



**HIT Standards Committee  
Precision Medicine Task Force  
Final Transcript  
August 31, 2015**

**Presentation**

**Operator**

All lines bridged with the public.

**Michelle Consolazio, MPH – FACA Lead/Policy Analyst – 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 Jon White?

**P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

Here.

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

Hi, Jon. 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**

Hi, Leslie. Andy Wiesenthal? Andrey Ostrovsky?

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

Here.

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

Hi, Andrey. Betsy Humphreys?

**Betsy L. 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 McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Here.

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

Hi, David. Eric Rose?

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

Here.

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

Hi, Eric. James Breeling?

**James Breeling, MD – Director, Bioinformatics, Office of Research & Development – Veterans Health Administration**

Here.

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

Hi, James. Lisa Gallagher?

**Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society**

Here.

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

Hi, Lisa. Josh Denny? Mary Barton? Mitra Rocca?

**Mitra Rocca, PhD – Medical Informatician – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences – 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.

**Mitra Rocca, PhD – Medical Informatician – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences – Food & Drug Administration**

Hi, Michelle.

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

And Maya Uppaluru from ONC?

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

Yes, hi.

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

Hi, Maya. And Mazen Yacoub from ONC?

**Mazen Yacoub, MBA – Healthcare Management Consultant**

Hi, I'm here, thank you.

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

Anyone else from ONC on the line? Debbie Bucci is here as well listening through the public line. All right with that I'll turn it over to you Jon and Leslie.

**P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

Okay, I have just very brief comments. Thank you all again for making the time and for being present. We've heard a lot of great testimony from a wide variety of folks and today is really a chance for us as a Task Force to start processing what we've heard and start throwing out the ideas for initial recommendations. So, thank you for your time and attention.

Some of the folks who are not on the phone with us sent me notes that said that they were sorry they couldn't be there, they are on a plane or something like that, but they look forward to engaging, so everybody is kind of pretty actively engaged and I appreciate that.

We are going to go through the work plan with you and we are going to hear about a summary of the themes of what we've heard and then we are going to start talking about folk's ideas of where we go from here. So, thanks for your attention that's all I have to say. Leslie the floor is yours.

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

Thanks, Jon, I think that I have been struck by all of these presentations about the struggle we'll have between a premature regulatory pressure and industry alone solutions and I think that as we go through our work we have to constantly think of that balance. There seems to be some strong themes around expanded family health history to support all the phenotypic data.

And I think back to a couple of years ago when, under the Standards Committee, the Patient Empowerment Team did recommendations on the Consolidated CDA patient header and the work that was done defining questionnaires and also device data recommendations and I think that might help our work today.

I think that as we review we have to consider the new constituents on the team like researchers and the patients themselves where they have not necessarily been included in our HIT structure and that might be some of the most profound changes we bring to the table.

It seems also to be that we have some difficulty around the recommendations on the genotypic data primarily because both industry and care processes are still emerging. Perhaps as we go forward a minimal dataset is a first step this winter.

But I was also really encouraged by the work that we've heard from Duke and the readiness that the Argonaut Project might have for trials or the Sage Project. So, I think there is great opportunity and I look forward to hearing from the team.

I think a lesson learned in the past in standards is we really want to keep from automating health and helping to create an environment where not too many silos are formed or too many quagmires are formed but that we can provide direction that will help pilot's success and for those pilots to help inform regulatory future. So, I think there is great opportunity from what we've heard so far today and I look forward to hearing from the workgroup as well. Thanks.

**P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

So, let's go to the next slide. All right, there is our membership with all the members. Next slide.

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

Hey, Jon?

**P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

Yes, Sir?

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

Some of us are...I'm not on a live stream so I've got a copy of the slides, if you could say the slide number when you change them so I make sure I stay in sync I'd appreciate it.

**P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

Yes, absolutely, okay. So, the slide we're on right now at the top says Precision Medicine Initiative Mission Statement and on the bottom it says number two.

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

Got it.

**P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

Yes. So, a recap of the mission statement of the Precision Medicine Initiative to enable a new era of medicine through research, technology and policies that empower patients, researchers and providers to work together toward development of individualized treatment. Next slide.

And this is the Task Force charge, slide number three at the bottom. Identify opportunities for innovative collaboration around pilots and testing of standards that support Health IT interoperability for precision medicine.

Recommend existing standards that are currently ready to support PMI.

Identify emerging standards and reference implementations that may require further pilot testing in order to support PMI.

And then finally to identify gaps in available data standards related to PMI.

And, you know, I'll just mention quickly there are two things that I think I would emphasize or use to add to the content of this. The first is that, you know, unless there is significant objection, which we can get to in the discussion, I would love for us to structure our recommendations back to the full Standards Committee around this charge and say, you know, here's the recommendations we have for you all to consider and here is how they are structured, it makes a logical, you know, frame for me and I hope it does for you too, but like I said, we can get into the discussion of that.

The second thing that I would add here is that it is a reminder and it was tweaked from you or it was, you know, brought up to me Leslie used the word "regulatory" I want to keep in mind that the initiative here is not on the...at least in terms of the NIH portion of it a regulatory initiative, okay.

NIH is going to be publishing funding opportunities in the near future to support the Precision Medicine Initiative and we're looking at requirements that would be incorporated into or suggestions for direction that would be incorporated into those funding opportunities but that is not the same as regulation.

Now, separately, there is, in the FDA and ONC portions of this regulatory aspects of it, the FDA is trying to understand how they can regulate next generation sequencing, okay, but they're not, you know, de facto writing regulation with the funding that they're getting.

ONC is working to advance standards and address privacy policies, okay, that support precision medicine and the Precision Medicine Initiative that could include regulatory actions but it doesn't have to. So, just keep that in mind that, you know, normally we're so focused on the CEHRT rule, right, or the incentive program rule or something else like that, this is just a slightly different program. So, let me stop there. Any questions not necessarily discussion but questions about that?

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

So, Jon, this is David, on your last point about ONC and it not currently being a regulatory approach at least let's say around certified EHR technology does it not make some sense that anything that comes out of this group might have, I don't know, inside track relevance if the day comes when certified EHR technology for example requires certification of pedigree tools or of the ability to incorporate biomarkers or something like that? In other words is it pre-regulatory direction or is that not even a relevant question?

**P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

No, no that's perfectly relevant, that's actually a really good question. So, I do...I'm not sure inside track is the phrase that I would use but I would think that, you know, maybe, you know, primary channel of, you know, advisory recommendations to the Secretary on certification.

Let's put it this way, it would surprise me if anybody right now, based on what we've heard so far, is going to say that for September 22<sup>nd</sup> we ought to recommend changes to the current rule, okay, and the current standards that we're recommending, I would be surprised. I'm happy to be surprised but I would be surprised.

In the future though I would, you know, especially as pilots get underway, right, for some of the standards and implementation specs that we think are supportive and as the evidence builds and grows around those I would see this as being a channel for future ONC regulation just as it's a challenge for, you know, most comments related to ONC regulation. Does that make sense David?

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

Yeah, it does and I can't...I know that you referenced Leslie's caution about premature regulation and I can't remember the words that I used in the presentation that you two did to the Standards Committee meeting last week or whatever it was, the most recent meeting, but maybe the better phrase might be to avoid premature closure and not really tie it to the notion of regulation itself, but just to the notion that this is a fairly rapidly evolving space and we really need, you know, more experience under our belts before we close it down and say this is the right way to do it whether that right way becomes regulatory or sub-regulatory, or just de facto standard.

So, that would be my caution to just reword Leslie's caution is not in terms of regulatory, premature regulatory but just premature closure in general.

**P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

Okay, yeah, no and I think that's very much consonant with what I was saying about, you know, there's a lot more dimensions to this than regulatory although that's some of it, but, you know, maybe not even the primary thrust of it.

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

Yeah.

