

**HIT Policy Committee
Draft Transcript
July 6, 2011**

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director

Good morning, everybody, and welcome to the 25th meeting of the HIT Policy Committee. This is a Federal Advisory Committee so there will be opportunity at the end of the meeting for the public to make comment, and we will have a transcript available of the meeting on the ONC Website.

For those of you not in the room we're in sort of a different configuration here; it's a little bit cheek to jowl, and I'd just ask the members if you could please speak into the microphone when you talk because the sound man needs to make this as clear as possible. And also, remember to identify yourself when speaking. So let's go around the table for introductions, beginning on my right:

Steve Posnack – ONC – Policy Analyst

Steve Posnack, ONC.

Josh Seidman – ONC

Josh Seidman, ONC.

Connie Delaney – University of Minnesota School of Nursing – Dean

Connie Delaney, University of Minnesota.

Eva Powell – National Partnership for Women & Families – Director IT

Eva Powell, National Partnership for Women & Families.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Larry Wolf, Kindred Healthcare.

Neil Calman – Institute for Family Health – President & Cofounder

Neil Calman, Institute for Family Health.

Patrick Conway – CMS – Chief Medical Officer

Patrick Conway, CMS.

Paul Egerman – Software Entrepreneur

Paul Egerman, Software Entrepreneur.

Gayle Harrell – Florida – House of Representatives

Gayle Harrell, Florida House of Representatives.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Paul Tang, Palo Alto Medical Foundation.

Farzad Mostashari – ONC – National Coordinator for Health Information Technology

Farzad Mostashari, ONC.

Deven McGraw – Center for Democracy & Technology – Director

Deven McGraw, Center for Democracy & Technology.

David Lansky Pacific Business Group on Health

David Lansky, Pacific Business Group on Health.

Judy Faulkner – Epic Systems – Founder

Judy Faulkner, Epic.

Charles Kennedy – WellPoint – VP for Health IT

Charles Kennedy, Aetna.

Linda Fischetti – VHA – Chief Health Informatics Officer

Linda Fischetti, Department of Veterans Affairs.

Marc Probst – Intermountain Healthcare – CIO

Marc Probst with Intermountain Healthcare.

Scott White – 1199 SEIU – Assistant Director & Technology Project Director

Scott White, 1199 SEIU.

Adam Clark – FasterCures – Director, Scientific & Federal Affairs

Adam Clark, FasterCures.

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you, and with that I'll turn it over to Dr. Mostashari for opening remarks.

Farzad Mostashari – ONC – National Coordinator for Health Information Technology

Hi. Thanks so much. Welcome to the 25th meeting of the Health IT Policy Committee. I want to actually first mention and welcome the newest member of the Health IT Policy Committee, who is Patrick Conway. I've had the pleasure of working with Patrick for some time, initially when he was coordinating the \$1.1 billion—was it \$1.1 billion, Patrick? Yes, \$1.1 billion for comparative effectiveness in the Recovery Act out of the Office of the Secretary for Planning and Evaluation. He was, before that, a White House Fellow, RWJ Scholar, and a gentleman, and he is now leading as the Chief Medical Officer for CMS, just an incredible portfolio of activities, which is stunning. And as we talked about integrating more what we do with Health IT into healthcare transformation more broadly, into quality improvement more broadly, there is no one that we could have asked who would more further that alignment between Health IT and the broader agenda for quality improvement than Patrick.

Patrick is a pediatrician and he leads the Office of Clinical Standards and Quality, which is responsible, get this, for all quality measures for CMS, quality improvement programs, quality improvement organizations in all 50 states, clinical standards, and all coverage decisions for treatments and services for CMS with an office budget, annually, of \$1.3 billion. So we're really pleased to have Patrick's engagement with the Health IT work and the opportunity to really make sure that what we do is as integrated and aligned with the broader healthcare transformation activities nationwide. So thanks to Patrick; he's also just a great thinker and a great all around friend. Welcome, Patrick.

I want to do really one thing today which is to review the recommendations from our last meeting and recognize that the recommendations of the Health IT Policy Committee to us were the result of really such

extensive consideration of expert testimony, significant input from a range of stakeholders including vendors and providers, and the countless hours of review, analysis, and deliberation by the members, and I really, personally and all of ONC, would like to express our great appreciation for the efforts of the committee, particularly those of the Meaningful Use Workgroup, in drafting the stage two meaningful use recommendations. As you know, I can't formally respond at this time to all of your recommendations, but I'd like to make a few comments on some key elements of the letter that we received.

First, I applaud the framework that was used. It was insightful and I think in some ways a breakthrough to focus on the priorities of the new national quality strategy, and using that lens to identify the key electronic infrastructure that meaningful use of EHRs can provide in supporting the country's objectives around delivery system transformation. That approach, devolving the definition of meaningful use, just makes a lot of sense.

Second, regarding your recommendation on the timing of stage two, we agree with your conclusion that widespread implementation of stage two systems in three to six months may well be infeasible and therefore could have a detrimental effect of keeping providers on the meaningful use escalator. Perhaps most importantly, the last thing we want to do is to provide a disincentive towards attesting for meaningful use in 2011. We should be rewarding providers that attest in meaningful use at the earliest possible time in 2011. We recognize that not accepting your recommendation to delay the start of stage two could negatively impact provider participation rates in the EHR incentive program in 2011.

Finally, we also agree, in principle, with your comment that extra time will help providers and vendors develop more robust EHR functionalities in the targeted areas that support key delivery system and national quality strategy priorities. In recommending a delay, you made it clear the need for an escalator to ensure that the meaningful use bar continues to rise over time in order for the country to realize the full benefits of Health IT. Precisely, I'm referring to your recommendation of the meaningful use requirements for stage two need to be robust enough to maintain progress toward the information support needed for health reform. By giving providers and vendors additional time, requirements for stage two can be more rigorous than would otherwise be possible if stage two were not delayed and were to begin in 2013 for some providers as originally envisioned.

In consideration of these thoughtful points, and the concerns expressed by multiple stakeholders, we agree with the logic of delaying the start of stage two of meaningful use for a period of one year for those first attesting to meaningful use in 2011. We also agree that it makes sense to maintain the current expectations for those first attesting to meaningful use in 2012, so that all providers attesting to meaningful use in 2011 or 2012 would attest to stage two in 2014. That would give all providers adequate time to move up the escalator for a robust set of stage two meaningful use expectations. Thank you.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Good. Thanks very much, Farzad. I think that's very helpful and it'll be very helpful to the industry and providers that are trying to work with the program, and as you say, we certainly don't want to disincent people to sign up early because that's one of the main purposes for ..., so thank you very much for those comments.

The rest of the agenda is a little on the short side, so we're going to give you the gift of time probably by the end of this. We're going to begin with the Privacy and Security Team recommendations on amendments to the record as they have a recommendation to have the EHR support that we have under HIPAA, and we have an interesting update from the HIT Standards Committee; as you know that's our sister ... committee and we have a relationship with them. And we haven't always been kept up to speed

with what they're going to do and they actually have a summer camp going on and they're going to brief us on their—instead of saying “what I did for the summer” – “what I'm *going* to do for the summer;” so I think that'll be very interesting to us and we also hope to have an update about the Direct Project, an important project in ONC.

Following lunch and potentially, if it works out, we might even have this before lunch depending on how the agenda goes, we've been asking for and we're going to receive an update on how this ... been going for stage one in CMS, so CMS and Josh will give us an update on that. And that's something we'd like to continue on our agenda as a standing item, because that's something we want to keep up to speed on; it'll definitely our work in a broad sector, not just meaningful use. And then we'll, as always, conclude with public comments.

Any amendments to that agenda? Okay, if not then I'd like to entertain a motion to approve the minutes that you should have all received before today's meeting.

M

So moved.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

And any seconds?

M

... second.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay. Further discussions, amendments? All in favor?

All

Aye.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

And opposed? And abstained? Thank you.

Let me make a slight comment to follow up with Dr. Mostashari's comments about the meaningful use recommendations from the HIT Policy Committee. As you know, the letter primarily dealt with the changes, some of the new things or the modifications, and we did have some comments about – well what about the things that didn't change. So we're right in the midst of preparing sort of a comprehensive matrix, somewhat akin to stage one, the ... matrix that will have it all in one place. The final rule for stage one, the recommendations from this committee about the stage two, and some comments about stage three; and that'll be coming out within the next week to help everyone along with that.

Okay, so let's move on to the Privacy and Security Tiger Team update.

W

Alright, Deven.

Deven McGraw – Center for Democracy & Technology – Director

Alright, well, as Paul mentioned our recommendations today deal with amendments and corrections to the EHR. I'm going to pause a moment on our list of members here to acknowledge the special assistance that was provided by someone not on the Tiger Team, and that's Dan Rode from AHIMA. As

we were sort of diving into issues that have connections to the legal-medical record we thought we needed to expand our expertise a bit to make sure that we didn't make any mistakes, and that was extremely helpful, so Paul—

Paul Egerman – Software Entrepreneur

I was just going to say, I believe that organization likes to be referred to as A-H-I-M-A.

Deven McGraw – Center for Democracy & Technology – Director

Okay, thank you. Thank you, Paul.

Paul Egerman – Software Entrepreneur

So we want to thank Dan Rode from A-H-I-M-A.

Deven McGraw – Center for Democracy & Technology – Director

From A-H-I-M-A. Thank you. Thank you, Paul. I stand corrected. Yes, he was of enormous help, as was our Tiger Team members, as usual, putting in a lot of dedicated hours for us to be able to generate the amount of work that we've been able to accomplish which is really significant.

So I want to start with a bit of a picture of where we are on amendments and corrections in terms of things that have already been said, either with respect to principles that have adopted by the Office of the National Coordinator or with respect to the HIPAA Privacy Rule. And it turns out that we weren't really digging in new territory here. The Office of the National Coordinator's Nationwide Privacy and Security Framework for the Electronic Exchange of Individually Identifiable Health Information has a principle that states that individuals should be provided with a timely means to dispute the accuracy or integrity of their individually identifiable health information, and to have any erroneous information corrected or to have a dispute documented if their requests are denied; and this was adopted by ONC back in 2008 and remains the sort of framework of principles that we've used in the Tiger Team to really flesh out all of the policies that we have put before you since we began doing this work.

In addition, that framework actually reiterates a concept that's been in the HIPAA Privacy and Security Rule since its inception, which is that patients should have a right to request amendments to information in their medical records and to have disputes documented if, in fact, there's a dispute about whether the amendment should be made. And in the materials that were sent to you—we didn't put it on the slides here but in the text document we actually have a summary of what is provided in the HIPAA Privacy Rule, and I won't go into excruciating detail but in essence, individuals have the right to request an amendment and if the entity makes the amendment, then they have to transmit it forward to anybody that the patient requests needs to have it, and then also to any entity that—say the doctor at a hospital reasonably believes may have received that information and potentially would rely on it to the patient's detriment if they didn't get the amendment.

But if there's a dispute about whether the amendment needs to be made or not, then in essence there's a process for that dispute to sort of be documented. The patient has the right to provide information disputing the record. The entity can include some rebuttal information and all of that sort of package of information then is supposed to remain with the disputed information or the information in question in the record, and then be transmitted forward anytime it needs to be transmitted. So it's pretty detailed what needs to happen in the HIPAA Privacy and Security Rule when a patient makes a request for an amendment.

But what we haven't really—we haven't really closed the loop on is to what extent can certified EHRs help entities honor those requests that are made by patients. And consequently, we came to the conclusion

that the same types of functionalities that would allow an entity to honor a patient's right to request an amendment and the need to, sort of, maintain documentation and potentially transmit it forward in the event of a dispute, but those very same functionalities would be needed even if the entity itself discovers the error and needed to sort of make the correction in its own records and then potentially transmit it to other providers who had received the data that turned about to be incorrect or needed to be modified, or even updated. So we really focused on setting some priorities for certification so that those technical capabilities to be able to assist entities in complying with those obligations would be present.

And so consequently here are our recommendations for your consideration. Certified EHR Technology should have the capability in meaningful use stage two to support amendments to health information, and in particular, to support compliance with HIPAA obligations to respond to patient requests for amendment, and specifically the system should make it technically possible for providers to make amendments to patient's health information in a way that is consistent with the entity's obligations with respect to the legal-medical record; so again, we're not talking about removing data from the record, but instead, correcting it in a way that is consistent with those legal-medical record obligations. But also to be able to append data that comes in from the patient in the event of one of those disputes about whether information in the record is correct, and then, of course, if there's a rebuttal; again all of that needs to sort of be housed in the record in some way. And so ideally if there's a technological way to make that happen, obviously it's much preferred since we want to move to electronic medical records.

Then by stage three we really believe that the technology should have the ability to transmit these amendments, updates, or appended information to other providers to whom the data in question was previously transmitted. So again, we're really talking about the technical functionalities that are needed to assist providers in complying with their existing obligations under HIPAA with respect to the transmission capability and we believe this will—it's going to take until stage three to be able to implement, and hence, there's a bifurcation between stage two amendments within the record internally, stage three ability to transmit an amendment when appropriate.

So consequently, as is always the case, we try to stay in the policy sphere and let the Standards Committee deal with the details about how this happens from a technical standpoint, and so we've asked the Standards Committee to then recommend any necessary standards and implementation specifications and certification criteria to accomplish those recommendations which would include the ability to incorporate amendments or updates that are transmitted from other entities.

We recommend that the technical capabilities be initially kept as simple as possible and then evolve over greater time to—over time to greater complexity including potentially greater standardization and even automation, where that's possible. So, you know, keeping it simple it's—I was reading through the standards, the S&I Framework presentation that we're getting earlier and it's very consistent with their sort of mantra for moving forward, which is the KISS principle and then evolving to greater complexity as the technology is able to support it and you have more widespread adoption of necessary standards.

So those are recommendations and before we move on to discussion and I make sure that Paul has a chance to provide any information that I'm sure I left out, we discussed two other things and specifically did not make recommendations on them and we wanted to explain why. We considered whether we ought to impose a policy requirement for entities who self-discover errors, as opposed to being alerted to an error by a patient, to have to transmit those corrections or amendments or modifications forward to other providers. And our sense was that this was not a place that we needed to go with another specific policy, that providers already, in their ethical and legal obligations to be accurate in their care, would make amendments and transmit them when they are self-discovered, that there was already enough, essentially law and ethical obligation in place, that we didn't need to layer on an additional requirement

that then we'd have to have a lot discussion about exactly what the scope of it would be, how would we apply it, how it would get enforced. We sort of felt like if the technical capability within the system to allow the amendments to be able to be made, and then to be transmitted forward, that providers would use them in their best judgment when they needed to, and then, of course, the patient's right to request an amendment, which is in HIPAA, is of course in place in the patient's—and the technical mechanisms would allow that—would help providers to be able to honor that.

