



HIT Standards Committee

Precision Medicine Task Force

Final Transcript

April 21, 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. Good afternoon everyone, this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Standards Committee's 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. 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. Andy Wiesenthal? Andrey Ostrovsky? Betsy Humphries?

Betsy Humphreys, MLS – Deputy Director – National Library of Medicine

Here.

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

Hi, Betsy. 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

Hi, Christina. David McCallie? David is here. 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.

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

Hello.

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

Eric Rose?

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

Eric is 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, Center for 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

Hi, Gil.

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

Hi.

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

Jim Breeling? Jon White? Joyce Sensmeier?

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

Here.

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

Hi, Joyce. Ketan?

Ketan Paranjape, MBA – General Manager, Life Sciences and Analytics – Intel Corporation

Yes I'm here, good morning.

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

Good morning, or good afternoon.

Ketan Paranjape, MBA – General Manager, Life Sciences and Analytics – Intel Corporation

Good afternoon, sorry.

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

Matthew Might? Maya Uppaluru? 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. Stan Crosley? Steven Keating?

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

Hi, here, thanks.

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

Hi, Steven. Terry Rauch? And from ONC is...I don't believe Teresa's on but Mazen Yacoub is on.

Mazen Yacoub, MBA – Healthcare Management Consultant

Yes, here.

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

Hi, Mazen. Okay, with that I'll turn it to you, Leslie.

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

Michelle...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thanks Michelle.

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

...it's David, I'm back. Sorry I missed roll call.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Oh, great.

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

Thanks David.

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

Thank you.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So today what we are going to do is start to deliberate on some recommendations, and we have an opportunity to include some of the feedback received yesterday at the Standards and Policy Joint Committee, as well as some items that we have been discussing through these particular meetings. So, what we're going to discuss today is...well, let's go to the next slide; I think we all know our charge...and who we are. And I think we need to update that, Michelle, as well. And to the next slide, please.

So just a reminder of our role is to accelerate opportunities for collaboration and pilots, to adopt policies and standards, support privacy and security of the cohort and I'd say usability; and advance standards that support a participant-driven approach to patient data contribution. Next slide, please.

So again we are hopeful that we can support all the federal partners in the PMI effort, coordinate and make sure that everyone's moving in the same data direction. Identify opportunities for collaboration and standards for particular use cases that support interoperability. Next slide.

So we have two meetings left, this one and the next and as a result of this accelerated timeframe, today I've put forward some recommendations that we might consider for...that both could be additive, could come out, could be discussed. So there is no right or wrong answer today, just an opportunity to discuss some of the things that have come out of these meetings. And then we'll...whatever we don't finish today, we'll talk about the next meeting and then prepare final recommendations. Next slide, please.

So some of the things we asked the people that presented, what are the data sources available? The gaps, are there known gaps that have high value that we need to consider in PMI? What efforts could be accelerated? And are there areas for standards that could be recommended to promote scalable and repeatable development for PMI?

One comment that we heard yesterday was that this really is an opportunity for a learning health system model because the new cohort...the addition of the cohort and researchers really add new stakeholders to the equation. And how we get information from the EHR back to the EHR from the patient, to the patient and the researchers is really an opportunity to make this scalable. So as we look at this work, we should think about it as a pilot for both PMI and a learning health system. So we'll start...next slide, please.

So let's talk about some of the big macro level information. So what was new to this group was the idea that genomic data, because of the size and complexity, and the new stakeholders, it brings us new things to consider in the ecosystem. So data sources for care might come directly from research or laboratories that are conducting the actual studies.

The volume of the data changes our assumption about how it moves as well. The data can be sourced from the patient. Aggregate data can be held outside the EMR platforms and research platforms and in this case, NIH. And patient registries can be a new source of data. Are there other items that we should

consider in this first area, the size and complexity that we want to convey in our overview or in our recommendations? So this is the first opportunity for some discussion.

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

What do you mean by patient registries?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Uh, what was brought up yesterday at the Joint Committee is that patient, or disease-specific registries I guess is a better way to say it, can be a good source of information and oftentimes are housed outside the EHR, but may be an area for consideration in that first phase.

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

So I, I mean this is David, by the way; I didn't listen in on yesterday's meetings so I'm not sure what got discussed but I think one thing that might not be covered in this, and maybe it's what...it's part of what you mean by patient registries is advocacy-driven aggregations of patients in the quest of solving specific problems for addressing particular conditions. So, you know the Multiple Sclerosis Society, just to pick a random...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm.

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

...society could become an aggregator of patients and their data and their family members in the quest to address needs that aren't going to get sufficient counts, even if you have a million members in your cohort, because of the rarity of the conditions being investigated. So...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

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

...you know, disease or patient condition advocacy groups and maybe that's the wrong word but.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay, I agree with you though.

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

Well it would also include...this is Dixie, I agree with David's comment. It would also include like the PCORnet patient powered research networks.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm.

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

All of those patient, you know patient-focused advocacy groups, whether it's disease or condition or whatever, but they're patient-focused, I think.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

Betsy Humphreys, MLS – Deputy Director – National Library of Medicine

Leslie, this is Betsy. It almost seems to me that the items under the main bullet which says genomic data are broader than genomic data.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm.

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

Yeah.

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

Right.

Betsy Humphreys, MLS – Deputy Director – National Library of Medicine

You see what I mean, I...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yeah, it's both phenotypic and genomic. Okay.

Betsy Humphreys, MLS – Deputy Director – National Library of Medicine

Yeah, so I think that the issue is there are all these sources of data and if we, and I agree with two that David and Dixie were adding into this equation and then another one, which I think we did discuss on the last call is the, you know the pharmacy benefit databases.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

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

Leslie, this is David again, you could just call that data to address precision medicine, blah, blah, blah instead of genomics.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Good idea. That's a good idea.

Betsy Humphreys, MLS – Deputy Director – National Library of Medicine

Yeah. I agree.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And if you hear typing, that's me, so I'm not going to mute, sorry about that. So, any other comments here?

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

This is...oh, I'm sorry.

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

This is Mitra from FDA. This is actually; I like David's comment because that also includes the device registries that FDA is very interested in.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay. And then also perhaps what we need to do is talk about the sources bring complexity, and here are the items. The size brings complexity, the size and the volume of data brings complexity to us and some recommendations around that. So it seems like we've got too many ideas conflated here.

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

Yes.

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

Yes.

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

Um, this is Eric and I'm not sure this idea fits here, but it sort of popped in my mind as I looked at this list and I think that the...part of the uniqueness of genomic data is its persistence; it's uniquely valid...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mmm.

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

...over...it's validity over time is uniquely persistent and, so what that means is that making it available over time as programs and institutions and entities that are custodians of the data come and go...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm.