**P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

So, yeah, that makes sense to me. All right, other questions? Okay, let's flip onto the next slide. Okay, so here is the work plan, here we are on the 31<sup>st</sup> and we have done, like I said, remarkably well up to this point, we're developing preliminary Task Force recommendations today and then over, literally, the next week and a half, we're going to iterate on those recommendations obviously not in the public meetings here although we will bring those back to our next public meeting on September 10<sup>th</sup>.

So, it's going to be a fast ride from here. So, appreciate your attention as we kind of go along with it. So, next slide. Okay, Leslie, did you want to take this part in terms of the summary of what we've heard?

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

Sure, I think that we have heard a good deal about the phenotypic data being as important as the genomic data. I think that was a big take away from each. Duke's representation of how they've used this in the primary care setting I think was very informative to each of us.

We also have asked for...or each organization about the problems they're going to solve and what data is the minimum dataset and what standards and gaps we should see. So, as we begin our discussion today that frames what we do going forward. We need to keep these things top of mind. So, with that let's go onto the next slide. Go ahead, Jon.

Or, I'll go forward, I think we've all heard these, there has been some great minutes reflected by staff if you haven't had a chance to review them I know I needed to and it really helped to solidify some of the important recommendations coming from each of these organizations. Next slide.

Jon did you want to say any more about the previous slide and some of the presentations we received?

**P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

Yeah, you know, 10 seconds worth.

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

Okay.

**P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

A pretty broad swath of folks, not necessarily, you know, completely comprehensive but, you know, we only had so many Task Force meetings. So, really good in the depth that they achieved. If folks see gaps in the information that we've collected either from straight presentations or from written comments, you know, feel free to highlight those in the discussion part and say "wait we didn't hear from this" and I'll seek information from these folks. So, thanks.

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

Thanks, I think that we have heard a lot about some of the challenging topics. Some of these challenges I think can help inform broader use cases so although that is not our primary task as we look at patient access and movement of data that helps inform all patient generated health data and all access and movement.

We haven't touched a lot yet on privacy, security and consent that's something that was talked about in several different approaches, but we haven't spent a lot of time on that as yet and it might be worth further discussion as we move beyond this initial Task Force recommendation.

Again, the minimum dataset is what we've heard from and also the emerging use of the APIs and I think all of the people involved in the Argonaut Project is also the developers and initiators, and champions of FHIR that helps us to see that even brand new use cases in industry can benefit from this redefined HIT ecosystem. Where we are going to include now the researcher and the patient I think that becomes and even stronger use case so I was encouraged by how many of the presenters we heard from were already touching on the newer technologies.

And then there was some discussion about the data storage and transportation and the idea that this data might be in several different places, who is the owner and how does that get moved will continue to challenge us on terms of provenance issues that have hit us in other areas will also be informed by our work. Next.

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

Leslie should...do you want us to think about what might be missing from that slide in terms of...

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

Yes.

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

Broad set of challenges or are we going to come back to that?

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

No that's a great idea Dave.

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

I mean, I think the two things...well, maybe one category that I think is missing, which maybe it's really two categories, but I'll describe it in two parts. As we think about how to incorporate ever more complex genomic testing opportunities into the workflow of the EHR I think there is a decision support around what I call diagnostic decision support which is basically which test should I order for this complex patient and that's going to be...the answer to that question is probably something that's going to have to come from some kind of a remote service rather than built into the EHR simply because it changes so quickly, the update cycles of EHRs really wouldn't keep up. So, you might call it decision support for CPOE of complex genomic testing. So that would be one category that I do not see represented here.

And then a second one that is kind of a corollary to that is decision support critiquing from a genomic perspective of physician order entry and pharmacogenomics is the poster child for that use case, you know, if the patient is being put on a drug which has a known variability based on genotype and you have access to the genotypic information of that patient then you should alert the physician how to possibly modify the dose and so forth, this work has been done in a number of places, Vanderbilt and other places quite successfully.

So, I would think those two are integration points between the genomic world and the EHR world that I don't see on here. Does that make sense?

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

That makes great sense, thank you and I would also add to that the flip side which is how do patients share in decision making with regard to this new kind of information available to them, the opportunity for results that are very complex and difficult, how does a patient learn to have the conversations and to share in decision making I think will be a significant challenge in the future as well.

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

Yeah and then...

**Claudia Williams, MS – Senior Health & Health IT Advisor – Office of Science & Technology Policy – White House**

This is Claudia...

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

There is one other component of that last thing you just described Leslie now that you mention it is, you know, one of the things about genomics is the meaning of the test is rapidly changing.

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

Right.

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

So, what are the obligations and/or policies around, and the mechanisms for updating the interpretation as knowledge advances so you may have a variance of unknown interest today and then tomorrow that variant turns out to be quite important. How do you discover that it's now important and how do you notify people and is that a separate test, is that covered under the consent of the first test, you know, all those complex questions that are somewhat unique to genomics.

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

Right.

**Claudia Williams, MS – Senior Health & Health IT Advisor – Office of Science & Technology Policy – White House**

This is Claudia I just had a thought that kind of connects this slide and the next one, as we look to shape and as NIH looks to really launch the PMI initiative some of these are going to be extremely near-term and we're going to need to get extremely tactical about what needs to happen in the next 6-12 months. Others of these I think are things that are much longer term having to do with how we shape and evolve clinical care using technology for bringing in genomics.

So, I would just encourage us as we start to segment out the challenges to keep a timeline in mind so that we can be as sort of aggressive and concrete as we can be for the near-term stuff while also laying out a pathway to build the capacity for the longer term. Because I think there's a risk that we sort of muddle those together and don't make the progress we need to make in the next year.

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

That's a good caution and when the funding is released there will be projects initiated and what we can do to help those projects be more cohesive is an immediate need. Thanks. Any other items that are major challenge in topics that we want to highlight from the group?

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

This is David again, I think, you know, there's a number of details that fall under some of these, you know, for example, how do you...what data do you return back to the EHR and what do you keep in the genomics and/or research space, you know, pretty high consensus I think that the EHR does not become a repository of all of the data, the terabytes per patient per study, but there is some subset of that data that, you know, people would variously call actionable variance or well understood variance, or structurable variance. We just want those in our world and call them biomarkers.

So, what are those biomarkers and what's the format under which they should be returned to the EHR and then where does the rest of the data stay, you know, the variance of unknown importance which is, you know, 4.5 million on average per patient, where do they live and who has access to them.

So, you know, one of the things here is that there is going to be a partitioning of the data because it's too big to just put copies of everywhere, you know, if you have a lab result you can copy the lab result to everybody that's interested and you don't have to worry about it. If you have a whole genome scan you can't do that and you don't want to do that. So, how do you partition the storage of the data?

**P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

Hey, it's Jon, so I'll offer a friendly amendment to that, which is basically just to kind of strike EHR and insert Health IT just in the sense that, you know, we're...I know you're in the same place, David, you know, we're moving towards modular world, you know, this may be returned to the EHR but it may be returned someplace else. It's going to happen through the information technology. So, you know, the data is the right focus, but does that make sense?

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

Yeah, yeah, I mean, I think the data is going to be partitioned out into...there are going to be owners and managers and curators of that data that go beyond our current well understood entities but it's pretty clear that there are a bunch of them that won't live in the traditional EHR.

And you can say some of it is like, you know, when radiologic studies were first introduced into the electronic record we saw the evolution of PAC systems because the images were huge relative to what EHRs of that era were accustomed to storing so we had, you know, a whole separate category to PAC systems.

You could argue today that you don't really need those because EHRs can manage that stuff internally as they've gotten better and maybe we see a similar thing play out here in genomics and the initial stages that we're in now is the genomic information is too much to put in the EHR so we'll have them somewhere else in a genomics repository but over time maybe that changes as well.

But I think, you know, by Claudia's, you know, near versus far, in the near-term we're not going to be moving terabytes of data across an HL7 interface into the EHR but we might want to move the 20 biomarkers that really matter.

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

And this is Leslie, to follow that up we might want to move those and have some standards around what a module...how a module would interconnect with other HIT. So, it really begins to help us to expand that idea that things may be permanently outside of an EHR but accessible..

