



**HIT Standards Committee  
Precision Medicine Task Force  
Final Transcript  
August 5, 2015**

**Presentation**

**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 the call. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. Also, as a reminder, if you aren't the one speaking if you could please mute your line that would be appreciated but not until after we do roll and so with that Leslie Kelly Hall?

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

Hi, thanks, Michelle and thank you all for being with us today. We've got some great speakers on hand and I think...

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

Hey, Leslie, not yet I'm sorry, we were just doing roll.

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

Oh, sorry.

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

I'm sorry.

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

Thank you, I'm here, go ahead.

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

Sorry, Leslie. Andy Wiesenthal? Andrey Ostrovsky?

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

I'm 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**

I'm here.

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

Hi, Christina.

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

Hello.

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

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? I know Eric is here. James Breeling?

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

Hi, yes, I'm here, sorry, I was on mute.

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

Hi, Eric.

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

Yeah, Jim Breeling here.

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

Hi, Jim. Josh Denny? 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.

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

Hi.

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

Mary Barton? And 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 from ONC do we have Maya?

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

Yes, hi, I'm here.

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

Hi, Maya and Debbie Bucci?

**Debbie Bucci – Office of Standards & Interoperability – Office of the National Coordinator for Health Information Technology**

Debbie's here.

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

Hi, Debbie and Mazen Yacoub?

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

I'm here, thank you.

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

And do we have any of our White House invitees on the line?

**Mina Hsiang, MBA – Healthcare Advisor – US Digital Service (USDS)/Office of Management & Budget (OMB)**

Hi, Mina Hsiang is here from the US Digital Service.

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

Hi, Mina. Okay, with that I'll turn it back to you now Leslie, thank you so much.

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

Thank you, boy we've got a great group everyone I think on the Task Force but one is represented so that is super. We are going to talk a lot today about the varying scopes and stakeholders involved from the National Library of Medicine to Intel, to Intermountain Healthcare and it's important that as we go forward we recognize that we have a task at hand and...does anyone else hear that? I'm sorry...

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

We did.

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

I'm hearing a lot of static.

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

Yes.

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

Okay.

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

So, if people can mute their lines if they aren't speaking it would be appreciated, thank you.

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

That would be great, thank you. So, it's important that we look at our charge over and over again so if we could go to the next slide, one more. So, we really are looking to identify opportunities. We have been given a charge to try to support and facilitate that one million people cohort so that we can really provide substantive information at the point of care and health and research.

So, as we go forward we're looking at both what's fit for use or fit for purpose as perhaps one phase and another lens to look through is what would be, if any, regulatory requirements going forward. But our goal is not to determine what's necessary for Meaningful Use as an objective for instance or to determine just what's needed from a regulatory point-of-view.

We really are charged with enabling and moving forward with this initiative and also to determine gaps and to help promote the industry in this direction. So, I just wanted to reiterate that Task Force charge. Next slide, please.

So our work plan, Michelle did you want to go through this or shall I?

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

Totally up to you Leslie.

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

Okay, why don't you take this one?

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

Okay, so we are working towards, this group, making recommendations to the Health IT Policy Committee at the September meeting and so hopefully we'll hear from a few folks as we go forward, take what we hear from the experts and form recommendations that we'll hopefully have by September.

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

And I think in support of that we are asking all of the speakers to provide comment both in presentations and also answer some specific questions in writing. So, what we're hoping to do is when the Task Force convenes to review all of the information we've been given we'll have a good idea of all of the different standards that could be supportive of this effort in some sort of rich review so we hope to have that presented to us I think during the working phase which is about towards the end of August. So, next slide, please.

This gives us an idea, thank you, it's August 31<sup>st</sup>, for trying to work on preliminary Task Force recommendations and we will have something in writing before then from staff that have prepared a synthesis of all of the presenters and the answers to our questions around standards that could be fit for use or regulatory recommendations.

Are there any questions about the work plan or our role? Okay, with that, next slide.

So, these are the questions and I'd like to hear from the Task Force if we've left any out or any additional changes they might recommend. So, we're really looking for the organization to answer both opened ended questions and also to ask some very specific questions about the standards that they use, what their opinions will be on the role of government to play in the use of these standards, what role might patients and consumers need to play as a new stakeholder group, and then also what challenges and what other data might be necessary.

Is there any feedback from this group? Have we left any questions out? Would you like to see some modifications to these?

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

Leslie, its David.

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

Yes?

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

I'm going to beat the same drum I always beat which is that you don't cause changes to occur by pushing standards on people you cause changes to occur by changing market forces to drive the need for a standard. So, what I think maybe missing here is what problems are you trying to solve and with respect to those problems where would standards help rather than...

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

Because...

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

What standards would help you because what does it mean to help you with respect to what problem.

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

Okay, I think that's fair, we can modify that.