The other issue that came up was whether we would place obligations on Health Information Exchange Organizations, which in the past we've designated as HIOs in order to distinguish between the noun form of the Health Information Exchange versus health information exchange as a verb, which doesn't necessarily occur due to some formal entity. And we began this discussion sort of towards the end of a call admittedly and we didn't feel like we had sufficient information to make a recommendation. We were not sure what the trend was with respect to HIOs in terms of existing policy in this regard. In addition, the plethora of models that are out there today probably suggests that different HIOs would take on different roles with respect to corrections, so that those that provide essentially transmission services from point A to point B, but don't store or hold data in the middle, would have a role of propagating an amendment forward, potentially, but wouldn't have a need to be required to make amendments of their own accord because they're not the data storage, they are an entity that provides a service in the middle, an intermediary, a HISP – we've had multiple terms that we've used in different contexts to refer to those entities.

On the other hand, you do have some Health Information Organizations out there that, in fact, do either persist data in the middle or provide translation services or compile an aggregate record that has been shared with participants, and so there is the potential for an error to be made that is, in fact, the HIO being potentially the source. And what would be the sets of recommendations that would occur in that context. So recognizing that, one, we didn't really have enough information to make a judgment call on that; two, we were dealing with a plethora of models for which we might not have a one size fits all recommendation necessarily, we essentially, in our recommendation letter, asked for input from you, the Policy Committee, and which we can take up at a later time.

So with that I want to turn to Paul and make sure I haven't left anything out or misstated something.

Paul Egerman – Software Entrepreneur

I think it was a great presentation, Deven. I would simply add that this may seem like a somewhat arcane subject, in terms of amendments and corrections, but it's actually really, extremely important if you consider that in stage two meaningful use we're talking about giving patients additional capabilities to view and potentially download their data. One would suspect that there may be, as a result, an increase in patients requesting changes or corrections or amendments, and to use an expression that's also been used a lot by other people is that as we do more and more information exchange, providers may find it necessary to like clean up for company in terms of how their data looks, and so this really goes to issues related to the integrity of the data, and some people say the integrity of the data in a lot of the EHR systems, it's not that it's bad but it isn't as good or as consistent as it needs to be. So this is a very interesting topic. It's a topic I suspect that we will actually be revisiting in the future, because as more and more information exchange occurs people will be more and more interested in this topic. For right now our focus really is simply on the data integrity, to make sure that the HIPAA obligations are met and there is a mechanism to transmit amendments. Our focus has not been on any of the workflow associated with any changes. So those are my comments.

So we're asking for approval of our recommendation and I guess we're also asking for people's reaction to this section called the additional thoughts.

Deven McGraw – Center for Democracy & Technology – Director

Yes, exactly.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

David Lansky?

David Lansky Pacific Business Group on Health

As far as the recommendations, I really admire your simplicity and directness on the issues. From survey work we did in the past there's a lot of evidence that consumers find this of very great importance and great interest, and they actually find one of the greatest values of the PHR or portal, the opportunity to inspect their record for errors. And when they do, they do find lots of errors, so I think it's a really—it's an important opportunity for us to take this step so I support it.

I want to make two comments that are really broader, with our Policy Committee hat on, because I think this is sort of a door opener into a couple of areas we probably should do more work on, and Paul as we think about our strategic planning cycle, that are probably of relevance to ONC more generally. So, one is with general patient safety interest and Partnership for Patients and the National Quality Strategy, there's going to be a number of efforts to improve our detection of patient safety issues and errors and this is a vehicle for that happening. So I'm wondering if ONC should think about a mechanism for tracking improvements in patient safety as a result of improvements in data quality which is triggered by this cycle of work we're now supporting. Because I think we do have an obligation, opportunity, to determine or demonstrate that what we're doing here makes a difference, actually at the end of the day. So if we could tie this to some of the other efforts going on at CMS and elsewhere to stimulate patient safety improvements with some concrete metrics and see that as we monitor the level of discovery of these errors and the improvements in systems to support reliable data, does that translate to reductions in harm, that would be a big win that we should all determine and if so, take some credit for.

The second area is I think this also is a door opener into the consumer-facing applications of EHRs which we have been a little reluctant to get too deep in because it's a little outside of the core statutory program around the EHR incentive program, but our charter as the Policy Committee does give us some latitude to start thinking more about the consumer-facing applications. And so I'm thinking about the usability issues and if simply dumping a whole ton of EHR data on a screen for a patient and saying, "find the errors" is kind of a where's Waldo problem and it may be an opportunity for the vendors to think about consumer-facing displays which lend themselves to discovery of errors because the issues the consumers are most knowledgeable about, let's say symptom self-reports or major events, are easily visualized on the screen and the patient can say, "Oh, that's not how I remember it," "That's not what happened," or "That's not what I reported" and instead of just having it be a formatting display that may be relevant to a provider's care provision but not relevant to the process of determining these kinds of possible errors. So if we believe there's a high incidence of these errors in the record, then we should encourage the industry to make it easy to detect them. And so some kind of—I don't know, it's not really a certification issue but it's a usability issue that, somewhere, I hope we can capture.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Really important comments. Thanks, David.

Neil, did you have your hand up?

Neil Calman – Institute for Family Health – President & Cofounder

Nothing quite as Earth shattering as David, but I support everything David said. But actually I want to make a comment on your number two additional thought issue. You know as I said at one of our committee meetings, I think it's incredibly important that we develop a mechanism for the Health Exchange Organizations to be able to pass on additions and corrections, and an example of that is that in New York City now through NYCLIX, our exchange, we get a notification that a patient's been in the emergency room the night before; you know the x-ray reading is off, and a reading that's been done by a resident that gets re-read by an attending the next day, and it's not infrequent that when those kinds of things happen, or when additional reports come, that the diagnosis can be changed, and that's a setup for a huge error. Somebody accesses the record the night before, says "well there's no fracture" but doesn't know that the thing's been re-read. And so this requires a whole lot of work, I would think, in terms of both our electronic health records, if we're the people reading the x-ray, knowing who's accessed our information so we can update the information to the exchange, and I won't even try to figure out all the workflows involved but I don't think we can pass this over. If people are relying on the information through an exchange they have to be able to know when that information's changed and be notified that it's changed so that they can take the appropriate actions.

Paul Eggerman – Software Entrepreneur

And if I can respond, those are great comments, Neil and you're correct in calling those workflow issues. What we limited ourselves to was simply the data integrity issues to make sure that there's standards and mechanisms to transmit the data and to transmit the amendments. And so what you're talking about is an issue that relates not just to the HIOs but also it relates to the EHR systems where fundamentally the record is dynamic, it always changes, and it particularly changes a lot in situations that you referenced, where you have residents and attendings where there might be additional opportunities for amendments to occur, and so there are some very interesting workflow issues as to who should get notified when that happens, and that was not part of our scope. Because we just didn't view that as a privacy, security, or data integrity issue. But it is a fundamental and interesting issue and probably an issue that needs to be addressed at some point.

Neil Calman – Institute for Family Health – President & Cofounder

Well if it's not the answer to number two where I'm saying yes, then I don't understand how it's different than saying yes to number two. Basically, what I'm suggesting is that there has to be a mechanism for amendments and corrections to be passed through the exchanges, because they're the only ones who really know who's accessed that information and how to pass that information through. So I thought I was answering that question but—

Deven McGraw – Center for Democracy & Technology – Director

Yes. No, I think you are, Neil. So we certainly have, with respect to certified EHR technology--we, you know, the recommendation directly addresses the capability to transmit. But for an entity that sits in the middle that's governed by a business associate agreement that may or may not specify an obligation to move data forward, I think that is one of the issues that we did want to get some feedback on because that would be—to make a policy recommendation along those lines would be something potentially above and beyond where we've gone today and where we have policy already in place that covers it. I mean, essentially, a collection of participants in an HIO could, through that business associate agreement that the HIO has to execute, be required to do the propagation of amendments of updates of changes to the record; but if the business associate agreement is silent in that regard, they don't independently necessarily have that obligation.

M

I had my virtual card up right after Neil's and I think that ... off of Neal's comments I think this recommendation and this subject is an excellent example of the potency of this particular legislation and the meaningful use program. So here's something where you couldn't do this kind of thing on paper, and David Lansky talked about the importance of this for consumers and the integrity of the information from their point of view, and Neil just talked about how important this is for the professional side of the health. And yet the market didn't deliver this functionality in any of the existing EHRs now and this kind of legislation, this kind of program, is helping make this crucial functionality possible. So it's just a really good example where we have the mix of the public and the private sector working to create tools that allow us to deliver better care and to measure that, so really excellent recommendation.

Gayle was next.

Gayle Harrell – Florida – House of Representatives

Yes. And I was going to bring up a lot of the points that Neil did, and I just want to commend you, Neil, for your thoughts and I want to go down a little different aspect of that. I think this is a critical issue that needs to be looked at – whether the Privacy and Security Tiger Team is charged with that or whether it becomes a governance issue of HIOs. There is a huge issue here that has to be addressed. And if we're going to put this off to stage three, you have a large chunk of time that there could be propagation of information that is incorrect going through HIOs that it is not updated with that later reading done by the attending, as opposed to the resident, and you are setting physicians up or providers up for huge liability issues. So you're going to create a lot of fear down at the lower levels on what's going to happen, because once you go to an electronic health record you then have the ability to propagate information to many, many people and it exponentially increases your liability. So I think this is going to be a key issue that I don't know whether, as the chair, you want to charge the Tiger Team to do this or whether this a governance issue that needs to be dealt with on HIOs; it has to be addressed.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Larry?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Thank you. This is really great, bringing us back to, in some ways, something I just assumed was covered, so I want to take challenge to some of the comments that said that existing EHRs don't allow for correction of information. My experience is that they do – they recognize the need to ... that information that's in the chart inaccurately and to preserve the history of what was originally there and when it was changed and the timestamps and the whole deal so that you can see, for just the reasons that's been described, the changes and what was known at different points in time and the possibility that actions were taken based on information that later proved to be either inaccurate or incomplete.

The second thing I want to comment on is this is also not new in regard to the x-ray example. There's a long history of EHRs having to deal with updates to earlier reports, whether it's x-ray reads or lab results, that there's a long history of this. Having said that, I sort of agree with thoughts on actually communicating that better, so it's not just there should someone have a question and look back into the record but actually is more highlighted than that, somehow in the interactions, and builds into the workflow in the same way that a new report might have originally triggered something that maybe these updates also need to trigger something. So I think the workflow actually becomes really important to this being effective.

But mostly I wanted to comment on an assumption that you made about the generalizability of the solution that's provided. So I don't think we can assume that just because someone says check, I

delivered the ability for a patient to get an entry into the chart and for the dispute to be reported, that also allows the organization's self-report or self-discovery to function in the same way. So I'll use this as a mini soapbox for something you've heard from me before. We should really look to enable general capabilities and encourage that what gets implemented supports the general capabilities so in this case, the ability to note something as being an error, to note a dispute about information that's in the chart, and then to be able to transmit that to people who have seen the original. And that the particular players involved, whether it's the patient or self-discovered or some other provider, that we encourage flexibility around the need to support a variety of those and that as we look towards extending meaningful use requirements and certification requirements that we focus on core capabilities with the notion that there's going to be variability in how those happen in the world. And that we not just look at the particular example that's in front of us.

Paul Egerman – Software Entrepreneur

Good comments. I also wanted to elaborate on your comment, Larry, about existing EHR systems because even in the example given of radiology amendments, part of the discussion that we had that was that actually a lot of the specifications for these transactions already describe how you're supposed to transmit amendments but the problems are that they're not like uniformly adhered to. So different systems transmit them in different ways, and that lack of compliance is a problem and will be a problem going forward so basically very good comments.

Deven McGraw – Center for Democracy & Technology – Director

But I think it's also the reason why there's a stage two designation for the amendment piece because there's a recognition from the folks on the Tiger Team with more technical expertise and in the vendor community who said this is doable in stage two, to have some basic certification criteria, even if you start out simple and evolved then into something that's more standardized down the road.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Good topic. We have quite a list. Larry, Marc, Charles, Judy, Eva, and Connie. And so Farzad you come to the top.

Farzad Mostashari – ONC – National Coordinator for Health Information Technology

Just – I want to make a connection between these recommendations and the recommendations of the Standards Committee around metadata. If we have a single source of truth for patients' record, if there were a universal record that could be the source of truth and we could—modifications, all modifications, amendments and adjustments go to the single source of truth and everyone, if they want to know what's going on with a patient then refers to that single source of truth, we wouldn't have this problem. But we don't have that situation. We have the situation where there are multiple representations of the patient's record kept in multiple places and information, we hope, will be more liquid and we'd be constantly bouncing back and forth between those multiple instances and unless we can tag a data element uniquely, and track its providence over time, track changes to that data element over time, every time that information bounces back and forth you're going to have another copy of that information, another duplicate that has to be sorted out – is this a duplicate or is this an amendment of what we had before. And I can just imagine, as the data liquidity really starts to take off, the workflow frustration of having to deal with, like—"I already took—that was a wrong diagnosis that I already took off. And now here it is again!" So it just, I think, underscores the importance on the standards side of being able to uniquely refer to and track an individual data element with the source that it came from, the provenance of that, and tracking it over time, including the modification amendments to that. And I think we are making progress on the metadata and this will be, I think, an important added capability.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Alright, thanks Farzad.

Marc?

Marc Probst – Intermountain Healthcare – CIO

Thank you. And I really appreciate the approach you've taken on this so thank you. And my question, maybe I should know the answer, but it's kind of a scope issue in what health information is, and is it all really in the EHR? How do you scope what can be amended? Is everything really in a single EHR or is it in multiple places?

Deven McGraw – Center for Democracy & Technology – Director

Well this came up a little bit in our discussions, which is why the recommendation refers to certified EHR technology as opposed to *the* EHR in recognition that there are often sort of component parts that are kind of pulled together to make one system. Since our recommendations go to certification, we're really sort of directing at the—making sure that the technical capabilities are part of the system for which taxpayer dollars are being spent. So either a single EHR or modules put together, certified EHR technology is where we're aiming at.

The HIPAA requirements for individuals' right to request an amendment is to a designated record set, which for those of you who don't know, loosely is defined as the information that is used as a basis for treatment, or for payment purposes. So it's part of a legal-medical record system but it's not necessarily all of it. And so since we're not putting additional policy recommendations on the table with respect to what types of data need to be amended when and we're sort of aiming or recommendations at the sweet spot that ONC has the authority has to, control maybe isn't the right word, but has some power, authority and some money on the table in order to influence, so we're looking at the certified EHR technology; whether that sort of encompasses the realm of all places where amendments might need to be made, probably not. But it's a good start.

Marc Probst – Intermountain Healthcare – CIO

So the scope is really the capability to do this?

Deven McGraw – Center for Democracy & Technology – Director

Yes.

Paul Egerman – Software Entrepreneur

And also, Marc, if you look at this we drafted this very narrowly or carefully. It's only amendments that have been previously transmitted. Because even within certified EHR—

Deven McGraw – Center for Democracy & Technology – Director

Well to data that's been previously submitted—

Paul Egerman – Software Entrepreneur

Data, right. Even within certified EHRs there's not technology to transmit everything so it would be amendments that you haven't transmitted so it's a way to ... been transmitted.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay, Charles?