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

Yeah.

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

To the appropriate parties.

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

Yeah and I think that's where, you know, FHIR and the API approaches is a logical way to go after it because, you know, a FHIR API can be implemented by anybody it doesn't matter what you are or who you are it's a simple standard Internet style API and new players can come onto the scene and implement FHIR and as long as we have the proper permission we can interchange the data.

So, it's one of, you know, jumping far ahead, one of my, you know, recommendations...one of the things I would support for us to recommend is an aggressive focus on identifying the appropriate FHIR resources that we think are necessary to describe the core data that we want to move around.

So, not so much describing who is sending and who is receiving but describe what it is they could send and receive if they wanted to use FHIR because it's a great way to do it technically it's an immature part of FHIR and the FHIR maintainers will tell you that so I think they would welcome input to make it more mature. In other words you're not spitting into the wind and them saying it's all done, because they would very clearly say it's not done. And it's flexible and malleable enough to be iterable in a rapid fire process unlike the v3 stuff which is just way too complicated to mess with in my opinion.

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

Well, I do think that...

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

And...

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

The idea of this really solidifies that this is not a document exchange specific problem in the best case or the final case. This is really about an evolving documentation from different sources that needs to be available for different reasons at the point of care at this time.

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

Well, I think that you'll have documents always because the narrative is never going to go away and shouldn't because it captures most of the human wisdom. So, you'll have a report that comes out of a genomics test that is going to be readable by an ordinary physician and they can see the English text on the screen that tells them what the test showed but you may also have structured biomarkers that accompany that report that are suitable for processing by a decision support system like a pharmacogenomics critiquing engine.

So you don't get rid of narrative in documents but you supplement it with the ability to move discrete data around. Now maybe you need to go and retrofit those structures into the CDA model as it evolves, perish the thought, but whatever, if we have to do that as the last step don't start with the CDA because it will just paralyze us.

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

And if I could add to that theme, this is Andrey Ostrovsky, modifying I think in point four and point five around not just EHR but HIT solution, I think it's important also to consider elaborating beyond just clinical data in point four and family history in point five because the care plan that is emerging and the standards for a care plan I think can have such a rich contribution to making precision medicine interventions. I think that can play a pretty major role and it would be...I think it's important to recognize that it's not just the family history component but it is the only non-medical piece of information that we should be looking at.

And for example there certainly can be long-term supports and services space there are standards being created there, there is also the ability of an HL7 patient generated goals present for this priorities project that is emerging and all of that work can contribute to I think the mission of the Precision Medicine Initiative and also I think it's important to continue to remind ourselves that the role of genes is pretty minor relative to all of the other determinants on health so this would be a good segue and acknowledging that, okay there's a lot of other things beyond just genes that are going to determine wellness and there are implications for that in terms of health disparities and making sure we're looking at the multiple aspects of determining health beyond just what your genes are determining.

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

Yeah, thank you for that I agree wholeheartedly. Are there other comments for this?

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

This is Eric, just in regard to what David was saying before about the idea of whether the raw genomic data, sequencing data would be stored or other sort of low level data would be stored in EHRs or not. I certainly think it's worth commenting on that. I do think that the comparisons to PAC systems was really apt.

I would probably just hedge that saying that, you know, this may certainly change should the technical, the current technical constraints related to storing large amounts of data change because you would want to allow for the fact that 15 or 20 years from now things may be as different from today as today is different from 15 or 20 years ago in terms of what we think has to be kept in some other system because it's too much data.

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

Other comments for consideration? Okay, next slide.

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

What slide are we up to just to double check?

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

We are on slide eight David.

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

Okay.

**Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society**

Leslie, this is Lisa.

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

Yes?

**Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society**

Lisa Gallagher I have a comment. Can we go back to the previous slide? So, you know, the bullet on privacy, security and de-identification of data I know that you said we hadn't talked about it very much and, you know, given that we do need to report out some recommendations, I mean, first of all I would advise that we separate those, they are often lumped together and we have to deal with privacy and security.

I think we need to think about...I like the notion of the near-term challenges and the longer term challenges. So, you know, thinking about exactly how the data would be stored and transmitted now versus what the potentials are for using new types of technology to collect it for example with patient's mobile devices and sensors, the use of other technologies that are coming into the forefront such as M-Bands and other ways to secure the collection and the transport of data from the patient side of things, you know, maybe put those on a spectrum. There is a lot to address there just from the security side and then of course the privacy policy side is something, you know, separate.

So, I'm not really sure what we're planning to do for the Task Force between now and our report out but, you know, we certainly know that's a big space.

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

Yeah, hi, this is Christina Heide with OCR, I would also just say that there is this other activity going on where we are developing a set of privacy principles along with the White House that will apply to PMI and the cohort that NIH is developing and it's somewhat of an iterative process that as the ACD Working Group is working on its report on the design.

So some of that is being handled on this other sort of track and I don't know how much this group will be delving into the privacy aspects of that and how we're going to relate the two activities if it is.

**P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

Christina, it's Jon White, that is a great point and it is a great opportunity for me to sound a little bit like Halamka, for me to reiterate that the wheelhouse of this advisory committee is data standards and implementation specifications, okay, for those standards and that doesn't mean we can't talk about other stuff but recognizing that there...as I've mentioned to you before, an advisory committee to the Director of NIH is giving a separate set of recommendations that will be complimentary to these. So, that is the wheelhouse for this group.

Like I said we can talk about other pieces of it and if there are important points that come up but data standards and implementation specifications are not the right place for those comments we can...you've got a pretty robust federal ex-officio/invited guests presence here we can make sure that we feed back that stuff into those other processes. So, it's a great point and I appreciate you bringing it up.

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

Yeah, this is David, my opinion is that we haven't scratched the surface of that incredibly complex space and that we should punt it to the other group. I mean, I think these are orthogonal concerns, the data format and encoding approaches can be used in a variety of different settings under different privacy and confidentiality rubrics. I think that's relevantly independent.

**Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society**

Right.

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

So, I would suggest we just stay away from them or call it out and say it's important but we didn't address it, we've had no testimony on it, it's a huge space, it's controversial, it's frankly not going to have a solution. You can't...

**Joshua C. Denny, MD, MS, FACMI – Associate Professor, Departments of Biomedical Informatics and Medicine – Vanderbilt; Office of the National Coordinator for Health Information Technology**

And...

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

De-identify genomic data.

**Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society**

And you're talking David about..

**Joshua C. Denny, MD, MS, FACMI – Associate Professor, Departments of Biomedical Informatics and Medicine – Vanderbilt; Office of the National Coordinator for Health Information Technology**

This is Josh...

**Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society**

The privacy and policy area?

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

Yeah, yeah.

**Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society**

You have to...

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

Because I don't think...

**Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society**

Yeah.

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

I'd just keep it as a, you know, a hugely important orthogonal access that we haven't touched on.

**Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society**

I agree and I think...

**Joshua C. Denny, MD, MS, FACMI – Associate Professor, Departments of Biomedical Informatics and Medicine – Vanderbilt; Office of the National Coordinator for Health Information Technology**

This is Josh Denny I've been...I just want to say that this is certainly a topic we've been talking about in the working group without getting into more detail.

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

Yeah.

**Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society**

But this is Lisa, on the security side I think, you know, that's why I said separate those out, you know, and if we want to make a statement about the privacy aspects fine, but, you know, there are some things we might want to think about and recommend with regard to security, you know, along that near-term and near term spectrum. We just, you know, we haven't gotten to it yet.

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

Yeah. Do you think there's something unique about security around genomic data? I mean are you suggesting...

**Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society**

Well, I think, you know...

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

A special...

**Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society**

Yeah, if we look at...I mean, first of all, you know, we need to go back to looking at security of large datasets and then, as I mentioned earlier, there are some ways that we may want to be collecting data from patients and, you know, a lot of what I read, as, you know, mobile devices and sensors and things like that well there is technology that's been developed, mobile body area networks and associated sensors that sort of design security in so there are technological considerations and, you know, future technology that can be looked at and standards that would facilitate that.