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

...is uniquely important, you know if, you know 10 years from now nobody's going to care what a particular person's sodium level was at 3 a.m. on a particular date, but they will care what their, you know, their full genome sequencing data is. So, I really think that it's critical that the PMI builds in this idea that if you sequence someone's genome, then you have an asset that comes with that a duty to somehow make sure that that...the availability persists so that someone doesn't have to ever have their genome sequenced again, unless somebody comes up with a better way to sequence the genome. But presumably that...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm, that's a great point because our whole electronic exchange is based upon episodic care right now, there's very little that persists. Even our chronic care management we hope that we have new and evolving information. So I think that's an important point right up front. Other ideas in this...yes go ahead Dixie.

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

I had another comment about, and Eric's comment kind of triggered this in my mind. I think we should be careful that we phrase all of this in terms of the availability of data and not imply where, you know,

where it's going to persist. Like the third bullet says, aggregate data held outside the EMR platform; truth is, most genomic data will be held some other place, but what...but the PMI program will have access to it.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

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

And I think it's important that we separate that because we, you know there are many data sources that we need not bring all the data into some central repository.

M

This...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay. And that was a great comment Dixie that was also echoed yesterday; the idea that this is not about getting...moving genomic data in its entirety from place to place, but providing access to it in a secure way and a usable way.

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

Mm-hmm.

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

Right. At the same time it's important, I think to have a standard interfa...you know API, you know like a FHIR API to access that data wherever it is.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yup. Okay, we...so I've got...captured those on mine, and I know staff is also working on those ideas. The second bullet gets to, and these are just not in any order of importance guys, this is just some ideas that we've gleaned here.

So data standards; we want this work to be interoperable by design, and in so doing we have some things to consider. It's...there's a very aggressive timeline and it...so it requires a use or a bias for existing standards. There are...we should consider acceleration of some standards initiatives and coordination of selected standards across all PMI initiatives. And this might also assume acceleration of patient-generated data work or standards. But also we should assume interoperable design is informed by the roadmap in any work that's done in not just NIH, but everywhere else so that we just simple have a bias for use of existing standards and want those to be coordinated. So does this make sense?

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

This is Joyce Sensmeier; one thing relating to the last section that brings...comes forward to this, I wasn't clear on the outcome of David's comment on patient registries and the clarification there.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm.

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

But if we're referencing clinical registries or disease-specific registries, there is a huge lack of interoperability between them and the EHRs. So that i...there are also implications for interoperability from that.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay. Mm-hmm. All right. So they might be a point of specific interoperable discussions.

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

Yes, agreed. And those should be occurring anyhow, but this'll perhaps accelerate them.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay. Any...

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

Leslie, we talked during the last call about how a lot of these research laboratories, not only the registries but PMI and PCORnet registries, they will not use common data models or data ne...or necessarily the same data vocabularies and value sets either. So I hope this bullet doesn't imply that they would.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

You know I think that's a good point. One of the things we've discussed was a need for a, is there a minimum data set for this cohort, specifically for this pilot that should be called out so that we could have as much participation on a narrow use case as possible in that very first phase.

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

A common data set for, like abstracted from EHRs or...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes, correct; a common data set extracted from EHRs, which might just be the one we already have and also is there a possibility for the patient-generated health data that's coming in for the participants who are us...themselves enrolling? Is there an opportunity to have a top 100 questions that are asked of the patient to be considered for this cohort? And could...

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

The Argonaut Project uses the common clinical data set, why wouldn't PMI use that as the...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Oh I agree with that, that's on the patient-generated data side, when we're getting information that isn't in the EHR, is there an opportunity to seek a top 100 or to seek out a common...with a common vocabulary for that, so we start out with computable information.

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

Mm-hmm.

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

This is David. I'm skeptical that the kinds of questions that are going to get asked by the narrow queries that will probably be relevant in, you know the precision medicine cohort could be rolled up into a top 100 questions. I mean, they're almost by design extremely precise questions. The easy, low-hanging fruit is you kind of wealth has been mined. People are going to want to know about very specific things like exposure histories during periods of life in particular settings and locations and such. So, it might be a nice goal, but I'll bet you that the long tail dominates on the questions that researchers are going to want to ask the patients.

Betsy Humphreys, MLS – Deputy Director – National Library of Medicine

Well...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Just because the nature of it.

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

Right, right. Go to, you know you can go to 23andMe and say, you know do you have a top 100 questions that you're research community wants to ask your members, and I'll bet you the answer is no, it's not, there's no such thing.

Betsy Humphreys, MLS – Deputy Director – National Library of Medicine

Umm...

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

I think if you would go to Genetic Alliance and ask them the same thing they would say yes, because they have, you know the PEER platform does have some very core questions and then each care community, you know comes up with their own and vets their own questions and adds those specific ones to it, but I don't know whether there's a hundred, I don't know how many there are, but there are some core questions that cut across all of the disease advocacy groups.

Betsy Humphreys, MLS – Deputy Director – National Library of Medicine

This is...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So where it is possible we would encourage that there would be alignment and coordination for this...for the questions asked of the patients, maybe it is a narrow phase initially, like the Care Alliance is talking about, and then we go from there.

Betsy Humphreys, MLS – Deputy Director – National Library of Medicine

Yeah, this is Betsy Humphreys; I...my understanding is that in terms of moving forward with the PMI, they will be asking sets of basic questions when they enroll people....

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm.

Betsy Humphreys, MLS – Deputy Director – National Library of Medicine

...and umm, the direct participants; and those questions and those...the data that they're asking for, they're basing that on what has been used already and found effective in, you know the Million Veterans Program, the UK Bioban...you know Program and things like Genetic Alliance and so forth. So they are going to be basing that around that. And I personally believe that if you are using, you know if people are downloading an App or using a web application or something, download something to provide patient-reported data, you know a set of it for the enrollees, then to my way of thinking there's no reason in the world not to standardize it...all these data under the hood.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm.

Betsy Humphreys, MLS – Deputy Director – National Library of Medicine

And it's quite doable.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Great.

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

But some...

Betsy Humphreys, MLS – Deputy Director – National Library of Medicine

I think that later on, I'm not disagreeing with David that when you go on beyond this point and you start dealing with identifying subsets of patients that are going to be included in specific studies, then you will get into a much more detailed, you know much more detailed situation. But part of it obviously is getting standard data so that you can even identify the subset of these people that might be useful for you to contact for your secondary study.

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

Yeah, this is David again; I mean I certainly don't dispute that we should standardize the stuff that is in common, but as is the case with clinicians and capture of phenotype, if you don't capture a precise phenotype, you're basically wasting your time and that'll be true of patient-generated data; if it isn't precise phenotypes, the power of the study will diminish drastically. So, we don't want to force a standard that eliminates the ability to go deep and narrow, including things that have never been assigned a SNOMED code...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

...because I'll bet you most of the questions never will ever be assigned a SNOMED code or an HPO code or anything else, but they'll be very relevant to the power of a particular study.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm.

Betsy Humphreys, MLS – Deputy Director – National Library of Medicine

Oh yes, it's usually the questions and answers are more likely to have been encoded in LOINC than SNOMED, because you're talking about...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

Yeah.