Charles Kennedy – WellPoint – VP for Health IT

My question is a bit of a scope question as well, which is when I practiced we were on paper and so this issue rarely came up, but when it did it tended to come up around mental health, behavioral health, family health types of issues. And I'm wondering did the Tiger Team consider that? Should these recommendations be considered as inclusive of that, or was that out of scope as well?

Deven McGraw – Center for Democracy & Technology – Director

No, we didn't consider it to be out of scope so—I mean I would say we didn't into that into any detail but certainly if you sort of look at the legal—the compliance with HIPAA and the patient's right to request an amendment, it is often in those areas where there are disputes about data. And HIPAA had such a detailed process for accommodating it, that I don't—I really don't think we felt it needed to be added to or augmented in any way. It was really specific. Make the amendment, if you don't make the amendment the patient has a right to have a dispute, appendage the data, and you can do a rebuttal, and then the whole package now becomes sort of part of the data that gets transmitted. We didn't touch amending that in any way; we didn't—we, for reasons discussed earlier in terms of self-discovered errors or amendments or needs to update that are in the ordinary course of business, we felt like the providers already had existing legal and ethical obligations along those lines. All we were aiming at is, does the certified EHR technology have a capability of accommodating that? And that's what we thought to accomplish.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

So Judy, that took care of your question? Okay. Eva?

Eva Powell – National Partnership for Women & Families – Director IT

Thanks, and I'd like to reiterate David's thanks for making this simple. I just have a quick question—

Deven McGraw – Center for Democracy & Technology – Director

Yes, we don't always do that, do we?

Eva Powell – National Partnership for Women & Families – Director IT

I just have a quick question about the comment on the previous slide about the requirement, or not imposing any additional requirements for I don't know, let's see—oh, the current legal and ethical obligations are sufficient for self-discovered data. And certainly don't want to impose unnecessary requirements, but I just started wondering, and this is really a question more than anything as to whether you considered in the case of data that has been transmitted to the patient, either as part of PHR, if there's an automated push of data because the patient's requested that. Because at least, again, this is my limited knowledge of HIPAA, that HIPAA covers only patient requests if I'm correct, and so if the patient's unaware that there was a mistake internally, if the patient isn't the one to find the mistake, then—and there's not a mechanism for correction to that patient who's then receiving that data, I'm just wonder if current legal and ethical obligations are sufficient?

And I ask that because I'm mindful of the fact that those of us in this room are of the understanding that patients having their own information is a good thing. But I know that that is not the case widely speaking and that there's a huge cultural shift that's going to have to occur and that will occur over time, but I guess that feeds into—at least what my view of the ethical obligations might be perceived as being, at least. And so I don't mean to complicate what you've worked so hard to make simple, but it occurs to me that I guess I'm not sure—based on my own knowledge, that we should necessarily trust that those ethical obligations and the legal obligations would cover when the patient isn't the one to find the mistake.

Deven McGraw – Center for Democracy & Technology – Director

We didn't address the issue specifically about making sure the patients are in the communication loop any time there is an error that is discovered; not alerted by the patient but an error that is discovered or an update to information that was previously sent, that wasn't the basis of an error in terms of communicating it to the patient. But we did spend a fair amount of time talking about, is there a need to step in and form and specifically make an obligation on providers - if you see something you have to say something, right? To borrow on a terrorist term. And in what context would that be triggered, right? And the struggle is that rather than policymaking to the lowest common denominator, right, the provider who hides, we chose instead to assume that people generally do the right thing and that when there's an error or an update that really does need to be transmitted, the provider will do so, was the general conclusion that people reached on the committee. Having said that, are there circumstances where that won't happen? Probably, unfortunately. We couldn't figure out a way to scope a requirement that would be within the scope of authority that ONC could enforce to make that right. And ultimately, you know, even given the diversity of opinion for folks who would prefer to have a little bit more clear requirements on people versus those who think that requirements are enough, I think inevitably the difficulty in grappling with what such a requirement would look like and how ONC, given that that's who we pass our recommendations to, would actually enforce such a requirement ultimately erred, had us err on the side of we think what we have is enough for most of the cases, but I appreciate the issue that you've raised.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Thank you. Connie?

Connie Delaney – University of Minnesota School of Nursing – Dean

Thank you, Deven and Paul. I'd like to particularly make a comment related to your comment, Paul, on the engagement of the patient and family in locating errors or inaccuracies in the record and applaud you for supporting the principle of transparency and, in particular, partnership with the patient. And I think this, again, going back to your comment, Paul, provides us with a strong opportunity to acknowledge the consumer input that occurred in April of 2010, and the work of these recommendations reflecting what the consumers were sharing with us at that point, which was consider us a member of the healthcare team and as partners in this agenda. So again I think it's an opportunity, Paul, to reflect on the positive accomplishments of Policy Committee. Thank you.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

And Judy I'll take advantage of the fact that your card is at this second--

Judy Faulkner – Epic Systems – Founder

Listening to this conversation going back and forth, I wanted to expand a little bit on what Deven just said because I thought it was very important. Neil's example of the x-ray; I think it's a really good example of something that clearly needs to be transmitted back, but as there becomes more and more interoperability opportunities where data is coming in for provider from many different sources about the patient who has shown up, I think there is going to be things that are not in x-ray that now has a second reading that is more accurate because it's done by a more senior person, but you're going to have minor inaccuracies, you're going to have incompleteness, and you're going to have things that are no longer relevant. And I think when Deven was saying we couldn't figure out a patch for that, how do you define all that? And if, in fact, we say it has to be everything then when all this data comes in you're going to have, I think, physicians who don't want to read it for fear that they're going to have a legal obligation to correct it. And I just wanted to mention that that was some of our discussion which was a very important discussion behind what we're saying. So you have the really obvious things like you've got to transmit that information about the x-ray. But I think there's going to be a whole lot more not so obvious things

that are incomplete or minor or not relevant that are going to make the whole thing very difficult, so I wanted to elaborate on that.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

And maybe I'll follow that up with another compliment to the workgroup in the sense of, even though it's maybe seem to be a KISS topic, the complexity that was raised in this discussion shows how you can't get it all right. And I think the balance that you've chosen, this additional thought, point one, is a good example of that. In general, people want to do the right thing, whether you're on the provider side or on the patient side. And with the lack of tools that currently exist, you almost can't. And so what you did was say we need to have these tools in place for everyone to do the right thing, at the right moment, and there's just a lot of judgment there. Without being overbearing and over-burdensome and having the concurrent unintended side effect that so many times when we try to do that. So I think it really accomplished a lot with this recommendation and in weighing the various options you had and topics that got raised. So thank you for doing it.

Farzad Mostashari – ONC – National Coordinator for Health Information Technology

The one point that I take away from the conversation though, and particularly points that Larry made, and Paul himself made, is that when we turn this over to the—recommendation is accepted and it's turned over to the Standards Committee, the standards used for being able to do this on the patient correction side should be designed broadly enough and generally enough, simply enough, that they can be reused more broadly for other types of corrections that are also going to be, want to be sent affirmatively according to the legal and ethical obligations of the self-discovered side.

Deven McGraw – Center for Democracy & Technology – Director

Right. Well you know I just took a peek back at how we worded them and you know we would agree based on the conversations in the Tiger Team we were really thinking from a technical capability that it should support compliance with HIPAA and support ability to make amendments for updates that the provider makes or self-discovered errors that get corrected and then potentially need to be transmitted forward. So here in recommendation one it's really the only place where we say in particular to support but it wasn't meant to be mutually exclusive in that regard and we could add a "but not limited to" just to make sure, or just take that phrase out altogether. But it was meant to—both of them are actually more broadly worded than the presentation they had suggested, so.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Any further discussion or comments? Okay, are we—the workgroup is asking us for approval of their recommendations and I entertain a motion to do so.

All

...

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

And second?

All

...

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Any further discussion? And all in favor?

All

Aye.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

And opposed? And abstained? Thank you very much to Deven and Paul and the workgroup.

Okay, now the question is whether—

Judy Sparrow – Office of the National Coordinator – Executive Director

Paul, John Halamka is just leaving a meeting so it'll be about a two minute delay before he can get on the line.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Two minute pause, okay. Just a little filler—

As I mentioned up front, the Standards Committee was created same time as the Policy Committee and we're both of the ... Committees that are advising HHS and Farzad in the office of CMS. It's—in general, we limit ourselves to the policy issues and then as this workgroup presentation illustrated, we pass them off for Standards Committee to work on either identifying or causing some standards to be created that would support the policy or recommendations of this committee. So George Hripcsak and I, for example, have presented to the Standards Committee about the stage two meaningful use recommendations and sought their input and they're working on the some of the standards related to those recommendations and so they're returning the favor, in the sense of trying to bring us up to speed on what's been going on in the Standards Committee and we make reference to them all the time, including this presentation, and it's important that we synchronize and keep up with each other's activities and as you will hear have a long agenda of what they plan to do with the remaining part of this summer.

Has John joined us yet?

Judy Sparrow – Office of the National Coordinator – Executive Director

... do you want—I don't know, do you want to begin?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay, Doug, why don't you go ahead.

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

Okay, so hopefully John will be able to join us shortly. What John and I wanted to try to do today was just to bring people up to speed on all of the activities that are currently going on within the HIT Standards Committee and some of the work that we're doing with regard to standards to both review and update some of the meaningful use criteria, to take a look at the recommendations around meaningful use stage two, and try to translate those into the standards that are needed to support them. In many ways our job is to skate to where the puck is going to be because it takes time to develop and get adoption of standards, and so part of what we've been doing is to try and anticipate where we need to be in some of the standards. Sometimes I think we've gotten it right, and I think sometimes we maybe haven't been quite on track with things, but I think it's an opportunity for us to take a look at the work that's going on here for you folks to ask questions about what we're doing, where we're going and sort of the approach that we're taking with things.

So, the agenda really is to cover three main topics. The first is to take a look at sort of the philosophical approach that we're taking within the HIT Standards Committee in evaluating the standards that are

available for meaningful use and to try to take the current set of meaningful use recommendations and to put them into buckets that allow us to get our hands around where that work needs to go, whether it's in the Standards Committee, whether it's in the S&I framework, and also how to approach it from a certification perspective. Obviously, our goal is to try to serve the policy objectives of the meaningful use criteria, but we also have to make sure that we have the right infrastructure, whether it's a functional certification criteria, whether it's a standard to support that, whether that's an implementation guide to help.

The second thing that we want to cover is some of the HIT summer camp activities. So, last year, we were accused of being the office of no Christmas, but this year it's all about summer camp. And so we'll review some of the activities that we have within the HIT Standards Committee, that stands for summer camp, and the activities that have been going on with regard to metadata, patient matching, ePrescribing, some surveillance implementation guides and the Nationwide Health Information Network.

John Halamka – Harvard Medical School – Chief Information Officer

And Doug, I am on the phone now.

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

Oh great. Good. And then, the last thing that we want to cover is some of the S&I framework initiatives. These were initiatives that were actually started back in December and January in an effort to sort of get ahead of the curve in some of those activities, and those have to do with some work on electronic lab reporting, supporting transitions of care standards, helping to simplify some of the standards we have around the clinical document architecture (CDA) and then some new work on developing standards to help support directories and distributed queries.

So John, I wondered before we launch into the next set of slides, we've just reviewed the agenda, whether you wanted to say any words of opening to the committee.

John Halamka – Harvard Medical School – Chief Information Officer

Well certainly, thank you very much for inviting us, and we absolutely need to work together because policy and technology need to be done in parallel without a waterfall effect of here's a policy, go figure out the technology. Oh, the technology doesn't quite fit here, get us a policy. So, this type of communication and having the Standards Committee and the Policy Committee always in dialogue is really quite important.

One of the challenges in developing standards is that I would say that standards cannot be legislated or regulated. Standards are adopted, and the measure of our success together is how many transactions are flowing. So, as you'll hear from Doug, we are guided by a set of principles that basically would be—I would call them simply as we will select no standard before its time. This is sort of reminiscent of that Orson Welles Wine commercial from the 1970s. We want to select standards that are well understood, are well deployed and are well tested, and if we have a use case or a requirement that is not typically been done in the U.S. before then we better do pilots, and we better make sure it's good enough before we legislate or regulate it. So, as we work together, I think that you'll hear about this notion of bucketing and figuring out what we can do today versus what needs to be piloted today versus what needs to be actually created de novo and recognizing that the standards process doesn't happen overnight. That may very well lead us to not specifying standards in the short term but instead functional criteria, and then as a next step after balloting has occurred and testing has occurred, the standards will arrive.

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

Great. Well, thank you John. So, why don't we dive into some of the activities that have been going on within the Standards Committee? So, back in April, as the HIT Policy Committee was beginning to refine their discussions around what was the policy objectives for stage two meaningful use, we then within the HIT Standards Committee began going through those spreadsheets and the policy objectives trying to identify gaps that we saw potentially within the standards and to try to triage some of the standards work. And in large part, this was the activity that we did in April that set up many of the activities within the standards summer camp working groups.

So, the thing is that within the HIT Standards Committee, there are a series of principles that guide how we go through and identify standards. I think I just want to reiterate what John said is that standards are not standards because we say they are. Standards are standards because people find them useful and they use them. And so, a lot of times, we have to try to take a look at what's out there, what seems to be on the cusp in terms of its readiness for adoption, and many times standards require refinement and iteration. We can't make them perfect in committee, but we want to make them practical in the community. And so, we need to make sure that we've got real world experience before these things sort of are promulgated on a national basis.

So, one of the first principles is that we need to keep it simple. We want to think big in terms of the impact the standards would have but start small, and it's important because there's nothing complicated that ever goes viral. We have to make sure that we have standards that are easy to implement. It makes it easy for us to test them. It makes it easy for people to know that they work. And so, it's important that we have simple standards that can solve a piece of the puzzle and can be part of a larger picture as they grow.

Second, we don't want perfect to be the enemy of good enough. So, we learn a lot through experience. And so, it's important for us to be able to get that 80% sweet spot or to be able to make sure that we get the basics down first before we add all of the embellishments and other features that would be useful. We want to make sure that we keep implementation costs as low as possible because clearly, that's something that's important with regard to meeting our objectives, and certainly, it's important over the long term as we need to maintain standards over time. So, things that have openly developed standards in which the cost of getting those standards and using them is minimal is an important aspect of the standards that are chosen.

We need to make sure that we design for the little guy, so that it's not just the big organizations that can implement but that in fact, that smaller vendors and smaller hospitals can also participate and use those standards effectively, and we recognize too, that people are at different stages in their development and their sophistication with regard to interoperability. And so, we don't want to create a single standard that is one size fits all, but we need to make sure that for a particular purpose, and there's lots of purposes for which information exchange can occur, we want to make sure that we have things that are simple to help support simple use cases, and as they get more complicated, can grow and build from that, but not necessarily say, here's the standard that will take absolutely every possible use case when 80% of the time, it might be used for just simple things.

