

PCAST Report Workgroup
Draft Transcript
February 16, 2011

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director

Good morning, everybody, and welcome to day two of the PCAST Report hearing. Again, this is a Federal Advisory Committee, so there will be opportunity at the end of the meeting for the public to make comment.

Let me do a quick roll call around the table starting on my left with Jody Daniel.

Jodi Daniel – ONC – Director Office of Policy & Research

Jodi Daniel, ONC.

Art Davidson – Public Health Informatics at Denver Public Health – Director

Art Davidson, Denver Public Health, Denver Health.

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

Paul Tang, Palo Alto Medical Foundation.

Stephen Ondra – NeHC – Senior Policy Advisor

Steve Ondra, White House.

Hunt Blair – OVHA – Deputy Director

Hunt Blair, State of Vermont

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

Dixie Baker, Science Applications International.

Richard Platt – Harvard Medical School – Professor & Chair

Richard Platt, Harvard.

Carl Gunter – University of Illinois – Professor

Carl Gunter, University of Illinois.

John Halamka – Harvard Medical School – Chief Information Officer

John Halamka, Harvard Medical School.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Jon Perlin, HCA, Adjunct Faculty, Vanderbilt.

Paul Egerman – Software Entrepreneur

Paul Egerman, Software Entrepreneur.

William Stead – Vanderbilt – Chief Strategy and Information Officer

Bill Stead, Vanderbilt University.

David Blumenthal – Department of HHS – National Coordinator for Health IT

David Blumenthal, ONC.

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

Wes Rishel, Gartner.

Steven Stack – St. Joseph Hospital East – Chair, ER Dept

Steven Stack, American Medical Association.

Mark Rothstein – University of Louisville – Chair of Law and Medicine

Mark Rothstein, University of Louisville School of Medicine.

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

Doug Fridsma, ONC.

Tim Elwell – Misys Open Source Solutions – Vice President

Open Source Solutions.

Eileen Twigg – Planned Parenthood Federation of America – Director

Eileen Twigg, Planned Parenthood Federation of America.

James Walker – Geisinger Health System – CHIO

Jim Walker, Geisinger.

Anne Castro – BlueCross BlueShield South Carolina – Chief Design Architect

Anne Castro, Blue Cross Blue Shield South Carolina.

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

Chris Chute, Mayo Clinic.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

David McCallie, Cerner.

Craig Mundie – Microsoft – Chief Research and Strategy Officer

Craig Mundie, Microsoft and PCAST.

Natasha Bonhomme – Genetic Alliance – VP Strategic Development

Natasha Bonhomme, Genetic Alliance.

Judy Murphy – Aurora Healthcare – Vice President of Applications

Judy Murphy, Aurora Healthcare.

Cris Ross – LabHub – CIO

Cris Ross, SureScripts.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO

Walter Suarez with Kaiser Permanente.

Linda Fischetti – VHA – Chief Health Informatics Officer

Linda Fischetti, Department of Veterans Affairs.

Alice Brown – National Partnership for Women & Families – Director HITP

Alice Brown, National Partnership for Women & Family.

Kamie Roberts – NIST – IT Lab Grant Program Manager

Kamie Roberts, NIST.

John Derr – Golden Living LLC – Chief Technology Strategic Officer

John Derr, Golden Living.

John Klimek – NCPDP – VP Industry Information Technology

John Klimek, NCPDP.

Gary Malick – ONC

Gary Malick, ONC.

Judy Sparrow – Office of the National Coordinator – Executive Director

We have a number of members on the telephone. Gary Marchionini, are you there? Neil Calman? Connie Delaney? David Lansky? Marc Probst? Scott Whyte? Kevin Hutchinson? Liz Johnson? Nancy Orvis? Marc Overhage? Did I leave anyone off?

Connie Delaney – University of Minnesota School of Nursing – Dean

Connie Delaney.

Judy Sparrow – Office of the National Coordinator – Executive Director

Oh, great. Thank you, Connie. With that, I'll turn it over to Dr. Blumenthal.

David Blumenthal – Department of HHS – National Coordinator for Health IT

I will turn it over to Paul Egerman.

Paul Egerman – Software Entrepreneur

Thank you, Dr. Blumenthal. Especially appreciate those exciting words this morning to help us get started.

M

... understated.

Paul Egerman – Software Entrepreneur

That's right. The people in the upper levels here were complaining about lack of heat yesterday. I told them ONC does not have enough budget for heat, HIMSS ... budget for words, too, sometimes. I want to welcome you and say good morning to everybody attending our second day of hearing. I very much appreciate everybody's participation. We had a terrific meeting yesterday. It was long. It was a little over eight hours, but it actually went by very fast. We also had an unbelievably great group of people who testified, some of whom—I see Scott Whyte here—some of the people here stayed over and continue to participate in our deliberations. I do know that we were not able to get to everybody's questions, because we had to run through everything on a pretty tight time schedule. But, as you can see the people who justified stayed afterwards. There was a lot robust discussions in the corridors. There were people here.

The people who testified are wonderful people. They took a huge amount of their time to come here, to prepare their written materials, to prepare their oral presentations. They are very interested in helping us. So, I would just tell you that if you have questions that didn't get answered, to remind you to send an e-mail to Judy Sparrow with copies to Bill Stead and me. We will circulate that among the people who testified. I think they'd be actually enthusiastic about answering your questions and we'll circulate the answers. They're available to assist us and we should take advantage of that going forward.

In today's meeting, this is our opportunity to talk about what it is that we heard yesterday and actually to begin discussing how we're going to craft our report. We have a report that's due in two months, which may seem a fair amount of time, but it's going to go very fast, especially since we have a difficult schedule for the month of February with the HIMSS conference next week. We do not have any more meetings in February. So, we need to get a lot accomplished this morning.

These, again, are members of the workgroup. I want to thank all the workgroup members for their efforts. I also want to thank members of the Policy Committee and Standards Committee who are here. Of course, I want to again thank the ONC staff who is helping us. We have a slide deck that we're going to present to you this morning, but the reason we have a slide deck this morning is that Judy Sparrow and Jamie Skipper and Doug Fridsma and Jodi Daniel were working through the evening to try help us put together materials. I want to again thank all of you for your efforts, which have really been superior.

This is the agenda, so what we're doing right now is trying to do our best to explain what we want to accomplish in this meeting this morning. To explain that, the easiest way we can do that is to again return to our workgroup charge. This is the charge which has four bullets.

The first bullet says to assist ONC, to synthesize and analyze the public comments and input to the PCAST Report. What I'd like to accomplish this morning, one of the things I'd like to accomplish this morning, is to make a lot of progress on that issue. I look at what the public says, synthesize and analyze the public comments. The public comments really come in three categories. There is, indeed, everything that we heard yesterday at the hearing. That's one category. There's the second category that we're going to remind you of, which is that ONC did a request for public comment on December 8th and—I forget the exact date, but—sometime towards the end of January received over 100 written comments from the public. So, we're going to review the information that we got from that. Then, what we'll be doing this morning is trying to see if we can synthesize all of that.

There's a third category of public comments that I also want to make sure I tell you about, which is as workgroup members and as members of the Policy Committee and Standards Committee, we very much want you to reach out and into your networks of people that you know. So, if attending the HIMSS conference or if you're talking to people at your workplaces, whatever feedback that you get from that also is public input that we want to make sure what that input is. Again, we're not trying to necessarily judge the public input, we're simply trying to understand it and synthesize it. That is the goal.

Those are the three categories. It's the hearing. It's the formal public written comments that we received, but it's also whatever informal input you're receiving from whatever constituents or networks that you have. Then, you go through the remaining three bullets. Discuss the implications of the report and its specific recommendations to ONC on current ONC strategies.

The third bullet is to assess the feasibility and impact of the PCAST Report on ONC programs. What I really would like to do in this meeting if we can get this far, is in addition to talking about public comments is to actually start on these next two bullets. What I want to try to do is get at least through the PCAST recommendation that's listed on page 77 and start to have that discussion. We started that a little bit at the end of yesterday when Craig Mundie put forward basically an idea or an alternative for what I call the first recommendation. So, what I want to do is to continue that discussion and see what other alternatives might exist to make sure that we understand that process, but at least to get that process started.

The fourth bullet that is listed here is to elaborate on these recommendations and how they can be integrated into the ONC strategic framework, which is a formal document that is reviewed, I think, at Congress once a year. So, we will do that process, also. But, again, today's goal is to make progress on the first one, analyze the public comments and discuss implications.

The way in which we did this is we had six panels yesterday and we had six moderators. We asked each moderator to put forward a slide that described what they thought were the major themes in their panel. So, what we're going to do in a minute is we're going to go through that. The comment I give you as you think about that is that the whole idea of going through the public comment is to simply write down what we heard. We're not trying to judge the public comment. It's not like we want to say it was right or wrong. It's just that this is what we heard. So, that's the entire purpose. Sometimes, that's hard to do, because

there's always the tendency to put your own impression on it. ... what I heard, but it really means that—no, we just want to say this is what we heard in the public comment.

The way this is going to work when we're all done is we're going to have a report that we give to the national coordinator. The way the report's going to work is on the issue of analyzing the comments there's going to be some executive summary that describes that this is what we heard overall. Then there's going to be an appendix where we have maybe a page or two written about what we heard for each stakeholder. So, that's the way to think about it.

Before we go to six panels, I also want to quickly review the top level directions from the PCAST Report to ground everybody. These are the issues that we've been discussing as a way to summarize the report. The very first issue says, "Accelerate progress towards a robust exchange of health information." That wording actually is like plagiarized from the report. It comes from—there's an executive summary in the report and this is like one of the very first bullets in the executive summary. So, we felt, well the best way to capture it was just to take the exact words from the report. We underlined accelerate progress. It's a clear theme from the report is greater urgency, greater priority around information exchange. So, we felt that was one of the top level directions of the report.

The second area where we talk the thing called an exchange architecture. These are not the exact words from the report, but we were trying to sort of summarize the concept. So, there an exchange architecture, which it does represent a slight difference in the way ONC has been approaching information exchange. So, it's to establish and exchange architecture. You see in italics the expression "universal exchange language," and then, you also see interlinks search capabilities. These are the two capabilities that when Christine and Craig presented yesterday, I think they called them pivot points or major issues. But, this is the universal exchange language and interlink search capabilities is basically the DEAS. So, that's the basic top level direction.

Then, there's a lot of other words here that you have to tease out. We had the strong privacy and security safeguards, of course. We have a reference to the population analysis, what you see in the second sentence, which is also seen in the report. Then, you see the remaining part of that second sentence, which does again come from the executive summary, which is, "The exchange architecture will enable commissions and patients to assemble a patient's data across organizational boundaries." So, that is the second top level direction.

The third direction is evolutionary transition. Again, I think that was discussed a lot yesterday. It's clear in the report. This is not rip and replace. As I read the report and I also listened to Dr. Cassel and Craig Mundie yesterday, I did not hear them say anyplace, "Well we want you to stop doing anything you're currently doing." That was not the message. There's not a message here that says don't do this anymore, do this instead. It's more a message of establish the vision in your architecture, establish priority around that and get going is basically the message.

Before I get into the panels, let me pause here and see if anybody has any comments or questions about this. Please be sure you state your name.

Tim Elwell – Misys Open Source Solutions – Vice President

For clarification purposes, we did say that number three was referring back to number two. Is that still correct?

Paul Egerman – Software Entrepreneur

Yes. We tried to do that by rewording it a little bit. Where it says, "evolutionary transition," in the earlier versions of this people would say, "Well what are you transitioning from?" So, we say, "from existing installations to the new exchange architecture." Is that responsive to your concern?

Tim Elwell – Misys Open Source Solutions – Vice President

Yes. I just want to make sure that we're not going in two different directions, because there was a recommendation that we refer back directly or that we indicate in number two establish a new exchange architecture. So, we refer back to or modify three. So, I just wanted to make sure that we're still on the same path.

Paul Egerman – Software Entrepreneur

Yes, that's right. I appreciate you saying that, Tim, because one of the things that's necessary to do is to do a little bit of wordsmithing on this, because there is a little bit of inconsistency. When it says, "new exchange architecture," we meant ... in number two. We need to clarify that. So, I appreciate that comment.

Okay, so those are the top level directions from the PCAST Report. There is a second group of concepts, which we're not going to go into this morning, although we do want to go into eventually, which is also part of our summary. This has been a very interesting discussion to write this down. There is one, these items that have three question marks after it, patient involvement. The reason it has three question marks was we weren't sure that we were saying in words correctly what probably needed to be said.

So, the issue there is there is a theme within the PCAST Report that includes patient involvement in the entire exchange mechanism. That's important to understand, because one of the things you need to think about is well, if we're talking about information exchange architecture, who are users of this information. Is it only an industry exchange architecture? In other words, is this only for providers, or is it for providers and patients? My understanding of the PCAST Report is that it answers it and says it's for providers and for patients, that the patients are involved in the process. So, I'm not sure we wrote that right, but that's what's intended there.

There are also, under letter F, is the old wording. There's different people who are responding to the way we have worded these issues and letter F. Wes Rishel, Dixie Baker, and Bill Stead have exchanged a number of e-mails and had rewritten something that—what ... I think is a little bit difficult to understand and they have re-expressed that in a way that is less difficult to understand. I wouldn't say it's simple to understand, but less difficult to understand. So, anyway, this is still a work in progress, but this will also eventually be part of our foundation for us to discuss some alternatives, suggestions as to how we accomplish what we consider to be the basic concepts.

What we now is talk about the panels. Now the six panels we had yesterday, five of them represent in effect feedback from the stakeholders. The sixth one is sort of in a different category. It was an overview of the PCAST Report. So, we have a summary of that, but I'm going to tell you the slightly different order. What we want to do first is review these five panels. So, what we're going to do is have the moderators go through that. We're not going to spend a huge amount of time on it, but the real purpose here is to find out did we capture the themes. Are we in agreement that this is like a summary of what we heard yesterday?

The first panel is Health Information Exchange and Healthcare Stakeholders. That's Wes. There you are, Wes.

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

We were discussing health information exchange and we had a very diverse group of presentations. Carol Diamond who has been active as an advocate in health information exchange and fair information practices through the Markle Foundation for a long time; Marc Overhage who runs what is arguably the most successful health information exchange in the country. Art Glasgow who is the Chief Technical Officer of Ingenix, which has acquired the Axolotl system, which is wildly used amongst some health information exchanges. They each focused on different aspects, so a summary is—you can almost see which speaker is being summarized in each bullet. But, I think a fundamental theme being raised by Carol and echoed in a number of comments is that the discussion in the PCAST Report on consent and

security through encryption is incomplete in terms of identifying the issues of trust that would go around building a wide indexing system.

The second and third points really come from the experience of those who have built health information exchanges to date. Their experience is first, that the data ... systems, the areas we might go to after doing an inquiry are not typically designed, funded, and configured for being a network server. They often don't meet reasonable networking standards for availability of the service for response time of the service and for data persistence. This is not just an issue of them having not thought about it. There are economic issues associated with adding those requirements to ... that are served by existing systems.

The experience universally among health information exchanges has been that the data source organizations need assistance in normalizing the data. That it would be delightful if they all equally belonged to the same standard, but in fact, every HIE has done some adaptation, according to sort of an economic model of how bad do we want their data. How much do we put into normalizing their data?

Then, a theme that came out in the discussion is that there are conflicting virtues between being very selective in pulling elements of data out of reports. There is no right answer. That is, there's potentially some loss of context whenever you take a group of related information that you might think of as a report and ... out data. On the other hand, it happens all the time. It's a very valuable way to do certain kinds of implications. The concerns seem to boil down to where the recipient would think they were getting all of the nuances associated with reading a report. They shouldn't get anything less than that, where they would think they're getting isolated data, that's fine.

Paul Egerman – Software Entrepreneur

Thank you very much, Wes. Great job. Question: Is that a complete summary, or as people recall Wes' panel, is there any items people want to add to this list? So, we'll start with you, Chris.

M

So, Wes, I think this summary is a really good one. I'm curious about your views on particular issue. I know you've thought about this a bunch. There was a conversation in that panel that I think sort of echoed through the day about the idea about not just assistance in normalizing data, but strategies for normalizing data and early and late normalization. I think the conversation was really around it's not just a technique, but it also potentially had some policy considerations and so on. I don't want to put you on the spot as our leader, but I just that that comment kept repeating during the day. I'd be interested in making sure that we captured that.

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

Well, I'm glad you asked. I was not bringing it up because I think it came up from the panel very much in the thing. But, if you talk about the discussion during the day, I think one of the things we got a clearer picture of over the course of yesterday was that there's a broad suite of interpretation methods anticipated in the approach of the DEAS. Everything from just send us whatever you've got and we'll figure out how to parse it to send us perfectly parsed data according to the way you want to parse it and we'll be able to use that, we'll be able to reparse it using other approaches and things like that. My comment is that that is an appropriate strategy for a long range system like that, that we in Standards tend to believe that—well, there's an old joke here I can't use on microphone.

M

Well, we've got to hear that one.