Betsy Humphreys, MLS – Deputy Director – National Library of Medicine

...but the, yeah, I'm not disagreeing with that, I do feel that in terms of, you know, I think we should look at all of this like we anticipate that the future will be longer than the past and the fact that it has not been standard operating procedure for clinical researchers to look at things from a standardization perspective in the past, doesn't mean that we can't get there in the future.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So would it be fair to say as an added bullet here, standardization, where possible, especially in the enrollment and pilot phase; examples include Care Alliance?

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

(Indiscernible)

Betsy Humphreys, MLS – Deputy Director – National Library of Medicine

Sounds good to me.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

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

Care Alliance, what's that?

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

Yeah, what's that?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Pardon me?

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

What is Care Alliance?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Oh, I'm sorry; I said the wrong name, Sharon Terry's group.

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

Oh, oh, Genomic Alliance.

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

Genetic.

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

Genetic Alliance.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes, thank you.

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

I guess I'm just...want to capture the notion that we, you know, we need an adaptable approach that allows for investigators to probe into things that haven't yet been standardized.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm.

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

If the only questions you can ask are ones that a LOINC code has been assigned to, you're probably not going to get early interest in research.

Betsy Humphreys, MLS – Deputy Director – National Library of Medicine

I cannot...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Or we'll get LOINC added to.

Betsy Humphreys, MLS – Deputy Director – National Library of Medicine

I cannot imagine, David that anyone thinks that we're going in that direction.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

Umm, well, that's what we're having this call...this conversation about, I just want to make sure that we don't pick a value set, I mean, you know look what we did with the problem list and requiring SNOMED codes; we eliminated a ton of useful information that had been captured in problem lists from the time...from the beginning that are not capturable in SNOMED and we had to wipe all that out.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm.

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

So, a very direct side effect of a regulatory approach that says, this must be coded this way created, I think, actual harm.

Betsy Humphreys, MLS – Deputy Director – National Library of Medicine

Well, of course the issue was what was in the problem list, the...and all of this. I don't, you know my feeling here is that I don't think anyone thinks that it will all be standardized, but I just have to say that I believe that in a lot of communities, if you don't mention that where standards are appropriate, we intend to use them, then people will take that as a license not to standardize anything.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yeah. I agree.

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

Yeah, I'm just anxious to a...I mean, we've seen the unintended consequences of overly precise value sets and I just want to make sure we don't make that mistake. I absolutely, standardize where possible and where feasible.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right, but on the, especially in this enrollment in this early phase from a patient point of view, I don't want to be asked the same question with a little bit of a nuance change for twenty different organizations. So, it's whatever we can do at that early phase I think is important. Let's move on to the next slide.

Another common theme is that there should be patient and provider education about the right uses for the data, both the pilot and beyond. And that in general, we've been working with as...that the pilot assumes patient access rights in line with all other PHI. This was another co...thing that was mentioned in the meeting yesterday and I think it's been mentioned over and over here about patients having access to that.

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

Which pilot are you referring to here? What's the pilot that you're talking about, is it the Sync4Science or is this the Precision Medicine?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Precision Medicine Initiative in general.

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

Okay, so that's more than a pilot, that's a 100 mil...200 million dollar long-running grant, right?

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

Pilot.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right. I'll change the wording.

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

The government can throw 200 million at a pilot, David.

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

Yeah.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Wait a minute; I thought it was 2 million.

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

I don't quite understand what that means, is it...access rights to what, to their...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

To data.

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

...what other PHI?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

To the genomic and I guess its back to David's phrase, right? Whatever is being stored in NIH about me, I have access rights to it.

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

What about the findings from the research? In some cases, patients don't even want access to, I mean...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

...and that's a big, controversial subject is return of results to patients. So I think we should be clear about that.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So in this case we were saying, anything I give you, I have access to; anything you test on me, I have access to.

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

Okay.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Did not assume the outcome of the research.

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

Yeah, I mean, is that our purview to weigh in on that? I mean, I'm happy that we...if we think we should, to express an opinion, but...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Well we're both policy and standards in this committee.

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

Yeah, there are policy, I mean because there's a large group of people working on this subject on behalf of the PMI...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm, right.

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

...have released a lot of work already and I'm sure will release more. And...

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

If we want to weigh in, I'd certainly...I have an opinion, I mean, do we want to? I like his question.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I think it has been mentioned in our group several times and it was brought forward yesterday in the Joint Standards and Policy Committee.

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

Okay.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So I think we're...it's appropriate to weigh in. Whether or not we have authority around that is a different question. There is work being done other places, but sometimes having these thoughts echoed in many places gives it a momentum of itself.

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

I...

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

And I would add including results, research results.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

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

And Steven Keating here just echoing that I totally agree with...on that and maybe even make the distinction between there's raw data and there's analysis results.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm.

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

And that patients always should have access to raw data, no matter what. And with the analysis results, there could be room for, you know requiring, you know genetic counselors or IRB...things like that, but I think we should separate the difference between raw data and analysis and there should be no limits on a patient's right to access raw data, if they want it.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

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

So this is David, you know I'm as big a patient advocate as they get, but just the caution that makes me a little nervous about that is, this data is ex...could be extremely harmful, so de-identification of the data is going to be a, or let's...it's not de-identification, it's anonymization is going to be important. But the degree to which you insist on reversibility of that so that an individual patient could find out what downstream things have happened to their data is the degree to which you increase the risk of re-identification, because you are essentially guaranteeing that the computer knows how to re-identify the data. So, it's not...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

One of the things yesterday...I'm sorry, go ahead.

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

No, I was just going to say it's not a free wish, there's consequences.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm. One of the things that came through yesterday was the idea that a patient should be notified when their data is harvested and why and how and by whom.

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

So again, that requires a ton of data tracking in data stores...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

...in databases that will make it much easier to re-identify the data...will increase the risk of unintended de-anonymization.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Correct, but if, I think back to Eric's point, this data persists forever and is viable forever, do we want...

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

At least the raw sequencing data...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm.

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

Yeah.

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

...both.

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

So maybe we might want to make that distinction between the data that's directly contributed by the patients versus secondarily derived data that may, in fact, be downstream and you want to be really thoroughly de-identified.

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

You know the...this is Dixie. The Regulatory and Ethics Workgroup of the Global Alliance for Genomics and Health is, you know coordinated among, you know 30 countries or something, an ethics framework that addresses all of these things.

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

Mm-hmm.

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

I think maybe we want to reference something like that, rather than try to flesh this out once again. You know, I would send you a link to that if you'd like, but...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

That would be great.

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

Okay, I will.

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

I like that idea. I like that idea a lot; this is such a complicated space.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

But I guess the caveat is, if that framework doesn't include the patient participation in the data, that's an area we would want to weigh in on.

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

Patient participation in the data?

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

If this group...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

It's beyond getting their own data, does it include the patient?

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

Yes it does, yes.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay. Great.

Ketan Paranjape, MBA – General Manager, Life Sciences and Analytics – Intel Corporation

Dixie, this Ketan Paranjape here, are you referring to the article they published in the Science Policy recently?

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

No, I'm talking about the GA4GH framework that's online and it's...