We wanted to make sure as well that we created building blocks because we don't want everything to be so tightly linked that we can't move as our knowledge about healthcare delivery and the way in which healthcare is documented changes. So, we wanted to make sure that we separated content standards from transmission standards so that we would have flexibility to use different ways to send information around but maybe have the ability to sort of standardize the content, so there might be a transitions of care document or there might be a clinical summary document, but that isn't so tightly linked to the way in

which you transmit it that you don't have flexibility to respond to new kinds of technology and new kinds of function.

We wanted to make sure that we create publicly available controlled vocabularies and code sets because if we want to get to the point where we can improve patient safety by having clinical decision support based on incoming information, that information when it comes in can't be in free text. It has to be in a format that allows computers to be able to manipulate it and to be able to identify when a drug interaction might occur or when there might be a new problem that needs to be addressed.

We wanted to leverage the web whenever possible and use what's out there. I don't think we wanted to develop sort of our own separate set of standards for transports or separate network, if you will, for exchanging health information, but to leverage in a secure way the things that were out there already, the notion of using this health internet or being able to leverage the features of the internet to support information exchange.

We wanted to make sure that we position quality measures so that they will encourage adoption of standards so that we link the data that gets transmitted and the data that we standardize with quality measures that we want to support, so that people aren't transmitting data on one side and at the other side using different ways of calculating their quality measures, making sure that the way in which we collect and exchange information, making that linked to the quality measures that we care about, make sure that the data is consistent across both of those areas.

And we wanted to create implementation guides. These are the recipes that technology folks use to build the systems. We wanted them to be human readable and have examples and testing tools so that when people are faced with an interoperability challenge, they have the tools that they need and the resources that they need to implement those things effectively and to do it so that we actually have everybody do it the same way and achieve that goal of interoperability.

So, one of the things that we wanted to do is as we were preparing for meaningful use stage two, we wanted to look at any revisions that might be necessary to adopt a certification criteria and learn from the experience that people have had in achieving certification of the electronic health records to see if there are things that we need to improve that will help align those with the policy objectives. So, there's been some things that we've identified. For example, some of the vocabularies or the drugs that are used with physician order entry, for example, we want to make sure that those drugs and those formularies are ones that are currently in use and that people have in their systems and not make certification a one-off essentially from the ongoing work. And we wanted to analyze the meaningful use working group draft recommendations. And so, we have spent some time over the course of the last couple of months identifying and looking at where we might need new certification criteria, and we've begun the work of trying to identify what the work of the HIT Standards Committee needs to be over the course of the next couple of months.

So, we have this notion of four buckets that we want to put information into. And so, this was our way of triaging the recommendations that were coming from the HIT Policy Committee. So, on the first bucket, there may be a performance measure that we want in which there are no standards that are needed because it's a function that we'd like to see as part of the EHR but it isn't something that is transmitting or requiring information to be exchanged between EHRs. We need to have good certification criteria there, but we may not necessarily need to identify a standard for how things are represented internally as long as that functionality exists.

Bucket B was to say that we think there are sufficient standards and implementation guides out there that we can either identify or that we've already identified as part of meaningful use stage one, and so, going into meaningful use stage two, we just need to make sure that they're still applicable and that there's no update that might be required.

Bucket C and D is where all the action occurs. In C is that there's existing standards perhaps but no implementation guide is there, so there's a standard, but it isn't really sort of pinned down to the level that gives us enough specificity to assure interoperability or to ensure information exchange or that there are existing standards and implementation guides but they're not out there being used. Perhaps we need more work or pilots or more implementation because there's a good standard. It's got an implementation guide, but at this point, nobody's really using it, and I think we have to ask ourselves the question why is that the case. Is it because there are no business drivers? Is it because there's something about this standard and implementation guide that prevents people from seeing the value of using those particular standards?

And then, I think the fourth bucket is the situation in which we don't have a standard there. There may not be an implementation guide or that there is existing standards that really aren't ready for primetime, that we just need a lot of additional work there, and we need some lead time to be able to get us to where we want to go.

So, we've gone through at least a preliminary set of recommendations. Some of this is a little out of date because you guys have continued to move forward, and as you know, we're trying to skate to where that puck is going to be. And so, when we take a look at the things that fit into Bucket A, things like CPOE, the entry process is really a functional criteria, we don't identify how that is internally represented, interaction checking, recording demographics, that's an entry process. Now, we may need to make sure that we've got the right value sets if we want to get the ability to pull that data, but things like being able to maintain a problem list, medication, allergy list. Maintaining it is not something that requires standards but perhaps transmitting it is something that would. Things like being able to represent a CDS rule, a clinical decision support rule, recording advanced directives, generating patient lists, these are all things that are important with regard to making sure we've got good certification criteria so that people have that functionality and can meet meaningful use, but the underlying standards, if we're not exchanging that information or if we're not requiring people to say share a CDS rule or being able to share in a standardized way patient educational materials, we may not need to identify a standard or an implementation guide around them.

In Bucket B, we've got some things in which we think there are some sufficient standards and implementation guides, so things like recording demographics. Again, we talked about that as being the certification criteria, but we believe that there are value sets from the IOM that we can use from that and propose those as standards. Reporting the CQM electronically, we've got a standard PQRS that allows us to do that, and there's an implementation guide that supports that as well. With drug formulary check there, NCPDP has some eligibility and benefit standards that we think that we can draw upon. There are other standards regarding immunization data and submitting electronic lab reporting that are out there. In some sense, the electronic lab reporting is an activity that maybe isn't in Bucket B but in C. We've been spending some time in the standards and interoperability framework to try to harmonize an ambulatory laboratory implementation guide that we think will make it easier and more standardized to have those standards used both in ambulatory and in EHR systems.

Bucket C is an area where we need to have some additional work, and we have started some of that work over this summer, so things like incorporating laboratory results. We need to make sure that we pin down the vocabularies and the terminologies that we're going to use for that. And so, we've been working on

developing a strategy around vocabularies and terminologies, that interoperability piece, that we hope will help make it easier for providers and for vendors to use certified technology. So, the LOINC set of vocabularies is big. There's a lot of different laboratory tests that can be ordered, but most physicians will use only a very small subset of that most of the time, and if we sort of apply an 80/20 rule to say what are the things that we think are going to give us the most value, one of the things we can do in our implementation guides, we can say here's the subset of vocabularies that we think you should use, and we want to make sure your systems cannot only generate those but don't break if we send you something that's outside of that laboratory set. And that gives us the ability not only to provide that value, that 80/20, but make sure that we future proof it. If there's a new test that comes out in terms of H1N1 flu surveillance and that test becomes important for the CDC, having systems that don't break when they get something new they haven't seen is also an important part of our approach to certification.

Providing electronic copies of patient information; we've developed and have been working very, very hard with the standards community and the standards interoperability framework to develop standards around physicians of care that leverage the clinical document architecture, that's the HL7 standards, as well as something called the greenCDA, which is a simpler way of sending that information around. And so, we're working on trying to get the vocabularies, the terminologies that we need, the way in which the package that gets transmitted looks like, that's the transitions of care, as well as trying to pin down the transport standards as well for how that would be exchanged.

And so, that's a key focus that we actually have started back in February, again, trying to skate to where the puck is going to be. Provider summaries on transitions of care, we've got, again, activity along those lines, and care plans which was one of the other things that showed up in the meaningful use stage two. There's a working group within the transitions of care group that's looking at that. It may be something that we can get by meaningful use, but it could be a Bucket D in which we need to do some additional work and pilots to get a look at.

Syndromic surveillance, we had an implementation guide that was in the initial regulations that the CDC is updated, and we've got a working group working on that as well. And the privacy and security assessments, we are continuing to track very closely with the Tiger Team to make sure that the standards and the certification criteria match to those things as well.

With regard to Bucket D, we may need to think about if what we are going to do is have CPOE and the ability to send orders, like laboratory and radiology. Clearly, that's a high priority, but we would have to take a look at some of the HL7 V2 message standards and perhaps devote some additional work into that to make sure that we've got those standards that would work. Many of the HL7 messages have been implemented within an enterprise, but the ability to standardize across enterprises is the challenge that we often times have particularly in the Version 2 messages around HL7. And we've got a whole host of things that need a lot of additional work. So for example, transport standards for laboratory or transitions of care, we've been looking at within the Nationwide Health Information Network Power Team at modular specifications that look at both direct as well as the web services based approaches that the current Nationwide Health Information Network uses.

We also have been looking at some of the additional pieces that we need to enable exchange. So, when we exchange information, we want to make sure that it's secure. That means that we need to have ways of encrypting that information and verifying that it goes to the right person and it's coming from the right person.

We're trying to take a look at activities around web portals and timely access and that may include personally controlled health records, and so, the transitions of care activities, trying to make sure that

those things map into that. Currently, we've got tests for health information exchange, and we need to make sure that right now, people have to demonstrate that they have attempted to do that, but if they fail, it still counts. And so, we need to get to the point where we have sufficient standards that not only can they demonstrate that they can do it but they can succeed in that as well.

And then, a whole host of activities that has had significant input from the Privacy and Security Tiger Teams around directories, what's the right approach to use with that, and again, we've got activities both within the HIT Standards Committee as well as within the standards and interoperability framework. So, we have a whole host of things that are on the plate for the Standards Committee. This includes trying to figure out what are the features that we need for clinical decision support, whether this is a functional criteria or in fact, whether we want to begin standardizing that. Clearly, if we want to have clinical decision support that is triggered off of data that is received or transmitted, then we have to start thinking about interoperability between the standards that we use for the information that's exchanged and the standards that we may need to use for how clinical decision support rules are implemented or at least be able to demonstrate that functionality.

EMRs, attributes for certification, this is something that may require a significant amount of work. And so, we're just exploring that right now within the committee and the ability to sort of view and download information. Clearly, we have activities within the Blue Button initiative that the VA has taken a lot of leadership there and whether those things can be also connected with some of the standards for how that information is viewed or standardized, I think that becomes important.

Summary of care, records; we're trying to take a look at that in the setting of our transitions of care projects as well. And then, there's a whole host of other things, timely electronic access, hospital labs, making sure that we've got structured electronic lab results where possible and that's something we've been working on with the electronic lab reporting initiative, making sure that we've gotten public health objectives, and we've got a working group that we'll talk about a little bit later with that as well, and then demographics as well including an expansion of the fields that exist within the demographics and seeing if we can leverage existing standards that are out there.

Privacy and security remain a critical component of the work that we've got going on and so, getting guidance, understanding single factor authentication, audit trails, how do we provide for data provenance, we've been looking at metadata as a way of providing data provenance and have gone through a series of work on that, and we've got some things that are coming up we've been looking at with regards to stage three. So, how to record family history, patient generated data submitted to public health agencies, adding new field again for the demographics, retrieving adverse drug events from the EHR and mechanisms for patient entered data.

The challenge that we have of course is that it takes some time not only to identify what standards are out there and get some good field guidance as to what works and what doesn't but if there isn't something that's out there, it takes us at least 18 months or so to be able to get a standard even if there's a standard existing, it has to get into an EHR. It needs to be tested. There's a whole sort of technology lead time that we need. The things that we've done with the direct project, having an existing standard and applying it in healthcare took nearly a year. That was lightning speed though from the point of not really having anybody thinking about that to actually getting adoption. And at the end of the day, it is about adoption. It's about getting people to use it. And so, we do better to focus on that and let the market essentially have a pull towards the standards than for us to push them and find out that they don't quite meet our needs.

The CDA consolidation project is a standards effort, typically it takes 18-24 months. We were able to actually do that in about six months, working very, very hard with HL7 in the S&I framework. And so, there are things that we're doing to try to accelerate but it's been a challenge, and I think we have sort of set up a set of activities that are going on over the summer.

I don't know, John, if you want to sort of take it from here because the timeline that we have for the HIT summer camp to review some of the standards and kind of where we are is an area that you've been working very, very diligently on and been shepherding a whole host of different committees together as they take a look at these things.

John Halamka – Harvard Medical School – Chief Information Officer

Right. I'm happy to take over. Thanks, Doug. As you look at the summer, we have been quite aggressive to the timeframes that Doug described, moving much faster than normally would be moved in a standards development organization or implementation guide selection activity. So, starting off in April and kicking off our activities looking at certificate recommendations so that if we're going to do transport from point A to point B, we can be assured of who is the sender, who is the recipient and that the data is not modified or intercepted along the way.

And then in May, we began to ask questions such as how do you uniquely identify patients. How do you ensure that the sender identification, the provenance of the data is identified? How do you ensure that there are privacy flags? We started to look at additional standards that we knew would be required for stage two such as ePrescribing of hospital discharge medications.

In June, we've been focusing on a variety of provider directory issues and patient matching strategies. I'll give you some more details in a moment.

In July, just two weeks from now, we'll be looking at syndromic surveillance and quality measures.

In August, the simple lab results that Doug already mentioned, the followup from the S&I framework activities on transitions of care, the CDA cleanup, multiple implementation guides by multiple organizations hits the IHE, HL7. How do you make sure we have one implementation guide that can be used by vendors and hospitals and eligible professionals and how do we start thinking about the Nationwide Health Information Network?

So, let's go to the next slide with the update on our summer camp, and you can see some of the five focuses that we have over the course of the summer really moving the industry forward by trying to select those standards and implementation guides which are mature and good enough and can be incorporated into the NPRM and then the final regulation.

Let's go to the next slide and talk about metadata. So as folks remember, the PCAST, the President's Council of Science and Technology advisors, produced a report on healthcare IT and accelerating the work that is being done to ensure healthcare information exchange for a variety of purposes, clinical care, public health and population health, patient engagement, clinical trials and research, and what it hypothesized is that we needed a universal exchange language regardless of whether we're sending a lab, an administrative transaction or a pharmacy transaction, create an envelope that would help us transport that package securely from point A to point B including who is the patient, what is the provenance of the data, who generate, who's sending it and you might need, based on regulations that could exist or policies that exist in a state or institution, some flags to say the package inside this envelope has particularly sensitive information and additional processing or consents may be required.

So, we had many, many calls and meetings and much testimony and ended up selecting some very simple XML constructs to identify patient demographics in an envelope to identify who is the sender including a certificate that would tell you yes this is actually a cryptographic proof of who's sending and the capacity if necessary to use privacy flags although most messages won't need privacy flags because the patient has consented to disclose. The simple transaction is between two providers with the patient standing there, but you could imagine some kinds of use cases where there are multiple queries to multiple institutions where a privacy flag for special handling could be required and CDA R2, some simple XML, has been selected and recommended for that.

So, Patient Matching Power Team, next slide, the challenge is this: We don't have a national healthcare identifier, we're not likely to have a national healthcare identifier anytime soon, so how, when we are looking at data for either care coordination or patient ... or population health, do we match the data to the right patient? And so, we have looked at a number of studies that have been done by RAND and others, looking at sensitivity and specificity. So, an example for you, it is conceivably better that if I, John, Halamka, show up at an emergency department and a query is done to multiple sites of care and my name is horribly misspelled and my birth date is completely mis-entered, that data about me may be returned in an incomplete fashion. That is the name, gender, date of birth match is not precise such that every single byte of data that exists in the community is returned perfectly. It is bad. It, in fact, is unacceptable to have the data on the wrong patient returned.