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

Not on the microphone, no you won't on the microphone. But, basically what we're saying is it's going to be really great once we get it running. We only have to get that final problem solved and then all of a sudden there will be complete understanding of semantics among the people who interoperate. The target moves at least as fast as the technology does. In a network that is comprised of a number of

source systems, they will have been designed over a 20-year lifespan. So, they will not all have the same ability to collect and send the data. So, a notion that we get the best normalization of the data that we can, but we don't require it, we don't fix it as a fixed target that can never change is a good one. I'm glad to see it in the PCAST Report.

M

I don't really care where we capture it, I just thought one of the big themes of the conversation that I heard anyway, was this tension around trying to come up with universal atomistic data in the context of where we have different normalization strategies and approaches, and where there's technical and policy implications of that. That seems to be at the core of trying to figure out how to imbed PCAST in what we're doing.

Paul Egerman – Software Entrepreneur

I could ... the issues. Does that belong in this panel or does it belong in one of the other panels?

M

Don't care.

Paul Egerman – Software Entrepreneur

We're just trying to write down what we heard and that that was a major theme.

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

I agree with another panel. I asked Craig some questions and I think he gave some very revealing answers. But, we might want to discuss that in another panel then, where it came up.

Paul Egerman – Software Entrepreneur

Deven?

Deven McGraw – Center for Democracy & Technology – Director

I just have a question. I'm trying to break some of the informatics language down for those of us who—here and also listening in from the public—what do we mean when we say normalization?

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

Sure. Every system will have a way of describing something that they observed: a blood test, or the demeanor of the patient, or blood pressure; just anything you can think of as an observation or conclusion or anything like that. They all represent that internally in the systems differently. There's a lot of reasons why they do that. How they represent it has a lot to do with what they can do with it and all kinds of things like that. But, it is harder to share that data the way it's represented internally unless everybody represents it externally the same way. So, normalized data is data that has been converted to the normal representation.

Deven McGraw – Center for Democracy & Technology – Director

How would that be related to structure data? Is it the same, or slightly distinct?

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

Oh, I'm so glad you asked. Structured data—drives Paul crazy, of course, but—structured data broadly just means we've broken it down into components ... organized name fields. When we talk about structured data as it's transmitted, the grouping of things is physically demonstrated by how they're sent and delimited in a message. So, you can say, "I'm expecting first the systolic blood pressure and then a diastolic," or you can say, "I'm expecting two readings," and you're going to tell me this is systolic and here it is, and this is diastolic and there it is. Two different ways of sending the same data—it has to do with how the data's physically sent in a message though, how the characters are strung together in a message. There are ways—and this is the discussion that Craig and I had—of really reducing the dependency on the—what you have there is a mixture of the message format and the semantics, the

There's ways of saying well we have a uniform format that is isolated from the semantics, and we send the semantics separately. That was the discussion.

Paul Egerman – Software Entrepreneur

That was a good answer. If I could try to do an example, Deven, unstructured data might be a patient is concerned about his weight. Structured data would be weight: 200 pounds. The structured data is very objective, the unstructured data less so.

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

Paul, I'm going to disagree a little bit. Clearly, your example is correct as far as it goes, but the string, the patient weighs 200 pounds would also be unstructured.

Paul Egerman – Software Entrepreneur

Right. It's structured if you normalized it ... value of 200 at a normalized weight on pounds ...

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

... data fields imposed

Paul Egerman – Software Entrepreneur

That's correct. That's correct.

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

I think Judy has a

Judy Murphy – Aurora Healthcare – Vice President of Applications

Wes, I heard you—

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

I have my card up, too.

Paul Egerman – Software Entrepreneur

Okay. We'll get you in a minute, Stan.

Judy Murphy – Aurora Healthcare – Vice President of Applications

Wes, if I heard you right, it gets displayed in the same way, I'm worrying about the mapping underneath. Don't we really have to—and the example I sometimes think of is how do you divide up elementary school, middle school, junior high, high, which ... places do different ways. Even if you end up displaying it the same way, what it may mean to the person at the other end may be different based on how they map to begin with. I thought normalization meant that you map it. You get the underlying codes correct before you display it, not just that you display it, because eighth grade or ninth grade may mean something totally different middle school, high school, junior high. But, it may be displayed as one of those, yet it still can imply erroneous information. So, I think we need to go down one level deeper that the mapping has to be the same.

Paul Egerman – Software Entrepreneur

That's a good comment. Just to remind everybody, what we're trying to make sure that we summarized what was heard.

Judy Murphy – Aurora Healthcare – Vice President of Applications

Well, I thought we were trying to get a definition of normalization.

Paul Egerman – Software Entrepreneur

Okay. That's correct. That's very helpful. Thank you, Judy. Craig.

Craig Mundie – Microsoft – Chief Research and Strategy Officer

Just two comments so that I can understand how best to use time this morning. I don't dispute that many of the slides are sort of a literal representation of what was presented. But, when we got to our session at the end, I not only tried to overview the report, but I tried specifically to comment where in the course of the day people made comments that I interpreted as either not really related to the PCAST Report, per se. Although, it stimulated a lot of conversation in this community or represented some—I'll just say—lack of understanding of what we were thinking when we put certain things in the report. So, it's unclear to me in the process today where do we try to intersect the interpretation or the additional comments that were offered or a discussion about whether they actually alter the way people think. There's no doubt we should record what they said when they said it, but at the end of the day, it seems like that isn't where we want to stop.

Paul Egerman – Software Entrepreneur

Great comment, Craig. Basically, that's what I'm hoping we're going to do in the second half of our meeting today. What I hope we can do as our starting point is we make sure we understand and agree with what was said. Then, we start talking about—

Craig Mundie – Microsoft – Chief Research and Strategy Officer

I just want to understand when we should get engaged in that conversation.

Paul Egerman – Software Entrepreneur

That's right. So, I'm hopeful that we can get to that. Completely appropriate. The purpose here is not the say whether or not we agree with what was said, we just want to say this is what we heard.

Did I hear Stan on the phone wanted to say something?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

Yes, there are two things. One is that the—I've got an echo, so I'm a little distracted, but I'll try and ignore that. This, I think, was the first time when people expressed the fact that they thought it was an aggressive schedule to incorporate the PCAST thing into the current phases of the meaningful use. Then, secondly, there was the discussion of the duplication of data that can occur in this more open exchange where data coming from a provider, a pharmacy, a PBM could cause duplication of information around the single prescription.

Paul Egerman – Software Entrepreneur

Thank you very much, Stan. Those are great additions. As you say, that's also a good way to look at this. As we look through this, people should talk about what their additions are. I want to also tell everyone, you sort of get two bites at this apple. What we're going to do is we're going to put this all together again. Wes will put together like a one page summary, then we'll circulate it. Then, people can comment on it and wordsmith on it, wordsmith it. So, thank you very much, Wes.

The next panel, which I'm sure will have— I'm sorry, Dixie, I missed you. I apologize.

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

I'm sorry, I should push it as far as I can.

Paul Egerman – Software Entrepreneur

I apologize.

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

It's not a problem. There was just one more topic that was brought up that I thought was extremely valuable to me. That was an exchange between David McCallie and Marc and Jim Walker where David asked about the relative value of documents versus discreet data elements. Marc was pointing out how it really isn't an either/or kind of proposition, but rather that many elements have meaning outside their

context. We talk a lot about data only within context. He pointed out how if we really want to do, for example, clinical decision support and search that we must treat data as individual elements. I thought that was a really important contribution.

Paul Egerman – Software Entrepreneur

Great, appreciate that. Thank you. The next panel is Patients/Consumer/Privacy Advocates. That's Mark.

Mark Rothstein – University of Louisville – Chair of Law and Medicine

Those of you who are here remember from yesterday, we had four very animated panelists. We discussed a wide range of issues with them. I want to review the seven major themes that were brought forward.

Number one is that consent is essential, but not sufficient. PCAST's heavy reliance on consent, and I would add as well as granular privacy controls, to achieve adequate privacy is a concern. The panelists expressed the concern that granular controls may be too complex for many patients, because they lack health literacy. They lack cognition. They're in poor health or whatever. They would be unable to deal with these demands. Reference was made to the HIPAA privacy rule, of course, as an example of consent not being adequate. As you all know, at first clinical encounters, the patients are given an acknowledgment to sign, often without the underlying notice that they're acknowledging. They do it as a sort of pro forma matter. If we change the name of the document that they sign to consent for whatever, that wouldn't necessarily mean that it was a more knowing or engaged patient. The panelists emphasized that fair information practices and legal regulation is needed as well.

Number two, the first goal of data use should be for treatment of patients and not for secondary uses. This was a very important theme. I want to come back to this if I can, when I get to number seven.

Third, privacy preferences must be dynamic. It was pointed out that patient attitude, societal attitudes, and patient health status all change over time. That certainly suggests that patients should be able to adjust their privacy controls.

Number four, we must do proof of concept of pilots of DEAS and privacy. As we heard yesterday, DEAS is a new concept and even if technologically it's not too demanding, as a matter of building trust in the public some proof that it actually works and it actually protects that privacy or doesn't compromise the privacy, it would be very helpful.

Number five, PHRs can play a role in patients' ability to express granular privacy preferences. I would add to clarify it by providing physicians with their PHR as this evidence. But, it was never suggested, I don't believe, by the panelists that a PHR could ever or should ever replace an EHR in terms of its clinical reliance.

Number six, concern about adequacy of deidentification and I would clarify as a privacy strategy. There are two issues related to deidentification as a privacy strategy. First, there was concern that the actual techniques of deidentification were not sufficiently proved. That's coupled with the frequently cited ability to re-identify even deidentified information. So, that's the first concern; sort of a technical concern. Second, even where deidentification is successful, patients object to the use of their deidentified information without their consent. I'm adding now editorially, it's not a matter of privacy so much, it's a matter of autonomy. All of the studies—and there are numerous surveys including one for the IOM—demonstrated the concern about autonomy.

Number seven, the panelists made abundantly clear that—and we sort of knew that by the inability in 90 minutes to get through all these issues—that many of the privacy issues were not discussed during the panel. There are others, and I would add including possible unintended consequences, of adopting the

PCAST recommendations or something similar to that. I want to tie that back to theme number two related to secondary uses.

If we make the data more valuable, if we increased the utility through a greater granularity or the ability to aggregate the data, the value of that information goes beyond the healthcare setting. That data would be valuable to law enforcement. It would be valuable to homeland security. It would be valuable to immigration. It would be valuable to non-medical researchers of all different types. It would be valuable commercially, etc. So, the question arises of whether there is a potential negative in creating data for one purpose that's maybe too valuable in other purposes. I'm not suggesting the answer to that, I'm just raising that as something that ties in with the recommendation of several panel members. That is to research some of the privacy issues that are raised.

Paul Egerman – Software Entrepreneur

Great. Again, this is intended to be a summary of what we heard. The privacy discussion, all the discussions are important, but this is one that is particularly sensitive. There are a lot of issues and concerns here. So, I don't want to redo the entire discussion from yesterday, because that would take a long time, but if there's a couple of comments.

Yes, John.

John Halamka – Harvard Medical School – Chief Information Officer

So, very briefly, because I had asked the panel recognizing the reality of structured and unstructured data, can we begin with something that's relatively straightforward like opt in consent at an institutional level as we march forward to more sophisticated granular approaches. I think we've heard uniformly from the panel that they thought segmentation was really important and should be something that we focused on now. So, see, I was trying to get us exchanging data as quickly as we could with good enough solutions. They pushed back a bit saying segmentation should be technically possible and we should focus on it in the near term.

Mark Rothstein – University of Louisville – Chair of Law and Medicine

Thank you, John. I will add that.

Paul Egerman – Software Entrepreneur

Judy.

Judy Murphy – Aurora Healthcare – Vice President of Applications

I think there was also some discussion on what are the expectations that patients should and shouldn't be able to do accurately. For example, there was concern that they would be able to read the legal agreements appropriately and there was concern that they would understand what it meant to tag data elements as private and did that really cover their concerns about what should be private. Would they be able to do that by themselves, or get on a Website, or have help? How would that be done?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

This is Stan. I've got a quick—

Paul Egerman – Software Entrepreneur

Go ahead, Stan.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

I think one thing they noted is that—similar to sort of not all of the privacy issues were discussed, there was one comment that basically said there's not enough detail in the PCAST Report that we really know what it's saying about how privacy worked. I think that's worth bringing up because I think all of us, in fact, still have slightly different views about what's being proposed. So, I think that leads to ambiguity in all of our discussions about this.

Paul Egerman – Software Entrepreneur

Terrific. Thank you for that. So, those are all great comments that we'll include in the summary. Again, we will be writing this up. People have another opportunity to go through it. This one will probably be a little bit longer than the others. So, we might even want to get a small, little, task force of people to make sure we write it up correctly.

Yes, I'm sorry. Go ahead, Steve.

Steven Stack – St. Joseph Hospital East – Chair, ER Dept

One other thing: I agree with the way John Halamka summarized that there was pushback. I absolutely agree with that. I'm glad you brought that up. If we didn't allow enough discrimination from the perspective of the consumer to be able to decide what was or what was not included.

One of the other comments that was also raised though was, as you mentioned, the complexity of the form. So, a family member of mine just had a procedure last week. You get the one-page, HIPAA disclosure form, which is meaningless because everybody just signs it. Most people, you find them stream in the emergency department on the floor when people leave because they don't read it. No one understands it. It certainly has an impact on the people who are providing the service though, because HIPAA, the doctors and the nurses and the hospital people not only interpret it and use it properly, but grossly misinterpret it. I mean, there's all sorts of information they are not sharing that they are perfectly able to share that HIPAA doesn't preclude.

So, the write up that is done, I think, needs to acknowledge, in a balanced way, the risks of not allowing enough independent or autonomy for the patient, but also the risks of allowing a lot of autonomy. Then the real risk of utter lack of inability to understand what that means, because the complexity of the documents to explain it would get so lengthy, no one will use it. So, it would be a meaningless right presented to them that they couldn't exercise because no rational person could understand it at the time they're getting care.

Paul Egerman – Software Entrepreneur

Excellent comment. Thank you. The next thing is with Population Health.

William Stead – Vanderbilt – Chief Strategy and Information Officer

Yes. We had input from Richard and Joyce. Through the discussion, I believe, these three high level themes emerged. First, that research and population studies require persistent record sets that can, in fact, be maintained and curated for a purpose that they could not be simply constructed on the fly. There are some sub-bullets under that around the idea that observational data that we obtain as a by-product of direct care is most easily suited or best suited for hypothesis generation, identifying ideas that might be possible, not for targeted research, separating out which of those ideas is true.

I actually got the next two bullets probably backwards. Research Data Models—they share a lot of features—are in fact tailored to the purposes of the study. Therefore, to a correct interpretation of, in essence, how to abstract the thing that we're interested in for research from, if you will, the continuous care data, takes interaction with the people that created the data in the first place. Semantic standards are important. They will constantly decrease the need for that interaction, but given the relationship of the design of the study, they may well not illuminate the need for that interaction. The final point that plays back up to the main theme is PCAST does not preclude. In fact, it can support these types of curated, data sets. You can, in fact, think of them as a middleware service of a sort, provided through exactly the same kind of distributed mechanism that Richard is doing now. That was theme one.

Theme two is that to do population research, we need to know the denominator. How many people are, in fact, in the overall population? We need to know the numerator. How many people are in the sub-population that we're trying to see if we have changed risk, etc.? Therefore, granular consent and opt out

by data suppliers could be problematic for both of those unless the current policies that data can be used, without consent or certain public, health purposes, etc. are, in some way, preserved within the consent structure. So, it's a second broad theme.

Then, the third plays back into what we've said before deidentification is problematic, both in terms of the degree to which you can actually deidentify data. I mean, in our work at Vanderbilt, we have experts that actually test the reidentification risk on every set, after it has, in fact, been obtained through a query before we let anybody use it. It's that sensitive to what's actually been retrieved. So, that's a challenge. The other piece of the challenge is that it plays back up into bullet two if we use the identification that can make it difficult for us to know what we're dealing with, in terms of the population constraints. So, I think those were the major themes that emerged.

Paul Egerman – Software Entrepreneur

Terrific. Thank you. The next panel was Providers—sure.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

So, this is a good summary, comments on all of the major points, though. Some of them are word snipping. I'd be happy to provide them later, but it's important for us, throughout, not to use the short-handed research when we also mean public health practice and quality measurements.

The second, with regard to the first major theme, I suggest that we strike that first sub-bullet. I know that we discussed the appropriate uses of observational data, but this is a long and rich history, this discussion. There's no need for this panel to weigh in on what the appropriate uses of observational data are. There are a couple of places where we need to soften these statements and say, "For some uses," or "In some cases." I'd be happy to do those offline if you like. With regard to the second bullet, the point that we ought to make is that we require identification of the population, its management and its health outcomes rather than try and focus this on the intervention.

With regard to the third point, the larger point—at least one I was trying to make was that the creation of a centralized database for general use is problematic. It's problematic for several reasons, not just the risk and reidentification. So, that's a major point that deserves attention by this panel with regard to the recommendation of PCAST, that there be a large, clinically rich, deidentified database for general use. I'm skeptical that will be workable. It seems to me that deserves discussion, but that was certainly a point I was trying to make yesterday.

Paul Egerman – Software Entrepreneur

Excellent. All excellent comments. What we'll do is we'll take you up on your offer to help us write ...—I appreciate that because we want to make sure that this is right. So, excellent comments.

Go ahead, David. Oh, you. Sorry.