Ketan Paranjape, MBA – General Manager, Life Sciences and Analytics – Intel Corporation

Okay, because the...I'm part of the REWG working group and we did publish this article in the Science, so I'll send the link to the group as well.

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

Okay, that's probably a summary or something, I haven't seen it.

Ketan Paranjape, MBA – General Manager, Life Sciences and Analytics – Intel Corporation

Yeah, it's a summary, yes. Yes.

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

Okay, yes.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

That would be great. So the next section is giving the moving pieces and parts of...in an accelerated timeline. Here are some recommendations up for grabs; ONC should provide a detailed project overview and ongoing review to the Joint Committee PMI of all the initiatives, the data requirement gaps, progress and standards used. It's one...it's a massive project, but trying to get it aligned.

ONC should require a report from PMI Initiatives when existing standards...data standards are not used or modified; a bias for use. That might be too strong given the earlier conversation. The question is, in ONCs coordination role, what can they do to provide oversight such way that we know when standards are being used and we know where there's opportunities for gaps or acceleration in work, what should that role be? Because this project, it says in eight months we've got to do this.

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

Role for ONC, is that the question context?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm, yup, mm-hmm.

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

Well sort of the authority of ONC is, you know, given by the HITECH Act and with respect to standards involves setting standards for certified EHR technology.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm.

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

I don't know that it extends out into the research community or to the PMI, but...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Well, it's certified HIT so anything that's...falls under that broader use.

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

Yeah. Well, I just, I mean, that's a non-trivial role, that's a really important role that's focused on, you know the standards at the point of generation of much of the data that will drive, much of the phenotype data will come from data...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm.

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

...under the purview of ONC, so maybe that's what the focus should be, on ensuring that those standards are appropriate for support of the learning health system and downstream research consumption, such as the Precision Medicine Initiative.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

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

I'm just, you know ONC isn't going to weigh in on; you know the names of genomic alleles...

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

Yeah.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Correct, but I think the role is coordinating and making sure that we have, where possible, especially on the phenotypic data, the use of standards and the bias for interoperability. And how do you do that without an inventory.

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

This is Joyce Sensmeier; one thought I had is they already publish the Interoperability Standards Advisory and there are updates to that annually and public comment to that as well. I mean, that's not regulatory but its guidance and maybe there's a role for this within that framework.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Great idea.

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

This is Eric, I have sort of the same ideas, I didn't hear the name of the person who spoke last but, ONC's role extends beyond just its statutory authority to define certification requirements, it can, and you know issue useful advice and convene experts and so forth. And I think that one of the big challenges to the PMI investigators is to understand how best to use this sort of patchwork of data that they're going to be getting from lots of different sources. And in particular, understanding what kinds of data are more versus less reliable...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm.

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

...may be really helpful and like, you know we've been discussing in part lab data and, you know the fact that laboratory information systems as a source of laboratory data may be more reliable than EHRs because they're more heavily regulated, they have to store more metadata and that information, you know may be useful to people who are going to be using the data collected by the PMI. So I think that that sort of helping inform the landscape of data sources and how to best use them is a legitimate role for ONC.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So would that translate as, consider validity of data sources as new opportunities for...give me an action item. What do you think specifically they should do?

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

Well, so I would say it's really producing reports, probably utilizing outside experts on how best to utilize data sources for the PMI. So it's...so validity is part of that, identifying overlap may be part of that so that, you know, you don't accidentally count the same thing twice.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm.

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

There are lots of dimensions to that, but basically how to make...how to best make use of the data that will be the data inputs.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm. Any other comments under that bullet?

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

This is David; I'll just be my generic skeptic here. The ISA is an interesting document, but it's all over the place, it's neither fish nor fowl; it's got standards in there that are very important and standards in there that have never and will never be used. I just think that the power to define the certification criteria is where ONC can make a difference.

Umm, and I'm not advocating that they regulate more necessarily, but that's where the power is and if there is to be, for example, some set of standard about patient-generated data that every EHR should capture through their portal enrollment process or something like that, ONC is the place where you could actually enforce that. And that's a consideration for the increasingly complicated phenotypes that we're going to want to deal with downstream, is, we probably will need some more standardization.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

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

I don't see that the ISA is going to give, you know the coordinating center of the PMI is probably not going to spend a whole lot of time reading the ISA, I don't...I doubt seriously.

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

Well this is Joyce again...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

...the agencies that presented to us, each of them referenced standards for interoperability.

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

Yeah, yeah the standards are there, I mean ISA is the document that describes those standards partially. The people that need to use those standards go deep into the direct, you know to the owners of the standards or to the profilers...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm.

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

...and work in those...we...I don't want to get sidetracked by the ISA, I'm on that task force too, so it's on my mind to try to figure out, you know, how to make the ISA more valuable and so we're going to...we'll work on that and hopefully make it more valuable. But meanwhile, the regulatory authority that ONC has where they can really make a change is in the standards that are in health IT.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm.

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

And they should keep that in mind as the needs of the PMI become more manifest.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay. Other comments? I interrupted someone.

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

This is...

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

Yeah, this...

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

Go ahead Dixie, this is Joyce.

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

I was just going to say that I think that, I know from experience, you know the research community does not seem to be automatically compelled or even interested in aligning the standards that they use with those that are in place for EHRs, for certified EHRs. And I think that there is a real role for ONC, but not a regulatory, not requiring anything like the second bullet implies, but if ONC can just work with PMI to identify opportunities to better align the vocabularies and the standards between PMI and EHRs, I think that would be...I think it would be a good thing for both sides. You know, I don't think it should be either one...either PMIs or ONCs sole obligation to make sure those standards are aligned, but if ONC can just review the PMI standards, make recommendations and that kind of thing would be worthwhile.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

Betsy Humphreys, MLS – Deputy Director – National Library of Medicine

I agree with that.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Joyce, did you have something?

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

Yeah, I would echo what Dixie just said, but my point is really non-regulatory. I think we have opportunities beyond that; not that that's not a part of this or couldn't be a part of this, but things like the ISA or other guidance, and Dixie's point was a great one in working together to come up with those recommendations. You know, if the industry is weighing in on that, I mean we are capturing the energy of those that take the time to comment, I think that's an important focus here. Also I think that giving that more credence in the industry will add value; so, I just wanted to share that. Thank you.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay. So perhaps even some sort of amendment to the ISA that includes the phenotypic data recommendations could be helpful.

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

Agreed.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

But non-regulatory. Okay.

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

Yes.

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

And also just to add one comment there, too...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

One...the...yes.

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

...Steven Keating here; I think it would also just be great for the ONC to allow the general public and other people who want to get involved in the PMI or using data, say a person wants to make an App that can connect their personal health data. Just an easy way that the general public can trust would be if the ONC could put out some very simple recommendations of where to look.

Because I get asked all the time from different companies and startups and providers, how can we get involved in this, you know what are the routes to go. And I think people trust the ONC enough so that it could be a really nice resource where people can read things without having to go through the ISA and all the complex legal...so they can read and have links in an easy to understand format.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay, so ONC should publish better understandable or should publish documents and volunteerism efforts?