So, hence we would prefer the notion that specificity, getting the right patient's data even if it's possibly incomplete is more important than getting the wrong patient's data intermixed. And so, in order to do that, you'll look at the data elements that you'd like, certainly name, gender, date of birth are required, but then you can get much better specificity by doing such things as zip code, last four of social security number, middle name, maiden name, healthcare provider, other numeric information that would be such things as maybe a payer number. These are the sorts of things we can use for specificity, so we are looking through all of the experience and many papers to date and will determine not specifically the algorithm that must be used but at least the data elements that should be used to achieve specificity.

So the next slide, ePrescribing Power Team, we have great ePrescribing in the United States, typically from ambulatory sites, but there's not a huge amount of ePrescribing that has been included in the regulations for hospital discharge medications recognizing hospital discharge medications may be filled by pharmacies inside a hospital organization. It's a different standard set, a different workflow. So, we're looking at where you can use the ambulatory standards and CPDP and where HL7, more of an inpatient standard going from a hospital to hospital-based pharmacy, may be appropriate.

And then, syndromic surveillance. If folks remember when the initial regs were created, included in those initial regs was the incorrect implementation guide for syndromic surveillance. It actually had it as ease reporting implementation guides, so ONC worked to create a new regulation saying actually for syndromic surveillance, there isn't an implementation guide yet. So, we are now cleaning that up and specifying the precise implementation guide. I know one of the challenges you have given us is to say can we achieve one implementation guide for the three-domain syndromic surveillance, immunization and reportable lab. These are three very different domains, but if one implementation guide describing three domains with HL7 251 is something, it is reasonable to do.

So finally, next slide on the Nw-HIN Power Team, we recognize that standards for vocabulary and content are critically important but also the transport. I've mentioned many times the getting it from point A to point B securely. There are queries response types of transactions. There are notions of email push kinds of transactions, many different approaches. So, the Nw-HIN Power Team is looking at all the ways in which transport might occur, and I think to use Doug's term, create building blocks to say if you need to

push, if you need to pull, if you want to use secure email, if you want to use more web friendly, here are building blocks one could assemble to ensure that data is not modified or intercepted as it goes in many different kinds of architectures from place to place, and there will, by September, be a similar set of recommendations for those building blocks.

Now, I recognize that all of the summer camp activity doesn't include everything you have asked for, many major items, but in parallel, is the S&I framework initiatives which Doug is leading, and Doug, why don't I turn it over to you to describe some of those?

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

Sure. Thanks, John. So, if you think about the various committees and groups that are working on different parts of solving this problem. The HIT Policy Committee helps us to sort of set the policy objectives and what we want to achieve with meaningful use and much of the work that's going on in the HIT Standards Committee is to take a look at if there are existing standards which is the one to choose and how is the approach that we need to go forward, but the HIT Standards Committee isn't going to necessarily have the ability to actually get the work done if we wanted to run a pilot or if we wanted to test out an assumption. And so, the standards and interoperability framework was sort of set up as a way of taking what we did in direct and beginning to apply that approach across some of the other standards that we felt needed to be refined or identified or developed.

In many ways, we try to set up, and we aren't always as successful as we'd like, but we'd like to set the S&I framework up as a do-ocracy, so that if you do things, you move up. And so, rather than having people talk about, well this is better than this or my standard is better than your standard, the idea is, is that the S&I framework gives people an opportunity to demonstrate that they can provide a clear implementation guide that's simple, that they can have working codes that supports the need and that people will actually take a look at it and use it.

So, one of the things, and this is sort of a continuation of the work that's going on within the Nw-HIN Power Team is that we're trying to take a look at the standards that are out there, and we don't quite have this completely fleshed out, but I'll at least begin to share some of our preliminary thoughts, and that is, is that when we think about standards, a lot of people say well you know we have a standard, it's been out there for the last six years, it is mature, we know that people have worked on it. It's balloted. It's been approved, and then you ask the question well how many people use it and then there's sort of this kind of well, we're using it and a lot of people say that, but it becomes hard to get to the bottom of a mature standard that's actually out there and being used.

Now, there are other things that are out there that people have sort of adopted and they're using, but it may not have that standards review behind it. And so, right now within the Nw-HIN Power Team, we're trying to take a look at the different ... for which we think are important. If we've got something that is highly mature and very adoptable, that's something that may in fact be ready as a national standard, but there are some things that are not quite as mature or they may be mature but not highly adopted yet. And so, we're trying to create both criteria and buckets that we can put these standards into. And so, if what we wanted to do is take a look at the existing Nw-HIN standards and specifications, the existing things that are out there, we're trying to identify those things that everybody is using that have a high adoption rate, those things that need some work and the thing that's nice about the grid is that if we've got something that has high maturity but low adoption, we know where we need to put our energy, which is get the standard out there, test it, pilot it, make sure that it actually works in the real world.

If we've got things that have high adoptability, maybe they're simple to use or the like but they don't necessarily have the maturity of the standards, then what we need to do is we need to focus our energies

within the standards development organization and make sure that those things that seem to be working actually have the broad input that standards development organizations get so that we create something that is not just specific to a particular highly adopted situation but actually has all the other pieces that we need with it with regard to the standard.

Now, one of the things that people asked for was an update on the direct project. And so, I have a couple of slides in here about the Direct Project. So, we took guidance from the HIT Policy Committee about a year and a half ago to kind of create and expand a way in which the specifications within the Nationwide Health Information Network could exchange information and to create a simple, directed specification that would allow exchange between known parties in a secure way. We announced the project in March of 2010. We kicked off in late March and early April, and within 90 days, we had our initial set of specifications in a working proof of concept. Ninety days later, we had some working reference implementations, and about ten months after that first initial kickoff, we had the exchange of vaccination and immunization information in Minnesota between an EHR and the public health reporting. We have been working very closely within the HIT Policy Committee to provide sort of the policy bumpers that allow us to work out some of the technology issues but do it in a sandbox that allows us to understand the technical limitations or understand the technical challenges and do it in a way that is still going to be safe for the information. So, some of the things that have come out of that, the Direct Project allows for the exchange, and I think that's a typo without exposing PHI to intermediaries. That's an important typo. Deven, you didn't catch that. Do you have it circled? Sorry about that. Provide high assurance that only receivers or delegates can access that PHI so that there's a way of encrypting the attachment that gets sent, provide that we have high assurance for organizational identity and allows for universal addressing and transport that enables any sender to send to any receiver and that is simple to implement and adopt. And so, again, following those principles that we had within the HIT Standards Committee. I think right now as part of the Nw-HIN Power Team, we're taking a look at the Direct Project and those specifications and seeing if we can include that as part of those specifications that are part of a Nationwide Health Information Network.

Now, back in December, we did a survey and we had some discussions within the HIT Standards Committee to try to get ahead of the game, anticipating what we thought were going to be important things coming up down the road. The pilot experience within the direct, we've found that we believe that the Direct Project will support predominantly transitions of care and consumer engagement. And so, one of the things that I think is going to be really important is that if we take the building blocks around certificates that ensure that it's encrypted and it's safe, we pair that with things like direct for moving it around in a standardized way, and we take standardized things like transitions of care as the package with a subset of vocabularies, that 80/20 rule, we have all the pieces that we need to have interoperability. We have a way of securing the information, moving the information, standardizing what the package looks like and making sure that the vocabularies and terminologies are also standardized as well. And we think that to help support transitions of care to support consumer engagement, to support public health reporting and electronic lab results is an important first step, and it's an important part of those building blocks that we think will help support information exchange and interoperability.

We have a whole series of initiatives that are going on as well within this. So, we've talked about the transitions of care. We started that in February. We also started the Laboratory Results Interface Project. We've just recently begun some early work on provider directories and digital certificate interoperability, and we've got some other activities that are kind of in the pipeline around helping to support the attachments of standardized information to CMS to provide documentation for billing transactions and some activities around record segmentation, distributed query or query health and a whole series of other things that are in the pipeline as well.

So, to dive down a little bit in terms of some of those initiatives, one of the initiatives is the Transitions of Care Project. We've talked a little bit about that. We anticipate that we will have a draft of what these transitions of care standards should look like in July. The idea here is that if you think about a standard mortgage contract, you've got a standard mortgage contract that everybody uses but you check the box to say we're going to do a rent back or we're going to include this is the terms of our loan or we're going to waive our inspection, it's got these modules that you would include if it's relevant to the transaction that you have. So, the transitions of care is trying to identify a whole host of what those modules would be and identify that as a standard, and then create implementation guides that say if you're sending the information from an electronic health record in an emergency room to the primary care provider, these are the pieces that are going to be critical to include. And if you're sending it as a consult between two providers, there may be other building blocks that you want to include, but that provides a lot of flexibility as well as standardization among those modules to help support transitions of care.

The laboratory results interface was an effort to bring together two different implementation guides around the same standard. There was an HL7 standard that had a highly constrained implementation guide for ambulatory care and a much broader general purpose standard that was an implementation guide that was more challenging to implement and probably needed to be refined to give to implementation to get the interoperability. And so, that particular project, again, is on track in July to have some initial recommendations, and again, right now in both of these projects, both transitions of care and laboratory interfaces, we're at the phase where we're really trying to identify pilots either within our states or beacons as well as among the vendors that are participating to make sure that we've tested the kinds of things that we think are appropriate moving forward.

Certificate interoperability is sort of a highly technical piece, but it's important because what we want is we want to make sure that we have the right attributes of that little digital representation of your identity. We have the right attributes that will allow us to exchange information. And the HIT Standards Committee has provided some recommendations about what we need for digital certificates both as it applies to the Nationwide Health Information Network as well as the Direct Project and the certificates that are used there and has provided some detailed technical recommendations with regard to what those features should be around digital certificates including making sure that it's cross certified with the federal bridge and that we collaborate with certificate authorities, those folks that are actually giving out those certificates so that we've got the appropriate level of assurance that the person who's exchanging the information or the organization is who they say they are.

We also have some work with the provider directories, and we've got sort of two areas here that I think are important. One area is that to be able to send directed exchanges or to be able to identify and secure that message, you have to find the digital certificate that's appropriate to use. And without sort of going into all of the details of what's involved with that, suffice it to say that if I want to send something to you, I need to find out what your certificate is so that I can be assured you're the only person who can open up that envelope. And so, certificate discovery or finding out where that certificate is an important part of having that secure exchange. And so, right now we're looking at the ways in which we can do that leveraging both internet technologies as well as some standards that are mature but not at this point adopted and figuring out how best we can support exchange now that provides certificate and encryption and build toward the future that may have a more robust ecosystem for that.

The second thing that I think is important as well is we have to make sure that we've got some way of getting electronic addresses or finding out where to send stuff or where to locate information; still trying to figure that out. One of the challenges we have is we have a lot of states that are currently in the process of implementing directory services, but I'm not sure that we've got that adoption yet that fits our principles. And so, trying to find the path of least regret among those standards so we know that there's going to be

certain things that need to be represented even if we're not sure about what the underlying technology should be, but we know we may need to have an email address or a certificate or some other kind of feature than being able to identify those that allows people to get started in creating directories testing them and then building towards that future that we may have more robust and federated ways of making sure those directories all work together.

So, I'm not going to go to lunch yet because I'm sure you probably have some questions. John, who is my counterpart here as well, did you have anything that you wanted to add or expand on?

John Halamka – Harvard Medical School – Chief Information Officer

Well, I think you summarized it very well, and hopefully you've seen there are a lot of moving parts, everybody moving as quickly as possible and trying to take into account your guidance, the PCAST report, what we're seeing as gaps from implementations in stage one, trying to bring clarity to constrain implementation guides and try to achieve interoperability that's as close to plug and play. It's a lot of work, and I would just describe it as, it's a journey. I'm not convinced that standards making will ever be done but year to year we will see a trajectory that gets us better and better.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

I want to thank both Doug and John for tremendous work. I'm not sure if it's summer camp, sounds more like a boot camp to me. It really is a lot of work. You pointed out how you're condensing things that take 18 months to years into 6 months or a year. It's tremendous, but I think that's what we need in order to execute on the national quality strategy and achieve health reform, so it's really wonderful work.

I do want to ask about some of the classification, you had your four buckets, and let me pick a couple examples to drill down on. What do you think the scope of your area of expertise and responsibilities are for these? So, drug/drug interaction, you listed as in Bucket A, which is considered a performance based measure, when we asked you to take a look at this area, here is what was behind that request. Drug/drug interactions; one, it's a no brainer in a sense of it's an important concept, an important topic, an important area where medication errors and medication harms arise, but one of the issues is even though the functionality exists in all of the EHRs, the high false positive rate make it close to useless in many cases. In other words, we need much better positive predictive value that the alert that's before us is something that most people will act upon most of the time, and that's not the current state of affairs. So, the standard that we were interested in is how can we raise the true positive rate of these drug-drug interaction alerts so that many more of them are believable or are appropriate for the individual patient and would be acted upon. Is that something that the standards committee would be taking up and how do you see your role in that kind of an issue?

John Halamka – Harvard Medical School – Chief Information Officer

So Doug, let me just start with one comment. So Paul, one of the things you want is to ensure that the medications are described using a consistent vocabulary and that not only the medication as its specific chemical but a category of medication so that when rules are written, you have unambiguous data in which to fire a rule. So, certainly as I think of the Standards Committee's work on vocabularies, we will ensure that we have RX norm, that we have NDFRT, that we have the standards that are necessary to categorize medications so when rules are written, they will work as well as they can. Now, Doug, maybe you would comment. I have not seen our role as to actually write those rules, conceivably there could be functional requirements, attributions or the nature of a rule being evidence based and credible, but that's really more of a certification criteria than it is a standard.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

I see how far you took the standards along, proper identification, standard identification of chemicals and drugs and classifications, the next standard are ways of representing these interactions so that we can stratify them in usefulness in a sense and effectiveness in the clinical practice, and it's not the traditional standards. I'm just partly asking where would this kind of work reside? So, the vendors and the provider organizations would like to have some industry standard that says here's a list of drug interactions that are important and prevalent enough that they should fire alerts versus here's the 80% that really don't meet that criteria. Maybe that's falling in between the cracks between our different groups.

John Halamka – Harvard Medical School – Chief Information Officer

And so for example at Beth Israel Deaconess, the rules that we have written typically are around the, what I'll call, FDA black box warning. If you give this medication in combination with another medication, significant harm to the patient will occur as opposed to the, oh there's a one in 10,000 chance that these two medications are taken with grapefruit juice that some minor symptom will occur, and so we've tended to use that black box designation as the rule that really will get the physicians attention. And Doug, are you familiar with any other industry classifications of the, what I call, the severity of rules?