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

Yeah, I mean, and the reason that I bring this up is I've been diving into some of the HL7 genomic standards that are emerging in FHIR and it looks to me at least, some of this isn't yet published so it could change, but it looks to me like they're focusing a lot of energy on standardizing stuff that goes on deep inside the sequencing lab and that may well be something that benefits from standardization but it's of relatively little interest to the Precision Medicine Initiative and certainly of little interest to the EHR vendor community because, you know, what goes on deep inside the lab is never exposed out to the clinical bedside.

So, you know, they may be developing standards that are fit for a purpose but it's not a purpose that we're particularly interested in and that's my concern.

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

That's a good point.

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

What's the target that we are trying to...in other words we don't have the big picture of how this stuff is supposed to work with respect to the clinicians and their patients to drive the standards against we're starting with standards and hoping that somehow that leads us to the big picture and I think that's unlikely to happen.

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

So, if we were to add to these questions what problem are you trying to solve and how would or perhaps what is the big picture of how electronic health records or HIT would enable or support a solution to that problem.

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

Yeah, something like that and maybe even slightly more specific given that we're advising the Policy Committee who is driving the Meaningful Use Program, what problems are you trying to solve that are relevant to the practice of medicine and consumer engagement or something like that because they may well be trying to solve the problem of, you know, how to get the sequencers to run faster but that's not our purview.

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

This is Betsy Humphreys I agree with David's comments with this sort of additional comment which is, if the efforts on standardizing things within the sequencing labs are addressed at making the data that comes out of them actually more accurate or meaningful or comparable across labs then it seems to me that this is very critical for precision medicine and for every other purpose. It may not be of great interest to the EHR developer or the clinician in terms of what's presented to them but the issue is if underlying all of this we don't have accurate standardized data then what's the point, right?

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

Right.

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

Yeah.

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

That is very important but not so much for what is going to be displayed or whatever, but if that is a core problem and, you know, my colleagues will know more about this than I do, and I'm not saying it is, but if it is a core problem then I believe it really needs to be solved or we're not going to get too much out of this are we?

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

Right.

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

Yeah and this is David, I accept that as a very friendly amendment. I totally agree. I think in particular that effects the nomenclature issues of what do we name these things so that by the time they land in the clinical purview the things that are the same thing are named the same way that's obviously huge.

My comment was more along the lines of, you know, standards that effect how they move data through the pipeline and some of the stuff that...how they model the genotype relationships that drive the knowledge models for interpretation those are way, way, way, way, way far away from the clinical purview that meanwhile we can't get biomarkers into the record.

So, we need to name them, name them correctly and find a simple way to move them around before we figure out the deeper stuff from this committee's perspective. The other stuff has to go forward but there are tons of other groups Mobile Alliance and others that are addressing those.

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

So, we'd like to know what dependencies are needed or in place from the lab data that requires us to have simple data for the clinician in care.

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

Leslie, in addition to that I think I would propose breaking question four under standards; this is Eric, into two questions. I think that one is whether the standards that they're using are...I guess I would describe them as structurally sufficient or if the intent of the standard meets their needs.

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

Okay.

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

And the second is whether there are quality issues with the standard. So, you know, for instance if they need something to, you know, represent phenotypes of genetic disorders maybe OMIM meets the structural need in terms of being designed to fit what the use case is but maybe...and I'm just making this up I don't know if this is true, but, you know, maybe it's too difficult to get terms added to OMIM when new diseases come up. So, I think those are two different questions about the standards they're using.

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

Okay, any other comments that you'd like to add from the workgroup? So, we will make an attempt and revised these and send them out to the workgroup and then also back to our speakers for written comment. So, with that I think we can move onto the next slide.

And invite Intel Corporation to participate. We have with us today Ashley I believe, is that correct?  
Ashley Rees?

**Ashley Rees – Marketing & Business Strategist – Intel Corporation**

Yes, that's right.

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

Okay, super and Ashley did you have any prepared comments that you'll be sending us or we don't have slides for you.

**Ashley Rees – Marketing & Business Strategist – Intel Corporation**

We did have some prepared remarks that I can either speak to you now or I can send to you what's the best way to do that?

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

Michelle, your advice?

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

Ashley if you could just speak to them now the meeting is transcribed and recorded so we'll have the written transcription of what you say. If you want to share additional material following the meeting we'll certainly take that and share it with the group as well.

**Ashley Rees – Marketing & Business Strategist – Intel Corporation**

Okay, great and as you know I'm kind of jumping in here for Yentram at the last minute a bit. Can you...how long would like us to talk for?

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

Fifteen minutes.

**Ashley Rees – Marketing & Business Strategist – Intel Corporation**

Okay, great. Okay, so I'll go ahead and get started then. So, as was mentioned my name is Ashley Rees and I'm the Program Manager for Life Sciences at Intel in our Health and Life Sciences Team. So, I think as far as the way we view precision medicine is really around the idea of compute and technology enabling us to capture the opportunity associated with precision medicine.