M

Go ahead, David. Then, I'll ... to you.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I agree that the point of that observational data was not to raise the debate about what you can do or can't do with observational data, but rather to point out that the data captured is a by-product of care is likely to be more similar to observational data than it is to data collected, specifically for research purposes. So, that was the point I was trying to get at and ask in that question. It's not a debate about what you can do with observational data, but just to comment that by-products of care are often observational.

M

Oh, by definition, they're observational.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Right, exactly. That was the point. If that's what's in PCAST, it's by-products of care.

M

Yes. Agree on that. Okay.

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

Along the lines of what David said first. I disagree with striking the bullet. As far as—... maybe, but there's a lot of people out here who believe out there—wherever there is—who believe that with access to all the observational data in the world, all kinds of things could be decided clinically overnight. I just don't think that's a representation of reality.

Paul Egerman – Software Entrepreneur

Just to make sure that we ground ourselves, the issue is not what we believe. The issue is what we've heard ... the feedback.

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

Well, I don't think the people who said this ... believe it's any different than what we believe.

Paul Egerman – Software Entrepreneur

That's fine but, but these are good issues. I'm just also a little bit concerned about the clock because I also want to make sure that we get to the issues that Craig raised. So, I don't mean to suggest that one way or the other as to how we—

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

Well, at the risk of incurring the wrath of the Chair, I'd like to make one more comment.

Paul Egerman – Software Entrepreneur

Absolutely, you can make one more comment.

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

The point that Stan raised about effectively data arriving from multiple tasks, the same data appearing to be duplicated because it came in from different sources, is highly exacerbated with deidentified data. That needs to be said.

Paul Egerman – Software Entrepreneur

I agree with that. Makes sense. So, go ahead,

Richard Platt – Harvard Medical School – Professor & Chair

I certainly agree with many of the points, but it's a question of emphasis, specifically on this bit about whether correct interpretation of the data requires participation of the originator. I believe what Marc Overhage has said—and something I sign onto completely is that when one is trying to achieve some kind of normalization process, at that point, that participation is important. However, once established, it is conceivable and plausible that ongoing data collection aggregation access either distributed virtual, persistent/non-persistent—we can do all the variations—many useful questions can be answered without the ongoing engagement of the creators of the data. It's important to understand, once a level of standardization or normalization has been achieved, then the subsequent, secondary uses for different, aggregation use cases, be they research, be they quality, be they new knowledge discovery, can be achieved and need not require—I don't think the statement on the slide captures that nuance.

Paul Egerman – Software Entrepreneur

That's very helpful. So, we need to do a fair amount of work on this to get this correct, make sure that you're comfortable and capture Wes' comment and certainly capture your comments, Richard. So, I appreciate—and yours, too, David, of course. We will take care of that.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO

Can I offer an additional theme?

Paul Egerman – Software Entrepreneur

Sure.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO

Another important theme is something—an exchange that happened that was very valuable is the fact that nothing on the PCAST Report recommendations seemed to alter or disrupt the current IRB structure. The role of IRB seemed protecting this human subject for research purposes. That theme should be highlighted because it's something that, as a message out there, is going to be an important point.

Paul Egerman – Software Entrepreneur

Excellent. Thank you very much, Walter. So, the next panel is Providers and Hospitals.

Steven Stack – St. Joseph Hospital East – Chair, ER Dept

So, I've observed, with all the panels, there were many things that were said. So, the things that I selected out of that may not represent all of the great knowledge we got. I'd say that panel four also made the same observations as the Privacy Panel—number one, two, three, and five on the bullets that are on our panel two slide. They seemed to agree with the consumers in that regard.

With regard to this slide itself, we've already discussed the concern about, perhaps, the PCAST timeline being too aggressive and the dangers if it were too disruptive to the investments that are already being made in meaningful use stages one, two, and three. It was not a disagreement that that PCAST recommendations were not useful or appropriate or beneficial, just the concern with how to reconcile it with the path we've already gone down quite a bit.

The item number two: the privacy tags potentially hindering normal institutional use of data. I don't remember who it was. It was Scott Whyte or Kevin who made the reference about contracting out, essentially, for things. So, you may have a group that helps you do internal, quality review, but it's an external vendor. Is that data exchange, or is that internal use? Things like interactions with SureScripts, an example was given about when does it become data exchange versus when it is internal use purposes? So, some clarity needs to be done there. The other thing would be, perhaps, in-patient and outpatient. So, the health system I am part of will have an inpatient EMR that's a large vendor and then, a different vendor for their community-based physicians. So, it's for the use of the internal stuff, but it's going to be exchanged data between two, different EMR's. So, when is that exchange outside of the walls versus inside? So, that's not clear.

As far as bullet number three, the propagation of bad data or the redaction of bad data, so the correction of it is concerning and problematic. A couple of examples: if a patient uses a false ID, which happens in my world more than I'd like, and then data's created in the wrong chart, under the wrong person's name or identity, and then it's propagated through this system, how do you retract that, down the road? How do you correct that error once it's found? It's problematic in today's world. It would be more so if the data now takes on lives in other places. Also, historical errors: so, perhaps a 30-year-old woman who says she's had a tubal ligation, but in fact – or the record says she's had a tubal ligation, but perhaps she has not, which leads to diagnostic or treatment errors down the road. How do you correct that, down the road, if that data has now been exported to numerous, different EMR's and incorporated?

Item number four: the middleware. It was clear that middleware could perhaps provide a useful bridge to legacy systems and bridging to attached meta-tags to data in legacy systems to make it comport a little

bit to the PCAST frame. On the other hand, there were limitations, described with that approach. I'd have to look to the technical folks here to explain those limitations because I was not savvy enough to capture all of that.

As far as number five, patient matching is problematic. The possibility of things, such as a single letter or number of entry, failing to yield a match, so you now can't find something you should be able to find, or what if you have a mismatch? What if you have a single number error that actually results in a lock on the wrong patient and now, you pull the wrong data in? I'm giving examples, but problems of accurate patient identification are apparently real from the perspective of this panel.

Then, the final point, which is here just because it was one of the first times it had been presented this particular way was the—and I'm not sure that it's necessarily germane specifically to the PCAST versus the bigger picture of HIT and HIE—potential novel use of personal health records to engage the patient in ways that were different, such as messaging and bidirectional communication with them in a way that might pull them into the use of the electronic record and help to drive adoption and propagation. Also, for privacy concerns, if the PHR were, in some way, the hub of their management, it reinserts the human filter, and the ultimate human filter, the patient themselves, into what they want to share it or not. There were some novel concepts described there.

The final observation I would make is, when we got on one or two of our little, side discussions, was the critical value of having both the patient and the clinician perspective because the idealized interactions we often describe in these settings may not necessarily capture the real world interactions that are happening. The example of the woman, scolding the doctor for calling to suggest a mammogram as preventive care—that does not meet with our idealized expectation because, of course, every patient would say, "Thank you for calling me. I'm glad you're concerned about me." In fact, in this, she gave a very valid example of where that could cause a backlash in the community she serves where folks may not then seek care.

So, thank you very much. I hope that's a reasonable summary.

Paul Egerman – Software Entrepreneur

Great thank you. David.

David Blumenthal – Department of HHS – National Coordinator for Health IT

Hi. Since I missed this panel, just to clarify a question: except for points one and four, it doesn't seem to me like these are particularly comments about PCAST so much as they are about information exchange in general. Is that accurate? Maybe tags, maybe slightly PCAST, but also privacy concerns would be generalized. The examples that you gave, which are sort of EMR to EMR within a system is that exchange pertains whether the data's tagged or not. So, I guess the question I had is, "Are there are any other points made that were unique to PCAST-proposed architecture for exchange as opposed to exchange in general?"

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

Paul, may I respond? It's a great comment. I look at, for example, the patient matching is problematic. That was related to the PCAST Report. The PCAST Report made some comments that patient matching as it relates to the DF. So, people will respond through that for the most part, in the context of reporting. The novel, PHR use is also a reflection of something that was in the PHR in the PCAST Report.

Craig Mundie – Microsoft – Chief Research and Strategy Officer

I just wanted to offer a comment since David wasn't here, and he asked the question. I'll say, as the PCAST monitor, I would tell you more than half of all the discussion yesterday had nothing to do with PCAST, per se. As I said earlier, I mean, I think the report brought to the surface a lot of things that people in the community wanted to discuss, but we're either completely neutral to PCAST, or frankly, PCAST was silent on the entire topic. So, that's why I had asked Paul at what point do we want to go

back through this because, the only thing I could do is certainly, we'd like to do is offer comments about many of these things as to whether they were actually PCAST-specific or not. At some point, this committee has to go back to its charge and say, "This is a general discussion of these issues," or "Is it going to confine itself to report on the PCAST-related elements of each point?" and which was what needed to be done in order to get the job done.

So, at some point, either you got to put the is this a PCAST specific-issue filter on each of the report elements, and you'll end up with two buckets. One bucket is the things that the community ought to keep talking about because there are going to be issues downstream, no matter how you implement any of these things. The other bucket, the specific issues that the PCAST Report speaks to. As I said, when we get back many of these comments, I'll reserve my other comments for when we get into the discussion.

Paul Egerman – Software Entrepreneur

Okay. I appreciate that excellent comment. Makes sense, especially in the context of Dr. Blumenthal's question.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

This is Stan again. I got my card up.

Paul Egerman – Software Entrepreneur

Okay, let me let David speak. Then, we'll have you speak, Stan.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

One thing that did come up that was somewhat PCAST-related was the debate about the value of documents versus granular data, extracted from the document. Dr. Mattison from KP made a strong recommendation that the document not be ignored. That's not necessarily PCAST-recommended, but at least some people have interpreted it that way. So, that was part of the discussion.

Paul Egerman – Software Entrepreneur

Judy?

Judy Murphy – Aurora Healthcare – Vice President of Applications

There are two topics I wanted to comment on. One, there was a bit of discussion of the trade-off. The words were, "Reproducibility at the expense of expressivity." Remember those from yesterday? The focus was on the context of the document is very important. They were feeling that would be harmed. The second thing was I thought that there was a general feeling among them—it was said in different ways—of don't change the course. Scott said words similar to that. Kevin Larson talked about interfacing, interoperability, working for them already. Teresa Cullen talked about don't add another standard to ICD-9, SNOMED, etc.

Paul Egerman – Software Entrepreneur

Thank you. Was Stan on the phone? Was somebody on the phone?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

Yes. Another comment was useful is that they said, PCAST poses some very interesting opportunities, but we needed to do some experiments and proof of concepts and prototyping in order to get experience before we could suggest general adoption.

Paul Egerman – Software Entrepreneur

Great. Thank you, Stan. Okay. So, they're great comments. Let's quickly— I'm sorry. Go ahead.

M

Yes, one of the things that happened yesterday was that the moderators continued to try to ask the panelists to find a small step that could be taken to go to PCAST. On this panel, I thought that there was

a moderate amount of consensus around trying to do that with regard to immunization, that there were several panelists who thought that might be an area where we could take some small step to try to test some of these ideas that Stan was just describing.

Paul Egerman – Software Entrepreneur

Great. That's actually very helpful. I appreciate that, Art.

Moving on to the very next panel, which is panel five. If you could take us through this rapidly

John Halamka, Harvard Medical School

Absolutely. Certainly want to thank the panelists. We heard from large and small vendors, home-built vendor, so to speak, and somebody who is an open source, service provider. Some major themes—five of these, David, are PCAST-specific. Two are not. So, if PCAST suggests that we will have an atomic—of course, the definition of atomic or molecular or segmented is not precisely done—we better not destroy the clinical context. The information still should be usable and understandable. So, point one: important to maintain the context of the clinical encounter, preserve the meaning when the data is reused for purposes other than originally intended. During the course of another panel, Paul, for example, mentioned if a diagnosis is an atomic data element and in the context of the clinical care, it was clear this was because a novel new diagnosis was made based on clinical judgment versus a diagnosis code was part of a lab or radiology order, it may have very different meaning.

If we are going to have an atomic or a molecular representation of the data, then we should try to capture data in a structured fashion to the level of granularity that's important. We've already had discussions, for example, about blood pressure and what it means to gather systolic, diastolic in a specific unit of measure. We should use controlled terminology. That's certainly going to allow us to privacy filters and of various types of reuse, population, health, or analytics.

We should separate the syntax. That is the nature of the container that is used to send data from point A to point B from the semantics that is the ontologies and the vocabularies that may be used, such that it may be a journey. We may start with sending data that is free text, maybe not be completely structured. Then, as time goes by, we may develop more sophisticated ontologies and vocabularies to represent it in a more codified way. So hence, we shouldn't wait for the perfect ontology and the complete vocabulary before we start exchanging data.

This is a theme in several other presentations that we should evaluate the burden of doing what PCAST has suggested in the context of everything else because it's a choice. If we have meaningful use stage one, two, and three, and ICD-10 and 5010, and now, we're going to build DEAS and universal exchange languages, that's the highest and best use of limited resources. Just a question, not an answer.

This is a non-PCAST point. Simply exchanging data doesn't necessarily lead to useful and accurate data. The data is only good as how it is captured at its source. One aspect of exchanging data: you need to know a little bit about who entered it in what context, whether it is complete or clean. As an example, gender is mis-entered in my institution about 3% of the time. It's a binary field. It's one keystroke. Hence, if somebody's gender appears to change multiple times over the course of their lives, that may or may not be significant. You'd understand that. This is, again, a non-PCAST point. There was some discussion about open source as being a consideration to drive low cost solutions in the industry. Nothing PCAST-specific.

Finally, one of the concerns about PCAST—we've heard from multiple panels—is this a rip and replace? Does this imply retooling of all of existent systems? Does this require a deviation from the path we are on? The theme was there are multiple ways to think about achieving PCAST goals, including using middleware that is a bolt on to existent technologies and existent standards that may get us to, "What is PCAST's novel reuse of data?" It is not necessarily a rip and replace, or a deviation from the path already outlined by meaningful use.

So, look forward to your comments.

Paul Egerman – Software Entrepreneur

Terrific. You nailed it, John. That was great. So, comments from Chris?

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

Thank you, John, an excellent summary, as always.

However, this point that was made explicitly in the PCAST Report and admittedly was repeated, needs some refinement. That is the separation of syntax and semantics. While I wholeheartedly agree that value sets, ontologies, content models, whatever you want to call them, can and should be independently developed. We cannot overlook the intertwined nature of information models and syntax and semantics specifically. Content without some kind of over-arching, information model, which historically has been represented in the syntax, is highly problematic. The poster child example I always use is heart disease in a box that says, “Family History” on top. It clearly changes the semantics of the content. That is an information model artifact. What we have not achieved is clarity as to where and how that information model, or schema, if you wish to call it that, is represented.

As I said, and this is a terribly important point, we have relied historically on syntax for that information model representation, which may or may not be appropriate, but to say blandly that we can or must separate syntax from semantics grossly overstates the problem. I acknowledge that, in the semantic Web view of the universe, we have relationship types that may or may not be curated that can finesse this problem. However, the PCAST Report—and the good Mr. Mundie and I debated this at the last ONC forum—the PCAST Report does not, in my reading of it, give sufficient emphasis to the requirement to maintain either a set of well-curated relationship types as a surrogate, if you will, for information model. Or acknowledge that the information model aspects of syntax are either required or require an alternative.

John Halamka, Harvard Medical School

Well stated. I use the example of allergies and what is the detailed, clinical model around the things that constitute an allergy.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

My suggestion is somewhat lighthearted, but John and Chris are using syntax and semantics to mean different things. I wonder if we need a glossary that agrees on what these words mean, in the context of this debate about PCAST because there’s a semantic mismatch between what you mean.

Paul Egerman – Software Entrepreneur

That actually could be a good idea although there is a nice ... in the PCAST Report that will—

M

....

M

Twisted. Twisted.

Paul Egerman – Software Entrepreneur

That’s right. So, these are great comments. Two—... very brief, but we’ll do

W

I’ll be very brief. It sounds like we need some normalization of the semantics. Anyway, I heard two things yesterday that I thought were interesting, coming from this panel. One was an acknowledgement that we may have a grander vision of the technology as it exists today than is appropriate, and whether or not the clinical decision support, in particular, is actually ready to take advantage of a highly granular, data

exchange. So, I thought that was very interesting. Then, the other thing that I thought I heard quite clearly—and this gets back to the atom—was that the size of the atom might, in fact, need to be quite different, depending upon the intended use of the atom. So, I thought that was something that was probably worth capturing.

Paul Egerman – Software Entrepreneur

Good comment. Excellent comment. Thank you. Tim Elwell?

Tim Elwell – Misys Open Source Solutions – Vice President

Relative to the point number six on the open source piece, I do think it was germane from the standpoint that, in context associated with the creation of pilots or prototype, the whole transparency, collaborative type of nature that is endorsed by the open source community would be suggested as an alternative model, to be able to drive adoption. So, I do think, John, that perhaps there is a piece for that, to be able to be supported.

Paul Egerman – Software Entrepreneur

Terrific. Great comments.

Now, we're running a little bit behind schedule. We want to get to the part of the discussion that Craig is suggesting. Originally, we had slides in here that also summarized the public comments that we've received. This is material that was already presented to the work group. It originally put in here, just to refresh everyone's memory, but because we're behind, I'm going to just click through all of that stuff, including the panel six that wasn't feedback. I'll hope that, by looking at this real rapid fashion, it refreshes everyone's memory.