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

Well, the thing about standards is there are so many to choose from. Obviously, RxNorm is a good way of describing. It's a vocabulary that tells you what the drug is, but taxonomies that kind of organize the drugs that says this is an SSRI or this is a cholesterol lowering agent or the like, there's still not consistency, a lot of different drug formularies and a lot of different ways of classifying medications. Sometimes you've got a drug that's got combination of medications in it as well. And so, how do you classify that? There's a whole host of those sorts of challenges. We do not at this point have a top 10 or top 100 drug/drug interactions that need to be tested or identified. We haven't identified that particular subset.

I think part of the challenge that we have is, and I think there are others that I think John can probably comment on this as well, is that oftentimes to get the kind of performance, Paul, that you suggest requires a nuanced approach that specific to the locale and the way in which the data is collected, the data that you have available to you, the kind of common drugs that are out there, and so, I know people often times will modify or tweak the alerts so that they get the right performance characteristics. There's always a risk that if we standardize, we actually can make the problem worse in addition to making it better depending on where we go, and so it's important to standardize the right things. Clearly, I think the work that we're doing in collaboration with the National Library of Medicine around the vocabularies and the subsets, one hopes that if we can identify what are the key vocabularies and subsets to move forward, we can use those for certification, we can constrain the problem that we hope people will build tools to and make it easier. I think that's going to be helpful.

I think the other thing is that ... and some of the work that Chuck Friedman and the Office of the Chief Scientist have been doing with regard to the SHARP grants has some of the decision support activities associated with it as well, and I think there is a tremendous amount of activity going on with EHR too to try to create a more standardized way of representing and using clinical decision support, but there's not a standard just yet. It's probably one of those things that fits into a D bucket if you will, but how we can move that up may be by creating functional characteristics and certification criteria that achieve those policy objectives now and build the building blocks like the vocabularies and terminologies, I think is a way of getting to that drug/drug interaction and patient safety issue that's so important.

John Halamka – Harvard Medical School – Chief Information Officer

And Doug, you wonder is there an opportunity for us to evolve what I'll call a best practice set. One of the things that we've worked on on our vocabulary task force is to say, here's a set of the 98% most likely ordered labs and a compendium of LOINC codes. If the Brigham and the Beth Israel Deaconess have each developed what they consider 200 really good actionable rules, maybe it doesn't make sense to ... for every hospital to do it that we all just pool together and create a downloadable set of those rules that we are going to make available free of charge for folks to incorporate into their systems as a reasonable starter set.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay, thank you. I have on the list Eva, Deven, David, Charles, and Judy. Eva?

Eva Powell – National Partnership for Women & Families – Director IT

Thanks for your work and as a member of the Quality Measures Standards Workgroup and also a transition, I've been listening in on the transitions of care calls, I know there's a lot of great work that you're doing. My question is how can the policy committee help you guys skate to the puck. What I think about when I hear you talk, is how very important all of this work is when it comes to care coordination and care planning and the quality measures of the future and meeting the national quality strategy, because as you've said, we need specificity but there's also a time element involved, and I feel like the Policy Committee has done a lot of good visioning, but all of us have been constrained by the timelines associated with meaningful use.

And so, as such we've all been somewhat behind the eight ball, and so I'm just wondering if there, particularly in these areas of care coordination and care planning, which is a pretty significant departure from the system that we have today, which is what we're having to deal with in the midst of all of this planning as well, if this is an opportunity really for the Policy Committee for the purpose of providing you all with some helpful direction to have as part of our strategic planning a more visionary process focused on these areas that are radical departures from the system of today? And David mentioned something earlier about that. Would that be helpful to you all and would that be something that would help you not necessarily have to skate to the puck but you would know what that puck looks like?

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

I'll say a few words but then I'll let John comment as well. I think the challenge that we have, and I think the thing that is helpful is the industry and those folks out there in the Standards Committee, the standards development community and those that are out there trying to implement these solutions, need as much lead time as possible to be able to get it right. The risk we have is creating a policy objective in which we have a six to nine month timeframe means that we aren't going to be able to generate a new standard if that's what's required. We can maybe dust off an old one, but those kinds of transformational changes just take time, and I think the industry needs to have clarity about where it is that we're going and sufficient lead time that they can try to figure out how to get there as well. And so, I think we can have laudable policy goals but if we don't have the technology to operationalize that in a way that I think meets those objectives, then we have to think about well how can we create something that starts to set the direction that we want to go, maybe provide some incremental steps along the way to get us there.

I think that's something that's really helpful is to have sort of a clear, here is one or two really transformational things that we would like to see happen, and this is what our target is and meaningful use stage two perhaps is a path along that way just sort of to make sure that we're on the right track but that we want a fundamental change. I think it's one of those things. I've used this analogy before. Sometimes I feel like I'm strapped to the front of a car going a hundred miles an hour yelling back directions to the driver, and I'm just looking over the bumper, and we're careening between the different

guardrails because we don't have that focus on the road that allows us to sort of say this is how we're going to get there, and it just makes for a pretty traumatic ride.

Eva Powell – National Partnership for Women & Families – Director IT

Well, your analogy of skating to the puck I think is a good one. In my mind, we know where the puck is, the puck is the national quality strategy. The problem as I hear what you've said is that that is not specific enough for standards folks to then do all of the analysis and prioritize the development of use standards. So, perhaps that's a role for the Policy Committee along the lines of what David has suggested earlier is to have a visionary process that is not constrained by meaningful use timelines going on at the same time that the meaningful use work that is constrained by those timelines that could then hopefully get you off of your front bumper.

John Halamka – Harvard Medical School – Chief Information Officer

And so, getting us your requirements early and often, recognizing that as we said, some standards are going to be ready today but other standards are going to take a while and therefore, as we understand requirements and we are faced with timelines, we'll decide together what are simply functional certification criteria versus what are tightly specified standards and implementation guides, and as Doug has said, this is going to be a multiyear process and we're going to go together as fast as we can.

Eva Powell – National Partnership for Women & Families – Director IT

Well, and it occurs to me also that you've said that standards are adopted, and we have a number of things that it sounds like you're already connecting to in terms of production pilots, we've got the Beacon communities, we've got public and private pilots, a number of them, the AAA ..., the IHI. We've got the National Quality Strategy and NPP work as well as the quality data model that NQS is coming up with. All of those are pieces to this puzzle, and it would seem that they could be really key members of this visioning process and pool all of the experience from those groups together.

John Halamka – Harvard Medical School – Chief Information Officer

Sounds good.

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

Thank you. Deven?

Deven McGraw – Center for Democracy & Technology – Director

Yes. And I want to thank you both for a really informative presentation. This really is quite the load of work and I appreciated the car analogy, and it just scared the crap out of me. We have to get you off the front bumper ..., we need you.

But I want to mention two things. One I want to just briefly say that with respect to the mention in the slide about the timely electronic access by patients through the view and download capability and whether there needs to be some transparency or warning to patients about the risks of downloading data, we actually have that teed up for discussion, I think at our next policy committee meeting. We've been working with the MITRE folks to prepare some material, so in terms of giving you more direction about what that might look like from a policy standpoint, it's coming, and hopefully very soon.

But mostly I wanted to talk about the patient matching stuff because the Policy Committee has actually issued recommendations on this issue. The Tiger Team hosted a day-long hearing on this matter, reported to the Policy Committee with findings and got feedback in December of last year, and actually issued recommendations on this issue from a policy standpoint. And quite frankly this is the second time I've heard a standard presentation where these recommendations were neither expressly mentioned or

referenced, and it's not just about taking credit where credit is due, it actually sounded to me like some of the direction that the Power Team is heading in is in conflict with recommendations that we made.

So, for example, in our recommendations adopted by the Policy Committee, we said there's no one size fits all algorithm that works for every purpose for which data is exchanged or accessed and needed to be matched. And whether you err on the side of sensitivity or specificity is dependent entirely on the purpose for which you're accessing the data, we heard that from everyone who testified, so statements about we decided to err on the side of specificity sound to me in conflict with in fact some of the things that we said.

The other thing that we said, and this isn't a recommendation that was endorsed by the Policy Committee is, the use of any particular data field should not, and we actually did underscore it on the slides, be required for a matching. So I don't get this sort of statement on this slide that the Power Team is discussing providing explicit guidance on which patient attributes to "require," I don't know what it means to put "require" in quotes, but at any rate we said data, you know you shouldn't require the use of any particular data fields because, again, depending on which algorithm you're using, some are going to be more relevant than others.

However, we did recognize the demographic data fields are the ones that are used, and when they are used they ought to be standardized. And then we had a whole host of recommendations that do seem to match more with the work that you're doing on standards with respect to data fields, although I don't necessarily see the one where we explicitly talked about developing recommendations on what should happen when the data field can't be populated because the information isn't available. What's the standard way of sort of representing the lack of data in a data field where data is customarily collected? So can you please respond to that? I'd appreciate it.

John Halamka – Harvard Medical School – Chief Information Officer

And I'll start. Marc Overhage oversees this team ... seems appropriate to make sure Deven and Marc talk and are aligned, but the notion, example, I recently implemented a patient matching algorithm between two organizations in Boston and I did not have at my disposal a set of what would be best practices, a set of evidence for sensitivity and specificity that will allow me to do that in what I would call an industry leading way, I guessed. And so to me, with the purpose of the Power Team is to describe what strategies are available, what are the performance characteristics of those strategies, and not specify an algorithm, but constrain the problem a bit so that those folks who have a particular use can make an informed decision.

Deven McGraw – Center for Democracy & Technology – Director

We actually did call for the development of best evidence, but I want to understand more of what you mean by "constrain" the problem?

John Halamka – Harvard Medical School – Chief Information Officer

Right. So for example it turns out that, and Deven you've been in Boston enough so you know, that south Boston turns out to be a place where a lot of folks with Irish ethnicity happen to live, or Irish ancestry. There turns out to be the name Maureen Kelly that occurs in that particular zip code so many times that it is actually not a necessarily useful thing to say, "find Maureen Kelly in south Boston." And so if you could take the industry's experience with patient matching and distill it into a set of guidelines that would then inform those who are now implementing patient matching to benefit from that experience, as opposed to everybody starting from scratch.

Deven McGraw – Center for Democracy & Technology – Director

Right. And undoubtedly we didn't want people to start from scratch, but I think it's important in terms of this sort of relationship of the two groups working together that at least where there are recommendations that have been put on the table after considered development, that those be reflected, and certainly in terms of standardizing the demographic data fields that is exactly what we knew was needed. We just did not think that data fields, and said specifically that certain data fields should not be required, and so certainly any sort of certification or standardization that results should not necessarily translate into a requirement to use certain data fields. Believe me, I, and I'll bet Maureen O'Brien lives in that zip code a lot too. So I get it, and I don't think anybody matches based on name and zip code alone for all of those reasons.

John Halamka – Harvard Medical School – Chief Information Officer

And so of course we want to specify then, what are the possible fields one might use as also part of a road map of standardizing the contents of those fields so that when you do select fields to use they are in reasonable shape.

Deven McGraw – Center for Democracy & Technology – Director

I think that makes sense, thank you.

John Halamka – Harvard Medical School – Chief Information Officer

Thank you, David Lansky.

David Lansky – Pacific Business Group on Health – President & CEO

Let me add my thanks to Doug and John for all this work and the whole team; it's really, really valuable and needed and certainly I'm speaking from the quality measures side and building on Eva's comments, we don't know exactly what these measures will look like in two or three years or in stage three, so we are skating to a moving puck, or a puck we can't really predict. And so I have two questions or suggestions for how you guys might help us. You're already delving into a number of areas like patient education and patient preferences that are very ambiguously defined, even in those of us who suggested it, and the measure concepts that the quality measures workgroup is working on and are also still concepts. So it is, for the reasons John said, at the outset going to be very difficult to adopt standards that are still fluid and diverse and pluralistic in how they're being used.

So I'm wondering two things; one is, had you contemplated creating a Tiger Team for lack of a better word, which would include additional expertise outside the current composition of the standards committee in these areas of patient reported measures, collection of subjective data, patient reported outcomes, that are some of the less traditionally utilized and standardized data in the EHR to bring some external expertise into developing a longer trajectory around patient reported information, and how and whether to be standardized; that's one suggestion.

And the second is to think about what I'll, for lack of a better word, call meta standards around patient reported measures so that we have some way of capturing and transmitting data, the content of which is still in flux. So I'm thinking for example; if we have a patient reported measures of orthopedic functional outcomes, we also patient reported measures of cardiac symptom outcomes, the instruments we'll use, and the way we'll capture and transmit the data is going to continue to evolve, but we know we're going to be capturing and transmitting that kind of data. So I think some meta data around those measures and some of this is in the quality data model that I think NQF is developing, but it would be very helpful to have a standard around that during the next several years as we begin to propagate and utilize those concepts, but we're not going to meet to the level of granularity that we are in some of the clinical data today. So I think it's a different kind of standard setting that we need for the next few years, two comments.

John Halamka – Harvard Medical School – Chief Information Officer

Good, thank you. Charles.

Charles Kennedy – WellPoint – VP for Health IT

Let me also add my thanks for your work, both for the work as well as for a very effective presentation. I guess what I want to do is kind of build on your car analogy, because I think it's a very effective one and I guess what I would say is, I'm not entirely clear where the road's heading and even whether you should be driving or potentially flying a plane. And what I mean by that is I feel like there's a series of issues that maybe falling through the cracks between the standards committee and us that need to be addressed. Farzad brought up one this morning that I think is very important and worried me for quite a while. He said, you know if you have a patient, we're creating an infrastructure where there'll be ten records of that patient rather than a record of a patient shared across ten providers. I think when you think about those kinds of issues, not only are there policy implications, but there's significant technical implications as well, and somehow I think we're not addressing those kinds of issues. I think some of the things you talked about Dave it also kind of fell into that bucket, so I guess I'm also offering a vote of support for this kind of visioning session around where are we really headed here and how are we going to make sure we're getting to the right place.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

I'll just comment on that last comment which is; I think we do need milestones because that's the way work gets done. Fortunately the milestones for stage three is 2015, but one of the comments that came up a couple of meetings ago I think is, can we take a breather and look at truly where the puck's going and look at, given stage one and stage two, could stage three look significantly different and not be an increment over stage two, and that I think David Lansky made that suggestion and it was well received and I think what we do need to do is essentially have a bit of a strategic planning session of looking towards stage three, or looking towards the new world almost, instead of even calling it another number. And I think we can do that, we can do that well before 2015. And I guess we'll have to develop this relationship with you along the lines that even David suggested, which is even though we don't know exactly where that is, and have the exact data elements, can we sort of figure out how to get there in time for 2015 instead of pushing it. So I think this is a really, really good thought, and I think just what the program wants us to do. So, well said.

Judy's next.

Judy Faulkner – Epic Systems – Founder

Again, I have a couple of comments to make, like some of the others. One is my favorite slide is your number four, the principles. I think that is a really good slide and I think that is also going to be an enormous challenge for you. I'm looking at the first principle, "Keep it simple," and the last principle, "Don't create a one size fits all standard," which to some extent compete with each other. And some of the thinking I was doing about that was that when John was talking about the FDA rules for drug-drug interaction I was thinking about some of the systems I've seen where in fact the individual physicians don't have, it's just going to be the extreme, this is really going to hurt you rules, but they can set their sensitivity choices, and it could be that or it could be I want to see something in the middle, or it could be I want to see every interaction, and that becomes an individual decision that they make. So I get a little bit worried about the one size fits all versus the keep it simple concerns.

