



Health IT Standards Committee Precision Medicine Task Force Final Transcript February 26, 2016

Presentation

Operator

All lines are now bridged.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Thank you. That took longer than normal. Good afternoon everyone, this is Michelle Consolazio with the Office of the National Coordinator. This is a joint meeting between the Health IT...I'm sorry, this is not. This is a Health IT Standards Committee Task Force, the Precision Medicine Task Force. This is a public call and there will be time for public comment at the end of today's call. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. I'll now take roll. Andy Wiesenthal?

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Andy. Leslie Kelly Hall?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hey, Leslie. Andrey Ostrovsky? I believe Andrey is on. Betsy Humphreys? Christina Heide?

Christina Heide, JD – Senior Advisor for Health Information Privacy – Office for Civil Rights

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

David McCallie? Hi, Christina.

Christina Heide, JD – Senior Advisor for Health Information Privacy – Office for Civil Rights
Hi.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Here, this is David.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi, David.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Hello.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Dixie Baker?

Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates
I'm here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi, Dixie. Eric Rose?

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects
Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi, Eric. Gil Alterovitz?

Gil Alterovitz, PhD – Faculty, Biomedical Informatics – Harvard Medical School; SMART/FHIR Genomics Lead
Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
James Breeling? Hi, Gil.

Gil Alterovitz, PhD – Faculty, Center for Biomedical Informatics – Harvard Medical School; SMART/FHIR Genomics Lead
Hi.

James Breeling, MD – Director, Bioinformatics, Office of Research & Development – Veterans Health Administration
Jim Breeling is here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Thank you. Joyce Sensmeier?

Joyce Sensmeier, MS, RN-BC, CPHIMS, FHIMSS, FAAN – Vice President, Informatics – Healthcare Information Management Systems Society

I'm here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Ketan? Mary Barton? Matthew Might? Mitra Rocca?

Mitra Rocca, PhD – Associate Director, Medical Informatics – Food & Drug Administration

I'm here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Mitra. Steven Keating?

Steven Keating – Patient Advocate/Consumer – Doctoral Candidate, Mechanical Engineering, MIT Media Labs

Yup, here. Hi, this is Steven.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Steven. And from ONC do we have Lucia Savage?

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Yes.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Lucia. Maya?

Maya Uppaluru, JD – Policy Analyst for Health Innovation, Division of Science & Innovation – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Yup, I'm here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Maya. Anyone else from ONC on the line?

Jeremy Maxwell, PhD – IT Security Specialist – Office of the National Coordinator for Health Information Technology

(Indiscernible)

Mazen Yacoub, MBA – Healthcare Management Consultant

Mazen Yacoub.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi Mazen. And who was the other person, I'm sorry?

Jeremy Maxwell, PhD – IT Security Specialist – Office of the National Coordinator for Health Information Technology

Hey Michelle, this is Jeremy Maxwell.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Jeremy, thanks for joining. Okay, with that I'll turn it over to you Andy and Leslie.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

(Indiscernible)

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Well we have a...

Josephine P. Briggs, MD – Director, National Center for Complementary and Integrative Health (NCCIH) – National Institutes of Health

The three of us from NIH are on, I guess we're presenters. Do you want to introduce ourselves now or later?

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

We're glad you're here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Yes, and we'll introduce you as we get ready for you to present.

Josephine P. Briggs, MD – Director, National Center for Complementary and Integrative Health (NCCIH) – National Institutes of Health

Terrific. Thanks.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Thank you.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So we had a pretty exciting day yesterday, the group of us that were able to hear firsthand the President's wishes for precision medicine. David and Arien Malec from the Standards Committee, me, Sharon Terry, Meg from Cerner and others were present and it was a pretty remarkable day. He spoke eloquently about the topics. We heard tremendous stories from patients, researchers and physicians

and the President was very passionate and well-versed. He spoke of big data; he spoke of the challenges of big data, the challenges of privacy and security. He also spoke about the opportunities for interoperability in data sharing and the need for the patient to be involved in receiving their information and contributing information to the record. It was just a remarkable day and maybe before I hand it over to Andy for comments, I'd ask David if you have anything to add from yesterday?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

No, I would agree, it was really fascinating. It was encouraging to see the President as knowledgeable as he was about the issues. He, you know, quite well understands the trade-offs and complexities involved in getting this right and understands the importance of it. So I was pretty impressed.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

It was a pretty cool day. Andy, would you have any opening remarks for the day?

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Indiscernible.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Andy, are you there?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

We're not hearing you.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

So, you can't hear me now?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Now we can.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Now we can.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

All right. Funny, didn't change anything but anyway, no, I don't have any remarks so I should have just stayed unheard because we have a very full day and I think we should just get on with hearing from our various expert presenters.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

That's great and I'd like to apologize and thank Lucia for her patience. In the last meeting we didn't get to you and I apologize for not doing my job and we will make sure that we hear everything today. We'd like to reserve our Q&A until the end and with that we're going to turn it over to our experts from NIH, Josephine Briggs and William Riley.

Josephine P. Briggs, MD – Director, National Center for Complementary and Integrative Health (NCCIH) – National Institutes of Health

Hi everybody, I'm really delighted to have the opportunity to tell you a little about what we're trying to get started here and to get your advice and input. Here with me today is Bill Riley. I'm the current Acting or Interim Director of the PMI Cohort Program. My deputy in this work is Bill Riley and the person who is going to be leading the project we're going to talk about today, the Sync for Sciences is James McClain and those people are here with me right now.

As I think you heard yesterday at the PMI launch White House event, one piece of this that we're quite excited about is a project being called Sync for Science. I think it's not a new name, it's been bandied around as a priority; I think Dan Masys was the inventor of the term. But right now we are in a position to put some resources and have the kind of partnership that will allow us to build some of the implementation feasibility steps for this pilot.

I think I'm going to turn the microphone to James or Bill and let them describe to you the pieces we're imagining for this pilot and then hear your thoughts. Our motivation in presenting this to you is to get advice and input on the most effective way to use this opportunity. So thank you for your thoughts.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And I'd like to remind the committee that a PDF was sent for your reference. Thank you.

William "Bill" Riley, PhD – Director, Office of Behavioral and Social Sciences Research (OBSSR) – National Institutes of Health

Thanks, and thanks Josie. So I want to start off by thanking Maya and others at the ONC who have already provided considerable input into this effort moving forward. I will say that this is probably the fastest we have ever funded a supplement to a grant at the NIH. The application came in on Monday. Is it really still this week?

It actually came in on Monday; it was reviewed by people by Tuesday at noon. It was discussed by Maya, myself and the project officer for the parent grant that Tuesday afternoon. We did some modifications to budget and those sorts of things and by sometime late Wednesday night and early Thursday morning, it was released for funding. So that's got to be a land speed record for the NIH, I will tell you.

So just a few things about what we're trying to do here. So there is a parent grant that's part of the BD2K or Big Data to Knowledge Initiative...there we go. Big Data to Knowledge Initiative that is with Isaac Kohane's group at Harvard's Medical School and their Center of Bioinformatics. And their work really was very consistent and within scope of some of the things that we wanted to do, so we thought this was really a good place to sort of supplement an existing grant and quickly get started on some of the things that we want to do.

Their goal is to focus on direct volunteers for those...most of you are aware of what the effort is for Precision Medicine Cohort, but in addition to participants coming from the health provider organizations where they have a health provider home and they have an electronic health record associated with them. In the realm of the direct volunteers, it's not quite so clear who their health providers will be, what electronic health records they'll have if they'll have any at all and how we might extract data from that.