I know Doug was preparing to help us go through this, but we'll perhaps do that if we need to schedule a refresh course on that. So, what I wanted to do—I'll just say if Doug had done it, I'm sure it would have been an excellent job. So, I'll just say, "Thank you for that great job, Doug." So, we'll just race through that.

This is what the staff tried to do, to summarize the entire hearing, like a small number of bullets. We should perhaps just quickly think about this in terms of, "Are these appropriate summary points?"

Have you read through this, Bill? Would you like to talk people through this?

William Stead – Vanderbilt – Chief Strategy and Information Officer I

No because there's some problematic ... there. I don't know how you're going to do that in the context of what you're trying to do with time.

Paul Egerman – Software Entrepreneur

Okay. So, what should we do to try to get this organized? We have some group of people who like ... something?

William Stead – Vanderbilt – Chief Strategy and Information Officer

We might need to work through it. Remember, if you look at the changes that took place in the panel slides between when they were first drafted and what we just saw, my sense is this needs the same work through, probably offline.

Paul Egerman – Software Entrepreneur

Okay, so what we need to do is—let's do an offline review of this. This is not ... review. First step would be let's update all the panel slides, based on the feedback that we got. Then, we'll circulate that. We'll circulate this and see if we can get a consensus around this so that you want to get into some of this very substantive issues and continue the discussion that we had yesterday.

So, one way to do this is—yes, so, go ahead, Craig.

Craig Mundie – Microsoft – Chief Research and Strategy Officer

... of order. So, you skip the summary slides of our presentation.

Paul Egerman – Software Entrepreneur

Yes. Did you want to go through that?

Craig Mundie – Microsoft – Chief Research and Strategy Officer

Well, there's at least corrections I might make to them, but I don't know whether—you don't have to do it online, but—

Paul Egerman – Software Entrepreneur

We should— I'm sorry

M

It might be helpful to ask Craig to do what we had suggested, which is we've been through the summary of what we heard from the panels. That reflects a variety of things. To have Craig's insight into those pieces would probably be our best use of time, the next block of time together, if that makes sense.

Paul Egerman – Software Entrepreneur

Absolutely. Go ahead, Craig.

Craig Mundie – Microsoft – Chief Research and Strategy Officer

If you want to go back to panel one, I'll just take each bullet point where I thought there was some interesting comment that I might make about the deliberations that PCAST had or where I think there's something that's been misconstrued in the report.

Let me just make a couple of other processing remarks. One thing I was struck by in the course of listening to the discussions yesterday and reading all the testimony was there was not much contribution toward how would you implement the PCAST Report. I mean, it was striking in that many of the comments related to some apparently detailed assumption about how the implementation would be done, like how would we retrieve an errant piece of data. I mean, that's a very low level system design question. At the other hand, people had very high level assumptions about what they thought the implementation might be. Of course, PCAST, in writing the report to the president tried to be circumspect about detailed prescription for the design and implementation, essentially attacking ONC and its processes to develop a set of specific designs.

So, yesterday, in my comments—and again, as I go through this today, I'm going to offer you not a formal, PCAST response, but one man's interpretation, reflecting a lot of our discussions and some of the underlying thinking about ways that these things might have been approached. PCAST was not—arguably, some people thought we were relative to presidential reports, quite prescriptive about a general direction, but that was because we felt that there was some urgency required in moving in a direction that was not being pursued by the community. It wasn't that what the community was doing was wrong. It's just it was our assessment that it was ... insufficient or might take much longer than the country could afford from an economic standpoint.

Christine mentioned yesterday again that a lot of the motivation in the president's tasking of this was asking the question of, "Are there some strategies that would produce substantial changes in the way in which we operate that would reduce cost?" Not much of the testimony was reflective of the fact that at the current course and speed is not generally moving the country to a path with sufficient cost reductions necessary to look out—this is over a multi-decade horizon, but to get us, as a country, where we need to be in terms of cost performance, if you will, of healthcare in the aggregate. It's very important to remember that in our tasking and what we wrote, part of the reason for urgency wasn't specifically just the

way that this could be a better way to operate the healthcare system as it is. But whether or not it was instrumental in allowing consideration of alternative payment architectures and other things which we didn't believe could transition without something that produced a patient-centered view of the information. So, I just want to highlight those points again as I'll now just give you the ink blot test. You show me a bullet point. I'll tell you what I was thinking when I participated in the development of report.

Clearly—just going now quickly through them—trust is more complex than consent: The report, in some ways, dealt with that by pointing out that we felt that in addition to the technological means, we needed to assume that there would be regulatory and other actions that would essentially create a framework that would not only build trust with the public, if you will. But really did put teeth into the idea that the people who were going to participate in this system had substantial penalties for malfeasance. So, we've clearly recognized that technology, by itself, doesn't solve this problem and expected that, through the regulatory action of ONC or other agencies of government or the action of Congress, things would be put in place that would put teeth into the elements of the system necessary to bring comfort.

Data source systems ... not even going to meet regional service levels: Actually, the thesis in the PCAST thinking was not that the DEAS would point you back, if you will, to the particular CAT scanner and say, "Go ask it for the data." The assumption was that, in fact, the data would be extracted in some way into some data warehouse or some other thing. That's where you would create, if you will, the alter-ego of the data that exists within the operating environment. Our assumption was you can't actually change the operating environment. That is wildly too complex and diverse, and wants to be, nor can you assume that, as somebody said, that machines don't break or aren't replaced on a generational basis.

So, our assumption all along was that some type of data archiving or warehousing had to be going on. That, in fact, could be designed for long-term reliability and is no different than the kind of extraction that's going to be put in place to support operational analytics and other things over time. And that data set that would then be encrypted at rest, thereby not projecting back onto the operating system requirement to alter the incumbent systems until such time as they deemed it useful for other reasons. So, the view was that the data that would be extracted—this would evolve over time—would be put into some high availability, and to support whatever intensity is required.

It was also clear that people seemed to assume that some of this would all just get pushed back down instantaneously into the way the operational environment in the hospital would work, but there was no such assumption on the part of PCAST. But rather that, stage by stage, more data would be extracted from the underlying system, put into this, if you will, outward-facing repository and that repository would then be indexed by the DEAS-type systems as required that the metadata which may, in fact, be missing or only related syntactically, would be synthesized.

What we talked about in the report again was that the metadata had two, basic, conceptual content. One was the providence information, which you can interpret as broadly as you want. Yesterday, in listening to all the comments, everybody who said, "Context is important." No one disputes that. Nothing in the PCAST Report says that a document can't be an atomic entity, but even a document, at the end of the day, is comprised of sub-elements. At the end of the day, all of those elements had some origination. What PCAST is saying is that the more that you can do to reflect the providence of every, low level data item, whether it's ultimately passed out with context in a document, or whether it's passed out in its most elemental form, at the end of the day, it's only goodness if you can have the providence be expressed.

Our expectation now is that most of the providence is not expressed, but implied. Therefore, in extracting it, by whatever means you choose, and putting it into, I'll call it, the outward facing repository, it's at that point where you extract it, that you synthesize any missing metadata or providence information as that component of the metadata. Similarly, at that point—I'll come back to the privacy comments later—that you would federate with it whatever representation of the privacy constraints would be required. Those were the two, broad things we talked about in the report: providence and access controls, if you will—privacy controls.

When you reach into a system, for example, and pull out, I'll say—I'm just making this up—an X-ray image or something. You say, "Well, okay, we have the X-ray image, but it didn't actually have all of its providence attached to it," but when you extracted it, you knew where you extracted it from. So, you might be able to annotate the image with providence data that was available from the machine or available in the context, but that's such a diverse thing. The assumption has to be that, if you choose that data to be available in this externally, visible way, then you will choose to make the metadata as good as it can be, but throughout our thinking, the idea that the perfect is the enemy of the good reigns supreme. That's why we said, "You should start with allowing completely ad hoc data to be presented and indexed where the caveats are, this is raw data. Here's the best providence information we have. Use it as you see fit." People who want to consume more structured data or data where there's additional context, the assumption is those services, as Bill or somebody called them, could be available. There can be things that could be pretty normalized. At the end of the day, I heard many people; say, "Look, even if you have normalization occurring, the ability to go back to the originating data in its most primal form is not a bad thing. It's a good thing."

Again, our assumption is that the cost of storage has declined exponentially to the point where the cost of keeping this redundant copy is not prohibitive. Like John ... remember, one of the questions that ... asked and many of the CIO's went and did for us in the report was people kept telling us how big the data was, like it was problematic to extract or keep these things.

So, we asked. We actually found—partners had the largest, per patient amount of data that was kept of everybody that we dealt with. Just to put it in context, we said, "Well, what if we just went over to – Ed, one of the economists who were there. They said, "Well, as a way of gauging the practicality of this, what if you just went out to, I'll say, Amazon EC2 with your Visa card and said, 'I want to buy redundant storage equal to the amount that the largest one we could find in the country had.' The cost looked to be somewhere between \$2 and \$3 a year to buy that storage online." Redundant, per person. Okay, \$2 to \$3 a year for person. If you look at what we spend per person on patient care, you say, would it be worth \$2 or \$3 a year? Our assumption was this didn't appear to be an implausible strategy. Again, we started with some rules of thumb, class of analysis about the practicality of these things, but we couldn't see a reason, particularly given that was the largest we could find in the country that, in practice. With the idea that you were going to phase into this, that the amount of redundant storage that would be required to get the system operational was not prohibitive within any organization that currently stores this.

Point three, I don't think is a PCAST-related comment, per se. I mean, normalization is a challenging task. Some of these things have to be done in context, but one of the things that we, I'll say, generally see happening in other domains as well where there are big, complex, data sets is that by always being able to go back to the, if you will, raw data or the most native data and being able to interpret it in context of applications in the future that didn't exist when you thought about doing "normalization" the first time, there's often value created in that. It's not anticipated uses or the ability to associate things that you didn't know at that time.

So, the PCAST, with this longer term view said, "That was why we recommended that you should have elemental metadata and preserve it." That, in no way, says that, at any point in the process, some normalization shouldn't take place, but it was our belief that there are many things where normalization isn't required. There are many cases, and will be many cases in the future, where the normalization will be done, I'll say, more like the human doctor does at the very end of the process. I'll point out, there are many of these data types that people talk about normalizing that, in practice, can never be normalized because, in fact, the machines change generation to generation, or two, different brands of machines. I mean, take a blood analysis where they print out for the doctor whether this is considered high or normal. High or normal is a function of the standard that was in use by that company on that day.

M

You talk about machines, you talk about the medical devices.

Craig Mundie – Microsoft – Chief Research and Strategy Officer

Yes, the medical devices.

M

Not the computer systems.

Craig Mundie – Microsoft – Chief Research and Strategy Officer

Yes, I'm talking about all of the medical equipment. So, these are the things that, at some point, if you presented a doctor at the end of the day, with all of my printouts of every blood test I've ever had, he would be able to figure out, "Oh, well, look, some of these were H's and other said 'normal.'" It doesn't trouble him because he has some context implicit in that, or he can go back and look at the actual value and say, "Oh, by my standard, that's okay."

Our view is that, more and more, the software systems, the decision support systems that we were advocating for would become more and more sophisticated. Therefore, their ability to do some of this late binding or post-normalization kind of thing in the context of the service being provided might also turn out to be interesting over time. So, nothing in the report says that, "Thou shalt always do it at the end, or that thou shalt always do it at the beginning." It just says that, if you have the elemental data, you can reserve the right to go all the way back at any point in time. No way does that neutralize the great work that people have been doing in creating data sets that are normalized.

It says, "Need to balance mobilizing data versus losing context." I spoke to that by saying, "Look, if you have some"—there's two ways to think about that. In the work of PCAST, we did not try to be very prescriptive about what we thought was in the universal exchange language other than, as I said yesterday, to think of that as a container. This is one of the comments on another slide that Carl wrote. The universal exchange engine is not a container for the data. It's a container for the descriptions of the data, if you will. That's arguably more important than saying the data itself is there because, in essence, you're trying to say the metadata is the thing that points you to where the actual data element is. It's ... can take place subsequently.

So, the idea here was that over time we expected that the technologies of describing not just the historical providence information, but essentially, more and more of this contextual information that Chris was just alluding to. It just gets better over time. If you go back, five or ten years, there weren't well developed languages for defining ontologies and semantics. People would, more or less, do that on an ad hoc basis, but some of the work in semantic Web, and then broadly, the idea of developing semantic networks independent of the Internet has driven that technology forward. So when we thought of universal exchange language, we thought it was a place where you could take the work that had been done in standardization. You could basically insert those things. You could put taxonomy and ontologies around them, and that ultimately there would be more and more capacity to have formal description of semantics.

Therefore, all of these goals of semantic interoperability would be enhanced in an evolutionary way. Much as Wes was implying with his unstated joke, our view was that you don't really want to try to think that all this is done with a snapshot of a perfect standard that exists at one point in time. But rather you have to almost allow this to be a continuous process where completely new things are entering the stream, and completely well understood things are ultimately codified to a greater and greater degree. And that it's the software that's interpreting, or extracting, this information and operating it in a decision support or operational context that will increasingly make that more to the province of software to assess, and less and less an overwhelming task for the person themselves.

Here, consent is essential, but not sufficient. PCAST heavily relies on consent, which adequate privacy is a concern. I guess my thought about this is, one, we clearly didn't believe that just having the technical approach was sufficient, and I made that comment earlier. I think there's a couple of other things that I want to offer about some of the discussions I'll say we had, and my own thinking about this in the privacy

domain. The idea in PCAST that there needs to be metadata about controls at an elemental level in no way implied that we expected the patient in the typical case to make adjustments for every data element in his record.

In fact, I would argue that in many other domains, where we see privacy issues emerging, including on the Internet, that it becomes clearer and clearer that the individual has to be given some high level conceptual—I'll say, profiles, that they can elect that create a baseline of conditions that would meet most people's requirements. That those things can be cascaded down in a more automated sense. The idea that people would go in as a typical case and administer privacy by putting their own statement on each individual data item is obviously impractical. There was nothing in the report that said, "Thou shall do it that way."

In fact, there was no specific design recommended, other than to say, indeed, that because privacy is such an important issue, and arguably, one that is not historically addressed much in the current models of exchange, which are viewed as largely institutional. You could say there is no architecture for privacy or involvement of the patient in that. I interpret many of the comments from the consumer and privacy advocacy groups as sort of reflecting or embracing the PCAST Report; in part because it advanced the idea that there, in fact, could be some technological way of reflecting the wishes of the patient in a more granular way.

Again, the report—I don't think says very expressly, but it's clear that the wishes of the individual ultimately will bump into the wishes of the society. That also is not a PCAST specific thing, nor something that's essentially confined to the medical domain. So, increasingly, we will find that as we see in, I'll say, in cases of infectious disease, or epidemia epidemic management, that the society sometimes comes together through its legislatures, or its regulators, and says, "We're going to share this data, or we're going to combine this data, because it's essential for the general public health."

So there's nothing, again, in the report that implied that in every case the patient's wish ultimately was the defining wish. Merely that their wish is recorded; and in fact, the wishes or requirements of any other privacy constraint could similarly be recorded there. Again, in my view, not a PCAST statement policy, but rather a goal by PCAST to suggest there was a generalized mechanism by which almost any policy could be ultimately implemented by the software that recorded those things, and ultimately the software that was interpreting them. There obviously would have to be a complete framework and design wrapped around that, for how that might work.

So we were trying to define a mechanism, and we made no policy statement at all. Or not one that would say that the patient somehow has a right over the right of everybody else. That's where society bumps into the individual. I don't think that's confined to this domain.

Second point, first goal of data used should be treatment for patients, and not for secondary uses.

Paul Egerman – Software Entrepreneur

Can I interrupt for a second? From a time point of view, because I think this is helpful, but I think we can't probably work through it all at this level of detail. Could I then maybe then go to the next panel and have sort of the biggest points you want to make on it, rather than trying to go with each one? Or would that not be helpful?

Craig Mundie – Microsoft – Chief Research and Strategy Officer

Sure. I can try to consolidate.

Paul Egerman – Software Entrepreneur

Okay. That's all I'm suggesting. I think we've got to deal with time.

Craig Mundie – Microsoft – Chief Research and Strategy Officer

Fine. One comment on this second bullet point, again I'll say that PCAST was contemplating. We were contemplating a world where everything is a lot more data driven than it has been in the past. I think it's going to become increasingly difficult to draw clear boundaries between the role of big data in defining research, and the practice of that as it relates to even clinical practice in the future. So while I historically understand that there may have been more of a view of a clean separation between these things, I would say those of us who were thinking about this in the PCAST work generally tended to think that data driven processes, as well as analysis and treatment and other things, that these going to be drawn naturally closer together over time, and you need to think about that as you try to establish policies.

Clearly, I said yesterday the policy should be dynamic. We thought a lot about the deidentification. I'll say again, the key here was the idea that—and I'll just point this out. As I understand HIPAA today, within a HIPAA enterprise, they can freely exchange the data within that context, and many do. In fact, the biggest ones that combine the payment capability, the providing capability, the dispensing capability and the research capability all operate within one domain, and it all moves freely in that environment.