The same thing kind of with if the BI and Brigham and Women's have code sets that work, maybe this should work for everyone as a starter set. And my observation has been that there's a lot of differences in starter sets for community hospitals, academics, children's hospitals, ambulatory care only, and other situations, and it becomes again, really hard to both keep it simple and to have one size actually fit all, because my experience has been it doesn't fit all.

The second thing I wanted to talk about was really back with what Deven was saying about being surprised at some of the things the Standards Committee is doing that I didn't think came from the Policy Committee and wondering about that. And the one thing that surprised me particularly was record segmentation which the Privacy and Security Committee talked about at some length, and I am kind of surprised to see the Standards Committee going ahead with developing standards for it.

John Halamka – Harvard Medical School – Chief Information Officer

Alright, so I'll make a few comments. How do we reconcile the notion of keeping it simple, but also not one size fits all? Here's an analogy; suppose we have requirements that you need to drive and you need to fly. Well, we could build flying cars, however it is probably better to start with existent cars and existent planes and recognize that, you know, for most use cases you choose a car or you choose a plane, you don't need one that does both, and so that's just sort of a keeping it as simple as you can. That is simple but not too simple, and not trying to suggest we're going to engineer absolute perfection by creating one thing that does everything for everybody. The trick is finding what I call the parsimony. What is the fewest number of simple standards to get the job done, and that's the balance we try to strive.

I certainly didn't mean to imply that it would be a Brigham ..., one size fits all drug-drug interaction set, just suggesting that it could very well be interesting for a consensus group to come up with a starter set of generally reasonable ideas for drug-drug interaction starter set.

And then finally, just with regard to what we're doing on segmentation, we really aren't doing segmentation, what we were just saying is this; is that, example in Massachusetts. It turns out we have not only consented to disclose, but we have consented to view certain kinds of information. And so if one sends a package from point A to point B, and the wrapper of that package says inside this package is information that you should have consented to view, it simply notifies the recipient that a consent is necessary to be obtained. It isn't trying to segment the record in a way that's highly granular.

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

I can add to the record segmentation. We've been working very, very closely with Joy Pritts and SAMHSA with regard to actually doing some pilots looking at that and seeing if we can understand the problems a little bit better in terms of the standards or the approaches that need to be done. I think too, one of the things that Joy has been, I think, taking a real lead in this regard is, she would like to use a similar process that we have within the S&I framework and Direct, again, going to the notion that adoption is the critical piece to this, so rather than doing the record segmentation work in kind of an isolation and then presenting that as, see, this is what we did. In fact she's been really working very closely with my office so that that record segmentation work is done in kind of a transparent and a public way where we can get more feedback and input into the project as well. So that's a particular project that really is being driven out of Joy Pritts' office, and we're trying to provide as much of the technical and the other kinds of support so that she can be successful in that.

W

But does that stem from the Policy Committee's direction as to what you should be doing with record segmentation?

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

I believe so. I mean it comes directly out of Joy's work with Privacy and Security Tiger Teams.

Deven McGraw – Center for Democracy & Technology – Director

We said that technologies to allow for the honoring of more granular choice such as is often required by certain states and with respect to federal substance abuse regulation should be piloted.

Paul Egerman – Software Entrepreneur

Establishing a standard for it.

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

And what's happening is, is really trying to figure out the pilot and figuring out what are the technical challenges and where are the policy challenges. Joy has been the one who's been tremendously instrumental in that.

Deven McGraw – Center for Democracy & Technology – Director

I mean the reality is, if we said nothing else on consent, there do exist laws in a lot of jurisdictions that place the kind of constraints on either view and/or access that John just talked about, and providers are going to need to honor them.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

I can't help but to make one comment on the airplane, car comment that John made. And it does have pertinence to this committee in looking forward, and it's using the design principle where you've got to figure out what is the problem to solve, not just how do we get there. So if we only look at cars and planes, we'll forget that actually patients didn't want to go anywhere, they wanted online access, for example. And similarly, if we only looked at quality measures because of what we have, we will forget what David mentioned, which is the patient report outcomes. I'd much rather know, can I walk again than what standard orthotics they use. So we do have to, that's part of the strategic planning, we have to go to that next step and see what the real problem to solve on behalf of the individuals, communities, and patients.

Next here on my list was Paul Egerman.

Paul Egerman – Software Entrepreneur

Yes, thanks. First, I want to reiterate what everyone else says, this is a great job of presenting a huge amount of work in a very complicated subject that does somehow include keeping it simple, but I really appreciate the effort.

I have a couple of questions. One is, on your slide 24, where you have this big Connect infrastructure and you show maturity and adoption low, moderate, and high. Aren't there actual metrics as to what define, say moderate or the boundary between moderate and high? Is this just sort of like a metaphor; I mean is this something that's really firm, or is this just sort of like a description of the basic concepts of what you're doing?

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

So I put this slide in, not because it's complete, but because it gives you a sense of some of the work that's going on within the Nationwide Health Information Network Power Team. That team has been charged with really taking a look at two things. One is to identify from the current set of specifications that we have for the Nationwide Health Information Network those kind of core elements that we think are ready to be adopted or recommended, or to be used, not just within the pilots that we have, but on a national scale.

The second thing was is that we want them to make sure that they can help us understand the criteria or the axes that we need to include. So that's it's not just the maturity of the standards, but there are other things that are going to be important, whether it's how easy it is to implement what is the cost, how much adoption has already occurred with regard to that. So this by no means represents a final slide or a final set of decisions, but I think what we're trying to do is to realize, if we have this notion of it's not one size fits all, that there will be actually people at different stages of maturity and sophistication in their ability to use and standardize information, what are those core elements that we think we want to start raising the floor and getting everybody to do without necessarily constraining those folks that may be way ahead of the curve and may be able to provide advice and guidance and direction, experience, if you will, in some of the emerging standards of the things that have been out there in the production.

Paul Egerman – Software Entrepreneur

And that's helpful. And I think in that explanation there's an answer to what I was looking for. And there's no specific metric that says high adoption means 10,000 transactions a day, or mature means that half has been used for over five years, over five days, or these are just sort of relative concepts that you have. You don't have any specific metric that tells you –

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

No, we don't have any specific metrics, but one of the things that we've asked the Nationwide Health Information Network power team to do is to help us understand their process or how they chose to make distinctions among the standards that were out there and to realize that again, that kind of standards maturity isn't the only metric. We'd like them to provide us some input about, when is something ready to be adopted on a national basis, when is something exceeds some threshold that says there's a bunch of folks across the country that are using this; we maybe want to let people know that this is something that

seems to be working, and when is it that there are standards out there that we think or techniques and approaches that maybe have some potential, but there's a lot of work that maybe needs to be done to have that happen. So we want to get that input and understand their process, but at this point we don't have any sort of metric that says, if it's 5,000 it gets international, and if it's 4,800 then it doesn't. We don't have any of those system metrics right now.

Paul Egerman – Software Entrepreneur

And then my other question is, I listen to this presentation and I see things like CDA, green CDA, PCAST, metadata, and that's sort of like a wide range of transactions, but the PCAST report did talk about this concept of a universal exchange language. And so I get the sense that we are not heading in a single direction here, that we are heading in a direction where we are going to pick and choose different standards for different circumstances for information exchange, but we're not heading in a single exchange language direction, is that correct?

John Halamka – Harvard Medical School – Chief Information Officer

And so Paul since you and I of course, spent many, many hours on the PCAST committee, let me answer that directly. We actually do have a single universal exchange language for all the enveloping functions. So that is to say one way with one set of XML based standards as suggested by the PCAST report to identify patients, provenance and privacy. And within that universal exchange language wrapper there are many possible packages recognizing that there are standards today for lab, for pharmacy, for administrative transactions that actually work extraordinarily well. So the UEL, Universal Exchange Language, becomes a wrapper around a payload of often existent standards.

Paul Egerman – Software Entrepreneur

And John, I think that's great. Somehow, and maybe it's just me, I missed that in this presentation, but I think that's an important step forward that when people talk about, they want to go where the puck is heading. And you and I are from Boston and so we know about hockey, and the puck goes wherever you hit it, and so this is the direction we're sending it, and I think that that's an important comment. It does have the issue that few people raised about the presence of that you have privacy ..., but I appreciate that comment.

John Halamka – Harvard Medical School – Chief Information Officer

And in fact as you guys know, the committees did debate. The privacy flag will rarely be used. It's for precisely what Deven described, where there are certain kinds of policies in place that necessitate a special handling flag, but in most use cases and architectures, there actually won't be privacy flags in use.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Great, Larry, last comment.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Wow, okay, so we've covered a lot of territory; I sort of feel like I'm at your summer camp and boot camp sounds about the right description. We've been really all over the map here, both with analogies and with lots of information. So let me begin by invoking actually something I think Latanya might have said if she were here, about the right technical model that can inform policy. So I think that there actually is a place for a rich dialogue with the Standards Committee on technology that we might not be considering that actually would help clarify policy. And I have a couple of specific examples in mind and I don't think I want to credit anybody except me and these might be either ridiculous or already in place, so I sort of run the risk of being a fool on this suggestion.

But it seems to me we spend a lot of time looking at specific quality measures and in some ways that feels like a stretch of health IT policy to be looking at particular measures. And I wonder if in fact we should be looking at the capability of systems to support whatever measures come down the pike and be looking to standardize how those measures get defined and how those measures get reported. So for example there's lots of narrative description in what makes up a quality measure and to have that measure be machinable and to then ask the EHR's or a technology piece within the EHR's might be a module, to then be able to accept that specification and then spit out the right set. But to do it granularly

to say here are the numerator patients and the denominator patients, or just here's the number so you can go report it, and then a similar set of standards for then reporting those things back, because even though you tell us that the physician reporting the ... XML is ready to rock and roll, we also have CMS saying it's not really ready.

So I think we need to look carefully at what we have for the end reporting standards so that both query capability and result set can be handled in an automated fashion. And that might then be an example of a place where we could simplify the certification criteria. So instead of having a long list of, you have to support all these quality measures, we say, you have to be able to accept a quality measure specification in this format and that will then imply certain things, so then, do you have granular data that then supports the data elements that those specs talk about. So it is a little tricky, you might actually be able to support the capability and then not deliver the result set that's needed. So it's not a perfect thing I'm putting out here. But I think that might be an example of where there could be some collaboration between a technology solution that could simplify the policy.

M

And Doug, do you want to maybe describe the quality data model and E measures activities, because that actually, what is going on?

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

Yes, there's a number of things that are going on. I think one is, is this notion of creating a model that tells you what is the important information that needs to be collected or represented as part of that quality measures and it involves the vocabularies and terminologies defining those things explicitly, so that you have a numerator and a denominator that are correct and trying to do that in a computable way so that it isn't a narrative subject to interpretation, but in fact it's a computable representation of what those quality measures look like. I think there is also work going on with trying to figure out what is the right way of reporting, and there are not only PQRI, but there's something called QRDA, which is an HL7 standard around quality reporting that's built on the clinical document architecture of the CDA. And so there are some alternatives to consider and to make sure that we apply the right standard and the right case.

I think there's another one and it's perhaps a little bit farther reaching. It gets to some of the technology issues or the architecture issues. Without standards there tends to be a centralizing effect, which says we don't quite know how to define this exactly, but do your best, send it to us and we'll figure it out. The problem is, is that the reason that we want to collect quality measures is not because we want a big database that has all of those things and nine months later we're going to tell you something about how your quality measures perform compared to someone else's. The reason we want to track that is because we want people to change what they do and we want them to improve patient care. And that means getting the results of the quality measure calculations as close to the people who will make the decisions that will impact patient care. That means that if we standardize quality measures and we provide that functionality at the source, hopefully we can provide results back in near time or at least in close time. And if we want to figure out what the country is doing and make some comparisons, we need to figure out a way that we can distribute that so that the bulk of the computation, if you will, occurs where the decisions are being made and we simply then sort of distribute a query and figure out what people are doing and sort of get those aggregate results so that the actionable things happen with the people who can make a difference.

I think the other thing to realize is that the other side of the same coin of quality measures is clinical decision support. So that if we define in a very computable way what the quality measure should look like, the other side of that same coin is a clinical decision support rule that can fire and identify those patients whose hemoglobin A1C is elevated, or those patients who are potentially at risk for a fall, because you've defined what that quality measure is and then now you can begin instrumenting your electronic health record and your healthcare system to provide the kind of feedback that you need to actually demonstrably make some improvements.

So I think, even things like the health query project that's trying to establish a mechanism to distribute queries across various electronic health records or organizations, can fit into an architecture that again, it

goes to this policy objective, you know if the goal is that you improve patient care, we need to make sure that that information is available as far down into the decision makers, and that means we may need to think about ways of standardizing that, providing that functionality with the boots on the ground. And so the H-Query Project, the E Measures Project, and some of the work around clinical decision support I think are all aimed at getting that expertise out in the periphery so that by the time somebody comes back and says your quality measure is; you aren't up to par with what the national average is. One would hope that you've already been making progress towards making a change in that, and you don't have to wait nine months to have that result.

M

Perfect, you're making me think of one more piece in that cycle, which is really then machining back the benchmarking information so that people can see where they are against a benchmark, not because it was set by a committee, but they can actually see, particularly as we get more granular data automatically reported locally what my community is doing, what my state is doing nationally, what's happening. So to be able to get that benchmarking stuff in there as well would be really great to communicate back. And I agree that the kind of decision support you're talking about is much more than the alert that pops up while you're ordering something; it's really part of a planning process of those patients at risk for things. And quality measures are one way of defining that risk because they've fallen out of some parameter. It's great, thank you.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

I want to thank John and Doug again for really a terrific report and a lot of work going on this summer that really complements the activities going on here and I hope we can continue to work together, particularly as we go towards a future state that's not as well defined.

So I think we'll break for lunch and I guess I could offer, but I think people are getting; one possibility is we have a half hour briefing from CMS about their Meaningful Use Stage 1. We could stretch this morning's session out there or break for lunch as scheduled and come back.

So Rob, are you still on the phone?

Robert Tagalicod – Centers for Medicare and Medicaid Services

I sure am.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

What we could do is, I don't think it'll be a half an hour, I mean we have a very brief report –

Robert Tagalicod – Centers for Medicare and Medicaid Services

The actual report will be released today ... senior leadership, and we certainly can go through maybe four or five major points and it won't take that long, unless there's an extensive question and answer.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay, Robert, we're just setting up, Josh is setting up in front of us and we're going to extend the period and appreciate your being on early.

Robert Tagalicod – Centers for Medicare and Medicaid Services

Great. Just tell me when to go.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Alrighty, let's go.