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

Yeah, just basically a guideline, a map of you know, what's the current status, you know for a brand new say Twitter or someone wants to make an App that can integrate, you know, people sending in Tweets about, you know how many their Fitbit results or something. Where do they go to look for what standards to write in the code?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

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

Very simple things like that.

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

And...

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

Mm-hmm.

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

I'm just...this is David; I just have to register that the ISA does not have sufficient information to make that decision.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

It doesn't...it's just not useful for that. If somebody from Twitter wants to figure out how to do that, they need to talk to people that deeply understand this field. And if ISA can somehow link them to that, maybe there's value there, but it's not enough information there to make those kinds of decisions. It's like a laundry list of standards with a lightweight scoring about whether they're used. It doesn't even have links to where the standards are in use.

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

If I could chime in here.

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

We're going to try to fix that, I mean we're going to make it better, I think but don't count on it for more than it is.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Might need to be done outside of the ISA.

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

Yeah, I mean, you know in the Precision Medicine Initiative itself, if someone wants to know how to get involved in that, that's obviously an NIH responsibility, it's their project.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm.

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

The particular subset of it relative to standards for data flowing from regulated health IT is ONC's purview.

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

If I could chime in here, Andrey Ostrovsky here, sorry guys, I joined the conversation late. I'm not sure if anyone mentioned this in the first half hour, ONCs Tech Lab. This is an initiative to try to curate the multitude of innovative things happening within ONC and outside of ONC. This could be an interesting place where this discussion and its themes could manifest as how to operationalize ways to take emerging standards or even discussions around standards and put them in a place where folks from within ONC, outside of ONC, academia, industry can come together, learn about whatever is most up-to-date and potentially find collaborators in the context of challenge grants, initiatives, priorities, etcetera, etcetera.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm.

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

So the Tech Lab, I think it was designed in part to address exactly this...some of these points.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay, I'll include that in the notes. And then is there any other comment under this bullet, because we'll move to the next?

So the next one is basically a placeholder, and the question we're trying to ask is, what is...what would recommendations be around timing or process or considerations for quality measurement? What...and this is all worded wrong, so don't worry about it. The issue is, this is a still very new process; we won't...we don't know what we don't know, and so it would be difficult to place quality measures against this today and so what recommendations, if any, do we want to have about the formation of quality measures against the initiative?

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

When you say quality measures, are you talking about data quality, data integrity or are you talking about quality of care? What is the quality measure, what context?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Well I'm talking about quality of care that...and the concern that was raised is, often times there's downstream consequences of quality measurement that will force a particular activity that's proven to be irrelevant later. And the Precision Medicine Initiative is still ve...so new, how do we or do we even comment on when the appropriateness of starting to consider that; is the data there? Are there processes in place that would allow for that kind of query? Is it something we want to stay silent on or something that we'd like to emphasize that it's still a premature opportunity? We don't know what we don't know.

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

Are you thinking of genomic testing and quality measures that might drive people towards genomic testing or away from genomic testing and measuring the quality associated with that?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

No, I'm thinking more of the HIT systems; so maybe it's something like of patients with this particular type of disease, genomic testing has taken place and is available in the EHR. That would be very premature to do something like that.

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

Yeah and I don't think that PMI as a research initiative has any immediate connection to that.

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

I agree I'd delete that whole bullet.

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

Yeah.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay, that's easy. All right, how are we doing for time, guys? Okay, let's go to the next slide. Okay, so we've got...this is just to revisit the pathway we have of recommendation; in that first space, it is really about EHR data and also data coming from the original or the participant themselves as a first phase. And we talked about; well let's go to the next slide.

So here's some of the detail under that and we asked consideration to be given on things like the Data Access Framework, PCORI, Sentinel, NCI. And then also we suggested, or discussed at one point in time, that the individual data use consistent FHIR-based API like for Sync4Science and Argonaut for data

donation so that when the data is coming into the NIH, we have an opportunity, whether it's coming from the individual themselves or from the electronic health record to have some query-based exchange. And although we thought that new resources may not be needed immediately, there could be the opportunity for acceleration.

And so that...there's a mention of FHIR here, is there any other comments we want to make in the detail here?

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

This is Mitra from FDA. We had...we discussed this I think two weeks ago so the, I had a few comments.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

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

One is to add i2b2 as a common data model, I mean just...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

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

And then the other thing is, so OHDSI used to be called OMOP so the Veterans Administration mapping to OMOP is the same one as OHDSI, so, just change it to, Veterans Administration mapping to OHDSI common data model.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

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

I don't think that we should take a position about that, that's a controversial thing between Mini-Sentinel and OMOP and I don't think that we should take a position.

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

No, no, OMOPs new name is ODHESI.

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

I know, ODHESI, yes, but there is a debate between whether we use the Mini-Sentinel, which is what PCORnet uses and is gaining momentum versus OMOP/ODHESI. I don't think that we should take a stand on which data model they use.

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

Ah yeah, no, I mean just fix the Veteran Administration; the OMOP is an old name.

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

I know I know that's what you're saying.

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

I've been on both advisory boards of Sentinel and OMOP, I think for the last seven years and I know the issue between the two.

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

Uh huh.

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

But the new name, they changed their name last year to ODHESI instead of OMOP and we have Sentinel out there too in the second bullet.

Betsy Humphreys, MLS – Deputy Director – National Library of Medicine

Yeah, and we're not taking a position.

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

No, we're not taking a position.

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

Oh I see I misunderstood what you were saying. Oh I'm...

Betsy Humphreys, MLS – Deputy Director – National Library of Medicine

We're not taking a position on the slide.

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

So they have multiple data partners, like they have Department of...

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

I see, I see, I misunderstood what you were saying. Okay. I'm sorry, yes. So sorry, yeah.

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

The Veteran Administration has...they last. And the other thing, NCI which, are you referring to caDSR? What data model of NCI?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I believe that was it. Mazen, do you remember? We were...

Mazen Yacoub, MBA – Healthcare Management Consultant

No, I'm sorry, I don't off hand. I could go back and take a look at the NCI material that we looked at earlier in the process.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

Betsy Humphreys, MLS – Deputy Director – National Library of Medicine

Leslie, on the previous slide, I assume we're not going back to it...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yeah, let's go back.

Betsy Humphreys, MLS – Deputy Director – National Library of Medicine

I thought we had a comment which I agreed with, which...where you know this notion of acting as if we were not going to start worrying about our working on the return of the individual patient's data to them, a participant's data to them until 2017. I recall one of our colleagues on the call saying that he didn't think that was a very good idea, and I certainly agreed with him.

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

Yes.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay. So we are going to change the...

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

That's me.

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

Eric I think, right?

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

What was the bad idea, I missed last week's call; the date or the notion?

Betsy Humphreys, MLS – Deputy Director – National Library of Medicine

Well essentially what we have here is that it's like a long-term thing that we start thinking about returning patient data to the participants.