So the idea that deidentification enters the equation is indeed a challenging problem. But again, you have to understand, and it's different than, I'll say, the Netflix example and others. If you produce a dataset and it's given to somebody for a purpose under a particular set of constraints, those people should be obligated and the protocols under which they operate, to not release subsequently—that would be a tertiary youth that may not have been provided for. That they can't be free to arbitrarily intersect it with other datasets for the purposes of reidentification.

We don't state that anywhere, but there's clearly no reason that you couldn't be clear about that; much as IRB and—I'm not an expert on that, but there are many protocols that govern these things. I just don't think enough thought has been given to the idea that these are not random college students that were just saying, "Come in and access the data." We're saying that they have an identity, they have a role, they are going to get access for a particular purpose. I think, again, in wrapping a total trust framework around that, you have to think about the rest of these issues, as well. Go ahead.

I think that, other than believing that we were entering more of a data-driven world and that we needed to find a way to aggregate the data; both at a patient centered-view, and a population view, the report, I think, didn't speak specifically to how the implementation would be done. As I said yesterday, there's no reason that you couldn't use a distributed model of data aggregation or analysis and then roll the results up. I don't think there's anything in the report that would opine about the specific design of any particular model of doing studies or persisting data.

Richard?

Richard Platt – Harvard Medical School – Professor & Chair

On pages 21 and 22, there are specific mention of a rich deidentified dataset. That seems to be a pointer to the existence of everything or most things are altogether.

Craig Mundie – Microsoft – Chief Research and Strategy Officer

So I'll just say, there was no—I mean, even if those words exist there, I can tell you behind it there was no intent to create one giant consolidated deidentified dataset. So, take that for what it's worth. So the rest of this, I don't think, is PCAST specific, so I'll go on to the next slide.

PCAST timeline—too aggressive to execute. Well, one, as I said yesterday, we felt there's a sense of urgency and that there was not, in fact, going to be a lot of additional money in the next five to ten years with which to address the question of transformation. So we felt that there was some urgency required. As I said yesterday, I think many people seem—when you make this assumption that it's too aggressive, it kind of implied you knew what it was. What the design recommendation might be. If you don't know what it is, then it can't possibly be too aggressive. In fact, as I said yesterday, we actually had exactly the

opposite view, which was, you should design and implementation scaled to meet the timelines of 2013 and 2015 meaningful use.

As I said yesterday, I see many examples of technological capacity that would indicate that given an appropriate scoping, at least in an initial implementation, that the challenge is more one of a system integration challenge than some of the things that people talked about—expressed fear over—of some gargantuan federal IT project that would inevitably run amok. And so I think the ONC could adopt a wide variety of implementation strategies, and that they don't actually have to be the same for each generation. As I said yesterday, and I think, Paul, you challenged me at the end, was I telling you to go walk off a plank, or something, and I don't think so at all. In fact, I would say, as I was thinking about it last night, that this group could recommend a process—I'll say, that again, parallels the kind of stuff that the SEC did with XBRL, where they basically gave nominally less than two years to the Fortune 500 companies to basically publish all their financial reports using that language.

So you could say, do you do everybody this way? Or if you say, "no" it's still important to get basic electronic record keeping going in smaller institutions. Maybe you say, "Okay, well the equivalent of the Fortune 500 of healthcare—you know, the 500 biggest hospitals should be basically our goal in 2013 is to have them to start to do some exchange this way."

As I said yesterday, if all you did was say, "Well whatever those things were that you thought you were going to send to CMS, or whoever gets them, in a meaningful use exchange, you say, "Well, fine. You just want to send those things, but you want to send them with this architecture." All right? You could say, "Well then, you can have your cake and eat it, too." But, the idea in our mind was to get started by driving a complete spike as narrow as necessary through the architecture of the whole PCAST system. To get that instituted broadly enough that in fact, you would start to get learnings. I think many things can be simplified, if you will, in order to address the downstream concerns, for example, about privacy. You could say that the only people who would use the first implementation, or who would be given DEAS access, would be the people who were supposed to be getting the data under the meaningful use depositing of the data, anyway. You don't have to say everybody can get at it.

So I contend that since our goal was to create an architecture that's starting at the metadata level and working up, was very, very flexible, and anticipated many, many different models of access and use. My view is that you should, as you think about a design, think about using the generality of that architecture to constrain the problem so that you have a narrow implementation that is deemed safe and appropriate, but that importantly, it intersects with a critical part of the population of participants. The 2013 and 2015 objectives, in order to begin to get some confluence of these things, in order to not end up with a very long delay in moving to learn about and figure out what an ultimately scaled implementation might be.

Comments about propagation or ... inaccurate; that exists in every one of these systems—operational systems today. It's a design question. And much like the question of the lifetime on the privacy information, there are design issues. I don't think they're PCAST-specific, nor do I actually think that the PCAST system is, arguably, substantially, worse. I could argue it's actually better. The reason is in the PCAST model, every instance of every piece of this data is sort of known where it went. You could say, even when you move it someplace else, you could require that that's also recorded in the DEAS. So, in a way, you could say that it's actually the solution to your problem of going back and correcting the data. Or at least—and the question that says, "Aren't there multiple copies of the data?" Well, of course there must be multiple copies of the data.

If you ignore the question of the deidentified ones, where the stuff has essentially been put into some specific context, I don't think that recovering the data in that environment is probably a worthwhile design objective, but again, who am I to say? But the specific ability to have an application program say, "Show me this data," and find that there would be multiple instances and you have to reconcile them, is something that might arguably be a way to solve this problem.

Paul Egerman – Software Entrepreneur

You've raised a lot of very good issues. ... one of the things that I tried to do—maybe I didn't succeed—as we did the hearing yesterday is I wanted to make sure that we didn't create what I would call an adversarial situation where people were saying things and you were having to defend the PCAST Report. As you go through these items, what you're saying is extremely interesting to us. But just to sort of route everyone, part of our obligation is simply to listen to what the stakeholders have to say and report it.

It's not necessarily to say it's right or wrong, and to the extent that there is solutions or to the extent that there's misunderstandings, that's very helpful. To the extent that there's solutions, or sometimes minor adjustments or changes that can be responsive to stakeholders, that's also critically important. But ultimately, one of the things I think ONC has done a very good job of is bringing the entire healthcare industry together on going forward with meaningful use. So the way that we do that, or the way that ONC does that, is to bring everyone together for these hearings and to hear them all out and understand what the issues are, and make sure that they're participants in the process.

Now, as we go through this, you're making some very—you just made some very important comments about what we need to do to implement, which is sort of where we left off yesterday afternoon. I apologize to you if I, perhaps, in an attempt to say something humorous indicated I was trying to get you to walk off a plank, or something like that. That was not—I always want some time in a government or a business meeting to work a Star Trek referencing. That's what I tried to do, but I guess that wasn't successful.

What I really would like to do, is to get to the point where we actually pick up the discussion that we were at yesterday afternoon, where you had just made some reference to it. Which is to sort of say, what is feasible for us to do to implement this? You have to understand we're going to report—we're doing our best with it. We understand these high level directions; directions to move aggressively, to establish the exchange architecture with the concept of universal exchange language, and some of the sort of search retrieval process. We understand that it's supposed to be evolutionary. We understand that the PCAST Report should be looked at as directional; that is we don't have to do it precisely the way it says there, as long as we accomplish a lot of these goals. So we're trying to listen to everybody and understand how to proceed. So that's what we're trying to do.

So what I'd like to do is I'd like to get to that—to pick up the discussion that we started yesterday afternoon, which you just now started. But also, if you have a few more comments on these slides, I don't want to—if there are some things here that you think are just plain inaccurate, especially on this panel six, I'll give you a chance to do that. But I'd like to proceed to that discussion.

Craig Mundie – Microsoft – Chief Research and Strategy Officer

Well, let me just, as quick as I can, finish four and five here.

Paul Egerman – Software Entrepreneur

Okay. If you could do it very fast, please.

Craig Mundie – Microsoft – Chief Research and Strategy Officer

I'll try to be quick, but again, this will be the only chance that PCAST, per se, participates directly in this process.

Paul Egerman – Software Entrepreneur

I don't know why you—we're happy to have you, whatever participation you'd like to have.

Craig Mundie – Microsoft – Chief Research and Strategy Officer

Well, fine. But, okay, I'm here now, and so I just thought since many of the things that were stated, I think reflected some assumptions about what PCAST was saying. I'm just trying, for the benefit of all the parties, point out when I thought PCAST was really saying something about that, and not. I'm not, in any

way, trying to be defensive about the report. Just to be precise about what we were considering, and what we weren't. Where I think that these issues are unique to PCAST, and where they are generic. For example, patient matching is problematic. We learned from many people, including John Halamka and others, that this has always been problematic.

Our view was that, again, the DEAS environment might ultimately bring more data to bear on the matching problem—in terms of guaranteeing uniqueness in an iterative way—than any one of the systems that might be used today within a specific context. So, we didn't think that the situation was any worse, and arguably might have been somewhat better. But again, all that comes back to the design, and, of course, there's a human element to that, too.

I will make one comment about the personal health record. In general, we were sort of advocates for the existence of a PHR. But yesterday, some of the comments kind of implied that the PHR was just the patient's offline copy of the clinical electronic record. Again, PCAST had a much broader view of what a personal health record was. That, in fact, it was the continuous record of health-related information, sensing information, and activities that the patient might choose to accumulate over time appended to whatever component of the electronic record was made available to them. That that composite was ultimately the thing that also wanted to be made available in an exchange kind of environment, although not this particular PCAST exchange architecture, going forward.

Okay, last one, number five. I commented about number one. The captured structured data of programming control terminology, I think, generally true. Separate syntax and semantics, I've commented on—

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... among themselves, clarified the definition of syntax and semantics. So we will suggest ... at this point ... which is very helpful.

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...

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And references Wikipedia.

Craig Mundie – Microsoft – Chief Research and Strategy Officer

In our view, again the burden question boils down to the assumption about what is it you're implementing, and when? So PCAST, again, was trying to say, "Hey, get the architecture moving." I can't answer the question I think Judy asked yesterday, specifically, is it worth it? Clearly, we thought that it was worth it to get moving in this direction, or we wouldn't have issued the report. But how you make an individual assessment, that's for ONC and others to work on. Ultimately, in the meaningful use and the incentive system, each participant has a choice today as to the level at which they participate. Certainly, nothing in the report would have advocated a change to that institutional choice. Clearly, we recognize that simply exchanging data doesn't lead to useful and accurate data.

One of the things that didn't come up much, but I think PCAST was very focused on, was the idea that if the data was more liquid, and more people—authorized people—could be given access to it, that you might ultimately, over time, see more decision support software tuned to specific practice levels emerge in the environment. One of our concerns was that while the major hospitals may in fact have electronic records and decision support, if you go to the elite institutions today, their doctors are not running around asking whether they should have a—what is the term? A data wizard, or somebody that follows them around to make their entries every day. Why? Because it's the decision support software that, as a byproduct, is largely producing the data.

Our concern was that to focus only on the digital record keeping, as opposed to trying to find a way to broaden the availability of decision support as the way in which the practicing doctor—particularly in the small practices—deals with the data should be a major focus going forward. And, in that regard, we were stepping beyond the idea of just electronic and digital copies of the paper record, and a workflow in the small practice that was the same as it's been today. We think that that's problematic, and therefore, part of the goal here was to create an environment where whether it was open source or other mechanisms, where other people would bring forward solutions better suited to the individual practitioner or small practice group.

I guess the last point; we did believe that there could be a variety of ways any particular institution might move to participate in this. We did see the emergence of quite a number of different software systems—some from major vendors, some from small, start-up companies, including those outside the United States—who are building data analytic platforms, different data warehousing capabilities. All of these things, in some way, tend to interchange, or exchange or access information in these lower level operational and clinical systems. So the thinking was that there was at least an existence proof that there was activity in this area, and it could be thought of.

The other thing that I'll just say, relative to this participation model, many of the large institutions today— independent of the meaningful use stuff—are starting to operate portals or other things to make data available to the patient. In my own view, much of the work that goes on to be able to extract and, if you will, portalize access to some of this information, in many ways mimics the kinds of things that would have to be done at least in an initial narrow scope implementation of getting at some of the data and putting it someplace where it's accessible. In a sense, the model of the DEAS sort of looks like a patient coming into the portal, except it's a program, not a person, and it's extracting the data for indexing purposes as opposed to reading their own record. But, again, this is just an example. By analogy, where we see a lot of activity happening already that made us think that each would have to pick their own strategy for implementation, but that there was enough varying types of activity in both middleware, portal generation and other things to make us believe that none of these things; particularly appropriately scoped in the early phases, would represent a dramatic burden for those who would choose to participate. I'll stop there.

Paul Egerman – Software Entrepreneur

I appreciate it, and you said a lot of things that were very helpful. I know I learned a lot, and I suspect other people did, also. So I really appreciate it, and I also want to thank you again for your willingness to participate in the entire process. It's really been fantastic, Craig. As I said, I want to make clear is that this is a situation where we want to work with you, we want to understand the report, and we want to understand how we can implement what is in the report. It's not intended to be a situation where you have to necessarily defend what's in the report. Part of our focus, of course, always still has to be to listen to all of our stakeholders and report what they're saying, and to be very sensitive to it. So that's what we're doing.

Now, when you were talking, you started to talk a little bit about some of the options. I look at the recommendations, what you see here on the screen is there's like six recommendations that are—4 O and C, that are summarized on page 77 of the report. The very first one says this—it says, "Move more boldly"—so it's the word 'boldly'—"Move more boldly to ensure that the nation has electronic health systems that are able to exchange health data in a universal manner based on metadata tagged data elements, in particular." I think the hyphen in in particular was not meant to be indicated emphasis—"In particular, ONC should signal now that systems will need to have this capability by 2013 in order to be deemed as making meaningful use of electronic health information under the High Tech Act."

So I read this first recommendation, and rightly or wrongly, I thought that that meant stage two of meaningful use had to require implementation what was described in the PCAST Report. The sense I'm having from you in now is that it's something narrower. So we don't have to implement it throughout healthcare, but we have to take this step forward. Is that correct, or is that not correct?

Craig Mundie – Microsoft – Chief Research and Strategy Officer

Well, again, I tried to share the way that I think about this interpretation, which was we never believed that with the wave of the wand ONC was going to be able to make all this complete this year, and such that everybody would be able to say, “Oh, yes, we’ll just do the whole thing in two years.” At a practical level, none of the PCAST people would have said the country can go from a standing start to a complete implementation of this recommendation in two years’ time.

In fact, we talked about that there should be some part in 2013, and another part in 2015. So implicit in that statement, was the fact that we recognized we would have to stage into this. I was suggesting that I think the way that we think about this—and in a way, it’s all in how you define the word, “piloting.” Many people called yesterday saying we should “pilot” this. In a sense, our view of piloting it was essentially to stage its production. In my mind, there are two different dimensions to that staging.

One is how narrow you define what has to be exchanged using this architecture in each of these two meaningful use periods. And the second, of course, is to define the breadth of the organizations that you seek to gain, to incent their participation in each of these periods. The reason we wrote it this way was to recognize that there were these unique funds available that ONC was charged with disseminating as incentives to get people to move in the right direction. So our view was that we should find a way to get at least some of the funds that are part of this disbursement process to incent people to begin to participate in a way that would lead to this general architectural model of exchange. As opposed to just very specific exchanges of information that were not done under an architecture model that would generalize to this broader set of problems.

Paul Egerman – Software Entrepreneur

So what I’d like to understand is what—you can be very specific—what are you proposing for stage two? I thought I heard you say something yesterday, but rather than me try to repeat it and get it wrong, can you just start and say this is what you’re suggesting stage two meaningful use to launch this implementation?

Craig Mundie – Microsoft – Chief Research and Strategy Officer

Again, I don’t feel that it’s my job, or PCAST’s specific role to design the system. All I could—I did try yesterday, and I’ll try again today, is give you one man’s ideas as suggestions for ways that you might pursue this. What I said was if you—to me, what was more important was to think about the architecture, which you summarized the key elements of it. Get the universal exchange language, get it defined. All right? Now, what we said ONC’s role should be, was to create, if you will, the container, and then to begin to populate that container with the historical good work that’s been done in standards and taxonomies. It can be directly, then, represented there. But because it’s an extensible environment, you could do it. So somebody between now and 2013 has to figure out the basic form of the exchange language container is, and put something in it that it deems to be sufficient for whatever these initial exchanges might want to be.

Paul Egerman – Software Entrepreneur

That’s sort of like what recommendations two and three are, right? Two relates to the initial minimal standards, and three relates to mapping of existing semantic taxonomies—

Craig Mundie – Microsoft – Chief Research and Strategy Officer

That’s right. Two and three are part of that process.

Paul Egerman – Software Entrepreneur

But the reason stage two has a fair amount of urgency around it is that it’s just a whole process around getting that right, and we’re—

Craig Mundie – Microsoft – Chief Research and Strategy Officer

... made it very clear to us that timing was important. So we basically tried to say that we thought, appropriately scoped, that these things could be introduced, at least selectively, in that time period.

Paul Egerman – Software Entrepreneur

And what I'd like to understand is what are the alternatives that we could think about doing in stage two? Dr. Blumenthal?