So the proposal that we have and that we just funded from Zach Kohane's group is to pilot the technical feasibility of being able to set up a FHIR compliant API that will allow us to identify which healthcare provider that participant has, determine if we can actually be able to extract their information, connect to that provider system, authenticate the portal and then get approval to transfer the information to the research group, which in the case of PMI would be the coordinating center. Retrieve that EHR data and at this point we're thinking about a very limited set of the probably easiest and it's always hard to say that any of this is easy. But the easiest data, which is primarily medication list, diagnostic codes and perhaps a few more standardized laboratory values and then be able to ping that EHR periodically to keep the research database up-to-date.

As you heard from yesterday, the White House has commitments and ONC has commitments from a half a dozen EHR vendors as part of this effort and so Zach's group will be working closely with them for an open source application that will allow us to be able to ping and extract this information and develop the open source reference implementation for the EHR as well. That's a quick overview of what we're doing. Maya, do you have things you want to add to that?

Maya Uppaluru, JD – Policy Analyst for Health Innovation, Division of Science & Innovation – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

No, that was great Bill, thank you so much.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

So, are we going to...Leslie, are we going to ask questions as we go or what...

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

We thought we would put those off unless there were questions for clarification, David.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Okay, say when.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Well we certainly have enough time; does this conclude your presentation?

Josephine P. Briggs, MD – Director, National Center for Complementary and Integrative Health (NCCIH) – National Institutes of Health

It really does, we are really here to hear what both...what questions we need to answer to get more targeted advice, but also open to suggestions as to what will make this pilot most informative. The time urgency to get this started is related to the fact of the White House commitment event where the six major healthcare provider organizations in the country have committed to help. And so they are going to be providing to the Kohane group the kind of interface access that is necessary to facilitate this.

I think that one issue that we're well aware of is when a potential volunteer gives permission, what kind of authentication process is necessary to verify that the health record comes from the right person, since we know that we're going to have to operate in a setting in which an ID is not available. And so the authentication issues will certainly be one piece of this pilot, but the other piece is working with these six major organizations about what rules for moving information around, what API details are necessary

to make this work. And that's what we hope to learn in the pilot, but we're well aware that we have on the phone some substantial expertise in this space so we're eager to hear your thoughts and questions.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Well we have the time for discussion left so I think we should do that now. I have one clarifying question and then I'll turn it over to the group to start discussing. You mentioned either six healthcare organizations or six EMR vendors; could you name those six please?

William "Bill" Riley, PhD – Director, Office of Behavioral and Social Sciences Research (OBSSR) – National Institutes of Health

I don't have that list in front of me, but...

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

I've got the list. It's Allscripts, athenahealth, Cerner, Dr. Chrono, EPIC and McKesson are the EHR vendors, according to the White House.

Josephine P. Briggs, MD – Director, National Center for Complementary and Integrative Health (NCCIH) – National Institutes of Health

Yup, that's correct.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

But you mentioned healthcare delivery systems, I didn't...I wasn't aware that there were also participating volunteer delivery systems.

Josephine P. Briggs, MD – Director, National Center for Complementary and Integrative Health (NCCIH) – National Institutes of Health

So it is anticipated that the awardee and the EHR organizations will identify the HPOs themselves. We are not doing that at this date. Ultimately, of course, the NIH anticipates funding health provider organizations to be part of the pilot, but this project, the Sync for Science, the health provi...initial set of health provider organizations is going to be developed by the grantee working together with the vendors.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Okay. Great. David, you had a question, I think, or did you have a further remark?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

I have a long list of questions, but I don't want to interrupt...

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

We'll ask the most important one first.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Okay. So, I guess maybe I'll make a statement and then ask a question about flexibility of what's written here in the PDF. So there are a range of decisions, some of which may seem fairly superficial on the

surface, which can have a profound impact on the difficulty and timelines of delivering something that's useful.

And my question really is, will we have an opportunity to, you know, sort of take this one paragraph summary of the notion and actually tease it apart and maybe restructure it so that some parts are pushed out to later, some parts might be made optional or not even...or dropped and so forth. In other words, can we tune it to feasibility?

Josephine P. Briggs, MD – Director, National Center for Complementary and Integrative Health (NCCIH) – National Institutes of Health

Well certainly you're welcome...we would be delighted to have you send us advice in writing that may go beyond what we can get in the context of this phone call. This simple summary is only one phase of developing the actual work specifications in this project and we anticipate working very closely with the Office of the National Coordinator in putting flesh on the ideas that you see in draft form or in initial form here. So, more concrete suggestions are indeed welcome.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Well, and I certainly didn't envision that we would do the design on this call, although I'd be happy to jump in, but is the thought really is sort of what's the process that we get to consensus on what we're going to actually build, is that going to be predefined and we have somehow committed to implementing something we've never, you know, we don't und...we didn't know what it was.

William "Bill" Riley, PhD – Director, Office of Behavioral and Social Sciences Research (OBSSR) – National Institutes of Health

Right, right.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Or do we have an iterative process where we can, you know, flesh out these details and reach consensus that solve the overall goal of consumer driven donation, but may in fact, not exactly line up with this current proposal. In other words, what's the process of landing on the detailed spec?

William "Bill" Riley, PhD – Director, Office of Behavioral and Social Sciences Research (OBSSR) – National Institutes of Health

Right. So David when you say "we" you're talking about the ONC, correct?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Well, I'm mostly talking about the vendors on the hook to implement something.

William "Bill" Riley, PhD – Director, Office of Behavioral and Social Sciences Research (OBSSR) – National Institutes of Health

Ah right, gotcha, gotcha, right.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

But, you know, plus whoever else wants to weigh in with opinions.

William “Bill” Riley, PhD – Director, Office of Behavioral and Social Sciences Research (OBSSR) – National Institutes of Health

...on the latter of those things that you said, which is that this is an iterative development process as we see it, and it's a partnership between the vendors, the awardee, the NIH and the ONC as we sort of work through the detailed specs. So this is not a waterfall sort of process, right? It's a very sort of iterative design process that we kind of see happening along the way and working through the problems. I mean, part of why we're doing this as a pilot is specifically for that reason that we want the vendors working together and with us to try to solve some of these implementation issues that we know have been there for many years, so.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Yeah, that's good to hear.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

As a follow up to that I have a question, this is Leslie again. Do you perceive working with a more either like an S&I Framework or this new...that ONC has created or this body? What do you expect in your structure for getting there?

William “Bill” Riley, PhD – Director, Office of Behavioral and Social Sciences Research (OBSSR) – National Institutes of Health

Well we could certainly get some feedback from you guys on sort of best how to approach that. We know there are already some standards and structures in place from the ONC and we're certainly planning on borrowing and using all of those, to the degree possible and it would be helpful to get some ideas from you guys on exactly how you think that ought to proceed. But, I know that the proposal that we have does talk about some of those structures and systems already in place, so.

Andrey Ostrovsky, MD – Chief Executive Officer – Care at Hand

Really quick to dovetail on that, Andrey Ostrovsky here; I think one thing that would be aligned both with the Precision Medicine Initiative and the ONC 10 Year Roadmap is a body of work that looks beyond what just EHR capability currently exist, particularly looking at standardized data sources that allow for more inclusion of what happens in the community.