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

Uh huh.

Betsy Humphreys, MLS – Deputy Director – National Library of Medicine

And I said that people have felt that even in the early stages, you could show the participant on the basic information they've provided, how they relate to the rest of the people that have signed up on the cohort or you could potentially do something. And you certainly shouldn't act as if we only start worrying about it in 2017.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

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

Yeah, so your concern is with the date, not with the concept; that's my question. I get you and I agree, I agree, that should be in parallel.

Betsy Humphreys, MLS – Deputy Director – National Library of Medicine

Yeah, so it's like this is...it seems to me, I wouldn't say it immediate, mid-term long-term, I mean I think this last one is just kind of a concern throughout the whole project. Obviously over time you can do more with it because you'll have more data, but...

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

How about just say in parallel? In other words...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

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

...aligned with all of the above, whatever is happening, keep this in mind, to the degree that you can make it happen.

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

Yeah exactly, Steven Keating here; I was the fellow who made that comment last time and I completely agree with you, just moving that date; instead of saying it's sort of in line, it should be in parallel with number one and starting right from the beginning as both an incentive for people to participate and also for people to feel safe that their playing a role in the process.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay. Let's go to the next slide; I think we can maybe...next slide. Okay, so here are some things, the common core data set is a minimum bar, that we have talked about, coming from the EHR, that also was not going to have a lot of information from the patient, obviously, or even non-episodic information, but a lot. Then we talked about the query-based approach and is this capturing some of the ideas; that we recommend that their design is with reciprocal query in place from the EMR for patient-specific aggregate requests and findings. So that it isn't just the NIH receiving that information, but by design up front, it also allows for query-based exchange from the EMR.

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

You mean from the EMR to query in to NIH?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes. Right.

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

What would they be querying? What was the thought here?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So the patients, the aggregate results for a specific patient; they might not have what is retrieved in the NIH. So it could be multiple provider sourced information, it could be the patient-generated health data that's there. Do we want to have any idea of reciprocity, which just gets back to the patient earlier that was being discussed, that the EMR right up front should also have access to patient aggregate information, or any information?

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

So the EMR...the PMI is serving as an HIE for those patients who enroll.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm. Correct.

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

Now that's a radical idea.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yeah, I thought...

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

Well it could be, it could be, as she just mentioned, aggregate, too; like Genetic Alliance's PEER system provides back to patients, you know, here's how you compare with other people who are similar to you. I mean it is an engagement technique that, you know might be very powerful.

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

Yeah, I'm...I mean; I think it's kind of a cool idea that ought to be thought about a little bit. I mean, it concerns me on the surface that the research world is not structured to be CLIA compliant or even HIPAA compliant and for physicians to implicitly trust it the way they would trust an HIE or some other service that's maybe querying into other EHRs like CommonWell or Care Everywhere or something like that. There's a big difference to put that burden of responsibility on the PMI, so...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

But if we want to model this for a learning system of the future, it's got to be a trusted source of information.

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

Well, but the learning system does, that's a loop that goes through a whole lot of learned operator curation, sifting, you know, data filtering, outlier exclusion; you don't just look at raw data.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm.

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

I think we should, you know, not dismiss the idea that the PMI provide some sort of feedback to individuals, because I think that's in the plan.

M

Yes.

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

But I agree with David that it shouldn't be seen as a source of their EHR data once it's there. And while I have the floor, it's not the common core; it's the common clinical data set.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Oh thank you Dixie, of course it is.

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

Good pick-up. Yeah, I kind of like Dixie's structuring there is that I think we may be going a little far to suggest that it's the EMR placing these queries, but that in fact, you know, returning data to the patient is a consistent theme that we've made.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

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

Maybe, you know, it's an interesting thought to say that that should be done in a standards based way so that a variety of consumer applications could take advantage of it with the patient's permission; that raises a whole host of identity management issues and such, to avoid people, you know, masquerading as somebody else to go sniff the genomic data of Brad Pitt or whoever you're interested in.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right. So that back to the...

M

Yeah, I think that's the point we added last week, yeah.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yeah, well back to this idea of reciprocity. If an EHR is enrolling a patient into the cohort, sending information back or do they, is there an idea of reciprocity where the EMR can query the cohort of information regarding that specific patient?

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

I think we were suggesting that not the EMR but that the patient.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay, so the patient acts as the intermediary for that?

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

Yeah. In other words, don't encumber it with the responsibilities of CLIA and HIPAA and all of the other things that are attendant on being, you know a trusted clinical repository for patient care.

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

Yes.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay. So you want me to strike that?

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

Well, suggest that, you know FHIR-based queries you could say designed with reciprocal query in place to support patient access to their aggregated results.

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

Yes.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay. I have...

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

And change the...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I have that early...later down, so I will change that, I'll strike it...

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

Maybe put an arrow back to the individual.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

M

So basically...

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

And in that sense, I totally agree that patients should have access to it, but the patient should also be able to, you know, say that they're willing to, you know connect it to an App that they trust. So there should be APIs in place that are under patient control to allow export of their data to third party sources. Under patient control so you don't have to worry about HIPAA and all that stuff. Just like, you know if you do your 23andMe you can download the raw data, and the patient can do that.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm.

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

And then they can do whatever they want with it.

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

Yeah, that's doable, I mean you know FHIR doesn't make a comment about that one way or the other, that's whatever authorization or authentication service you wrap around it and so far, OAuth 2, the one that most of us are using, would certainly support what you just described.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

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

Well once it gets back to the App, the patient can do whatever they want to with it.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

M

Right, the key is that you have to share it in that FHIR format, so everything is common, you can write one App one time, you know.

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

Yeah, I see what you're saying, yeah.

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

That's right. The key is just making the barrier super low for patients so that if they want to do it, it's not a big hurdle. Like right now, it's a huge hurdle to try to download and understand and send data out. It needs to be simple for the patient to make that choice.

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

Yeah, no, I think that's good. I don't recall seeing anything about that in the common...in the coordinating center RFP so; it'll be interesting to see how NIH reacts to that.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

The other item was do we want to suggest that when enrollment takes place, there's something that passes back to the EMR that says, hey there is a National Institutes of Health ID for that patient and a record locator service or something that says there's something there now that can be retrieved at a future date. Do we want to be explicit at all? Because it seems to me that you also have a new opportunity were you've got another patient ID being generated at the NIH, you have a record locator need.

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

I don't know that it's as much a record locator thought as it is the ID...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm.

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

...you know, we would...in our system we'd call it an external alias, just basically says, this patient is also known as, you know NIH number XYZ.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

Which would frankly be quite helpful in future submissions, although again it does increase the risk of exposure, right? Every time you...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right, but isn't the risk of not getting information to the provider greater?

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

Umm, well we...I don't, again not totally clear how that information's going to get back to the provider and what information...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm.

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

...that is, does it go through the consumer? If its consumer donated data, does it go directly to the provider? I'm not sure that it does.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

No, it goes directly to the cohort if its consumer provided information. The EMR won't have any place to store it; it's not necessarily relevant. But this concept says hey, if we've enrolled the patient, we now know they're enrolled and here's their ID. And at least we know, at a future date, that we can consider this source of information.