I mean, we could make some comments along the spectrum of, you know, how we think this will be implemented initially and what kinds of things we want to look at going forward and sort of outline the security challenges because I think this is something that has to be considered in parallel with everything that we do and right now I just sort of see it as a “yeah, we have to worry about security.” I think there are some things we can look at and say, and perhaps even could have...if we had the time gotten some testimony on some of the newer technologies.

So, I’m not really sure Jon and Leslie, you know, given the timeframe that we have left what we can do but, you know, I might be able to come up with a couple of bullets for recommended future studies.

**Claudia Williams, MS – Senior Health & Health IT Advisor – Office of Science & Technology Policy – White House**

So, this is Claudia and I think that’s an excellent point and could dovetail nicely with some follow on work to the privacy guidelines that was announced when those were released which is that we’re going to have a parallel effort focus on security for the ultimate PMI data cohort and it would be extremely helpful for this group even if it is at a fairly beginning level to outline the kinds of security threats and challenges that are going to be most important to resolve in bringing together the data stores for the PMI effort and in transmitting the data both from delivery systems but equally from patients themselves in order to aggregate the data.

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

...

**Claudia Williams, MS – Senior Health & Health IT Advisor – Office of Science & Technology Policy – White House**

So, in terms of...on security I don’t think this group has to go all the way in saying “here’s the solution.” But saying “here are the challenges we’d love to see addressed as that work goes forward” would be extremely helpful.

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

This is Leslie, David in answer to your question what’s different about this is that what is different is the data sources are coming outside of the traditional EMR/HIT world coming from research, coming from the patients, coming from others and so how do we make recommendations to have a secure environment from what used to be foreign participants and I think that is unique and it would be worthwhile to highlight that as a problem to be solved.

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

Well, Leslie, I...

**Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society**

I...

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

I have no problem calling out the new channels of data require, you know, new thoughts about security, but I would disagree that personally collected data is any different whether it’s got genomic data in it or not. I mean, PHI is PHI.

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

Agreed.

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

I mean, so...

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

Yeah, agreed.

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

It doesn't have anything to do with the PMI it has to do with healthcare in general.

**Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society**

Well, it has to do with the fact that, you know, how we collect it from the patient, the mechanism. If it's going to include mobile devices and sensors, and things like that, you know, it needs to be looked at but there are ways to do it. So, there are...

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

Right.

**Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society**

Technologies out there emerging. So, those are things that we want to look at in parallel.

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

Yeah, I'm just saying, and it's a pedantic point I realize but there is nothing unique about the personal Precision Medicine Initiative and that data, that data is just as sensitive if it's being collected to manage the patient's diabetes. I mean, it's still sensitive data and if it's coming in from...

**Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society**

It is but if it being collected on a mobile network with, you know, sensors and other things then there are different security challenges, benefits data within the system that, you know, for...

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

Yeah, yeah.

**Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society**

Covered entities and business associates collecting it.

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

Yeah.

**Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society**

You know there...it's worthwhile I think to call that out because really I think this will be the first time we're looking at collecting and integrating this data together with clinical data and research data so let's look at it, acknowledge it and look at it and I think there are a couple of technologies we can recommend to look at also.

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

It would be great Lisa...

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

Yeah, I mean, but...

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

To get your feedback initially. I do think that what this initiative does is to accelerate and highlight the need for data coming from new parties...

**Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society**

Right.

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

It just happens to be that our Task Force and PMI has the first one to say this is a lot of data, its big data and it's coming from and to new participants and stakeholders. So, it gives us an opportunity to shine a light on an area that we know needs work.

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

Yeah, just recognize that it's already happening at scale in EHRs today long before the PMI was ever put on the proposed budget.

**Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society**

Yeah, this is...

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

This is not new is my point.

**Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society**

Yes.

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

But more often or not handled in current tethered systems or proprietary systems not necessarily by coming from externally supported or external systems but let's move...

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

No it comes in over the Internet. I mean, diabetes...

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**  
Right.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**  
You know weights, scales, glucometers all that stuff flows over, in our case, Qualcomm.

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**  
Yeah.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**  
But my point is just simply that this is a problem we all have to solve writ large.

**Mitra Rocca, PhD – Medical Informatician – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences – Food & Drug Administration**  
That's right.

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**  
Correct.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**  
And PMI is just one particular interesting subset of use cases.

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**  
Correct.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**  
So, I totally agree with the importance of the problem, it's broader than this group that's all I'm saying.

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**  
Yeah, I agree.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**  
And it's pedantic, I'm, you know, I'll stop, I'll shut up.

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**  
Oh...

**P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**  
No, David, you are famed for your pedantry so.

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

**Mitra Rocca, PhD – Medical Informatician – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences – Food & Drug Administration**

This is Mitra Rocca from FDA, we actually worked on and we had a task order through the Harvard Team who are contracted on the Sentinel Initiative on aggregating two large data sources but not using any PHI. So, we looked at different algorithms for de-identification of data if that helps.

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

That does and we did hear some testimony the last time about an organization that took information from other non...well it had PHI in it but it had very little...no phenomic data or other patient generated health data. Are there other big items that we need to include here?

**Betsy L. Humphreys, MLS – Deputy Director – National Library of Medicine**

If you go to the...this is Betsy Humphreys, I agree with what David said this is going on all over the place maybe the PMI will be a very obvious place where it is going on too.

But on your next slide which is what you said where we're supposed to be focused, how can ONC, my feeling is that I'm a great believer in stating the obvious not everything we should be doing here is talking about standards development some of it should be talking about, and I think we've all been here with the earlier goals, stating what standards are currently being used which should absolutely be used in this initiative as well.

And I think that content standards, certain messaging standards and whatever, I think that for some of the players that are getting interested in PMI and may really be not that knowledgeable about what's going on or has been going on over low these decades in the drive toward greater standardization of EHR content I think we actually have to have as part of this report that we're recommending or we're assuming that it's a sine qua non that for the phenotypic data that is routinely collected in healthcare and already has a designated national standard well that should be the one that is used in PMI.

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

Well stipulated.

**Betsy L. Humphreys, MLS – Deputy Director – National Library of Medicine**

I don't think anyone would disagree I'm just telling you that if you make the assumption that everybody knows this there will definitely be some people who don't know. So, I think it should actually be incorporated in whatever report goes out from this group.

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

So, Betsy, this is David, can I ask you an overly specific question but maybe it'll flesh out...help me understand what you're saying. One of the things that we're debating internally at Cerner is what nomenclature to use to capture structured phenotypic data and so one choice of course is SNOMED. SNOMED is ubiquitous for lots of reasons but it was not designed to capture phenotypic data and it doesn't have any kind of ontology to help the user in capturing the data so you have other choices like HPO which is purpose built to capture phenotypic data.

**Betsy L. Humphreys, MLS – Deputy Director – National Library of Medicine**

Well...

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

Would you say you shouldn't use it because SNOMED could be used or is that something that's just open for more discussion or how...

**Betsy L. Humphreys, MLS – Deputy Director – National Library of Medicine**

Well, I think the issue is the definition of phenotypic data, right? I mean, HPO which is something that is being...there is an effort to link it and there is a lot of work going on with the IHTSDO and the HPO group, and we're also doing work related to UMLS but the thing that I'm saying is here when you say "what is the phenotype of the patient" what are you talking about?

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

Well...

**Betsy L. Humphreys, MLS – Deputy Director – National Library of Medicine**

Are you talking about very detailed observational or, you know, particular manifestations in patients that have very complex and rare diseases or are you talking about signs and symptoms that occur in patients who have very common diseases and so forth? Do you see what I mean?

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

Yeah, but...and I think the answer is all of the above, right? I mean...

**Betsy L. Humphreys, MLS – Deputy Director – National Library of Medicine**

Yes, but all I'm...

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

If you want the lab data...

**Betsy L. Humphreys, MLS – Deputy Director – National Library of Medicine**

What I'm saying...

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

There is stuff in HPO that you just cannot capture readily in SNOMED for example.