And I think that's relevant because precision medicine obviously isn't just the medical stuff, taking into account more upstream health determinants through standardized data elements, particularly like the work being done within the eLTSS Workgroup. I think that would be really groundbreaking to incorporate that body of work, given that most of the partners at the table are EHR vendors rather than more broad HIT vendors.

Josephine P. Briggs, MD – Director, National Center for Complementary and Integrative Health (NCCIH) – National Institutes of Health

You know, I am trying to help us all understand the framework in which this project, which is a very small piece of precision medicine, has to be placed. We are working here at the NIH to do a kind of layered implementation process in which we start with a simple core set of data elements and then as our grantee community is awarded and brought on, bring in things like the socioeconomic and community and environmental elements.

We are not anticipating in the first six months moving...we will be asking for a pretty rich set of participant provided information, but the...many other layers of precision medicine and individualizing health are going to be developed by the Steering Committee for the PMI Cohort Program. So the Sync

for Science pilot is intended to address the immediate short-term challenges of linking at all with the electronic health record, not to solve the steps and capture of a much richer dataset.

We totally agree the much richer dataset is very much what this is about, but our challenge in the short run is to develop a lean implementation plan that focuses on the most important data elements. Or maybe they're not the most important, they might be the easiest, but...

Andrey Ostrovsky, MD – Chief Executive Officer – Care at Hand

Thank you for clarifying.

Josephine P. Briggs, MD – Director, National Center for Complementary and Integrative Health (NCCIH) – National Institutes of Health

Aww...

Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

I have a comment, do we ha...are we running out of time?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

No go ahead Dixie.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Go ahead Dixie.

Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Okay, this is Dixie Baker and I have been working with Genetic Alliance and the patient-powered research network under the PCORI Initiative and where we found, and I think where you will find the barrier is not with...so much with the EHR implementation, but with the providers' implementation of the EHR technology. Because right now we know that certified EHRs are capable of doing much more than what providers are actually doing in their portals.

For example, you know very few of them are actually making C-CDAs available and its other issues. One of the issues and this is related to that, but one of the issues that I know was talked about a lot yesterday, I doubt in the open forum, but I know in the hallways it was, was the issue of ownership, of data ownership. I think this will be an increasingly big issue that the PMI will need to deal with.

And the final point I wanted to make is that also we know that with the APIs, the requirements in both the Meaningful Use regulation and the Certification regulation, a lot of providers are quite concerned about their own responsibility and vulnerability and liability relating to protecting the patient from using, you know, from something that happens with their application where a malicious application. And I know this...the one you're talking about here is a PMI application, but at the same token it requires them to open an API that they are very, very resistant to doing. And I'm talking about the providers, not the EHR vendors.

M

Right.

Josephine P. Briggs, MD – Director, National Center for Complementary and Integrative Health (NCCIH) – National Institutes of Health

I agree with...

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

This is...

Josephine P. Briggs, MD – Director, National Center for Complementary and Integrative Health (NCCIH) – National Institutes of Health

...everything you just said, I don't think...we're not unaware of these challenges and in fact, being able to clarify to the HPO organizations that we award through this process, what our expectations are going to be is a very real and active concern and issue for us right now.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Well so I'm...this is Andy Wiesenthal and I'm with Dixie because I think the challenges, as much as they will be difficult with helping the vendors work through, as David said, an iterative set of technical targets for how the information will flow out of their products, what's in there is at the mercy of how the individual health delivery systems decided to define the data.

So I'm imagining you're going to want gender, right? And you may think that's easy, well I'm here to tell you that it's going to be hard because whatever...whoever they recruit, whatever delivery systems they recruit will very likely have defined gender differently.

Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Um hmm.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

And, you know, if you could ask for 20, 30, 40 elements some of the things you're asking for actually I'm surprised to hear you say that lab is maybe off the table. Lab would be pretty coherent compared to some of that stuff.

William "Bill" Riley, PhD – Director, Office of Behavioral and Social Sciences Research (OBSSR) – National Institutes of Health

Well Andy, I don't think you heard me correctly then because I didn't say lab was off the table, I said that we were going to start with some initial limited sets, right, again incrementally building their dataset over time. That includes some standard lab values to the degree we can...the ones that are more standardized than others. There are ones, as you know, that are not as standardized as others.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Right.

William “Bill” Riley, PhD – Director, Office of Behavioral and Social Sciences Research (OBSSR) – National Institutes of Health

I will point out, going back to your point. And I think it’s an important one for us to look at is that as we get work with these vendors who are going to be working with health provider organizations and pulling data to be able to test that the point about doing that from multiple health provider organizations within the same vendor is a good point so that we can begin to look at some of those variations and how we address those.

And then the other thing that I think we’re going to need help from people with your expertise and others on is around where do we curate this data? How much of it is done at the health provider organization before it gets there? And our preference is after it gets into the coordinating center on our end, but that’s a very messy dataset as well. So...

Andrew M. Wiesenhal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Yeah.

William “Bill” Riley, PhD – Director, Office of Behavioral and Social Sciences Research (OBSSR) – National Institutes of Health

...all that process is going to be tricky.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I...

Andrew M. Wiesenhal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Yeah it is and I would...as long as I have the bully pulpit I’ll say one more thing and then everybody else wants to pile on, so I have to let them. But again, this Andy; I think you’re right that work of mapping from whatever they’ve got in their data model at the provider level to whatever the target definitions are is going to have to happen at the provider level.

I would urge you to help this committee, this task force and the larger Standards Committee, to really adhere to our stake in the ground, that they use the standards that we have determined are the standards; that they use SNOMED CT, that they use LOINC, that they use the other standards that we have decided are the appropriate ways of transmitting this data. No one is going to do that easily, but this is a place to start, with a limited set that everybody agrees to that you can sort of collectively define. And I’ll shut up because there are a bunch of people who wanted to ask questions or make a statement.

Josephine P. Briggs, MD – Director, National Center for Complementary and Integrative Health (NCCIH) – National Institutes of Health

I don’t know if you’ve had a chance to listen to...to look at our RFAs, but I think we were very explicit about the use of the standards ONC has established and we plan to stick by that.

Andrew M. Wiesenhal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Good.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

It could be useful to provide that document to this committee; I don't think we received that.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

No.

Josephine P. Briggs, MD – Director, National Center for Complementary and Integrative Health (NCCIH) – National Institutes of Health

Okay, it's in public interface, but we'll certainly pull the relevant language. It actually was written by ONC, not by us.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Great.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

This is David, I want to chime in a little bit on what Andy just said and I think we're headed in the right direction here, it feels pretty good. But I will point out, and I made this comment in the session that Maya moderated yesterday, that there is quite a bit of work by a significant subset of those six vendors in the public, open work with the Argonaut Project to develop the exact APIs that are putatively needed here.

And as part of that work, a lot of conversation already under way and a lot of testing under way to reconcile some of the data value set mapping questions; certainly not every one of them, but a fair number of the important ones; getting agreement, for example, on how to encode blood pressure in a consistent way. Surprisingly, that turns out to be a non-trivial challenge.

So, you know, it would be a shame to ignore that work, I mean, we are already well on the way to doing exactly what's required here and the degree which we can align with that would be great.

Josephine P. Briggs, MD – Director, National Center for Complementary and Integrative Health (NCCIH) – National Institutes of Health

Yeah, I totally agree and that is part of the reason for this conversation is to...we're aware of the Argonaut Project, although a non-IT geek like me doesn't really understand it, but we do really want this project to very much be compatible with, and in certain areas it may be a little ahead of where Argonaut is, but we want it to as synergistic as is possible with what's going on there.

