did not allow me to provide every single comment that this group did. And then you'll also see attached

as an outgrowth of our team work, a document that was authored by Jim Hansen of Dossia, who was one of our co-team leaders, and he also continued to discuss with our team members new ideas, and so this has continued to evolve beyond even the workgroup effort and I would just really convey the passion of this group. We feel we did a lot of work, but it's still incomplete. We hope that you'll support an ongoing Patient Engagement Team and are very proud of the work we've done.

**John Halamka, MD, MS – Harvard Medical School**

So, I would tell you, having read all the materials, that you're group probably gets an A+ for the quantity of material generated in the time frame that you had, it was truly amazing and I think the interesting ONC question, you know Farzad and Steve have stepped out of the room, is they have some very forward thinking recommendations with some very interesting workflows and as I often use my wife, who is going through a very complex care process right now, it's clear that those workflows would empower her care; however, the industry isn't quite ready for every one of those workflows and sometimes that's because of political issues or staffing issues, or standards issues, so, it's as I've mentioned to you in January, it's like what do you say is a menu set, what do you say is a core, when do you make it happen and how do we change society. So, I really found what you've done is an excellent framework for a lot of further discussion, so thank you.

**Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

Thank you.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

And I thought that the point about policy helping innovate standards and standards helping innovate policy in the example of the CC me as an example of how potentially simple standard for continuing, ongoing, kind of subscribe and publish model, might provide disruptive thoughts, innovative possibilities to policy. That's a great point.

**Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

Thank you.

**Jonathan Perlin – Hospital Corporation of America**

So, a number of cards are up. Let's go around the room. Dixie, I saw your card first.

**Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences**

Thank you, that was a really nice presentation. I'm really pleased to see more patient engagement involvement in our group. One of the topics that frequently comes up, no matter what topic we're discussing at the time, is the enormous challenge that our industry has with regard to patient identity and assuring the accuracy of patient identity, and I personally believe that a Patient Engagement Workgroup would be an ideal body to take that on, to help us solve that problem.

**Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

We would welcome that effort.

**Jonathan Perlin – Hospital Corporation of America**

Thanks for bringing it up. You know, (indiscernible) issue just to take Farzad off the hot seat on this one, I mean, this is third rail issue and then I can tell you that patient's with considerable health needs tend to value care over some of the very, you know, legitimate privacy and security concerns. One might imagine working forward to a dialogue where, you know, there's optionality for those to choose, it certainly does. . .would solve a number of the difficulties. Notwithstanding that, you know, all policy technology is directed towards trying to solve or go around something for which there is another approach.

**Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

I think that the group had one phrase that we used which was "the data should be provider-protected and patient-directed" so that we have a chance to say, you know, who we are, identify who we are, identify the

use, but also understand that as adults, we have a right to choose to do with that data what we will, after we download that information. So, that was an ongoing discussion, but, these are real issues.

**Jonathan Perlin – Hospital Corporation of America**

I saw countless cards come up, after that discussion. Is that on this subject, Jodi, or?

**Jodi Daniel – Office of the National Coordinator – Director of Policy & Research**

I can wait.

**Jonathan Perlin – Hospital Corporation of America**

You sure?

**Jodi Daniel – Office of the National Coordinator – Director of Policy & Research**

Um hmm.

**Jonathan Perlin – Hospital Corporation of America**

John Derr?

**John Derr – Golden Living, LLC**

Yes, I just want to point out how valuable the committee is to what many of us had talked about offline, and that's having patients have some skin in the game, and this is the way we can identify that, so they will have some obligations to take care of themselves. I think we have to help them that way, otherwise they just won't do it.

**Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

Agreed.

**Jonathan Perlin – Hospital Corporation of America**

David McCallie, is your. . .on this topic?

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

It's a leftover, but I will compliment you on terrific slides and excellent thoughts.

**Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

Thank you, David.

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

Terrific.

**Jonathan Perlin – Hospital Corporation of America**

Then the last word on this discussion, we move to the public comment period, after that, Jodi Daniel.

**Jodi Daniel – Office of the National Coordinator – Director of Policy & Research**

I just wanted to say thank you for that presentation, it was really great and as a person in ONC who is responsible for our consumer health activities, the thinking is really helpful and even if there are some challenges, some of this is incredibly forward thinking and may not be implemented immediately in some of the discussions, particularly the technical discussions, I think having some of the thinking the forward looking ideas and concepts on the table, to help shape policy thinking, is really, really valid and useful and so, I would encourage you all to continue and we'll talk internally about how we can support ongoing discussions.

**Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

Thank you. Thank you very much. We would really like to see these overarching themes being used as a way to say, "are we engaging patients?" And that that's a question that each of us in our roles always ask. Not just patient-centeredness, but patient-inclusiveness. So, thank you.

**Jonathan Perlin – Hospital Corporation of America**

Tim Cromwell, you may get the very last word.

**Tim Cromwell – Veterans Health Administration – Director Standards & Interoperability**

Thank you. So, we heard Dixie make a recommendation, and so this is more of a procedural question. Dixie made a recommendation and we heard Leslie pick it up and say yes, and so, we want to take that on, so now what happens? There's an issue out there that is just dying to be solved and it's urgent and it's, as Dixie said, it's ubiquitous in every one of these in direct and exchange and health information exchange interoperability, it keeps coming up of how to securely, privately identify the patient.