**Betsy L. Humphreys, MLS – Deputy Director – National Library of Medicine**

Well, I understand that...

**Joshua C. Denny, MD, MS, FACMI – Associate Professor, Departments of Biomedical Informatics and Medicine – Vanderbilt; Office of the National Coordinator for Health Information Technology**

That may be true...let me, you know, but I think the...there is a lot of distinction here between kind of what are the sort of layers and the onions of use cases here and the broader use case. I mean HPO certainly has better descriptions and more detailed descriptions of a lot of that detailed genetic phenomenon but it is not that it arises to Mendelian phenotypes but when you talk about the, you know, sort of standard use case of the documents that most of us are writing they're not at the, you know, the level of detail that exists in HPO and HPO would underspecify a lot of the clinical diseases that we much more commonly see.

So, you know, you could think about this as different layers of implementation timelines even or layers of support, you know, and to me, you know, the layer with SNOMED is certainly much more prescient towards a lot of our goals for genetic analyses and healthcare represented data probably than, you know, where you could go with HPO, but it certainly is not trying to gate it's use case it's just where, you know, I would see the need for better representation transmittal and sort of utilization across implementation efforts and kind of where SNOMED currently would cover probably than HPO at least in the near-term.

**Betsy L. Humphreys, MLS – Deputy Director – National Library of Medicine**

Well, thanks, Josh, you've said it much better than I, but I think my principle is simply for those elements that are routinely exchanged in healthcare we should be saying those are the elements for which you should use the same national standards that have been designated for EHRs.

**Joshua C. Denny, MD, MS, FACMI – Associate Professor, Departments of Biomedical Informatics and Medicine – Vanderbilt; Office of the National Coordinator for Health Information Technology**

Yes.

**Claudia Williams, MS – Senior Health & Health IT Advisor – Office of Science & Technology Policy – White House**

This is Claudia and I'm sorry I have to jump off but I just wanted to...on that comment and take it to another level of specificity which I think one thing that would be super helpful from this group is to appropriately answer the question as the PMI initiative builds out how can it build on the broad-based requirements in EHRs that are going to be manifested in 2015 CEHRT?

So, if you imagine you're going to have a common data model, you have an ability for patients to get their data, right, you most likely have an API and I'd like to see what the delta is between that likely set of requirements that we anticipate will be a sort of universal and what is likely going to be the phenotypic data we need from the EHRs whether those are questions around data quality or whatever that's a very concrete gap, if there is a gap, and we'd like to really understand what that opportunity and gap is. So, that's just an extremely concrete thing that would be very, very helpful as we launch that effort.

**Betsy L. Humphreys, MLS – Deputy Director – National Library of Medicine**

So, thank you, I agree with that and David I just wanted to say that I still run across people who are saying because SNOMED or LOINC or whatever is not good for this particular case that I have I'm not going to use it and then they head off into another room acting as if they're going to recreate the entire rest of SNOMED or LOINC in order to solve the problem and all I'm saying is I think we should have a set of recommendations which is clearly making it clear that we really don't want anyone to do that.

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

Yeah and Betsy thanks for that clarification. I certainly agree with that. I'm honing in on those areas where I think there maybe gaps or where there may be additional power in a vocabulary that is not a part of our current standard and either you incorporate that power by factoring it back into SNOMED for example or you may admit that you need to expand the range of choices.

You know so I'll look at one, you know, kind of trivial example, if you look at the pedigree model in the v3 HL7 it uses the role codes, the standard set of role codes for v3 but it turns out if you go and cross map that to the types of relationships that can be captured in a full blown pedigree there are many that are missing from those role codes and they don't make sense as role codes because they aren't really roles but they are important relationships between two parties that generated a child. And so I would say that's a case where, you know, the role codes, value set is just inadequate and we shouldn't try to push it forward into a FHIR pedigree model, we may need a new value set.

**Betsy L. Humphreys, MLS – Deputy Director – National Library of Medicine**

Yeah, I think that the issue here is that we...I can imagine both things. I can imagine cases where the correct thing is to say "okay, for this set of data we need this standard and it isn't one of the ones that we have." I can imagine that.

I can also imagine where we say "well, we need to augment or connect, or whatever this to one of our standards because that will suit the purpose."

What I think we want to be crystal clear about is that we are not encouraging anyone to reinvent an existing standard we've already nominated in a slightly different form because it isn't perfect because there is no such thing as a perfect standard.

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

Right.

**Betsy L. Humphreys, MLS – Deputy Director – National Library of Medicine**

And if we keep doing that then we're doomed and I think we've finally gotten over the...we've moved ahead from that point and I just don't want this effort to in any way allow us to backslide.

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

Yeah, yeah I understand. I do think we should question automatic mapping that merely recasts a robust vocabulary into LOINC for example just so that it can be LOINC because then you kind of guarantee that it's 6-12 months out of date all the time and I know that, you know, some folks are talking about doing that in the biomarker space and maybe it's okay but it seems to me to be kind of silly to just automatically reassign it to a LOINC code for example.

**Betsy L. Humphreys, MLS – Deputy Director – National Library of Medicine**

Well, I think we need to get into all the discussions and I think they are detailed discussions...

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

Yeah.

**Betsy L. Humphreys, MLS – Deputy Director – National Library of Medicine**

About what solves the problem in the most effective way and the cases that we will start to identify as we do more of this work or have already been identified but I think that's kind of independent from...can be independent from some general principles that I just feel that we have to state them because when you are dealing with the entire research community, as we will be, with PMI or a larger one that might not have made effective use of EHR data in the past I think that we need to understand that some of them may not even be aware of what's already going on or has already been done.

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

Yeah, yeah.

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

...

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

So, our rule is no gratuitous new value sets.

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

This is Eric, I think with the time that our workgroup has I don't think we'll be able to probably solve this problem or even make a definitive recommendation necessarily but perhaps we could at least articulate where the tensions lie that need to be considered and, if I might, I'd like to try very briefly to articulate what they are.

That we have on the one hand terminologies that are widely in use, and SNOMED is a great example, that have some terms that adequately represent information related to PMI, an example is that there is a SNOMED code for Factor V Leiden patients, and the advantage of using those terminologies is that they are already in place and we are every day accumulating instant data on patient records in EHRs that could be used to facilitate precision medicine activities and at the same time they are...those terminologies are not necessarily designed with the idiosyncrasies of genetic data particularly in mind and so for instance SNOMED doesn't have links to identifiers in other terminologies whereas HPO does, you know, HPO has links to for instance open codes that in turn link to HUGO gene identifiers. So, there is, you know, potential tap there using those terminologies to have more of a smooth path or at least a smooth processing of raw genomic data to the data that needs to be brought to bear at the point of care for precision medicine, which I think is kind of the Holy Grail.

So, I think the tension there is that the ideal terminologies to represent this data are not necessarily in common use and the ones that are in common use are not necessarily ideally architected and so maybe if we can just express that in our findings that at least will shed light on that critical issue...

**Betsy L. Humphreys, MLS – Deputy Director – National Library of Medicine**

I...

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

Which I think is what Betsy and David have been talking about.

**Betsy L. Humphreys, MLS – Deputy Director – National Library of Medicine**

That's a very good point and I think the other issue is how do we solve the problem and whether we want to embed, you know, just...since it is true that in the context of the UMLS SNOMED is actually linked to a number of the things that you just described.

So, I think that the issue here is that in addition to the general use of SNOMED we now are finally in a situation, as we have been for the last maybe five or six years, of greatly expanded use of it in healthcare, as a result we are now getting a lot of focused attention on what's missing, what's needed, how do we improve the vocabulary and a lot of changes and improvements are being made to it because it is being used.

So, I think the issue here is to figure out going forward what else do we need and what is the best way for that content to be curated and maintained, maybe it will be in the context of one of these other standards, maybe it won't, but, you know, I believe we'd all agree what we don't want to do is replicate the level of effort and content that already exists because it isn't perfect for some other purpose.

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

Yeah, so...