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

I think it warrants discussion and thought, I think it's pretty tricky, but I like the idea of at least saying it needs exploration and specification.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

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

I mean, I don't know enough about what the current thinking is on return of results from the PMI, you know, to whom under what triggers; we'd want to accommodate whatever the thinking is. And it would probably involve something about shared identifiers.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm.

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

Sharing identifiers.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So we want to accommodate results reporting and future use cases.

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

Well return of results.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm.

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

It depends really on, I mean, if the EHR provides de-identified or anonymized, pseudoanonymized data to PMI, they...the EHR provider would then hold the link to be...to re-identify the data. So, if they happen

to...if research happens to come up with a discovery that could benefit the patient, there should be a way for the EHR to get that result such that they can then look up the patient and apply whatever the new knowledge is.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm.

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

But the whole idea of the EHR just querying the PMI seems really foreign to me, but the idea that it's possible that the PMI might return a result that could be useful to the patient, I think is in the, I mean I think that's in the vision.

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

Yeah.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

But Dixie, back to your original thought, they're going to do both anonymized, but also patient-specific data; the...of an individual patient, they're enrolling that patient for the...

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

Yeah, the individual enrolls themselves.

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

Right.

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

But in addition, they're already...they already have pseudoanonymized data that's got a wider scope...the linkage.

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

At least in the Sync...the current Sync4Science pilots I don't believe there's a way for the data collector, the one that's exercising the EHRs APIs to suck the data out, I don't believe there's a way to push anything back to generate, you know a link in the other direction. And maybe that's something that could be considered.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Isn't there a registration function, a technical registration function between, well, I guess that would...

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

Well that's being debated. At the App level there may well be, but not at the individual patient level. The patient will register into a...something outside the EHR entirely.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm.

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

Get consent and then...

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

Right, well what about what they already have, you know the databases that they already have imported, they do retain linkages back to the patients. I agree with you with respect to patient, direct patient enrollment.

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

Yeah.

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

But if they're...through their provider...

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

No, I mean I think it's an interesting concept of what's the...the interesting question is, what's the role of the physician, of any physician, in this process with respect to the patient and the PMI researchers?

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

Yeah.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I think that from a patient point of view, it's my trusted intermediary. It's my trusted advocate and if they're completely in the dark, or not able to participate in the future, I think that's unrealistic.

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

But you think...but I agree with you, the patient should have the ability to say, I want to share with my trusted advisor named so and so and so and so, but does it automatically go to them just because they had a hand in capturing the data in the first place? I'm not sure...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Well any other order for care would include that.

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

If the patient chooses; you don't get care unless you go seek it.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right, but when the doctor sends it to the lab or the doctor sends out an order for any other thing, that information comes...it's assumed that the provider is included in those cases...

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

Right.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

...as the primary recipient but in this case it's...

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

And that's all, that's all regulated under, you know the rules of direct treatment.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

This is a consumer-genera...a consumer-driven decision to donate data to research. I'm not sure there's some automatic assumption that their providers are notified about that.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Well when the provider is the one doing the enrollment on behalf of the patient...

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

The upper arrow...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

Well, they made that clear that in one of our calls a couple of weeks ago that the patient is always going to have to consent, including re-consent.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

So I don't think there's any data flows where the patient isn't in the loop at least that was the point made to me, because I raised some of these concerns way back then.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

And they said there would always be a patient consent, even if it involves re-consenting for already existing data.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So the question is what degree does the EHR and the doctor, who has...

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

Yeah, automatically gets...yeah.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

...and knows the patient, automatically get notification. And I believe a patient at the ID from NIH, is something that lets the provider know that this information is available or this patient is participating, that will be out of sight, out of mind.

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

Well I think there's...so there's the technical question of how do you establish the identity linkage.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm.

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

But the thing I think we've been discussing is more, you know, is it automatic the sharing or is it something that goes through the consumer?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm.

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

I don't think...the identity linkage is already in HIPAA, that's already in there that the provider can retain the linkage and so that the patient can be re-identified at a later time. So that's already there. And I don't think we're trying to figure out the mechanisms, I think we're just trying to figure out whether that's a possibility...possibilities, and I think it should be.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yeah, I do, too. So I'll put on here, results and I'll do, yeah, I'll try to come up with some language that is a little bit squishier than what it has now, but it's talking specifically about some notification and identity should be provided back to the EHR at the point of enrollment.

M

(Indiscernible)

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

...David's point it should be, you know with the permission of the individual.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

It shouldn't be an automatic thing, but it should be...

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

So that's the distinction, is it automatic or is it with...through the individual; and I don't think we've resolved that yet.

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

I don't think it's automatic.

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

But I think Leslie's saying it is automatic.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Well the patie...he's enrolling the person on behalf of the patient, so...or...

M

No, who's he?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

The doctor, the provider is doing the enrollment on behalf of the patient, the patient's not doing it directly, they're going through the health provider organization's EHR. But I'm fine with saying the ID and information goes back to the EMR with a patient consent, I think that's fine.

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

Can I ask a quick question, its Andrey here.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm.

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

The notion of a provider being thought of as a physician, I just want to bring to our attention with this increasing emphasis on community-based interoperable exchange of information, you know with the Medicaid 90/10 rule, all that stuff; there will be more and more opportunities where the care team members that are inputting data or getting conse...more importantly, helping to get consent from a consumer, not just a patient but from a consumer, they're not going to be doctors or PAs or NPs or nurses. So I don't think it's anything we have to act on right now, but something that we should really keep in mind because it has practical implications around standards and now that we will have the infrastructure and piping for interoperability to extend beyond just the traditional medical setting.

And one other point, or maybe it's truly more of a question, this whole notion of who is giving consent; have we discussed or could we at some point put it in a parking to discuss consumers that have limited cognitive capacity and their wish to participate in an informed way, in these efforts, in the Precision Medicine Initiative related efforts and are we thinking...have we given enough thought to those considerations? I know that opens up a whole, very important can of worms and maybe not something within the scope of our conversation now, but something we should really consider from an equity perspective and has a lot of practical implications, I think for how we design sharing of data.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Well one thing that could be considered, and I think we discussed it earlier was the, I don't know if I'm pronouncing it right, the WCAG AA standard that is used for accessibility. Today under VDT this standard is a single "A" but that doesn't get to more of the design principles for people who have some impairment, which the double "A" does; and I'm not an expert at this, I was just told that...

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

Got it.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

...I think that's something we should consider, especially for the individual patient enrollment. NIH should be following accessibility standards to have the highest level of enrollment opportunities, and for

people who are very interested and engaged and want to participate. So we need to probably note that somewhere in accessibility.