Robert Tagalicod – Centers for Medicare and Medicaid Services

Great, I'm happy to report on the Medicare and Medicaid EHR Incentive Program and this is for the June reports, and I'm happy to report that there are over 68,000 that have registered year-to-date for the Medicare and Medicaid EHR incentive programs, and bottom line we urge providers that are considering participating really to register so that we can verify their eligibility, that's one. There are 17 states at this

point that are now open for registration and those are Alabama, Alaska, Indiana, Iowa, Kentucky, Louisiana, Michigan, Mississippi, Missouri, North Carolina, Ohio, Oklahoma, Pennsylvania, South Carolina, Tennessee, Texas, and Washington State. So as we talk about Medicaid and Medicare, the Medicaid EHR incentives have been paid to over 2,400 eligible professionals, or EP's and eligible hospitals for specifically adoption, implementation and upgrade or AIU of certified EHR technology. And just in June alone that is 984, or 41% of that total number.

In terms of Medicare, EHR incentives have been paid to over 560 eligible professionals and eligible hospitals for the successful demonstration of Meaningful Use, and that's 241 in June or 43% of the 560 eligible year-to-date. In total, there are over \$273 million in incentive payments that have been issued so far, and as I began giving you this report, we will be issuing formally the June report later today. So if you could hold on until after 4:30 and we will be distributing, after we apprise senior management of these numbers. Elizabeth Holland is here with me, as well as myself, to answer any questions that you might have in terms of these numbers, otherwise I'll turn it over to Josh.

Josh Seidman – ONC

Great, thanks Rob. I'm going to just sort of balance some of that quantitative data with some qualitative reporting from the Regional Extension Center program. We will also begin in August to be collecting some empirical data as well, from the regional extension centers, which will give us much more detail and what's going on with the priority primary care providers. That's the focus of the REC program.

I guess what I would say first of all is that we have identified quite a number of what we call movers; these are the meaningful use vanguard cohort, and these movers are sort of leading the way in their areas. And so of the 62 regional extension centers, 42 of them have now identified movers, there are about 1,330 of them around the country, and what each extension center is doing is thinking about how to leverage the experience of those providers. And again, most of these are either small practices or are safety net providers. They have been having what we'd call movement events, these are ceremonies where they're really celebrating the terrific accomplishments of these providers. Nine of these events have been held so far, really spreading all across the country, and there are nine more that are already planned over the next quarter. And I thought I would just give you five takeaways from those events. Most of these actually come particularly from my experience of being at a Delaware mover ceremony just less than two weeks ago. It was held at the Medical Society of Delaware and it's really quite remarkable. They were celebrating 23 successful Medicare Meaningful Use attestations, and I think there are five takeaways I'd give you.

The first is that the Meaningful Use Program has pushed a lot of providers over the hump. So where there were a lot of providers kind of sitting on the fence, you know they've obviously been thinking about EHRs for a long time, the incentives I think helped to kind of get them over that hump. Once they've made that decision to purchase an EHR and decide they want to go to a paperless practice, what they're telling us is that the Meaningful Use program has given them some focus. It has helped them to identify what they should be thinking about, what they should be focusing on with a very specific end in mind. And it was very clear from talking with them, from talking with other movers around the country what this is all about, and it's really all about trying to improve patient care.

The third is that it's very interesting; the movers really are true leaders and I think I'm sometimes sitting in this room and you kind of think well, all of these movers are the Neil Calman's of the world, but there are all kinds of movers; there are these solo practice docs, just sort of figuring out as they go along, and some of these have been on an EHR for a few years, but some of them just came online with an EHR in 2010. And what's happened is that they really span the whole gamut of providers, so it's not just what you might have thought of as someone who's really always been a leader in EHR adoption.

One of the fascinating things about this mover ceremony was they had two patients present, they had patients presenting, this is at the Medical Society of Delaware, and they had patients talking about what an EHR has meant to them as a patient and also as a caregiver for their family, the ability to access data, to be able to monitor what's going on with a loved one. They talked about what it means for them to be able to just get the information they need when they need it, and to feel like their practice, and with some

of them it's just sort of a perception, well my practice is kind of up to speed, my practice really knows what's going on because they have management of the information about my health.

And then the last takeaway is that everything that every single mover has discussed about Meaningful Use, you know you think you all are talking about billions of dollars; they're not talking about the money. As I said, I think that it helped to get people over the hump when they talk about Meaningful Use, they're talking about what were the real world tangible improvements in quality and patient experience. And they talked a lot about patient experience as well as specific demonstrable improvements in clinical quality measures. So I think again, this has really helped to give them focus and helped them to focus on what really matters.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Thanks, Robin and Josh, that was really helpful. And I have to say that when the Meaningful Use workgroup had a hearing, and included this panel on folks to span the gamut from safety net ... center, it too was a moving experience, since people really appreciated how it helped them help themselves. It's exactly the five messages that Josh just gave. So I think this group is to be congratulated in the sense of the amount of time and true personal dedication that you all have had in trying to get this right, as right as we can for any public policy, and moving the country and many of the individuals in that direction, and it was wonderful to have a compliment of having patients say, you know what, this has been a step forward and been wonderful. And I also like the fact that he mentions the caregiver too. That "patient experience is so much about the caregivers that are around them."

So at any rate, thanks for that report. Any other comments or questions to Josh, Rob? Neil?

Neil Calman – Institute for Family Health – President & Cofounder

Yes, Josh, congratulations. I mean I think it's great to get this feedback and we need a lot more of it. Do we have a budget, do we know whether, as we're starting to get these reports of numbers and things like that, do we have something to compare it to, to know that the trajectory is where we hoped to get in three to five years so that we kind of know what this path looks like. In other words, how are we going to know if we're sort of undershooting by making the requirement too stringent or if people are adopting more quickly than we thought so that we have an opportunity to perhaps get some of our other imperatives put into the next round of requirement. I mean how do we know where we are compared to where we want to be? Is there somebody that's done some projections about what we would want to expect after the first, second, third, fourth, fifth years in terms of rates of adoption or numbers of people that have achieved Meaningful Use?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Robert, Elizabeth, do just want to take a crack at it?

Elizabeth

Yes, this is Elizabeth. We actually did do projections in the impact analysis of the July 28th final rule. I will say that those projections had a low and a high uptake assumption, and our projections are very much higher than what we are experiencing to-date. And so as people continue to attest, we will really be looking at the performance on attestations when we are formulating the regulation for stage two, because we're trying to get as many people on the bus as we can and it is something that we're very sensitive to at this point.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

I would mention, representing the Meaningful Use workgroup that, and Farzad referred to that this morning, I certainly have heard a lot in the field about people delaying specifically because of the catch-22, they would have been put in, and actually as of this moment still nothing's changed there, but Farzad certainly sent a very strong opinion, a signal that the department understands this. But I think there is this pent up demand to attest, but yet not want to get into this catch-22 predicament. So hopefully there is that latent demand that hasn't been fulfilled yet and that's part of, so you could meet your projections from your final role. Other comments or questions? Eva?

Eva Powell – National Partnership for Women & Families – Director IT

This is actually kind of a springboard off of Neil's question. Are we also finding out where the difficulties lie for those who are having trouble attesting? In other words in the core and the menu set of items, are there items that people are just not dealing with at all, or what's the story there?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

For the regional extension centers, when I said that beginning in August we'd begin to be tracking that data. A lot of it will include that kind of data, so we will be tracking what is the threshold. So for example if the policy committee is thinking about, well, what's the appropriate threshold for say ePrescribing in stage two, we'll have some data on for the people attesting to Meaningful Use. Are they at 41%, just meeting the threshold, or are they at 80%? So we'll have some of that data. We also will have data on which objectives on the menu set people have chosen to attest to. So that will give us some sense of, are there certain ones that people perceive as being harder, or maybe they've tried them and they're harder, or whatever.

The other thing is that through the regional extension center data, we will actually have Meaningful Use data from Medicaid providers because obviously in 2011 states are just doing AIU, adopt, implement, upgrade, so we don't have Meaningful Use data for the Medicaid population, whereas many of the RECs are supporting Medicaid providers, or a significant portion of their providers are Medicaid providers, and so we'll have some data on them as well. Charles?

Charles Kennedy – WellPoint – VP for Health IT

You know I'm not particularly troubled that the numbers are low for some of the reasons you mentioned as well as others, but I do think it's something we really need to keep our eye on. Is there a way to kind of survey a member of EMR contract deployment? I know that data's out there, but I would think we've got to keep a very close eye on that, because if we don't see the hockey stick kind of growth, you know there's some fundamental things we need to be thinking through, so I would really encourage us to look for some additional leading indicators and discuss that at future meetings.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Good point. I know anecdotally vendors are reporting fairly ... sales, but it would be nice to get some data, ... the EHR VA can help us. David?

David Lansky – Pacific Business Group on Health – President & CEO

... early in that forum did you get any response about the quality measure strategy and whether people are responding to the core, the alternate core, and that sort of thing?

M

We will also have mentioned in terms of the data that we're collecting from the regional extension centers. We'll have some information on which measures they're selecting, so we'll have some of that as well. What I can report is that the people who are attesting to Meaningful Use are really using the electronic generation of these clinical quality measures to not only measure performance, but monitor it, and having real time data completely changes a practice. So being able to know virtually in real time how your practice is performing on your HbA1c, or your blood pressure, or whatever are your clinical priorities for your practice, really changes how they go about managing their population and of course being able to identify all their hypertensives at risk and so forth.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

And I can certainly attest to the veracity of that statement. We measure and report to ourselves quarterly, which is almost near real time for those kind of things, and it changes behavior, and it really allows you to perform much better.

Any other final comments? You know I think it's a wonderful way to end today, because it's really heartening to hear some of the positive feedback and the positive results of the programs that are spawned by high tech and the work of this group. And through CMS and clearly the work of CMS and ONC in this and we're just an advisory to them. Now it's time for public comments, if there's any.

Judy Sparrow – Office of the National Coordinator – Executive Director

If anyone in the room wishes to make a comment we have two microphones up here at the table. And if you're on the telephone just press *1 to speak. If you're on your computer you will need to dial 1-877-705-6006. And Carol Bickford, would you like to go first?

Carol Bickford – ANA – Senior Policy Fellow

Carol Bickford, American Nurses Association.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

I just wanted to thank Rob and Josh for a wonderful report, and thank you, Rob, for being on the line early and being willing to go early. Thanks.

Carol Bickford – ANA – Senior Policy Fellow

Carol Bickford, American Nurses Association. It's very helpful to have the FACA calendar present on the ONC website, but now with summer camp it's impossible to find anything in relation to that emerging activities. Is there a mechanism for ONC to also give us a calendar of the meetings that are going on so we can dial in and try and catch up with the train that's going very quickly?

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you, Carol. Would you like to go next?

Tom Bizzaro – First DataBank – VP Health Policy & Industry Relations

This is Tom Bizzaro, I'm Vice President of Health Policy & Industry Relations for First DataBank and a pharmacist. As you may know, First DataBank provides drug-centric knowledge bases that are used and integrated in numerous clinical decision support applications, and we're very familiar with the issue of over-alerting. Making alerts more specific and helpful to the clinician and patient requires knowledge of the clinical expertise of the user is it a physician or a pharmacy technician, the practice setting, is it a community hospital or an oncology center, you need access to patient specific information, and you must address some of the liability concerns around clinical decision support. Numerous discussions have occurred in the past on the issue of over-alerting. As far as I know there have been no best practices defined and no critical list of alerts that have been made publicly known. There's an issue that needs to be addressed, and with us now moving toward a Nationwide Health Information Network, standardization of vocabularies and messaging, I think we're in a position to address this issue and it must be addressed, and I would welcome additional discussions on the issue at a national level. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you Tom, and Robin Raiford.

Robin Raiford – Allscripts – Executive Director, Federal Affairs

Hi, Robin Raiford and I'm here as a messenger to pass something on from the CIOs of the Healthcare Association for New York State and a meeting I was with them last week, and they expressed their a bit of frustration and concern of something that sounded very unique that I had not heard and I have not heard it brought up in the committee is the issue we have talked about in policy committee, as well as standards, of aggregating data. And they talked about how some of their eligible professionals who are in multiple locations with multiple EHRs, with multiple databases, have no way to aggregate and determine unique patients. And there's no FAQ that says how deep does unique patients go, so that if you're an uber-sick patient seeing an uber-specialist that you might follow them around the city, so you realistically could be in all three locations which have three different EHRs. And short of sending every piece of data you have to the data warehouse, how can those eligible professionals participate even though they have something, and they have no way to aggregate the data, so that has come up.

And the other question that came up was the issue of the Medicare Advantage Program having there are three pages in the final rule that if you zone in on Medicare Advantage they're in there, the exemption they have from quality measures other than the yes/no, when you get in the attestation tool is that their

yes/no, it doesn't say anything about if your Medicare Advantage and report ... in the other three things that you don't report. Is that something that's addressed by ONC and CMS, or in the FAQ's, or is a short discussion in policy to look out for that aggregation of data issues, because it just keeps coming up as a stumbling block for some people. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you, Robin. Chantel?

Chantel Worzala – American Hospital Association – Sr. Associate Dir. of Policy

Good afternoon and thank you for as always, a very robust discussion. I just wanted to make sure the folks on this committee understood something that Larry Wolf referred to, which was a proposed rule put out by CMS last week Friday. There are two rules, one for physician payment and one for hospital outpatient payment, but both actually addressed the Meaningful Use Incentive Program, and in particular the standards used to automatically report quality data to CMS for Meaningful Use. And in those rules CMS, and I quote, says, “Since the publication of the final rules, we have determined that it is not feasible to receive electronically the information necessary for clinical quality measure reporting based solely on the PQRI XML standard,” that is the standard that is currently required for certification of EHRs. I think I've lost the quote, but the point is we now have an ONC regulation requiring a standard for reporting of data to CMS that CMS has concluded is not feasible to use for that purpose. So I just want to make sure folks in this room understand that, and certainly look forward to hearing from ONC how that conclusion by CMS might flow into the standards and certification roles. Thanks so much.

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you, Chantel and thank you for all of the public comments, and I'll turn the last word over to Dr. Tang, or wait, no, nobody's on the phone.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay, well thank you so much, thanks for extending the morning so that we can all finish early, and have a good summer until we see you next month. Thanks a lot.

Public Comment Received During the Meeting

1. Public Comment Question for P&S Tiger Team please: Make amendments to a patient's health information in a way that is consistent with the entity's obligations with respect to the legal medical record (i.e., there should be the ability to access/view the original data and to identify any changes to it). How prescriptive is this to view original data online and then what was changed? Ex: Old Medication and now the new, Old Problem and now the new, Old Allergy and now the new list. Old and new values must be retained or is simple enough to provide an audit? Thank you
2. Need to have CONSISTENT metric for maturity... Direct is only in pilots, yet NwHIN Exchange is in production... How does this compute?
3. XDS/XDM/XDR/XCA has an equivalent metadata packaging that is ALSO supported in all transports including DIRECT
4. Query is just as adopted as Retrieve... How can Retrieve be more adopted than Query when the only way to Retrieve is to have previously Queried?