David Blumenthal – Department of HHS – National Coordinator for Health IT

If I could make a respectful suggestion, I think the PCAST Report has obviously served the purpose of introducing a new—maybe not a new perspective, but an additional perspective in terms of our discussions, have had to accomplish information exchange and manage privacy and security. It's really ultimately going to be up to The Office of the National Coordinator, The Department of Health and Human Services, the executive branch of the federal government; wherever you want to put responsibility, to decide exactly how to respond to the report. I think we should—rather than doing either exegesis of the report or necessarily asking Craig to do that work for us, it would be really helpful to us, at the Office of National Coordinator, for you all, the really smart people sitting around this table, to say, "Okay, based on what we understand of the PCAST Report, these are what some ways to proceed might be." Not necessarily—I think if PCAST supports it, that's great. If PCAST doesn't support it, we'll have to understand why. ONC will respond accordingly, and maybe change what you all—not recommend, but change, look at some of the options and add other options. But, I think that in many ways what PCAST accomplished has already—what PCAST needed to do, has already been accomplished; which was to start this discussion. Now it's up to us to take it forward.

Paul Egerman – Software Entrepreneur

That's very helpful direction. So the basic issue is what are the alternatives that we can think of for stage two? I'm going to rephrase that. What are the alternatives that we can think of? I appreciate that this is an HHS activity, but I also wanted to have a welcome mat open to the PCAST people, because I feel that it would be great if we came up with alternatives that they could influence, and that they felt comfortable with.

David Blumenthal – Department of HHS – National Coordinator for Health IT

And I don't think you have to—presumably Craig is reachable by e-mail, and by phone. After we've discussed things; you've discussed things, you can ask him his reaction, or Kristine's, or others. But, I think for your—to make the best use of the great minds around this table, I think you should do a mind melt around what's next at this point. There isn't a lot of time left today, but there may be other opportunities going forward. I think we've gotten a lot of great discussion out, and a lot of material on the table ready to be processed. Now the processing is critical.

M

Absolutely.

Paul Egerman – Software Entrepreneur

Great comments. So, issues; what are the alternatives? Wes?

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

I put my hand, my ... up before you asked the question. I just have one question, if I could ask Craig, that would enormously help. We're under a lot of time pressures, and I literally don't know how to respond until I know the answer to this, okay. So, Craig, if I heard one thing today that I think probably would change a lot of the discussions that we've had, it is that the UEL is not to convey the data. I think you said that a little while ago. The UEL is to convey the metadata. And it's quite a shift in direction from most people's thinking about what gets sent over the Internet. So, can you help clarify that a little bit?

Craig Mundie – Microsoft – Chief Research and Strategy Officer

Well, when I offered that comment, it was really related to Carl's specific point in the summary of the remarks from yesterday. I don't think, personally, that there's sort of an absolutely clean partition between—what we didn't talk about in the report, but is obviously required is that there has to be a protocol for exchange. In a sense, it's a bit like saying, "Well, we told you to go make HTML, but we forgot to tell you to go make HTTP." Right? Our assumption is, of course, that as part of designing the system, that the transport protocol is not a controversial thing. Many of the things that have been being investigated within indirect and other things are, in a sense, a way of having a transport mechanism.

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

No, I don't have an issue about the protocol, at all. I agree—

Craig Mundie – Microsoft – Chief Research and Strategy Officer

So what's in the language? We're trying to get it, without being overly specific, the idea that you need to have a way of expressing the metadata so that part of the universal exchange language is how do you specify the providence and how do you specify the privacy? How that essentially gets extracted for the purposes of the index is a design question.

M

Let's just take the world's most—

M

There's more than one question.

M

... this is all one question. One common document, which is John Halamka's CCD—CCR, everybody knows that informatics would be a lot more complicated if he wasn't as healthy he is. But, he publishes his clinical data, and you can see it. It says his name, and it says that he had Lyme's Disease, and it was resolved. He has this allergy, and he has that allergy, and so forth. Now, would the universal exchange language—clearly it has metadata, it's about John. It's about his summary of his health, that was created on such and such a date. It has something about his preferences for his requirements for privacy. Does it also contain the fact that he had Lyme disease? I'm just trying to say, is there data in there, or just data about data—

Craig Mundie – Microsoft – Chief Research and Strategy Officer

No, no. Ultimately the data has to be there, too, because—

M

Okay, thank you. That was my question.

Paul Egerman – Software Entrepreneur

Good. So, the topics that we have are—let me see if I can restate it. What are the alternatives that we can think of as to how ONC in stage two of meaningful use, can respond in a way that is aggressive and shows urgency and priority? So that's the issue. John, do you have any alternatives?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

I'd like to put my card up.

Paul Egerman – Software Entrepreneur

Okay. I'll put you on the list, Stan.

John Halamka – Harvard Medical School – Chief Information Officer

So purely as a straw man, if you take some of the elements of the PCAST Report, we've seen notion of this universal exchange language, and metadata. We've seen the notion of leveraging what we were already working on, and the standards that are already promulgated, and the notion of a DEAS. So let's

say this, we heard yesterday in the testimony immunizations in an issue. If there are any pediatricians in the group, you know that managing immunization history across the lifetime of an individual is actually a challenge, and it's actually going to be a great public health benefit to manage immunizations more widely.

Stage one requires in the menu set that every physician in the country choose one of the public health data exchanges. Even though they are optional, you have to pick one. So what if we said, stage two you do have to exchange immunization data with a state registry? It will be HL-7 2.5.1—that's the payload, but it will be wrapped in metadata—the universal exchange language. It will be sent through direct, or connect, or some other transport mechanism we all agree upon, and then the government will create a DEAS that would enable the 50 state registries with consent issues, obviously, and privacy protected, to aggregate data at a person level in a virtual federated fashion for query by EHR. So that in stage three, we could say that every EHR through certification criteria, has the potential of querying the immunization history of an individual. So this proposal, the docs want it, the patients mostly probably want it. It actually leverages existent standards and existent EHR functionality, but also allows piloting and prototyping of a DEAS on an issue that I think is not so controversial; immunization coordination.

Paul Egerman – Software Entrepreneur

Just so I understand right, the recipients of the public health organization, and so, in effect, what you're proposing means that for stage two, we don't have to address some of these privacy issues as part of the stage two implementation of public health organization, which are sort of a different status. Is that right?

Craig Mundie – Microsoft – Chief Research and Strategy Officer

Well, of course I would ask people smarter than I from a legal perspective, and so Jodi and Deven, can an individual choose not to have their immunization data deposited in a public health entity, or choose to prevent it from being queried? That, given state laws, etc., I can't answer.

Deven McGraw – Center for Democracy & Technology – Director

Typically, the public health uses of data—access use and disclosure—is not—choice doesn't apply. At least at the federal level, and typically not at the state, either. But you'd have to really not depend on my off the top of my head assessment of that, because we're talking about 50 different state laws, plus D.C. and territories. But having said that, if you—we don't have a system today where nationally people can easily query and pull immunization records. If we're going to create one, I think we'd need to think about to what extent is that like a trigger situation for the tiger team's recommendations. Also whether you might want to, just as a matter of ethics and building trust, to allow people to have some choice about whether their data can be queried in that fashion, and by whom, and for what purposes can the query be executed. So it's a little more complicated than can be answered.

But certainly I'm not suggesting don't explore it. I like the recognition that we'd have to think about what that means. Again, we're creating a different mechanism for accessing that data. It's the same type of data that today we exchange for public health purposes, but we are opening up a pathway for people to get it where we really haven't sort of defined the parameters terribly well about how we would do that. We would want to do that, I would think.

Paul Egerman – Software Entrepreneur

Terrific. Did you want to say something, Jodi? Okay, great. So that's extremely helpful, and that's one alternative. The question is, are there other alternatives that people have? David? I haven't forgotten you, Stan, but David?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

So, it seems to me that the PCAST Report has to be contrasted to sort of the null hypothesis. The null hypothesis is not doing nothing; the null hypothesis, I would suggest, is XDS, which is not universally used by everyone who wants to create indexable and charitable data. But it is, in fact, the dominant profile that's in use today. All the major vendors, and most of the smaller vendors support it.

So I would wonder if the assessment that we ought to be doing is what does PCAST say that would change how we think about the way XDS works? We've got hundreds of XDS experiments underway, some of which are in heavy use in production settings, and some of which are nascent in the states. XDS has a registry that has metadata sent to it in the form of CCVs, or whatever else you want to send, but CCVs is the common things.

It has edge repositories that catch the data under the control of the firewall of the original institution, if you so choose to configure it that way. It has a security model that implements the availability of completely granular security, if someone would bother to specify the granular protocols through ... XML structures. It uses an outdated technology stack, but it's a stack that everybody's system supports already, so it works. So I wonder what's—the major difference, it seems to me, is the patient-centric approach of PCAST versus the provider-centric approach of the way XDS is currently deployed. That's a policy difference; not a technology difference.

Paul Egerman – Software Entrepreneur

And XDS is a good comment, although I view XDS as like technology; it's a way to implement. I still want to make sure that I understand what are the alternatives for stage two in terms of what we implemented. What are we going to put in as the stage two requirements? So I don't think we necessarily, at this moment, have to address the XDS issue.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I was just saying that since that is—I mean, much of PCAST is about technology; the DEAS and the UEL are technology specifications. I'm suggesting that we have workable technologies today that are very close to the spirit of what's suggested by PCAST. Deploying an XDS in a different way than we currently deploy it today might be an experiment. So for example, the immunization use case could be done with XDS.

Paul Egerman – Software Entrepreneur

Right. So my point is, let's just decide on—you call it an experiment, but it's going to be a requirement for stage two of meaningful use. Let's decide on what those requirements are going to be, and then we can talk about what is the best way to do that.

Stan, did you want to say something?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Paul, this is Carol. I want to get in the queue, also.

Paul Egerman – Software Entrepreneur

Sure. I'll put you down on the list.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

Yes, I don't want to be contrary, but I actually don't think you can make something a part of phase two, and make it part of the incentive. Because if you listen to the discussion and what's been said, everybody would say that PCAST is, in fact, directional. By what's been said today, there's work left to do to get from that direction to implementable standards. To go back to the example of the business recording rules, that maybe happened in a year, or two years, from when the language, itself, was known and you could require it.

We're at the stage where the universal exchange language has not been defined, and so I think actually the best we can do, is do prototypes and experiments that would lead to implementable standards that we could then mandate in phase three. I don't think we're at a stage—I mean, if we started today, we're not going to have a universal exchange language for six months. Then you factor in the time that it takes people, then, to incorporate that into their systems. Even if it's faster than what we've done before, I don't

see any way that you could mandate and predicate payment of incentives on something that hasn't even been defined yet.

Paul Egerman – Software Entrepreneur

That's very helpful, Stan. So, you're suggesting we do pilots.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

I like the pilots, and I like immunizations, and I would add to that list of possible things that people could think about. What everybody always asks for, and would have, I think, the greatest value in exchange, would be medications, problem lists, allergies, standard lab data, standard text documents. All of which, I think, there's a vast collection of things out there that is eminently worth sharing. But I think, in the phase two timeframe, the best we could do is actually establish the standard, do experiments that prove the standard is workable, and then require, perhaps, in phase three, something that would then be based on incentives.

Paul Egerman – Software Entrepreneur

I appreciate the comments. One of the advantages that we have is we don't have to make recommendations. We can simply list alternatives, which is great. We can list the alternatives, and so you have given some alternatives.

I would suggest that, in my opinion, we do have to respond somehow in stage two, to this call for urgency. Perhaps it's adequate to do pilots. There might be other things that we might be able to do in stage two that are infrastructure or foundation related. It would also be to consider as one alternative. So one question I would have is to look at the work ... and direct is doing, whether that work might be candidates to be included in the stage two meaningful use, to move forward. So that would seem to me—I don't know if people consider that an additional alternative, but sort of like a package of infrastructure. Infrastructure means some of the issues with encryption and security and perhaps we could add some things at a provider level; directories and all the areas and concerns such as possible candidates for stage two meaningful use, but also advance what we're doing as an alternative.

Jim Walker.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer

On the criteria we've used for meaningful use thus far, first we said we wanted meaningful use that actually improved patient care. Not structural architectural sort of developments. So that's the point of the name, meaningful use. I understand that's where the money is. Because of that, two of the criteria that we have used pretty consistently for meaningful use mandates is that there is either scientific evidence or very strong reason to think that whatever the measure is correlates very closely with patient wellness. That can't be said of this, at all. We don't even know if it will work.

Then the second was, is it in production somewhere—even just one place in the whole world—so that we have some confidence that asking everybody else in the country to do it might work. Then one last thought, as 2013 is not a reasonable timeline for anything, but if we were going to set it, we need to make sure that we set timelines on everybody in the value chain. As people kind of implied, the UEL and the DEAS, and all of that would have to be specified and ready to implement by some date, long enough in advance, that the people expected to implement this and their vendors would have a reasonable amount of time to do it. It can't be that we define this December 2012 and then people have to have it in 2013.

Paul Egerman – Software Entrepreneur

Actually in comments, if I—

Jim Walker – Geisinger Health Systems – Chief Health Information Officer

The alternative I propose is we make it voluntary, and prove that it works somewhere.

Paul Egerman – Software Entrepreneur

Okay. So you're making an argument that wherever is implemented—you have like two or three issues. Whatever is required has to first be proven operational somewhere. You are saying also concern about timeframes, which everybody is concerned about.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer

The other standard would be that it have a credible relationship to improved patient outcomes. That has been the definition of meaningful use thus far.

Paul Egerman – Software Entrepreneur

One way, though, to respond to that might be to put some of these requirements elsewhere, in certification and ... governance. So that would satisfy your concern on that issue? That perhaps we can move forward, but—

Jim Walker – Geisinger Health Systems – Chief Health Information Officer

Yes. So one part of the argument would be it would be reasonable to say this is part of HIT certification by some date, and then some date a year or a year-and-a-half after that, it might be reasonable to talk about care delivery organizations really being responsible to do it.

Paul Egerman – Software Entrepreneur

That's great. Steve? Thank you, Jim.

Steven Stack – St. Joseph Hospital East – Chair, ER Dept

All right. Two minutes, four points. The first point, to discuss the systemic syntax of HIE divorce from the semantic ontology of real world execution converges on irrelevance. That probably doesn't make any sense, but we're speaking in a vocabulary that's very rarified here. I think when we listened to our individuals yesterday, we're talking about theoretical science and they're applied scientists. They're trying to actually use the stuff.

I think that it is important to kind of remember that, because to the extent that PCAST talks just about how we exchange data, I agree that a lot of that stuff is irrelevant that's on those slides. Once we begin to say what we are exchanging, and the reasons we're exchanging it, then most of that stuff becomes relevant again. On pages 18 and 19, when we've got clinical cases where I think a lot of the frontline people would say that they've misrepresented—not intentionally, but in part, the reality of what's happening in those settings and what's really needed, then I think it has perhaps misstated how it's going to be used by the people using it.

On page 46, when it says that, "A patient cannot make meaningful privacy choices unless he or she understands the flow and use of information, and can therefore make informed choices." Then further below it says, "It also allows for more finer grained individual privacy preferences to be more persistently honored." Well, those points came up in that slide, that there are potential implications downstream to that.

That doesn't say—the technology's agnostic to how it's used. I get that, Craig. I understand that. So nothing in PCAST would suggest it must be used a specific way. But the end users reading the report and using the examples and the language wrapped around the technology cannot help but then think in real life use cases how it will apply. So I think that that kind of discussion is absolutely essential if this is to have real world relevance to the people using it.

With respect to meaningful use, I think we need to be much less cavalier with how we toss that around. Fundamentally, that is a program that applies to providers; individual clinicians and facilities, who are going to either get a carrot or a stick for doing or not doing what meaningful use requires them to do. They are very, very incredibly dependent upon a technology community, a policy community, a legislative

community across the federal governments and state governments to provide those tools and enabling policy to let those tools be used.

Many of those tools and policies do not exist and have not yet been robustly even conceived of. So to say that by putting it in stage two or stage three will make it thus happen, really has this whole health sector in the middle as to help us pawn in some ways, being buffeted about by requirements that they are not in the position to deliver. So I would just observe that the people who spoke yesterday, I think, are incredibly knowledgeable and demonstrated a level of understanding that I think is very uncommon. Yet, even for them, they were talking about executional frontline realities, about just upgrading systems so they're comporting with the current version of a Web browser, that are so far beneath the level of sophistication we're talking about now that I think it shows that the real world of execution, that theoretical possibilities, are widely divergent.

Paul Egerman – Software Entrepreneur

Those are excellent comments. I appreciate what you're saying. One aspect of it that is similar to Jim Walker's comment that some of this may not belong in meaningful use, although some of the technology stuff could be put—

Steven Stack – St. Joseph Hospital East – Chair, ER Dept

One last thing that I want to say, Paul, and please don't misunderstand that, is obstructionism for this. Because we have got to make this succeed. We will not make healthcare work for this nation if we don't advance it. I think we just have to be very careful about how we choose to advance it.

Paul Egerman – Software Entrepreneur

Great. So thank you very much. Bill?