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

Thank you, thank you so much.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm...umm, let me put that in here. So the next bullet talks about the...we've already mentioned this several times, the patient is really going to act as an exchange mechanism because the data sources not in the EHR will come from the patients themselves. And this item on the...the last item, the enrollment process; could that follow the VDT recommendations from the API Task Force or do, or perhaps not, do we want to suggest that when a health provider organization offers enrollment to a patient, they can do so using the existing mechanisms.

Like go to the patient portal, sign up, here's your user ID and password, you've identified the patient's identity at the actual encounter. The patient goes onto the portal and now they can also en...self-enroll. Or do we suggest that the enrollment process from the patient themselves is something uniquely and distinctly apart from the HPO or is it both/and? So this gets to process and it also gets to identity management. Are we going to suggest that LOA 2 is enough, because that's today what is...goes on at the currently level on VDT? Do we want to stay silent on this? Do we want to recommend that this inbound information coming from the patient specifically into the cohort that we recommend an LOA 3 process?

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

Well the current Sync4Science pilot, which is you know a pilot on purpose to try to figure stuff out, is based on the assumption that the patient's control of their portal account is adequate.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

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

So whatever mechanism was used to establish that the patient has access to their own portal account is what will be leveraged to provide access to the patient-controlled donation. I don't believe they're making a comment that you should go back and revisit your decision about granting portal access, you know...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm.

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

...it is what it is and it's usually based on personal recognizance and the like.

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

It's...we discussed, I remember in the Tiger Team once, that the, you know a portal account access, they do know the individual so it's more like LOA 3. So the only question here is whether we make a recommendation regarding if an individual just of their own volition appears at the door of the PMI and says, I want to sign up. Is that what you're asking?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yup, I'm asking for kind of both. I agree that in the...going through the health provider organization and using the patient portal that should be enough. The question is, if the enrollment process is coming from a patient to NHI...NIH, do we require or suggest a higher level of identity management?

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

Than just nothing? You know, I think we need a higher level, I think that would be the same level is, you know, I think LOA 3 is what you're talking is...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

It is.

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

...like...world.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yup.

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

But that...so you're talking about the getting started, the patient who just says, hey I heard that I can donate my data.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

And I go Google it and I get...I land on a website and they say, you can donate your data, sign up. You're saying, what, should we comment on that and what level of a certainty that should be? The initial...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes.

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

I don't know why we need to comment on it, number one; but we could. Umm

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Do we...

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

...be getting into a Pandora's Box because then we also would need to, I think, comment on if a representative, you know enrolls them. You know, people could be enrolled by their personal representative and how do you prove that you're their representative and the law changes from state to state and, I think that's a Pandora's Box.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So we don't want to make any recommendations with regard to identity proofing for an individual providing information to the cohort?

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

Well it's, I think the question is recommendations on identity proofing for individuals who want to enroll in the...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm.

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

...program to donate data to the Precision Medicine Initiative; I think a footnote is, they can't get at their EHR data unless they go through the vetting process that's in place for portals. So that's one safeguard that's in place just, you know, kind of if you faked out the master site and pretended to be somebody else, you couldn't get the portal login, hopefully, to get phenotype data out of the EHR, so we could describe that. I mean, you know they just let a big grant to Vanderbilt and a whole bunch of other collaborators to go study and investigate and put together the portal enrollment site; I'm sure they're having extensive discussions on this.

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

Mm-hmm.

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

I don't know that we have a lot to add beyond what they will already be working through.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Just that we hope somebody is working on it.

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

Yeah, I mean attention, you know...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I agree that if it's through the portal I'm...if it's through the portal, that's good enough. And it might be that we suggest that the...whatever App the NIH uses, it's going against the API eMAR API under the patient's control just as we're talking about any other App and it has the right to contribute data from themselves and the EHR if they followed the normal process of going through the patient portal.

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

Well but I think there's two steps; there's an enrollment step that's completely outside of any EHRs purview.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm.

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

That enrollment App will be hosted by some NIH-funded entity. Once enrolled, the patient can then point the enrollment App at their portal, at which point they have to also authenticate into the portal.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

So the question is, the initial enrollment, or as I understand it, the question is at that initial enrollment, do we want to make a comment about level of assurance of identity of the patient who...of the consumer who claims to be enrolling. And I think that's a hugely important question, but I'm not sure it's our purview is, I guess, my opinion.

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

...I mean once we make a comment about identity proofing, then do we go ahead and make the comment about the strength of the authentication that needs to be used?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm.

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

There...I would be supportive of making some statement about, you know that there should be assurance of, you know strong security authentication and identity proofing for any individual who's coming through, you know, outside a health organization, but I wouldn't pick out just identity proofing or one particular piece of it.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay. So I think that's a...I think that that is a good way to go, but we should not be silent on that direct enrollment process because the implications are this will be used for care and research and at some point in time, we need to connect these dots with a high degree of trust. And it gets back to, does the ID get shared from NIH? Does direct enrollment, is it strong enough assurance and identity proofing that the data can be a trusted source? I think those are big questions and we should have some comment on it.

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

But I think one thing we can weigh in on, if we want, is to say that we are comfortable with the existing identity management of patient portals...

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

Yeah.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm.

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

...or access to their health record through their provider's portals.

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

Yeah, that's...

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

I mean, we can say we think that's an adequate approach. I mean, they already have...it already is being used every day.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right, being done.

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

So...

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

You said there's an App that they're developing for patient enrollment?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I said if, I believe they are.

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

Yeah...Apps...

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

I mean, if they were doing that I would be willing to say that that App needs to be a confidential App and not a public App. I mean, you have to be able to trust the App as much as you do the individual identity of the patients.

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

There's a lot of debate in the Sync4Science group about that, but I won't go into it here. You can imagine the debate.

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

Yeah, I...yeah, yeah.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay. So it's like the perso...the direct...NIH direct enrollment should include strong assurance and identity proofing, ahh, the existing current patient portal models are adequate and we encourage, um...

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

Analogous to the pa...the existing patient portal model.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm. Okay.

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

Or equivalent to or something to, I was trying to say equivalent to...assurance equivalent to the existing patient portal model.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay. And then...okay. Okay, I'm looking at the clock and I think we have to get public comment and that's a good place to stop. We've got a lot to change and edit, and what we will attempt to do before our next meeting is go back, make these edits on the slides, send them out to you ahead of time so you can make sure you've got comments back and then we'll go on to any more items that we need to

discuss and consider that are found also inside these slides that you've got today and we'll work on that until then. So, Michelle, you want to open up for public comment?

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

Lonnie, you want to open the lines?

Public Comment

Lonnie Moore – Virtual Meetings Specialist – Altarum Institute

Yes. If you're 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. And I want to thank Leslie, she did a great job presenting to the Committee the other day and thank you Leslie for corralling everybody and getting us all together and consolidating all these comments; we really appreciate it.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

No problem.

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

Yeah, we're a restive bunch.

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

Yeah.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

David, that's why we love you.

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

Yeah, you'll learn one of these days.

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

We keep asking you so we must love you, David. All right, thank you everyone, have a good afternoon.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thanks guys.

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

Thank you, bye, bye.

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

Thanks Leslie, bye.

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

Thanks, good bye.