William "Bill" Riley, PhD – Director, Office of Behavioral and Social Sciences Research (OBSSR) National Institutes of Health

I'll just add that I know...so Josh Mandel, who's on Zach Kohane's team has been working on that Argonaut Project, part of why we wanted to have them include us because we knew they were fairly involved in that effort.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Yeah and we, I'll speak just personally, we...my group here at Cerner, and I think this is shared by the other vendors that I've talked to, have a lot of respect for Josh and applaud that decision on your part.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

This is Eric Rose, I think this is pretty exciting. I had three comments, two very quick, one a little bit longer that I hadn't heard come up. One, I think that I would pay particular attention to patient identification; I think that that is going to be a rather sizeable challenge. People's names change over time, patient records get merged and split and so forth within a single EHR, so I think that that deserves quite a bit of attention.

The second quick one is, I would, if you haven't already figured this out, I think one important question will be whether the permission given by the direct volunteer is considered to be in perpetuity or needs to be renewed periodically. I think you'll be better off if it...it's more complicated, of course, to implement but you'll be better off long-term if its renewed periodically because if, you know, people start to be concerned about how the data is being used, so on and so forth, and they have to take...

Josephine P. Briggs, MD – Director, National Center for Complementary and Integrative Health (NCCIH) – National Institutes of Health

We agree, yeah.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

...posi...

Josephine P. Briggs, MD – Director, National Center for Complementary and Integrative Health (NCCIH) – National Institutes of Health

Yeah, we totally agree.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Okay. So the third thing is, which is a bit broader is that it makes total sense to me to start where the barrier is lowest with the EHR vendors who are ready, willing and able to make this work. The risk there is that you'll...is introducing bias into the data sample of course, because the American population is not randomly distributed...or the records are not randomly distributed among different EHR vendors, there is systematic variation.

There are some EHR vendors that are more commonly used in rural environments and critical access hospitals and public institutions and so forth. And so I think you have an opportunity with your pilot to actually determine whether the patient population that you get is representative of the American people. And you could compare various pieces of data with databases that are collected on a more systematic basis like NHANES and see to what degree your patient population differs and then that will help, I think, guide strategy for the Precision Medicine Initiative overall to make sure that you're really getting a good representative sample, which I think is necessary to meet the overall goals of the initiative.

William "Bill" Riley, PhD – Director, Office of Behavioral and Social Sciences Research (OBSSR) – National Institutes of Health

So let me clarify because I think that's important. We're going to have bias in places other than just around the EHR because the PMI Cohort, you know, just by the very fact that it's a direct volunteer cohort at least in part, will not be a representative sample. But you're absolutely right, one of the things that we plan on doing is comparing data, whether it's on the EHR side or just on the direct volunteer side, however that is collected; comparing that against representative samples, weighting as necessary,

doing a number of other procedures. So if we need to be able to do representative sort of estimates, that's possible...

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Um hmm. Okay, great.

William “Bill” Riley, PhD – Director, Office of Behavioral and Social Sciences Research (OBSSR) – National Institutes of Health

...large and diverse sample where we can get small levels of exposure with small levels of subgroups of a disorder and still be able to have enough in to be able to answer some of the precision medicine questions that we have.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

This is David, one quick question on that, is the pilot going to actually get committed donors or is it a pilot of the technology and the donors would have to make the commitment when the full-blown system is up and running.

Josephine P. Briggs, MD – Director, National Center for Complementary and Integrative Health (NCCIH) – National Institutes of Health

We're actually talking...there are two pilots going on. The Sync for Science pilot will not be getting committed volunteers; it's a pilot of technology. We are also starting a...

M

Hello?

Josephine P. Briggs, MD – Director, National Center for Complementary and Integrative Health (NCCIH) – National Institutes of Health

...second pilot which will begin...

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

This is Michelle, we've had a lot of background noise during today's call. If you aren't speaking, if you could please mute your line, that would be greatly appreciated. Thank you so much.

Josephine P. Briggs, MD – Director, National Center for Complementary and Integrative Health (NCCIH) – National Institutes of Health

One point...

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Do we still have our speaker? Go ahead, please.

Josephine P. Briggs, MD – Director, National Center for Complementary and Integrative Health (NCCIH) – National Institutes of Health

One point that was made earlier that I didn't leap in on is this question of, so issues like how is gender coded? We are going to view our core dataset as coming from the participants and we've been working hard on various ways one can ask questions about gender, but we'll view that core dataset as the reference against which the EHR data is compared. And so we are not going to necessarily have to

homogenize the variables for every data field, because we will take what the participant provides us as our standard.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Well I...this is David; I think that's a smart, flexible approach, but I think the vendors are also at the same time interested in understanding what does it mean to be compliant with a FHIR profile for EHR usage, with the understanding that the more compliant we are, the more useful these APIs become to people who want to consume the data. So, I don't know that we've had the debate about gender yet, but we certainly had it, in the Argonaut work anyway, about some of the other fields that have a lot of variation.

So I like the flexibility, but boy I hope we can do a better job of kind of getting a profile that defines the data at the source and put the mapping burden on the people who actually understand what they've been capturing rather than a guesstimate downstream when you're detached.

Josephine P. Briggs, MD – Director, National Center for Complementary and Integrative Health (NCCIH) – National Institutes of Health

Sounds good.

William "Bill" Riley, PhD – Director, Office of Behavioral and Social Sciences Research (OBSSR) – National Institutes of Health

Right.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

So Leslie, this is Andy. We've had...I think we've heard from David and Dixie and Eric and I'm wondering if other members of the workgroup have any ideas that they'd like to describe or questions.

M

Yeah.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Go ahead.

Gil Alterovitz, PhD – Faculty, Center for Biomedical Informatics – Harvard Medical School; SMART/FHIR Genomics Lead

Yeah I'd like to...can you guys hear me though, I think I was on mute before.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Who is this?

W

We hear you.

**Gil Alterovitz, PhD – Faculty, Center for Biomedical Informatics – Harvard Medical School;
SMART/FHIR Genomics Lead**

Oh hi, this is Gil Alterovitz, can you guys hear me?

**Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP;
International Health Terminology Standards Development (SNOMED)**

Yes, we can hear you.

**Gil Alterovitz, PhD – Faculty, Center for Biomedical Informatics – Harvard Medical School;
SMART/FHIR Genomics Lead**

Okay, perfect. Okay, so maybe I've been thinking I'm off mute. So yeah, a couple of things; so one, I guess I was wondering about this clarification about the overall program. There are going to be a series of these pilots, is there a goal eventually to include some of the richer data? When you look at precision medicine it talks about, you know, genomic data, lifestyle data and so forth and also, for...is there kind of a desire or a need to define certain use cases that are going to be looked at? Or has that been done already, perhaps?

**Josephine P. Briggs, MD – Director, National Center for Complementary and Integrative Health
(NCCIH) – National Institutes of Health**

So some of this was done by the Advisory Committee to the Director Working Group, which...and their report we are now charged with implementing the recommendations in that report. It did, indeed, develop a set of use cases and it's, I think, a good place to start to think about where the NIH has been thinking about this issue.

We are, in this stage of the project, taking on this particular aspect of the movement of data, to worry about its standardization. We will be funding, in the summer, a coordinating center and a set of health provider organizations with a broad charge for standardization of data movement and the development of the data resources for all the important elements you mentioned. But this is a step-by-step incremental process and what you're hearing in the Sync for Science is only one step in a process that will take a few years to really get done right.