William Stead – Vanderbilt – Chief Strategy and Information Officer

I resonate with the comments that have been made, and I think that we maybe need to flip this around and say the first thing we've got to do is understand the report and propose—this group may not do it, so maybe the alternative—how to propose one or more implementation approaches. For each implementation approach, you can then basically say, "What part of this is so well known that it could be deployed and certified as it stands, and that we could build adoption around? What part of it needs an end-to-end test bed? What part of it is frank research that would flow across into that?" We would then be able to say, "Okay, this is the part that can hit certification in 2013 and/or whatever." I think really the alternative we might propose is a framework for tackling it in that way, if that helps at all.

Paul Egerman – Software Entrepreneur

It does help, Bill. I think you laid out some framework. What I was trying to do was simply to get a list of possible alternatives. Do you think we should proceed with that list, or are you suggesting—

William Stead – Vanderbilt – Chief Strategy and Information Officer

I think it is fine to proceed with the list, but as I hear this discussion, I'm hearing everybody bumping up against the same problems of can it be defined in time, and then can it be realistically dealt with by all the pieces of the system if we start with meaningful use. So I'm not sure if in the end we won't have to flip it around. But, your call.

Paul Egerman – Software Entrepreneur

Okay. And those are great comments. But I guess my question is in fact the framework. In other words, the issue is going to be can we get this done in time, is it feasible. We have to look at every alternative with those—

William Stead – Vanderbilt – Chief Strategy and Information Officer

If we come at the alternatives as is stand-alone items, then in a way we miss the point that the urgency is around—to borrow a prior term, of getting onto an escalator, as getting on to a path that will ultimately

allow such an architecture to come into place, and to have that happen as quickly as possible. And as we see that path, we can then note, aha, this is the piece that will be ready for meaningful use at this time, and we would get at it.

I think what I'm suggesting is maybe more of a process we can suggest for how we answer these questions, than trying to answer them directly. I like John's suggestion of a potential thing. I recognize all the caveats that are put around, whether it may or may not yet be at that point. So, we've got workable representative alternatives, so I was just proposing a framework in which you might get

Paul Egerman – Software Entrepreneur

That's interesting. I'd be curious if anybody else has a view of that. I know you, Carol, are trying to say something. You want to comment on Bill's comment about a process, or do you have another topic that you wanted to discuss?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

No, my comment is very related to Bill's comment. I just want to say, listening to a lot of the discussion yesterday and today, there's been a real focus on technology, and standards, and data, and normalization, and all those good issues. But I just want to say again, and remind everybody that all of these decisions have really significant policy implications. While we refer to the need for a policy framework, we don't have one to guide these kinds of decisions.

And just in the last sort of half hour of discussion, I just want to say contemplating a national search capability for anything, is a very significant policy discussion. It needs a very significant conversation, because to date, the way information sharing has evolved has been through parties who develop relationships with each other, or who have the appropriate agreements or protections in place to enable that sharing of information. I just think we really have to understand that there's no way to procure, or to impart through data or technology, the capacity to do that at a national level in the absence of a more comprehensive framework.

The other thing that I want to raise again, is this issue of we get right to standards and metadata and where the metadata is, and all of that. But there are enormous policy implications, and I mentioned yesterday that encryption is definitely one mode of protection, and there is no complete protection. But one way of using a policy framework is to implement things like data minimization. In other words, you expose the minimum data in order to offset any potential risk.

In terms of indices on the network, I think there's a very significant policy discussion that needs to happen about what the right approach is from a policy standpoint before we get too far down the path of standards, and which standards, and which metadata. Because it will be too late by then. So if we are interested in urgency and expediency, I would say there needs to be a fast track on really sorting through a set of guiding policies that should inform the selection and construction of both our architecture and standards.

Paul Egerman – Software Entrepreneur

Thanks, Carol. Very helpful. We certainly have a very interesting challenge in terms of what we're trying to get accomplished. I was very interested in Bill Stead's concept about process. What I want to first do is find out—we've got a couple of alternatives on the table. There's one that John Halamka put forward with immunizations. There's a second one that ... called like infrastructure. I'm sensitive to Jim Walker's and Steve Stack's comment that maybe these don't quite belong in meaningful use.

But my first question is, are there any other alternatives that people want to raise? If so, I'd like to hear those, and then we can start talking about the process. So, does anybody have any other alternatives for this issue that you want to raise?

Hunt Blair – OVHA – Deputy Director

I have two comments; one that's general, and one that's specific. Hopefully the general comment will make the specific more understandable. I think it builds on what John suggested with immunization registries, and on all of ... work. I apologize; I'm going to read from my notes.

So, this is probably grossly oversimplified, but since I'm arguably the least technically sophisticated member of the workgroup; I'm not a doctor, a lawyer, or a computer scientist, I'm going to take my prerogative to be simplistic. My read of PCAST and the conclusions that I have taken from the testimony, is that a lot of the conflict that we're experiencing really has to do with the paradigm framing more than disagreement about ends or goals. I think PCAST is asking us to accelerate development as a truly distributed network of health information, which at the risk, again, of stating the obvious, means we have to evolve beyond centralized institution and organization centric structures of paradigms.

In a distributed network, every node has an equal footing. That's the basic concept, right? And so, the institution centric versus patient centric is also the wrong paradigm or the wrong conflict. It's not an and/or, it's not an either/or, it's and both. I think that what PCAST is calling for is not just an ultra-large scale system change to the health information system. It's talking about changing the fundamental dynamic of the healthcare system, itself. The report doesn't really reference, although Craig and Kris yesterday, and Craig again this morning, talked about how important the sort of what generated a lot of this work has to do with meeting our need to change the funding mechanisms and structure.

So, how do we start with that? I do live in the frontline, real world implementation. A question that's been unresolved to date in the state HIE world has been, "What's the long-term national view for health information exchange?" Both the noun and the verb. I think PCAST really offers us a possible answer to that question. The state HIEs, they are at various stages of evolution. And in discussions that we've had with Dr. Blumenthal, one of the questions has been, "Can we plant a flag and say, 'This is what states' HIE should be?'"

I think maybe PCAST is offering us that flag. State HIEs could be—many of them could be relatively soon, serve as DEASs and enable supporting the distributed network that includes providers, small and large, the whole like let's design for the little guy as well as the big guy. I think that we could build on direct as a transport mechanism to HIEs and have just as Dr. Overhage was saying yesterday, there's a lot that we're already compiling there. A lot of us in our state's HIE plans have already begun to articulate working on transporting immunization data. That's like already baked in to what we're doing.

So I think there's a lot of possibility there that is consistent with the overall directionality of PCAST and with the investments that are already being made. That I'm not saying it's not technically challenging. I think it would need a whole new level of focus from ONC—a sort of how you then move that forward in specifically the context of HIEs as a sustainable component, central gathering place of nodes and distributed networks. But, I don't know.

Paul Egerman – Software Entrepreneur

So is your alternative ... John Halamka proposed immunizations, so look at immunizations and indirect, and the role of the HIE, and to have an alternative involve the HIE as part of that process perhaps as a precursor to establishing the DEAS. Is that what I'm hearing?

Hunt Blair – OVHA – Deputy Director

Or to have the state HIEs evolve into also having a DEAS service. You could pick up the kinds of transmission of the kinds of data that we want to have in meaningful use stage two, anyway, and have in 2013, where it's possible. In 2015, it better be possible everywhere to have that transport to the HIE and that be that the place where this information is available to be queried.

Paul Egerman – Software Entrepreneur

Great. Interesting alternative. So thank you very much, Hunt. Again, we're talking about alternatives. Anybody else has alternatives? Deven?

Gayle Harrell – Florida – Former State Legislator

Paul, this is Gayle Harrell. I'm on the phone. Is there a way to make a comment?

Paul Egerman – Software Entrepreneur

Yes. I'll put you in the queue, Gayle.

Deven McGraw – Center for Democracy & Technology – Director

It's actually related to a lot of comments that have just been stated, but maybe crystallized in a slightly different way. And one new one. So, in the exchange that we've been looking at in terms of the indirect program, and also within the proposed criteria for stage two from the meaningful use group, it all looks—and I know you hate it when I say this, Paul—but it all looks very much like push transactions where you use a provider directory. You know who you want to send the information too, and we're sort of creating the infrastructure and the policies around how to make that happen.

What we haven't really started to do is to think of the query response type of transactions where you're looking for data on a particular patient. So related to Hunt's comment about the needs and that this is a possible role for state IHEs to play. Related to Carol's comments about the need to set up a policy infrastructure for a query response type of models that look a lot like a DEAS or a record locator service, if you're looking at the Markle Common Framework.

I had already started to have discussions with Micky Tripathi, who is one of the co-chairs of the information exchange workgroup, that that's sort of the next frontier in terms of both policy as well as whatever standards need to be developed. I think you have to set all of that up whether you are doing it for a particular use case, or whether you're broadening that for other types of data that you would search for on a patient's behalf. It's a very similar set of policy issues that arise. It doesn't get necessarily any simpler because it's immunization data versus something else.

So, I think that where there's an infrastructure from a policy standpoint that we have in place to pursue query response models that are based on looking for the records of a particular patient, I think we need to pursue those. I don't think we could do it by stage two. I think we've got stage two sort of set up for directed type exchanges. But we have to put the mechanisms in place now if we hope to be able to do any of that by stage three.

Then I guess the new idea that I would put on the table is maybe not so new if you're a tiger team or policy committee member is this idea of needing to pilot granular consent methodologies; methodologies that work for granular consentants. So whether that's the data tagging approach from PCAST; whether that's the segmentation option that John laid on the table; whether it's options for segmentation that are in the segmentation paper that got released this week; we have already stated as a policy committee that those need to be piloted. The sooner we begin that, the better. So there's some synergy there, essentially, with PCAST.

Paul Egerman – Software Entrepreneur

Let me see if I've got this right. Deven? So you're re-emphasizing the need for a pilot on granular consent, and you're saying that we need to pursue query response—not necessarily as stage two, but I'll pick it up and let Carol sit on some of the policy issues. That, in some sense, could actually fit well with the suggestion like Hunt's where you start to gather information, sort of like lays the foundation for the query response process, but at the same time we get an opportunity to develop how that works.

Deven McGraw – Center for Democracy & Technology – Director

Again, I use the term "query response." I think if there are similarities to what's been proposed in PCAST as a DEAS, but without a lot of the detail that I think a lot of us were seeking from a policy standpoint.

Paul Egerman – Software Entrepreneur

That's excellent. Thank you. That was really excellent. Judy?

Judy Murphy – Aurora Healthcare – Vice President of Applications

I think I have a higher level question to ask first, which is, what is our obligation? Is our obligation to take the PCAST Report and begin to implement it through meaningful use? Or is there an obligation to evaluate the PCAST Report to decide whether it should be implemented through meaningful use? I don't get the answer to that one.

Paul Egerman – Software Entrepreneur

Well, we need to keep in mind we're a workgroup that can forward information to policy committee and the standards committee. We don't really make decisions. So obligation is just to tell them what their alternatives are. It's going to go through whatever process it's going to go through. We're not saying, "This is what meaningful use should be." We're just saying, "Here are your alternatives, and here's the reasons why we think these alternatives are good and bad." That would be my answer.

Judy Murphy – Aurora Healthcare – Vice President of Applications

Okay. In that case, I would say that working on the universal language is one of the key things to start in on, because that will help everything. That will help interfaces, it will help immunization, it will help everything. I like immunization. I don't like putting into certification, because that means that it has to be developed, which does take away the time spent on other things that are done to help patient care. So I would push back on that.

I support Deven's policy issues. I'm a little bit concerned about are we supporting, and are we looking at the paper version, or the discussion version? Because as Richard said, there are discrepancies between them. You found one of them. There are some others in there.

Paul Egerman – Software Entrepreneur

Paper version of ...?

Judy Murphy – Aurora Healthcare – Vice President of Applications

Of PCAST versus the discussion version. That's what you were commenting on earlier, Richard, right? Something on one of the pages that didn't match the discussion about it.

Richard Platt – Harvard Medical School – Professor & Chair

Yes.

Judy Murphy – Aurora Healthcare – Vice President of Applications

And I think that that's several things in there; is this rip and replace, or is it not rip and replace? It repeatedly says transition from EHRs to the PCAST proposal. If it says transition, I do think that means replace. However, maybe it's peel the band aid off slowly rather than rip. I think whatever is the right thing to do should be done. I'm not going to push back on that.

But I do think that we have an obligation; not just as a committee—not just to look at what's in here, but to go to the bigger question of, "What is the right thing to do?" which you're trying to do in meaningful use. And I think we all come from where we've been. So if David McCallie and I are the ones asked, we're going to think of our products, which are EHRs and our experience. I think Microsoft is going to think of ... and their products and their experience. So I think that each comes from where they are, and that's what I think that—and if you've got a genomics person, we do some nifty genomics stuff. I think that'd pretty cool.

So the thing though, is, what is our charge, what are we supposed to do? Are we supposed to implement PCAST?

Paul Egerman – Software Entrepreneur

Well, again, this workgroup is simply going to give alternatives for how this is going to work. That's going to be a different discussion. There are limits as to what the workgroup could do or I could do. Somebody came up to me yesterday evening and said, "Can you postpone ICE 10?" And I kind of dismissed that person, but somewhat strangely a second person asked the same question.

It's not like I or the workgroup has—all we're trying to do is lay out the alternatives, is simply what I want to say and help ONC understand the alternatives. The policy committee, the standards committee, those will be a lot of discussions, how it gets folded into it. Meaningful use, if anything happens, will be subsequent discussion. So I want to make sure we get some people in the bleachers to have a chance to speak, because I know you're long suffering over there, and there's no heat. So, we'll start with Linda.

At this point, I just want to remind you. We're looking for if you have alternative ideas as to what should be happening in stage two relative to this.

Linda Fischetti – VHA – Chief Health Informatics Officer

Sure. First of all, I do want to say that for our committee to be successful with recommendations of alternatives, we do need to come up with a forum. This is such a constrained environment, those who have microphones and those who do not. We need to come up with a forum where people can come forward and assert that they have a solution.

For example, the model driven health tools that we're working on was already called out by two of the respondents to ONC. What the patient preference model that we are going to be demonstrating at HIMSS we think is an exact ... of the privacy and security chapter. But where do we bear it to Carol, and Deven, and the technologists, and the physicians, so that we can have that communal conversation and forum about is this truly a viable alternative? I think that that's going to be important for us as we, as a committee, come up—or you, as a committee, come up with your goal

Then secondly, I would also pose that as Arian is working on the what do we already have indirect that is relevant to and instantiates the ideas of PCAST, we should ask in David's office to have Mariann Yeager do the exact same thing with the nationwide health information network. There are absolutely some reasonable parts and pieces to that.

Paul Egerman – Software Entrepreneur

Could you say the last part again? I couldn't quite hear you.

Linda Fischetti – VHA – Chief Health Informatics Officer

We should ask Mariann Yeager in David's office to do the exact same thing for NHA and exchange.

Paul Egerman – Software Entrepreneur

Okay. I see what you're saying. That makes sense. Actually, exchange is also an issue. No one has raised this, but some alternatives could be to see if we can do some projects with VA, or DOD, or with exchange, because that's a fairly robust environment. Interesting comments.

Walter?

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO

Yes, very quickly, a couple of suggestions. I think you're hearing a consistent message about the strong concerns around trying to do something in stage two, or even stage three, with respect to requirements. And I think that's an important position. I think the two suggestions I wanted to make—one is, and it's sort of along the lines of Linda's comments, is this is a possible direction. This concept expressed in the PCAST Report, and a series of possible ways of implementing the ultimate goals of exchange and interoperability, and certainly privacy.

I think the concept of allowing pilots to test some of these concepts should be expanded to allow pilots to also test alternative ways of achieving the same goal. So it's not constraining the pilots to test exactly recommendations three, four, and seven of the PCAST Report, but also allow pilots to demonstrate alternative technology approaches to achieve the same goals. So that's the first recommendation, is to really consider the pilot to go beyond and perhaps in alternative directions from what is recommended in the PCAST Report.

The second recommendation is more of a concern. I think in many respects we're putting technology in front of policy. It's been expressed several times, the concern around the lack of a policy understanding; specifically about one of the most significant uses that is described in their report, which is the use of metadata and tagging for privacy purposes. I don't think we have—and it's been expressed several times, the right understanding of the policy implications of applying that into the privacy context.

So even as we start to consider pilots on how metadata tagged elements describe a direct privacy choices of consumers, there needs to be a policy analysis of that, and kind of a definition of how this will be done in the policy environment that we have for privacy. I think it's foundational that we have some sort of a policy reading of how this technology approach of achieving privacy can be executed. So, a policy report, a policy analysis, on the possible implementation of this approach for privacy purposes, I think is fundamental.

Paul Egerman – Software Entrepreneur

So you're advocating for more pilots, and also much more policy development simultaneously with that.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO

These analyses of policy analyses are

Paul Egerman – Software Entrepreneur

That's great. I haven't forgotten you, Gayle, but first we're going to do Cris.

Cris Ross – LabHub – CIO

So my comments are, I think, the most closely aligned with Carol's and Hunt's. That's this idea that the exchange part is where all the hard bits are, and the gnarly problems are, around privacies, around security, around implementation, and so on. Actually, the data element access services recommendation part of PCAST isn't listed on this screen under one of the four elements. But it's one of the areas that I think we focused as being a problem area.