**Betsy L. Humphreys, MLS – Deputy Director – National Library of Medicine**

So, I think...we can figure out a way to solve this problem and I'm just saying that a group like this that's making recommendations about standards needs to I think state some general principles of what we expect to have happen in a PMI world which is planning on getting data directly from EHR systems which will in fact be data that is standardized in this way in the way that's required in EHR systems. So, we just need to say we know that's going to happen and we know that's going to evolve and that has to be part of the problem, I mean, part of the solution and part of the plan going forward in terms of the PMI initiative.

**P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

Yes, Betsy, it's Jon, so stipulated. Eric's note of caution is appropriate notwithstanding it though I think that the most value that this group of, I'd say pretty...can offer, is that to the extent that we say that there are areas that are in evolution and bear further attention, you know, there are areas of standards where standards were established but their use in PMI bears further attention and perhaps pilot activity.

To the extent that we can be very specific about those and David's example is not a bad one, okay, at least we can discuss it I think the more helpful that we will be to the Precision Medicine Initiative, right?

You know for God's sake we're the standards experts, okay, so to the extent that we can say, yes, these are the conical standards that are used for the use of precision medicine or for the purposes of precision medicine these are areas that are in evolution, you know, and they bear further attention as the initiative proceeds ahead.

Again, we can focus the attention of, you know, NIH funded projects, you know, public commenters, other folks like that on those sorts of areas as we move ahead. So, Betsy that principle will be so stipulated I agree completely and I think to the degree we can be as specific as we can about those areas that look a little fuzzy would be good.

**Betsy L. Humphreys, MLS – Deputy Director – National Library of Medicine**

Yes...

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

This is Leslie, I would like to add onto that Jon and maybe I'm wrong, correct me if I'm am, but the recommendations seem to be even we come up with something that is very specific in its use case maybe it is HPO it's this idea that governance and evolution has to be sound to accommodate a very fast moving industry where there is a desire to accelerate that movement even more so through the use of data standards.

So our recommendations aren't just the standards but that the governance of those standards be able to evolve, adopt and accelerate. And I think that should be part of our overarching themes not just a particular named standard to get to the evolutionary nature that both, well that all of you have spoken up about.

**Betsy L. Humphreys, MLS – Deputy Director – National Library of Medicine**

Yes, I agree, Leslie that's...this is Betsy again, I think that's a great point and I think one of the things that the PMI initiative has a real opportunity to achieve or to, you know, help move us in the right direction is essentially to get where it is appropriate for research community and the health communities in the same room on the evolution of their standards rather than meeting in two separate places and then ending up with things that have to be integrated after the fact, some of that will be required but there has been more of it going on in history than really was required or desirable.

**Joshua C. Denny, MD, MS, FACMI – Associate Professor, Departments of Biomedical Informatics and Medicine – Vanderbilt; Office of the National Coordinator for Health Information Technology**

I'll second both of those points. I think it's a great point. It's just the idea that we can evolve quickly, be nimble and then that sort of gets back to the earlier discussions on which specific things if we have more flexibility and activity around supporting different things then you can actually adjust more quickly.

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

The other thing that we sometimes get, this is David, get confused or tripped up on is the difference between the nomenclature for the purposes of encoding and communicating the facts versus the knowledge models that may be underneath those nomenclatures which are helpful in navigating the nomenclatures.

So, I think no one would argue that SNOMED should be changed as a way to communicate the facts but there may be missing aspects of knowledge models that make navigating SNOMED for the purpose of locating the appropriate fact to codify about a patient extremely difficult to do whereas something like HPO may facilitate that because of its linkages to OMIM and HUGO.

So, you know, preserving the knowledge models, the power of the knowledge models even if they are...their end results have to be mapped to something like SNOMED is part of the challenge. The same with RxNorm, you know, we send the drug as an RxNorm code but much of the power of RxNorm is in the fact that it understands the models between generics and products and products and packaging and all of those things which are included in what you send, but you wouldn't want to live without that knowledge model behind it.

**Betsy L. Humphreys, MLS – Deputy Director – National Library of Medicine**

Yeah, that's a very good point and I do feel that sometimes people have felt more than they needed to that if the model or the knowledge model or whatever wasn't exactly right for them than that was a good excuse to also...

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

Yeah.

**Betsy L. Humphreys, MLS – Deputy Director – National Library of Medicine**

Rename everything or have a whole other set of identifiers when actually they could have used the extent ones and just provided a different, you know, knowledge structure in which to locate the appropriate ones for a particular purpose.

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

Yeah, no that's a good point. Do you think that in the case of SNOMED in particular that there are jurisdictional issues that make this more complicated than just human frailty? In other words, countries that don't want to license SNOMED who want to encode their genomic data and therefore pick something like HPO? Is that something we have wrestle with?

**Betsy L. Humphreys, MLS – Deputy Director – National Library of Medicine**

Well, I don't think you have to wrestle with it but I do feel that if you have ever done a comparison of what's in HPO and what's in SNOMED you would realize, you may have done so, that it would be totally ludicrous to expand HPO to cover what is in SNOMED and maybe vice versa they should all get together and I think they're doing that.

But I do think that some countries have thought that it's a lot easier to develop a whole new clinical terminology than it is to deal with the acquisition of one that already exists even though it's, you know, broadly adopted in many countries and really available for low resource countries in every other thing. So, I think people have been making some strange choices in that regard, although I believe more people are seeing the light.

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

Yeah, yeah.

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

So, it's really this is Leslie, so it's really the prevalence, governance and habits of SNOMED today and that the gaps that exist that HPO might fill versus HPO saying it's going to accommodate everything in SNOMED which would just be ridiculous.

So, is it possible for our recommendations to include that the HPO brings new information needed to an existing governance and prevalence structure that SNOMED has and that we encourage that these parties work together to further refine the need versus having at the worst case a new standard formed or a moderately bad case and ongoing argument.

**Betsy L. Humphreys, MLS – Deputy Director – National Library of Medicine**

Yeah, well, I actually...I will take it as my action item to send the group what I can determine about the current status of discussions which I think are actually positive and useful between the IHTSDO and the HPO crowd.

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

Great.

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

Yeah that would be good and I think Leslie just, on your comment, I think, you know, maybe the way to express it is given the Precision Medicine Initiative's desire to leverage and reuse the data that's being captured as a side-effect of the Meaningful Use Incentive Program, which has enumerated a set of national standards, we want to reuse those standards everywhere possible and if there is data knowledge models or other data that is not yet incorporated into those US in use standards we would encourage that be done. So, there are things in...

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

That's nicely said.

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

Yeah, there are things in HPO, you know, from an ontology perspective that are, as far as I know, haven't been replicated into SNOMED although they certainly could be. You know SNOMED can represent any kind of a relationship if somebody wants to just do the work but you wouldn't want to sacrifice that knowledge just to use SNOMED. So the best of both worlds is to pull that knowledge into SNOMED somehow.

**Mary Barton, MD, MPP – Vice President, Performance Measurement – National Committee for Quality Assurance**

This is Mary Barton I just want to emphasize one thing you said which is if there's good standards elsewhere we should use them across the board.

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

Yes. Well in particular the ones that we've already laboriously achieved as part of Meaningful Use, you know, 20 whatever 8 billion dollars down the road at least we've got some common nomenclatures in use and we should...

**P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

I thought you would have said lovingly, but you know. Okay. So, look this is all good discussion. Let me try to recapitulate it for you. I think what I'm hearing is, you know, we should certainly be using standards where they exist and for this I think that we, you know, fairly clearly try to point back to previous standards that have been recommended by the Standards Committee to the Secretary, okay, and the same thing for implementation specification.

I think there is a qualifier under that, is that for certain instances the ends of precision medicine, you know, are, you know, perhaps not completely or ideally served by existing standards, instances where we've been able to identify those include 1, 2, 3, you know, whatever those will end up being, and that for this we recommend further dialogue, further discussion, you know, perhaps, you know, piloting, you know, right.