**Gil Alterovitz, PhD – Faculty, Center for Biomedical Informatics – Harvard Medical School;
SMART/FHIR Genomics Lead**

And the Sync for Science is it kind of they'll be one pilot or there will be a series with different foci, like how will that work? I wasn't clear if this is kind of the one program or...

**Josephine P. Briggs, MD – Director, National Center for Complementary and Integrative Health
(NCCIH) – National Institutes of Health**

That's a good question. We have, right now are in the middle of working out the details for the first pilot. If it seems to be a useful exercise, it's certainly possible that we could again work with these major vendors and do a subsequent stage. We're trying to break this complex field into manageable bites and what you're hearing about is what we're trying to put together as kind of bite one.

**Steven Keating – Patient Advocate/Consumer – Doctoral Candidate, Mechanical Engineering, MIT
Media Labs**

Hi, this is Steven Keating, I have a couple of quick comments here. First of all, I think looking at some of the health information exchange groups like Healthex might be a really nice way to integrate between the different codes because they're getting EHR data from dozens and dozens of different situations.

And another question I had for you guys is around direct volunteer...so, as a participant in the project, what kind of control would they have and what kind of incentives would they have to join? Like are there ways that this can be structured so that people are really excited to participate and, because do they, you know, have potential authorship on papers in any way or be recognized or, what is the benefit to the direct volunteer that's going to get them excited and push this forward and talk to their doctors about wanting to consent?

William "Bill" Riley, PhD – Director, Office of Behavioral and Social Sciences Research (OBSSR) – National Institutes of Health

Yeah, so it's a good point. So first of all on the H...the health exchanges, that's a really good point and we'll follow up with that. As far as participants are concerned, I will tell you we have thought about this an awful lot. One of the other pilots is a direct volunteer pilot where our focus actually is on is how do we engage them? How do we keep them engaged? What are the motivations for making this happen?

And particularly, and this is kind of related to some of the EHR work as well is, what sort of feedback is most useful to them to keep them engaged? And that could be around electronic health record data. It could eventually be around genomic data. Early on it will just be some of the basic data that we can collect from what they provide to us. Calorie expenditures or calorie intakes from diet and physical activity data they provide us, for example. So we've been talking about the EHR pilot, but we also have a direct volunteer pilot that really is focused primarily on how do we optimize engagement of the participants moving forward.

Steven Keating – Patient Advocate/Consumer – Doctoral Candidate, Mechanical Engineering, MIT Media Labs

Yeah and I think for that, in case you're interested, it could be really helpful to work Dave...Human Team or the PatientsLikeMe at the personal genome project where they have amazing groups of people who can see the benefits and I know they're very eager to potentially work and they have APIs and could be a really easy way to integrate.

William "Bill" Riley, PhD – Director, Office of Behavioral and Social Sciences Research (OBSSR) – National Institutes of Health

Thanks, appreciate it.

M

But from the...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Hi, this is Leslie and I have a follow on question to Eric's earlier point about patient ID and then also a cross of pilot. So we heard last week from the FDA's Data Common Project and it seems that although they will be focusing primarily on the genomic data, when we start to leak this data, the idea of patient ID and who the patient is and how do we aggregate that...decisions have to be made across the different areas. How do you perceive that happening?

Josephine P. Briggs, MD – Director, National Center for Complementary and Integrative Health (NCCIH) – National Institutes of Health

So, well, it's a very important problem and there are a number of bioinformatics groups working on it and we hope to utilize the best available expertise in this area. My understanding is that there are some very informative algorithms being developed that allow you to assign a probability that a given record in

fact represents the same person and that depending upon the information in it, like depending on whether the name is John Smith or Josie Briggs, you may have different probabilities that you have the right record. And that at least one step in this is going to be to decide what kind of error limits are tolerable and what are not. I think this is an area where the informatics expertise is moving rapidly and we hope to take advantage of the best thinking in this area.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

This is David; I want to jump back to the previous point about incentives and maybe point out the obvious but it might not be, in that the way the vendor community, particularly the ones working through the Argonaut Project are thinking about these APIs is that they are multipurpose and would serve many needs, other than just the Precision Medicine Initiative.

Josephine P. Briggs, MD – Director, National Center for Complementary and Integrative Health (NCCIH) – National Institutes of Health

Absolutely, I mean, we're kind of a second thought to the development of these APIs, is my understanding, but we of course consider ourselves to be an important second thought.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Yeah, totally agree, but to the degree that we can make these multipurpose so that consumers find benefit in these APIs for lots of things, not just precision medicine...

Josephine P. Briggs, MD – Director, National Center for Complementary and Integrative Health (NCCIH) – National Institutes of Health

Right.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

...is it will influence how important they become in the consumer's awareness of what aspects of their data they have access to and can control. So we want a whole suite of applications that can take advantage of your health data to make yourself healthier and/or to contribute to science. So I'm glad we're aligned there, too; that sounds good.

William "Bill" Riley, PhD – Director, Office of Behavioral and Social Sciences Research (OBSSR) – National Institutes of Health

Good.

Josephine P. Briggs, MD – Director, National Center for Complementary and Integrative Health (NCCIH) – National Institutes of Health

No and I think that one of the things that the Precision Medicine Initiative hopes to build is a cohort of a million people who kind of understand that, who get it and are engaged in looking at their health data, in donating their health data and how to build that is what we are thinking about day and night.

Mitra Rocca, PhD – Associate Director, Medical Informatics – Food & Drug Administration

This is Mitra Rocca from FDA, going back to Leslie's question and at FDA actually for the Sentinel Initiative we had a task order linking two large sources of data using, without using any PHI so if you're interested, we published a paper on that, too and we worked with our coordinating center...on that project. So we had a gold standard which was linking them using PHI, then we used a complex algorithm were linking them without EHR, but for Sentinel Initiative we don't have PHI, everything is de-identified and aggregated so.

Josephine P. Briggs, MD – Director, National Center for Complementary and Integrative Health (NCCIH) – National Institutes of Health

Right. Yeah, we've been working closely with Rich Platt and are pretty aware of the Sentinel process. He's also the lead investigator in a project that I've been leading called the Collaboratory and we are definitely hoping to learn from that experience.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

This is David, I want to jump in on that patient identifying point and make one more comment just a sanity check that we're thinking the same thing.

Josephine P. Briggs, MD – Director, National Center for Complementary and Integrative Health (NCCIH) – National Institutes of Health

Don't count on us being sane here.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

No, no, so far you're batting a thousand so this is good. Or I'm batting a thousand guessing or whatever is the measure; but the OAuth 2 model is predicated on the notion that the consumer authenticates themselves into their own portal account.

Josephine P. Briggs, MD – Director, National Center for Complementary and Integrative Health (NCCIH) – National Institutes of Health

Right.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

And so they've been provisioned an account where identity, you know, proofing has already been done in order to get the portal account in the first place, and presumably that's done with a lot of robustness; so the pilot itself won't have to wrestle with the patient identity matching problem. That's really for the downstream consumer of the data, which as I understand it is really coming in the future, that's not part of the pilot, per se.