So as a suggestion: Number one, I like John's suggestion of trying to do a complete thing on a limited domain. That makes sense. I think separate from that, and not competitive with it, but additive to it, is if trying to do a broad DEAS kind of implementation across a broad domain is really a bridge too far for 2013, then what could we do in 2013 that would be foundational?

It seems to me if we were to separate, or de-couple, the access elements from the metadata tagging progress, we might be able to do some things in 2013 that would get us in that direction. To get the data better positioned so that it could be put into an access kind of environment at a later date. The challenge there, of course, is that that depends on the pace of ... and others, who would be involved in improving metadata tagged data elements and models. But I think we have to confront that.

The last piece that I would say is, perhaps there's a way, in addition to what ... John just talked about around a limited domain, perhaps separate from decoupling the metadata tagging from the exchange. Maybe a last thing that we could do to look for a very thin way in which we could get metadata tagged environment in an environment that would be safe. Maybe something like provider identity tagging. That's one of the things that we know we need to do. It doesn't contain personally controlled health information. It would be a way for us to test our ability to actually exchange something meaningfully across a bunch of domains that didn't raise privacy insecurities.

Paul Egerman – Software Entrepreneur

Could you explain a little bit more what you mean by privacy provider identity tagging?

Cris Ross – LabHub – CIO

To be able to identify a provider in context in several different health systems, for example. For us to be able to exchange data or push data to the right location, for example. It's like a patient identifier, but it doesn't carry the privacy risks that a patient identification would. That may not be the right example, but I sort of like the idea of trying to find something thin across the whole system where you could test the idea without engaging all the risks associated with it.

Paul Egerman – Software Entrepreneur

Great. Dixie?

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

Yes. Thank you. First of all, I think this kind of brings together a lot of what I've heard here. I like the idea of using immunization reporting in the pilot, but I think it's going to hit up against both state public health—both the public health paradigm relationship between states, and states having control of their public health. It will hit up against privacy issues that Deven suggested. The HIPAA really doesn't address—they say, "Yes, you have to share information with public health" but it doesn't say anything about who can then have it afterwards. So I would like to suggest that in this pilot that we limit the pilot to just testing the concept of pushing data with its metadata tag to a DEAS, but making it available only to those who would have access to it otherwise, which is something I think that Craig mentioned this morning. So not really push too far—try to push too far, or we really will hit up against all these policy issues.

Paul Egerman – Software Entrepreneur

Great. Thank you, Dixie. Carl, I would encourage you to be brief, if you would.

Carl Dvorak – Epic Systems – EVP

There was some discussion of the need to do policy work. I just wanted to urge that the policy work not be viewed as something that has to come before some of the technology work. Because one of the struggles that we're having with the policy discussions was they were assuming they knew how it would be implemented, and often assuming incorrectly, or in ways that are options. So having some parallel effort to have something on the table where we can say specifically what we're talking about would be very helpful in structure and policy discussion.

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

That's what I was trying to say.

Paul Egerman – Software Entrepreneur

That's great. Thank you.

W

Paul, if I could just respond to that, I would just say ideally they happen together.

Paul Egerman – Software Entrepreneur

Okay. That is helpful. We are out of time, but I wanted to make sure we got to Gayle, because you were in the queue. So, I'd ask you to be brief, but—

Gayle Harrell – Florida – Former State Legislator

Thank you, Paul. Of course, unfortunately, I couldn't be there today. I have a committee hearing in Tallahassee as a State Representative. But I have a great concern from the state's perspective in developing the state HIEs, and the amount of money that we're spending in grants down to our states. I

know we are going to be spending \$19 million in a contract that's already been let. The PCAST Report has created a lot of confusion as to where the states need to be going along this line.

So I would encourage us, as a policy committee, to really look very rapidly at making some decisions—not too hastily, but making them fairly rapidly so that we can direct the states and we have some sense of where the states need to be going on developing their HIEs. Several things I'd like to comment on; I like the metadata tagging for privacy. Of course, as you all know, that's been a major concern of mine. I think that that should be included within any pilot that we do, and make sure that we understand how that can be used, and how successful it is.

In stage two, meaningful use, I think perhaps we ought to limit what we're doing simply to push data, since we're not really sure how or what mechanism we're going to use on the query; whether we're going to go with the DEAS model, or how things might happen along that line. Those policy discussions need to be really discussed and decided as quickly as possible. Perhaps maybe we ought to encourage our states to wait before they start going too far down and how they're developing their state HIEs until we have some policy discussions and policy decisions.

So perhaps the ONC might want to encourage or let the word out to states that perhaps you want to hold back a little bit in expending that money and moving too rapidly, because there may be a change in direction as to how these things are going to be set up. I would also encourage perhaps using one of the state's HIE projects as a model in a pilot. Then, using the resources down at the state level.

I just want to comment that perhaps I am the least technically savvy person on the committee, and also definitely on the front lines. So, I thank you for all listening, and look forward to hearing the rest of the discussions.

Paul Egerman – Software Entrepreneur

We are out of time, but can you be very brief, Eileen?

Eileen Twiggs – Planned Parenthood Federation of America – Director

Sure. I actually don't have a new alternative to add, but I just did really want to reiterate that I think that the policy development and parallel is critical, even in the two, I think, seemingly harmless examples that have been—or least harmful examples that have been thrown on the table around immunization data exchange, and testing out exchange on provider identity data. I could list, off the top of my head, a couple of issues with those that would need to be resolved.

For instance, for provider identity data exchange, for what use? It was proposed across a wide variety of recipients, and I can tell you in a world where your providers have protestors on their front lawns, I think that we really need to be careful about intended use and outcome. Then for immunization data, where you have a complex Web of state laws around emancipated minors and their rights to consent on their own versus their parents' rights to consent for them, and immunization related to reproductive health, I just think there's a lot of complicated issues in here. So I really want to urge that we couple policy development with any technology efforts.

Paul Egerman – Software Entrepreneur

Great comments, Eileen. Wes, you get the last word. Please be brief.

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

I'm going to pile on Deven's suggestion here. I think that within the bounds of existing HIE projects—not for all of them all of the time—the ability to configure some specific efforts to go to operation with appropriate policy and model for granular consent really gets both to the heart of what ... wants to take us, which is the ability to find data, and would move us along. I don't see that as necessarily generating any meaningful use requirement in 2013.

Paul Egerman – Software Entrepreneur

Great. Thank you very much. We are out of time, because we want to give some time for public comment. I wanted to see if I could—sure, absolutely.

David Blumenthal – Department of HHS – National Coordinator for Health IT

Just to let everyone know, those of you who work on the policy of standards committees know that this is not the only thing that's going on at ONC. We are working on a governance rule. We're working on privacy and security recommendations. We have a health information exchange workgroup. Policy is not being ignored, so I would encourage you all to go forward thinking about what can be recommended without feeling like you have to solve every problem in this group. That's point number one.

Point number two is if we believe that in ten years we need to have a—or five years—a robust capability to do the kinds of work that's contemplated in the PCAST Report, and then frankly, it has been contemplated in other sessions, we need to start. Despite all the concerns and worries, your advice, or your laying out alternatives on how to start, would be valuable. So I just urge you not to be paralyzed by your uncertainties, because if you share the aspiration, and if we all discipline ourselves and realize that someone is going to have to make choices about how to start the process of moving towards that aspiration.

I think one of the things that the PCAST Report has done, has said we can't postpone the decisions about how to do this much longer. Thank you.

Paul Egerman – Software Entrepreneur

That's great. That's very helpful. What I put up here on the screen is our schedule. Right now, we only have two meetings scheduled between now and when we have to do our final report on April 13th. We have a meeting scheduled March 3rd and also March 17th. In advance of those meetings, we'll try to do some work to help prepare the members. So it seems like we should need to prepare two groups of documents; one is some summary documents from the panels about summarizing the public comment, but also to write down where we stand on these various alternatives so that we can continue the discussion. So we will work to get some materials together before March 3rd. I'm taking a guess that we're going to probably ask to schedule one or two additional meetings to try to complete the work.

To pick up on what Dr. Blumenthal said, we have—it's sort of like an honor to be with this group of people; very thoughtful, intelligent people. A lot of experience, and experts in a diverse set of issues. I think ONC got us together because they must have a hard problem to solve, and so that's why we are being brought together. But, it's also, as Dr. Blumenthal's comment, is a very good one, we do not have to solve every problem in healthcare. We only have to try to help ONC understand the report, and understand what possible alternatives that we have in terms of responding to the report.

Then we don't even have to choose the alternative. Basically, that will be done by other people. But I do want to thank everybody, and I want to open it for public comments. Judy, if you could do that, please?

Judy Sparrow – Office of the National Coordinator – Executive Director

Yes, we'd like to invite anybody in the room who wishes to make a comment. Dr. Loonsk?

John Loonsk – CGI – Chief Medical Officer

Thank you, Judy. I'm John Loonsk, CGI, and I'd like to comment on the suggestion for immunization access, and I'll offer a potential alternative. I very much appreciate the public health opportunities offered forward in the sentiments for immunization access, but there are a number of issues there. One is that essentially it would entail the authentication; that authorization of a very broad group of providers against a relatively limited organization set.

Another issue is that I'm not sure that Willy Sutton would send you directly to public health organizations to index data. It's not driving a stake through the system that's suggested by the PCAST Report. If we

want to advance something more fundamentally changes the dynamics and has reutilization potential for provider capabilities, as well, I think we want to be indexing something even if only in a very narrow band, in healthcare and with providers.

I concur with the suggestion that there's a lot in XDS, and a lot in NHIN—funny for me to stumble on that—exchange to build upon. I would particularly point to the fact that in the PCAST Report, the sentiment to move forward with public health uses addresses or points to a very basic need that's not yet addressed, which is for public health case reporting. A very narrow piece of clinical data around public health case reporting, which is relatively easy and clean from a policy perspective, because public health agencies are authorized by law to reprieve, to access public health case reports from clinical settings, has the benefit of authenticating a very small group of public health organizations who have the—again, state requirement to access these data.

Yet doing it against provider data, which indeed will have many secondary benefits in building the kind of system that I think PCAST envisions. Currently there is no real path forward in meaningful use for fully electronic public health case reporting, and this could be an excellent way forward in that regard. Thank you.

Paul Egerman – Software Entrepreneur

Very helpful. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you. Mr. McNamara?

Tim McNamara

Hi, my name is Tim McNamara. I think some of you, certainly John Halamka knows, I actually introduced XPRL to the SEC a long time ago. John, I think I was in your office in Cambridge eight years ago, if my memory is correct, and said, "Gee, you ought to look at this."

It's been a lot of times in ... that it didn't happen. The good news is that the mapping software to go from XML to a version of XML to the second generation or XPRL alike designed for healthcare has gotten to be very, very good. And you wanted a path, David? I'll give you one. Here's an unsolicited proposal for ONC. We will produce the universal health language using the existing SDO semantics with one dataset for all of the codes, links, context, everything else. We'll have it submitted to Oasis, and it will be provisional by 2013. I'll work for cost, or at least whatever a GS 15 makes—I don't know. I don't know if I could hire anybody else for that, some of these people I can't.

M

... unsolicited proposal.

Tim McNamara

Well, it's transparent. I think what we have to come to grips with here is the PCAST Report does point the way, and we have to recognize that XML was never going to work because the original XML in 1998—by the way, who has a 1998 cell phone in here? 1998 computer? That's the point. It allowed you to have heterogeneous schemas, and when you have that, you can never have—and you will never have—interoperability. I feel sorry for all the money that's been spent on all the HIEs and everything. They're not going to work. They cannot work technically. It has never been a possibility for them to work technically. So I'm afraid that we have to own up to the fact that in economic terms it's called sunk cost. I can't do anything about it, but we need to move on. Thank you.

Paul Egerman – Software Entrepreneur

Thank you, Tim.

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you. Robin Raiford?

Robin Raiford – Allscripts – Executive Director, Federal Affairs

Hi. I'm Robin Raiford. I'm Executive Director of Federal Affairs at Allscripts. I will tell you that I've been listening to this robust conversation for a day and a half from my home office, and thought this public comment was so important I drove down here. And managed to get here in time.

... just has come up within the last hour, within that last hour the concern over the timing. I would just say on behalf of vendors, there's not a vendor out there not concerned over the timing of when the final rule of stage two is proposed to come out early in 2012, and for customers to have to be live in order to meet their one full year of meaningful use for hospitals by October 1st. That means build, certify, test, deploy, start using, get it in there, put in discreet fields, and all that, within a nine month period of time. There's not a vendor out there that's not concerned about that.

I would say also that when you look at the quality measures that were proposed, and that there were 44 total proposed, to the ambulatory space, that when you go out there and look at the 167 some odd vendors that are out there that are certified, when you start opening them up one at a time, one at a time, 14 products are certified for all. The others are certified for nine, and are having to go back and put the others in because of a timing thing of what was happened and when it happened.

An example of you think the rule is final until the clarifications start coming, and it's not really final until all the clarifications are done. An example of that was the issue of the ED, and what do you doing about point of service, 23. It's going to be all ED patients, so vendors wrote to include all the ED patients. Oh, no, it's not going to be all ED patients, it's going to be just observation and admitted patients. Got to write another report. Then another clarification; oh, by the way, it's going to be both, which meant more code, more reports. It just takes time to write the code. I just want to express that, and thank you for your time.

Paul Egerman – Software Entrepreneur

Thank you, Robin. I appreciate you effort driving over here.

Judy Sparrow – Office of the National Coordinator – Executive Director

And we do have one comment on the telephone line, if you could please identify yourself.

Galen Mulrooney – U.S. Department of Veteran's Affairs

Yes, this is Galen Mulrooney. I'm a contractor to the U.S. Department of Veteran's Affairs. All of these comments are mine.

Just two quick points. First I wanted to mention that I really appreciate Craig's clarification of the PCAST member's thinking. I had a whole bunch of questions, technical questions, reading in between the lines trying to figure out what the PCAST was trying to do that Craig answered almost all of them. There's one left that I think I would like some clarification. Just to let you know, I'm a techie, not a clinician. So, I stumbled a lot over what was meant by data, and what was meant by metadata.

So I would appreciate perhaps some additional document or ... document that might go a little bit more into detail on that. So a lot of the things that were mentioned as cited as possible metadata. Likely machine on which a test was made or the person who actually operated that machine, I would consider to be data, not metadata. So I think a lot of the clarifying that question will solve a lot of answers—or would answer a lot of questions for techies, like me.

Second, I would also like to commend to the committee the work of an effort that I'm involved in called the Federal Health Information Model. This is a project that is the modeling project undertaken by the federal health architecture program, which is a coalition of federal agency partners. That effort is actually trying to produce ... information model based on industry standards; especially HL7 version 3, but also ... and X12 for use by the federal agency partners, and we've already been able to demonstrate that we can

produce multiple kinds of artifacts, including clinical document architecture artifacts and mean based artifacts—the National Information Exchange Model from that model.

So I would expect that the metadata tagged structure exchange language that the PCAST Report envisions could be produced by that model, and that modeling effort is already underway. So it's something that could be leveraged. Thank you for your time.

Paul Egerman – Software Entrepreneur

Great. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you. We have no more public comment.

Paul Egerman – Software Entrepreneur

Great. I want to thank everybody. It's been a long day and a half, but I think we made amazing amount of progress. We've got a lot of work, yet, to do. Before I end, though, I do want to remind everybody that at 1:30 this afternoon, I guess right here in this room, we will be having an HIT standards committee meeting. So this is your opportunity to go to a double header. You can attend the standards committee, John Halamka and Jonathan Perlin. It's an amazing thing to see how they orchestrate. So that entire process, and I hope you'll consider that.

So thank you very much, and thanks again to Judy Sparrow.

Public Comment Received During the Meeting

1. IRBs and Privacy Boards are no longer necessary to enable consent for research. They were created when it was too expensive, too difficult, and too time consuming to contact people for consent. THAT IS NO LONGER THE CASE. Technology is fabulous for contacting millions of people easily and cheaply. Alan Westin's work shows that only 1% of the public would ever agree to unfettered research access to PHI. And vulnerable populations are even less supportive of research access. See Alan Westin's slides at: <http://patientprivacyrights.org/media/WestinIOMSrvyRept.pdf?docID=2501> I can also provide the FULL report as an attachment to Judy Sparrow later.
6. The public has never agreed to a broad use of PHI for public health. All public health uses of data (until the last few years because people interpret the HIPAA floor as allowing it) was by statute for ONE specific disease. PH never had a law or mandate to do whatever research the PH officials decided they wanted to do.
7. Central data bases COULD be safe, because the scale could allow the ability to afford state of the art security. Also if data in data bases is encrypted or unreadable or indecipherable, and the keys were elsewhere, they could be far better protected than most data is today.
8. Actually Steven Stack's comments about the ER and consent is absurd. I have run an ER too---ER docs will ALWAYS break the glass, whether or not there is consent because the highest medical ethic is to SAVE A LIFE. there is NO need to design all system where ALL doctors have access to ALL data ALL th time to be sure ER docs can break the glass. They can just do it. The rest of the time, when patients are awake and conscious, they PREFER to be treated with respect and ASKED for consent before someone uses their data.
9. Where there was NOT nearly enough detail was about de-identification
11. There is actually a lot of detail about privacy in the PCAST report
13. Halamka finally heard
14. Segmentation is really really important--right!!!