I mean, you know, frankly, you know, these, you know, whatever winds up getting funded is a great way to, you know, kick the tires on stuff like that and find out what does work well and what doesn't and that, you know, those ought to be considered. Does everybody...does that sound right to everybody roughly?

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

Yes.

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

When you write it down I'll read it carefully.

**P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

Okay, all right that's fair. Good. I've also pretty clearly heard recommendations from Lisa and others that we're going to take a...break out privacy and security and we're going to try to take a good look at those but view that with the understanding that, you know, there are many other folks looking at these and there are other, I'll use David's word, orthogonal dimensions to the standards and the implementation specifications and that's good.

Are there other kind of large framed, you know, things that we ought to be considering for recommendations that haven't been captured on the slide that we've all been looking at for the last 30 minutes?

**Betsy L. Humphreys, MLS – Deputy Director – National Library of Medicine**

Jon, this is Betsy, I'm not sure it's a large one but depending on the decisions related to the nature of the cohort maybe the system is going to include, but we'll all know soon, going to be defined as including newborns and children. Then it seems to me that although...that we really have...there has been a lot of standards work both on the content side, SNOMED, LOINC, the specification of which tests should...you know recommendations for nationwide newborn screening tests and also work done on the HL7 side for the newborn screening messages.

So, my feeling is given all that work that's gone on and the importance of that if from a precision medicine point-of-view if in fact newborns are included I think we might be able to make a specific set of recommendations...specific recommendations that the newborn screening standards guide and whatever and everything that it recommendations is really fit for purpose and should be adhered to.

**P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

Okay, I love all my children equally, especially the young ones so I think we will tee that up as a potential to discuss. How does that sound?

**Betsy L. Humphreys, MLS – Deputy Director – National Library of Medicine**

Fine.

**P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

Okay.

**Joshua C. Denny, MD, MS, FACMI – Associate Professor, Departments of Biomedical Informatics and Medicine – Vanderbilt; Office of the National Coordinator for Health Information Technology**

Jon, I think you'll have no surprise in thinking what I would say, but I guess I would just harken back to what the data standards could be and ways you could derive or give patients control over selecting out in a standardized way kind of whatever it means to say all of your EHR but to get, you know, sort of a comprehensive but structured, you know, sort of standardized definition around that which could support, you know, multiple layers of what it could mean to be all in a way that others could interpret and potentially computationally import.

**P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

Oh, my gosh, Josh Denny throws a hand grenade into the middle of the task list discussion. Okay, so...

**Betsy L. Humphreys, MLS – Deputy Director – National Library of Medicine**

That's perfect, we definitely want to say something about that.

**P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

Yeah, so I would...so that's a great question. So, I actually want to hear two people respond to that first and anybody else that wants to, but I would first love to hear Leslie offer her thoughts about that since that was kind of roadhouse.

Then I want to hear, as much as I've heard from David today, I want to hear from David a little bit more, because, you know, as our representative here from the developer community, you know, when somebody says to you, give me all of my data, you know, I'm sure your eyebrows go, bloop, and I want to hear what that means to you. So, but Leslie, you go first.

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

Well, I think that the words that we heard from, I can't remember her first name, Ms. Savage of OCR, the computable consent work that's going on, I think Debbie is quite fluent in that and I think that will be helpful to us because we do need to have...to consider that especially if we are going after the pediatric patient initially.

But the whole idea of "all" and what we explain to people for that use is really going back to, do we explain things in a way that's in plain language that people understand what it means both from the consumer point-of-view and then technically what is "all."

We have to accommodate both book ends here not just what's technically "all" and defined but what is explained to and consented by patients where consent is needed. So, I think that's worth some further discussion.

But, you know, this data is being held in stewardship for patients and what we don't understand doesn't mean we shouldn't have access to it. That same argument could have been made for keeping women from voting, you know, it's just we have to have access in order to... and understand what that access means in order to make future decisions and in order to be more integrated into the care process and care team.

So, I advocate transparency and access and then with it comes the ability to provide education to people to know what it is they are using and consenting. That is a good problem to solve when there is transparency and access there is more need to understand it, it's a problem we want.

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

So, this is David, Jon would you ask your question again because Leslie answered a slightly different question than I thought you were asking and I want to answer the right question.

**P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

Oh, no worries.

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

And if I answered the wrong question I want to know that too.

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

But, no...

**P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

This is why...

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

I think your answer was really good it just was not what I thought you were being asked. So, I just want to make sure I understand.

**P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

I mean, this is Washington people answer the questions they want to and we have to ask them all the time. So, the question I was asking was, what does...so for Leslie it was, you know, when somebody says, you know, we need to make recommendations or we should think about making recommendations on standards for, you know, being selective or completely inclusive of all your data in an EHR, you know, what does that mean to Leslie or patient participant as kind of avatar here.

And then for David, as an avatar of the developers, you know, when somebody says that to you what's your reaction and what do you think it means and, you know, what do you think the expectations are that you've dealt with for folks when they say, give me all my data and, you know, you've tried to give it to them and maybe it's expectations are aligned, what are your experiences around giving people "all of their data?"

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

Yeah, great, you know, non-trivial question, I mean, you know, sort of...and I'll, you know, caution that I can't speak for the industry obviously and I might even be on thin ice speaking for my own company although usually they let me do that and then I have to coax everybody out onto the ice with me.

I think that, you know, a philosophical approach would be, you know, absolutely all your data is all your data and you should have access to it. The challenge is that this may be incredibly difficult to do if you try to get to a 100% not the least of which is much of the data that is tied to a patient ID if you look at a foreign key on a table is, you know, operational data that's used to run the system, you know, it might be tracking the intermediate status of a result if it's in process and it's technically tied to the patient but it's not of any interest outside the system. So, all your data has to mean something different than just all of the rows and the tables that have your ideas as a foreign key.

And so a practical approach that I would recommend we take is to say, let's think in terms of FHIR resources and enumerate the resource types that we feel should be included in data exports and enable the vendors over time, as they support more and more of FHIR to have an expectation that, you know, marches forward over time that this increasing set of resource types be readily exportable on demand for whatever use case be it donation to a research interest or pulled down to a SMART phone App that lets you dive into your data.

So, for example, you know, what Argonaut will give us is conditions, medications, observations, encounters, a couple of high value things like that and I would say of course that's included. If we get further and have for example a pedigree that defines...I mean a resource in FHIR that defines pedigree then I would say, well that ought to be included and then if we get further and we, you know, have a resource that defines biomarkers then that ought to be included and so forth. And, you know, go forward and, you know, driven by the pragmatics of the industry's ability to map their internal data elements to these standards-based resource definitions.

And then for the research community the way I would send that data to the research community, and this is something else I'd like us to propose although it may be premature at this point because we haven't talked about it very much, is that on export from the EHR what we export should be a FHIR bundle that contains all of the as yet defined resource types.

And then the research community can read that FHIR bundle in and process it with their own ETL tools into whatever data shapes their data models require, you know, that's in contrast to the current model where it's custom ETL strips for every research project which ends up costing a lot of money and taking a lot of time and doesn't solve the mapping problem that exporting as a FHIR bundle would solve.

So, long winded answer to say, you can see what I'm trying to do is to leverage the hard work that we've got to do to make FHIR a malleable way to get data in and out of our EHRs.

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

And this is Leslie, and I would add to that not only the resource bundles but also identifying is this aggregate de-identified bundle or is this an identified specific, patient specific and aggregated bundle.

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

Well, Leslie, so...

**Joshua C. Denny, MD, MS, FACMI – Associate Professor, Departments of Biomedical Informatics and Medicine – Vanderbilt; Office of the National Coordinator for Health Information Technology**

You know...

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

Can I jump in...

**Joshua C. Denny, MD, MS, FACMI – Associate Professor, Departments of Biomedical Informatics and Medicine – Vanderbilt; Office of the National Coordinator for Health Information Technology**

I was originally thinking of it as patient specific, a patient going and getting that data...

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

Yeah.