Josephine P. Briggs, MD – Director, National Center for Complementary and Integrative Health (NCCIH) – National Institutes of Health

Correct, on the other hand, the question of what data elements are necessary for that makes the patient identifier issue not completely irrelevant.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Yup, good point and the FHIR profiles have to be actually extended to account for U.S. specific identifiers that aren't in use in international settings and include things like gender and ethnicity, which are not allowed in most countries, only in the U.S. So those extensions are in place, but they need to be vetted as part of the overall matching process. I think that makes good sense.

William "Bill" Riley, PhD – Director, Office of Behavioral and Social Sciences Research (OBSSR) – National Institutes of Health

That's helpful.

Josephine P. Briggs, MD – Director, National Center for Complementary and Integrative Health (NCCIH) – National Institutes of Health

Thank you. Yup.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Michelle, this is Andy, I want to just pause for a second and do a time check. How are we doing?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

I think that...

Josephine P. Briggs, MD – Director, National Center for Complementary and Integrative Health (NCCIH) – National Institutes of Health

Team needs to sign off in about four or five minutes.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

And I think we need to move on anyway, so.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

All right; s I would suggest that there may be many, many other questions. We'd be happy to collate those and transmit them to our NIH colleagues. You can tell, I hope, that we are all very, very excited by this. It's a wonderful opportunity for the country and there's nothing like a deadline from the White House to focus one's mind, eh?

Josephine P. Briggs, MD – Director, National Center for Complementary and Integrative Health (NCCIH) – National Institutes of Health

It's correct.

W

That's the truth.

Josephine P. Briggs, MD – Director, National Center for Complementary and Integrative Health (NCCIH) – National Institutes of Health

I want to make it very clear that this is intended to be a very close partnership with the Office of the National Coordinator; we're bringing as much of their time and energy into this, thinking about this as we possibly can and so we expect to benefit from their input and to do our very best to make this as synergistic and as synced for PMI as it can be.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Well that's wonderful.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I would just add congratulations to the six vendors who have agreed to participate who are not necessarily natural bedfellows but have overcome a lot of things and a lot of, I think, bad press and come together to this effort, I think that's applaudable.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

That’s great and I’m also going to tell all my colleagues who are researchers who apply for grants at the NIH to make sure that when they do their cover letter they say the President wants this by Thursday.

William “Bill” Riley, PhD – Director, Office of Behavioral and Social Sciences Research (OBSSR) – National Institutes of Health

There you go. Sounds like a plan.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

All right; thank you.

Josephine P. Briggs, MD – Director, National Center for Complementary and Integrative Health (NCCIH) – National Institutes of Health

We’ll keep you informed as this moves along.

William “Bill” Riley, PhD – Director, Office of Behavioral and Social Sciences Research (OBSSR) – National Institutes of Health

Thank you very much.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thank you.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Next.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Next, Lucia. Thank you for agreeing to come again and to present to us; apologize for the last meeting and look forward to hearing from you.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Thank you and hopefully you can all hear me okay. I know that you have had the slides we produced for quite a while and so I’m going to kind of go through my section really quickly, which is about a lot of the policy work we’re doing to make the whole privacy compliance world be able to be done more effectively by computers.

And then I’m going to turn it over to Jeremy Maxwell, who’s also on the line, who’s going to spend about five minutes just giving a high level summary of some particular work we’re doing to try and develop some standards for technically documenting choices of people to participate in research or not. And we’re really trying hard not to do redundant work there, so I’m sure you’ll have lots of questions. And then that will leave about 10 minutes of balance where you can ask either of us whatever questions you want.

The other thing I would say by way of introduction going back to Dixie’s remarks very early on about providers and sort of the automated retrieval of data, we do have an API Task Force sponsored by both

of our FACAs that is ongoing right now, which we are hoping will contribute a lot of really good information to not only interoperability in general, but in particular, to benefit PMI so that we can automate some of these processes. So, feel free to log in to the public line to any of those and if you work through Michelle and you want an update on that, we can supply one as we get farther in the process; Josh Mandel and Meg Marshall are the Co-Chairs of that task force. So next slide, please.

So I just wanted to sort of let you guys know that this problem of making how we document what people's choices are amenable to being done by computers and persisted in computers is something here at my office we've been working on since I arrived in October of 2014 and PMI lets us...gives us a new avenue to do the same work, but we've actually built an entire two-year work plan around this concept.

And so this slide just, you know, what you guys had put in the task force in your recommendations last fall in contrast to what we had put in the roadmap; this is a problem for the health system as a whole and need to make it easier for people to do it right and bring the power of computing to it. Next slide, please.

So this slide, slide 13 here, just basically sets out exactly what we're doing. So I'm not going to actually go into the detail of every slide underneath, but I will tick off the things on this list. And all of these were set forth in the Interoperability Roadmap and this is probably really familiar to David, because he already had a presentation on this last fall.

But the first...number one, we have to explain HIPAA better and I think that between ONC and the Office for Civil Rights we've done a really amazing job of that in the last two months. Fantastic new guidance on access and patient's rights to get their data, what it should cost, that was yesterday and our corollary work is our FAQ sheets on, you know in fact how HIPAA allows data to be moved when it needs to go for patient care without having to go through a lot of paperwork, unless you've imposed that on yourself.

Secondly, we know we have a big challenge with state law and research is not immune from this challenge; in fact, there is a very microscopic PCOR...PMI work stream to sort of make sure that what they...what we're trying to accomplish with PMI it doesn't run afoul of state law. But we have a larger ambition which is to sort of ignite a nationwide discussion about the fact that the wide difference in state law makes it hard to bring computers to this work, partly because it's confusing and the developers don't know what to make the computers do and partly because the people using those computers are also confused. That work is going really well; I won't belabor the point today.

And then we have a lot of work going on to sort of develop a consensus framework for the privacy and security principles that should underlie patient-centered outcomes research. And then there's corollary work that Jeremy will talk about which is standards about that. And I want to pause and, so that work is funded by the PCOR Trust Fund, but it's distinct from and kind of a sister to the work of PCORnet.

So if you remember, PCOR actually has two sections within its funding; one is to PCORI for all the work they do with PPRN and all their other work. And the other is to HHS actually for various work that needs to be facilitated to take patient-centered outcomes research concepts and bring them to the entire research infrastructure.

So ONC has a wide variety of funding grants there, but my office has two; the first one is to develop privacy and security framework for patient-centered outcomes research, and we're looking at some

other aspects of that as well. If you follow on ONCs Tuesday LISTSERV, we provided links in there; they are also later in this slide. And the second is, corollary to that, we have a framework which is principles oriented and then we need to have technology that brings those principles to life in an automated way. So Jeremy will talk about that in a little bit.

And then obviously, we're doing a ton of work behind the scenes to support PMI overall, whether it's working with OCR on active guidance, working on the privacy principles of PMI and every time we come to that table what we're thinking about is, can we get to a place where the principles we are embracing and the technology we are helping to facilitate make this something where we can get away from the paper? Next slide, please.

So Jeremy, do you want to talk briefly about the Patient Choice Technical Project? And I think what we'll do is we'll just leave you guys with the rest of the slides which kind of illustrate all that work, and let you ask us questions. So, baton handed to you, Jeremy.

Jeremy Maxwell, PhD – IT Security Specialist – Office of the National Coordinator for Health Information Technology

Sure. Can everyone hear me all right?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Um hmm.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Yeah, go ahead.

Jeremy Maxwell, PhD – IT Security Specialist – Office of the National Coordinator for Health Information Technology

Okay, great. So yes, the work that we're working on is, we're calling it the Patient Choice Technical Project and what this covers is harmonizing standards around being able to capture, you know, patient choice and, you know, consent decisions that individuals make. So there are kind of three phases that we're working on.