**Jonathan Perlin – Hospital Corporation of America**

What I'd like to do is, because I couldn't agree with you more, is to take that offline and have some conversation with ONC and find what way we can bring that forward in a way that's as constructive as possible given the great unspoken, of the political delicacy of that particular conversation and its critical importance to, ironically, the care that all are really striving for. What an amazing day, you know it really is. I think when you reflect back after today, it was a very thoughtful and effective discussion. I think, you know, the capstone to the day was Leslie's presentation, the work it represents, what a milestone that is in and of itself, not only in progression of thinking and engagement around patient as partner, but also in terms of capability for us to contemplate in the context of Meaningful Use and the advance of Meaningful Use. So, it really is a terrific capstone to what is a milestone in the progress. Hope Farzad that you and the Office, you know, are. . . I know it's been the Office of no Christmas, the office of no Summer, but. . .

**Leslie Kelly Hall – Senior Vice President for Policy – Healthwise**

. . .known as the office of no Week.

**Jonathan Perlin – Hospital Corporation of America**

I think that's true as well, but I hope that when members of your staff go home, periodically, and irregularly, that you do take a moment just to really feel good and proud about the progress that the process has spawned. I personally take great pride in all of your work and great appreciation as a consumer and potential consumer of health care for all that's been achieved. So thank you, and I think we owe a round of applause to the ONC for. . . John?

**John Halamka, MD, MS – Harvard Medical School**

So, if we just reflect on where we ended up today, after all the fine work of Steve Posnack and all the group here, we have a set of very parsimonious content standards that are basically. . .they're HL7 2.X, 2.5.1 most of the time, or consolidated CDA, which everyone is feeling increasingly good about. We have a set of vocabularies and code sets, mostly curated by NLM and really parsimonious, one per domain, and we actually, together, came up with one transport requirement for the country. So, wow, content, vocabulary and transport and a skinny-down set of specifications; who would have thought? Now, let us see how the public reacts. Thank you so much.

**Jonathan Perlin – Hospital Corporation of America**

And as they say on top gear, and with that bombshell. . .for those of you who catch the top gear allusion. . .Mary Jo, we'll turn to you, really do. . .I think what was so exciting about Leslie's presentation is that it is continuous. . . with bringing public comment. . .look forward to that.

**Public Comment**

**Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology**

All right operator, would you open the lines for public comment and would anyone in the room who wants to make a comment come forward to the table? We'll take anyone in the room first, while we're waiting for anyone to come on line.

**Caitlin Collins – Altarum Institute**

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

**Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology**

Go ahead.

**Lindsay Hoggle - Director of Informatics at Academy of Nutrition and Dietetics**

Good afternoon. My name is Lindsay Hoggle, I'm Director of Informatics at the Academy of Nutrition and Dietetics formerly the American Dietetic Association. We represent 73,000 members which comprise us as the largest group of food and nutrition professionals in the world. First of all, I want to thank you very much. I've been involved in following the two committees since its inception in 2009 and, I just want to thank you today for addressing our concerns on food allergies; we felt that they are very much a patient safety risk not to address them, so, I really appreciate your discussion on that and addressing the issue. There still is one more issue that I have, that I consider at this point, a patient safety issue, and I want to share that with you. In discussions with other people, several people recommended that I look for diet orders or nutrition and the use cases and in looking at use cases, I could not find nutrition or diet ever addressed, which is not uncommon, we kind of take it for granted in that we normally eat. The Joint Commission, however, in any inpatient setting, requires that the care provider write a diet order before the patient can eat. The patient cannot receive any food without this. While mishaps in this area are not well documented, they are well known to those of us who have practiced in acute care.

Last week I sent out a call to several colleagues for examples of this and I wanted to share those with you, just to make everyone aware. A few of those include: A patient who receives food when in fact their order is NPO, nothing by mouth, for surgery. This almost universally causes a delay in the procedure and/or surgery, which indirectly increases health care cost. One colleague wrote, "We have instances where a diet order did not follow the patient from long term care to acute care, the patient on a dysphagia diet due to difficulty swallowing, was placed on a regular diet inadvertently and ended up aspirating. Renal patients who often have restrictions on protein, sodium and perhaps most critically potassium when their kidney can no longer filter potassium appropriately, intake has to be restricted on potassium or the patient's potassium becomes dangerously elevated, which can lead to fatal cardiac arrhythmias. Enteral feedings where free water flushes rarely are accurate or omitted completely upon transfer to long term care. Error rates in this area have been documented at 50%." One colleague wrote, "My practice this week saw one patient with no enteral orders upon transfer, another in which partial enteral orders came over after 5 p.m. with the rest of them coming over in a packet the next day."

Additional issues include children with inborn errors of metabolism who require medical foods to survive, fragile, brittle diabetics who required careful coordination of insulin and food intake and those patients whose poor intake during hospitalization have an increased risk of falls due to weakness or infection. Our list is rather long. These are just a few of them. What I would like to ask is that we first consider prioritizing critical clinical data which we consider a diet order to be, prior to some of the other more burdensome task in requirements of Stage 2 Meaningful Use. Thank you for this opportunity to comment.

**Carol Bickford – American Nurses Association**

Carol Bickford from the American Nurses Association. I want to thank the Empowerment group for their timely presentation and the wonderful thoughts that you've provided. Now I challenge ONC to take that material and make it available for those of us who stepped into the pledge to put the "I" in HIT, take those messages, get them into media, comments and so on and trickle that down to those of us who've stepped up to the plate. The same message coming from many people is much more powerful than many diversities. The second point, please, please go to NCVHS, take a look at all of their testimony and their recommendations in relation to the unique patient identifier for medical care. Many of us are out here clamoring for the opportunity to opt into that option, we don't want to be less than. . .sigma in our combinations of our health records.

**Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology**

Operator, do we have anyone online?

**Caitlin Collins – Altarum Institute**

We have no comment at this time.

**Jonathan Perlin – Hospital Corporation of America**

Well with that, I would again thank everybody for your participation and especially for all the hard work that recently occurred between meetings. We stand adjourned. See you next time.