**Joshua C. Denny, MD, MS, FACMI – Associate Professor, Departments of Biomedical Informatics and Medicine – Vanderbilt; Office of the National Coordinator for Health Information Technology**

Themselves or sending it someplace else, you know, whether that be a research use of something else.

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

Yeah and this is...

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

So...

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

That's certainly what I was describing, this is David again, but Leslie to your point, given that everybody's de-identification needs are different they need to blur the data or mask the data, or obfuscate the data in different ways.

I would say that the bundle that is exported is identified, fully identified data and has lived inside the firewall and then the researcher can define an ETL that turns it into the de-identified data that matches their particular needs.

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

That makes sense.

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

There is no one way to do it.

**P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

And folks...

**Joshua C. Denny, MD, MS, FACMI – Associate Professor, Departments of Biomedical Informatics and Medicine – Vanderbilt; Office of the National Coordinator for Health Information Technology**

And the only thing I would say about that list is I really like David that way of thinking about problems it's actually kind of in some ways what I think about too.

The one thing I would say is to me the higher priority for most use cases that I think about clinical and research would be to get the clinical documents in, you know, versus like the pedigree and stuff like that.

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

Yeah and I agree that's one of the biggest mistakes we've made in the Meaningful Use Program is we focused on the damn CDA instead of on textual documents, gigantic mistake, but we can fix it.

**Joshua C. Denny, MD, MS, FACMI – Associate Professor, Departments of Biomedical Informatics and Medicine – Vanderbilt; Office of the National Coordinator for Health Information Technology**

Those documents are huge.

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

You know you can send some documents to FHIR.

**P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

How do you feel about that David?

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

I love documents. I mean, FHIR bundles can include documents they are usually include it by a URL to the actual binary of the document but that's a detail that could be figured out, it can be embedded if you want to.

**P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

Andrey were you trying to get in?

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

Yeah, I just wanted to offer a quick comment both as a vendor and as a provider. One thing that I think has been a real fault of the whole patient education effort, especially around consent, is we often design a really poor experience in educating the patients and often times the patients that need to be educated the most are the least served by our education efforts of, you know, a 10-page consent document and a poorly communicated verbal description of what this all means usually is delivered in the setting when a patient is already bombarded with information about "hey, you have a new condition, oh, by the way here is the implications for your finances and your welfare, and your health" and so just the whole design around patient education and informed consent is fundamentally broken across the board and I have not seen anyone do it well.

Having said that, I'm going to switch roles from my doctor hat to the vendor hat, we found that efforts, let's say in Massachusetts where folks had to opt in to have their data shared, those efforts have been so slow and woefully stifling some of the really cool things that can be done around information exchange. Whereas Maryland there is an opt out process for patient consent and sharing of their data and there I mean things are humming with a lot of efficiency.

So, I think if there was a recommendation report to PMI it would be something along the lines of we need to have very good, well-designed, informed consent processes with good data stewardship and if there is an opportunity for an opt out rather than opt in approach we would be able to get much bigger scale with informed consents and I don't know actually if there is a true balance between the two, but those are just some of the challenges we've been facing.

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

I will applaud you on that, this is Leslie.

**P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

Okay, so that's...

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

Are you...Leslie you favor an opt out model?

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

I favor informed consent where there is opportunity for people to know what they are consenting to and what they are not consenting to and in general when people are informed they have less concern about privacy.

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

Yeah but the radical difference in the purported rates of agreement imply there is something wrong because if they were fully informed you would have equal rights. So, I'm just raising the question.

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

And I...

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

I don't want to get us side tracked by that.

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

Okay.

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

I was just surprised at what you said.

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

Okay.

**P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

That's a bear discussion. Okay. So, we're at 1:28. There is the possibility that there are further areas or specific ideas for recommendations. I'd ask that if you have them we hold them for off line discussion. So, I really appreciate the amazing discussion that was a great job folks. I think that we've got a lot to chew on.

Leslie, my sense is that with staff, we get busy down to writing a first set of recommendations this week and that for everybody's Labor Day reading pleasure we try to get something out in advance of the weekend. Does that sound reasonable to you?

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

Yes, let me know how I can help.

**P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

Oh, yeah, you will don't worry. So, Michelle, let us thank you. Thank you everybody. Michelle, let us go to our public comment as is custom.

**Public Comment**

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

Lonnie can you please open the lines?

**Lonnie Moore – Meetings Coordinator – Altarum Institute**

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

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

While we wait to see...

**P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

And...

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

If anybody is on the phone...sorry, Jon.

**P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

No that's okay.

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

There was a comment through the public chat that I'm going to share from Francie Grace. Her comment is genomic decision support very important for both clinicians and patients who often are blocked by doctors, hospitals, insurers in getting tests they want on tissues, tumors to get full information that could help for future, I'm sorry, current, future and med decisions.

Genomics reports should be written like lab reports so that everyone, patients included, can understand what they say in the medical record in order to take action and also in order to be checked for obvious mistakes.

**P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

Okay.

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

Plain as possible language will also make it easier for reports to be read accurately by clinicians speaking various languages. The days of English only are over for doctors and patients, and patients furthermore may wind up being treated anywhere in the world. Very technical terms that need to be used can point to explanatory URLs as is done in some hospital patient portals...are good examples.

If people feel their data won't be saved they are less likely to cooperate at the rate that is needed for PMI to succeed. This needs to be part of the security conversation so it is an area where ONC can really pave the way. And we'll share this via e-mail as well. And we have no further public comment. Sorry, Jon.

**P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

No, no, no perfectly interrupted, well done. So, with that on time and under budget thank you very much everybody and we look forward to e-mail iteration...

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

Jon, I'm sorry, I have to interrupt again, we have a public comment now.

**P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

Oh, by all means, by all means look forward to hearing it.

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

I'm not sure who it is, so if you could please state your name and the organization that you're representing, as a reminder you have three minutes, please go ahead.

**Michael Schnitzer**

Hi, this is Michael Schnitzer I represent a precision alias and I just wanted to challenge the notion that genomic data is sort of no different than other PHI. I think that from a privacy and security stand-point and a public adoption stand-point really than any effort is going to have difficulty getting off the ground with that assumption and some of the reasons for that are simply that genomic data, you know, represents a biometric.

I don't think we can really provide people true informed consent when we don't know the totality of implications of not only what the predictive value of their data is but also to the extent that data gets frontloaded as identified and there is a data breach we really...we have no idea really the creative ways that this data could be used. So, to the extent that, you know, we can expect data breaches to occur I think that frontloading all genomic data if de-identified in whatever scheme you like to me makes the most sense.

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

Thank you. Okay, now back to you Jon, sorry about that.

**P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

That's okay, no, appreciate the thoughtful comment. So, thank you very much everybody. We are going to reconvene publically next on September 10<sup>th</sup> so until then I will see you on e-mail. Leslie, any parting comments?

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

None, it's been a great discussion, I really appreciate it.

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

Thank you, everyone.

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

Thanks, bye-bye.

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

Bye-bye.

**Joshua C. Denny, MD, MS, FACMI – Associate Professor, Departments of Biomedical Informatics and Medicine – Vanderbilt; Office of the National Coordinator for Health Information Technology**

Thanks.

**W**

Bye-bye.

**Public Comment Received During the Meeting**

1. Francie Grace: Genomics decision support very important for both clinicians & patients, who often are blocked by MDs/hospitals/insurers in getting tests they want on tissue/tumors to get full info that could help for current/future med decisions.

Genomics reports should be written like lab reports, so that everyone - Patients Included - can understand what they say in the medical record, in order to take action, and also, in order to be checked for obvious mistakes. Plain as possible language will also make it easier for the reports to be read accurately by clinicians speaking various languages - the days of English only are over, for doctors and patients, and patients furthermore may wind up being treated anywhere in the world. Very technical terms that need to be used can point to explanatory URLs, as is done in some hospital patient portals, Sloan-Kettering a good example.

If people feel their data won't be safe, they are less likely to cooperate at the rate that is needed for PMI to succeed. -- This needs to be part of the Security conversation, so, it is an area where ONC can really pave the way.