We are finishing up use case development in the next two weeks or so in the first phase, where we're looking at basic choice for treatment, payment, and healthcare operations. And so basic choice, you know, we're using the definition as we defined it in ONC's Interoperability Roadmap, so this is the basic choice, "yes I am in health information exchange," or "no I am out." And then we'll be doing some, once we finish up use case development, we'll be moving into a piloting phase and developing an implementation guide sometime in the September/October time frame.

And then once we finish up that, we'll be moving into phase two where we look again at basic choice, but for research. And then phase three will be following after that where we get into kind of the sticky widget of granular choice for both treatment, payment, healthcare operations and research. The idea is not that we develop three different standards, the idea is that we harmonize standards and at the end of the project we have one standard that we've worked with throughout and have, you know, grown and evolved that over time, obviously working with standards development organizations and folks in industry to help develop and test out some of these things.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

And Jeremy can you be sure you cover like how the process is working?

Jeremy Maxwell, PhD – IT Security Specialist – Office of the National Coordinator for Health Information Technology

Um hmm.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Okay, thanks.

Jeremy Maxwell, PhD – IT Security Specialist – Office of the National Coordinator for Health Information Technology

Yeah, yeah, so how it's working is we have a public stakeholder group that meets every Friday. So we have a set of contractors that are doing the majority of the work and then we use that public stakeholder group as a sounding board, as we are working through the process and so they provide a lot of feedback, a lot of input.

And we're currently in the pilot to recruitment phase, so we have a couple of folks that have signed up to be pilot participants and test out some of the standards and use cases that we're developing, but we could always use more. And so if you're interested in parti...being a, you know participating and partnering with us in this process, you know, there are kind of two levels of involvement. You can come to the public stakeholder working group that meets every Friday and be part of our kind of a sounding board. Or be, you know, for a little bit more serious commitment, you know, you can explore being a pilot participant and partnering with us in that way.

Now just to have a little scope, you know, bounding. Some of the things that we're not looking at as part of this project; we're not looking at ways to express consent to the patients or the users, you know as in like the actual design of the consent form or what should be consented to or should not be consented to. We're focusing more on the technical standards of, you know, once the patient has expressed a consent decision or a consent directive, how that is captured in a technical way and in a standards based way that can then be interoperably exchanged with other health information systems and those target systems understand what the original consent directive is, right, be able to make that consent directive interoperable and exchangeable. So that's the focus of where we are.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

And then, this is Lucia...go ahead Jeremy. I was just going to talk about the timing. The...so, good and bad news is that this work was already in flight both for our privacy and security legal framework for research and for these technical standards when PMI was announced. So we are able to really account for PMI's needs as we go through the process that we had already designed; develop use cases, pilot them, you guys are pretty familiar with that.

The bad news is that in fact these projects will be underway well into 2017 because they are very complicated and because we need to have time for pilots to run their course. So that's kind of the, you know, we're not going to have any answers for this task force or for NIH this summer. We'll be able to report on what the work is that's ongoing.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

So it says you're only covering the two choices, yes and no; how is that complicated with respect to what you just said? Is just this phase one is yes/no and then you're going to get more complicated or?

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

It's a both/and; I think there are two levels of complexity. One is that by the time this work started, because of the way the PCOR funding worked, there are organizations that already have their...have developed their own standards for doing this. And so one of the things that makes it complicated is we don't want to muddy waters that seem to be running clearly, but we have to figure out where those waters are and so we have to, you know evaluate the landscape really David and that's agile, we're not starting from scratch, and we recognize that.

And then the other part that makes it complicated is making sure architecturally, and Jeremy will jump in if I've got this wrong, that what we develop can then become extensible to more complicated consent environments.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Okay, I have other questions but I'll let you finish and then I'll ask them.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Jeremy, did I get that basically right?

Jeremy Maxwell, PhD – IT Security Specialist – Office of the National Coordinator for Health Information Technology

Yes and...intended.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

And I don't know if there's more formal presentation you want to give Jeremy, I'm really mindful of the time or do we want to just turn it over to the Chairs to facilitate questions?

Jeremy Maxwell, PhD – IT Security Specialist – Office of the National Coordinator for Health Information Technology

Yeah, I think that we covered the high points, so we can move into Q&A.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Great, well David, it sounds like you're number one on the hit parade again, so why don't you go for it.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Yeah, I've been doing these calls long enough to know to just jump in.

Jeremy Maxwell, PhD – IT Security Specialist – Office of the National Coordinator for Health Information Technology

We know David never has any questions.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

You guys thought you were...

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Not on privacy for me ever.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Yeah, you thought you were rid of me when you got me off the Standards Committee, but I'm back.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Right.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

So one is just a comment, there's an inconsistency when you talk about computable consent and computable privacy and you might want to align those terms, because I think they're quite different. And I would suggest that neither one of them is the right term, it's really you're talking about computable sharing permissions; so it's the inverse of privacy. It's like what do you want to share that trumps the built-in privacy?

And, you know, if it's a complete inverse, then those two are equivalent but from a perspective of where you're trying to go with this is you really want patients to authorize sharing in certain patient-controlled ways. And that's different from consent and it's different from privacy. So that's just an editorial comment.

My question and I know this is really going to be off-subject of the PMI but, how does basic choice relate to TPO? TPO is a legal exemption, it's a...are you suggesting...override...

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Oh David, you always go right to the core. So...this is Lucia; so here's the thing is right, TP...the choice to have your data exchanged electronically or not exchanged electronically is not a feature of HIPAA. But it is a feature of the privacy compliance landscape because of state laws and institutional policies. And so that's really what that's all about is, right?

If we can make sure people really understand how HIPAA works and if that...that one thing that is not in HIPAA is a requirement that you offer people a choice about having their data electronically exchanged. If you offer choice and they say no, you can still fax it for TPO, it's still being shared; it's just not being shared in a very interoperable way; that's one thing. And then what we proposed in the roadmap is, you know, help people understand a) being given a choice for exchange is not in HIPAA, but if you want to make that choice, that choice may have consequences and laying those consequences out now that we are six years into the post-HITECH world and we have a really good sense of what those consequences are.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

So this is Andy...go ahead Leslie.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

This is Leslie...go ahead Andy.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

No, no, you first.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

There was a pilot last year demonstrated at HIMSS in the interoperability showcase using FHIR and it was the concept of computable consent. Does this pilot take off on any of that work that shown?

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Honestly Leslie, I haven't studied it in depth and I wasn't able to get to that demonstration, so I don't have a perfect answer. But what I hear in the field other than that is that there are lots of demonstrations that assume that you have to get documentation and what we're trying to sort out for people is, when do you have to have the patient take action as a requirement and when do you not have to have the patient take action as a requirement. And there's a very, you know, specific difference there between the healthcare delivery setting where TPO applies and the research setting where you don't get a participant in a research study unless they take action to participate.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thank you.

Jeremy Maxwell, PhD – IT Security Specialist – Office of the National Coordinator for Health Information Technology

And from the...

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

So that's the sort of two-part nature of the word...of the definition of the word consent. One is, I consent to you moving my information in one direction or another, as David puts it, removal of the privacy constraint. The other is consent to a procedure, consent to participation in a project. And I guess while I know what you're talking about in this context, when you use the word consent people who are healthcare practitioners largely think of the latter and not the former.

And so maybe you need to just say, instead of using the shorthand consent to say consent to removal of privacy constraints for the use of my information or something like that; I don't know what the right expression is because otherwise the end user audience may be very confused about what it is that you are building here.

M

(Indiscernible)

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

I appreciate that but I'm actually going to ask Jeremy to weigh in here because he has a very compelling computer programmer perspective on this about what it looks like under the hood. Jeremy, could you talk about that, it's sort of the same thing we talked about Monday...Tuesday I mean.

Jeremy Maxwell, PhD – IT Security Specialist – Office of the National Coordinator for Health Information Technology

Oh gee, now that you've built it up, I'm not sure I can deliver. So yes, so the comments around choice of vocabulary is definitely something that we'll take under consideration. I believe in our use case document we...the term of art we use is privacy consent directive, so partly that was just, you know, me being lazy in presentation and not using the terminology that we adopted in our use case...our draft use case document, so I apologize for that. But also you have...

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Yeah, I understand and in our context it's okay, we know what you're talking about but for public consumption, when you're talking to healthcare professionals, doctors, nurses, social workers and the like, they think about consent as, you know, I'm going to let you operate on my leg. And to confuse them in thinking you're going to come up with ways of doing electronic consent is...you don't want to do that. So in documents for public consumption, especially when you're directing these HIPAA clarification communications at healthcare practitioners, you need to be clear about what this is.

Joyce Sensmeier, MS, RN-BC, CPHIMS, FHIMSS, FAAN – Vice President, Informatics – Healthcare Information Management Systems Society

This is Joyce Sensmeier; I have a question about SDOs whenever it's appropriate.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Go ahead, Joyce.

Joyce Sensmeier, MS, RN-BC, CPHIMS, FHIMSS, FAAN – Vice President, Informatics – Healthcare Information Management Systems Society

Okay, thank you. I noted that you mentioned and also on the slides it says you're going to be aligning your work efforts with standards development organizations and I wondered if you had preliminary thoughts about what one that might be and just do want to encourage this work to get planted at the end of the day in an SDO for maintenance purposes, etcetera.

Jeremy Maxwell, PhD – IT Security Specialist – Office of the National Coordinator for Health Information Technology

Yeah, that's the goal. And so we have a couple of candidate standards for consideration for this work, so the IHE basic patient privacy consent standard is one of them and then a couple of the HL7 standards. So, for example, you know someone mentioned FHIR, so, you know HL7 FHIR specification is one of our candidate standards for consideration, as well as the HL7 ID for CDA, the consent directive piece of that. So yes, we agree with that sentiment.

Joyce Sensmeier, MS, RN-BC, CPHIMS, FHIMSS, FAAN – Vice President, Informatics – Healthcare Information Management Systems Society

Thank you.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Although I would...this is David; I would point out that none of those standards have received anything approaching reasonable widespread use. So, you need to solve the problem of something that works and then figure out how to standardize it. Don't just assume those standards are going to work because they have not been used, certainly the FHIR one hasn't even been balloted really, but the...has not seen widespread use in computable ways.

Jeremy Maxwell, PhD – IT Security Specialist – Office of the National Coordinator for Health Information Technology

Agreed, that's why we're building significant time into our schedule for piloting.

Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

This is Dixie, could I just kind of comment on, I agree with what both Andy and David are saying about this we're really not talking about consent or computable consent but what we're really talking about is granular rules for sharing. And I would also notice that or note that as we move into the genomic era, these rules won't just be sharing with others, but in some cases patients choose not to share certain information, even with themselves. So it's really important that we use vocabulary that really applies to all of these kind of data flow rules or data sharing rules or, you know, and not just yes, no, send my data, you know. It needs to be much richer than that.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

It's...Dixie, this is Lucia. You know you guys are all sort of identifying our pain because at ONC we have such diverse audiences and the terminology, in fact, is quite overlapping and confusing and we do spend...we try really hard to be very clear about it, but different professions have different idiosyncratic terms that it's very hard to overcome sometimes, consent being one of them. It is true that a consent to treatment is different than a consent to share, but when you go out and look at what policies people have enacted relative to privacy permission, that's what they call it. So it's a little bit challenging.

Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Yeah, others are addressing the same topic so, hopefully it will come out in the end.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

It's really a data sharing agreement, I echo that as well.

Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Yes, exactly.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Michelle, we're out of time according to the agenda we need to go to Q&A or go to public comment, is that correct?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

I think we have a little bit more time for public comment if we need to, but we can certainly go to questions.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Great.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

I think we're there.

Steven Keating – Patient Advocate/Consumer – Doctoral Candidate, Mechanical Engineering, MIT Media Labs

I have one quick comment, if that's all right; Steven Keating here.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Go ahead, Steve.

Steven Keating – Patient Advocate/Consumer – Doctoral Candidate, Mechanical Engineering, MIT Media Labs

If you're talking about clarifying for HIPAA, which is great, I would also love to see if there could be some clarification for CLIA and the Common Rule. And there's just generally for the general public there's so much confusion around what is research data versus clinical, what can be shared, what can't be shared. For example, if there's your genome sequence that was done on a non-CLIA certified machine, can you still have access? Can you share that? There's just a lot of unclarity in the rest of those policies that would be great to clarify for the general public, I think.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And the notice of privacy practices as sort of a template like we did earlier, I think several years ago ONC did that, but specifically related to genomics and PMI would be very helpful.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

This is Lucia; so just a couple of comments about that. Obviously the Common Rule is still being developed and so how like what form it takes and how that is explained to stakeholders has yet to be done by my colleagues over in the Office of Human Research Protections, but you guys know that's on the docket.

And the other thing I'd say is I think that that is a key goal of the PMI process, I don't know if...is still on the line, but my understanding from working with them behind the scenes is that the intention of PMI for the way participants agree to participate is, in fact, highly hel...forms that don't require high levels of health literacy to understand them, in plain language. and in fact, in multiple languages so that we can reach our diverse American population.

So that's a different challenge that our work to develop a standard will conclude after the recruitment for PMI starts and so I do believe there will be unfortunately paper involved in the initial PMI

recruitment. But in terms of the content of that paper, there is a plan to address that issue of comprehensibility, plain language and cultural...reach to culturally diverse populations.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Great, thank you. I'll just comment that in my former organization, Kaiser Permanente, in the Southern California operating region alone there were 40 different primary languages among the membership.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Yes, you know I'm from Oakland, California which has, you know, 11% Hmong, which isn't even a written language.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Right. And then not to mention the people who speak Amharic and, you know, this is a major Ethiopian community; I'm from Oakland, too. There are lots of language issues.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

There's also trends in using graphic novels to communicate with people, so there are all kinds of opportunity there.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Good. So, I think we are at the time for public comment, yes.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Operator, can you please open the lines?

Public Comment

Lonnie Moore – Virtual Meetings Specialist – Altarum Institute

If you are listening via your computer speakers, you may dial 1-877-705-2976 and press *1 to be placed in the comment queue. If you are on the telephone and would like to make a public comment, please press *1 at this time. Thank you.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

It looks like we have no public comment. So thank you to all our presenters today and our next meeting will be on March 16 and good luck and safe travels to all of you going to HIMSS. Have a nice weekend.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Thank you, bye, bye.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thank you, bye, bye.

**Gil Alterovitz, PhD – Faculty, Center for Biomedical Informatics – Harvard Medical School;
SMART/FHIR Genomics Lead**

Thank you very much, take care.