So, now that we see that technology is moving us towards a new environment where understanding the genome is leading to unforeseen breakthroughs and things like identifying new strains of complex diseases, offering treatments that are individualized for patients we need to rethink the laws and regulations that govern this genetic information and the standards involved in sharing it.

So, a couple of things that I'd like to talk through, first thinking about sharing and using the data then moving onto some of the other aspects like using EHR data for research and machine readable consent, funding privacy and then lastly the ability to bring genomic data into clinical decision support.

So, first starting off with sharing the data we see that more than 90% of US physicians are currently using electronic health records and this is incredible progress, it's a critical basis for becoming the data engine to provide a comprehensive data summary of patient health and well-being. This is only going to allow us to know the tip of the iceberg until we have the genetic information built into patient information documents and that we can ensure that the records are available to the patient's care team.

Then using the analytics associated with big data targeted individualized medicine can really replace today's trial and error efforts and we think that's where policy can help deliver the comprehensive record so supporting the integration of whole genome sequence data into health records including clinical decision support tools using the leverage of the US Meaningful Use requirements in order to activate widespread adoption by providers.

Not only will this allow physicians to have a full picture of a patient's medical history but it can also serve as an invaluable platform for research into the correlation of genomic markers with clinical data. These electronic health records can give much needed contacts to genetic information.

Lastly, on this clinical decision support tools integrated with medical records are essential in order to allow physicians easy access to new patient appropriate diagnostic tests as well as to the automated resources required for interpretation of test results.

So, I think a couple of key challenges coming out of this area are related to standards and creating and insuring the interoperability of technical standards for managing and sharing sequence data in research and clinical samples.

We also need to develop a technology platform with open standards designed to enable secure storage with a computational architecture and application programming interfaces or APIs that support Apps and services.

These standards need to provide global interoperability, scalability, stability and resiliency and serve as building blocks for further innovation.

We also need to deal with the new dynamics associated with this data, where to store, how to access and how to make use of millions of variants for each individual, do we need to store them all, do we want to keep them all and how do we access the information we need in real-time.

In the absence of an open and interoperable solution these closed proprietary systems will, by necessity, be created so we need to move quickly before the walled gardens are erected.

The second key aspect that's important to us is thinking about the evidence associated with electronic health records and using genomic data for electronic health records and consent. So, with the adoption of electronic health records comes enormous potential for the value of data held in millions of patient records and this is data that could help researchers determine whether a new drug is better for the treatment of high blood pressure than a less costly generic or what the rate of increase is in the diagnosis of Alzheimer's.

Today the use of this information is regulated by a series of consent requirements constructed for a very different type of research. In clinical trial research when comparing groups of patients taking new drugs versus those that take placebos discrete consent is necessary.

But how do we use today's population data now documented through EHRs to closely examine how treatment outcomes vary among genetic groups and what's the appropriate way for broad consent now and in the future when we look at de-identified data that could be used for research for new treatments.

We encourage the pursuit of a standardized machine readable consent form that allows patients to donate their data to ongoing research without the need for securing and faxing consent forms each time that patient's data is requested. A more longitudinal approach for patients who choose to participate in further studies would be accelerated through a standardized machine readable form.

The International Rare Disease Research Consortium has recognized this problem and has assembled a task team with the GA4GH Alliance in order to explore machine readability of consent and the impact it can have on data use and accessibility.

With each state taking action in this area, with the Texas Health Information Exchange taking a lead through their White Paper talking about how machine readable consent would factor into local and statewide medical networks, about 47 states broadly have some degree of digital HIEs and those can either do or do incorporate some form of machine readable consent.

To keep privacy and security risks manageable we need to enable much broader sharing of data and support research that requires more than fully de-identified data the best practice of a multi-layered approach to security should be used. De-identification is combined with other safeguards including encryption, tokenization and access controls which must be usable for performance and robust to effectively mitigate risk and avoid compelling end users to do work arounds when security just gets in the way.

So, moving onto the third area related to funding and reimbursement. So, as we think about accelerating this precision medicine in some of the standards one key aspect is reimbursement. So, we see that insurers, including Medicare, are funding genomic testing for specific chronic diseases like cancer, HIV and heart diseases in patients and their families which have significantly offered predictive and prevention choices. However, limits on reimbursement place both the patient and the healthcare system at risk.

As we consider cost saving policies that will transform healthcare delivery, genomic mapping will need to be one of the chief considerations to enable our healthcare practices to target and accelerate care. Whole genome sequencing will provide the research to produce better outcomes while generating savings from unnecessary tests, drugs and inappropriate diagnosis.

Lastly, at the...fourth, we'd like to talk about patient protection and privacy. So, right now the US has one of the world's most far reaching protections for genomic information, GINA, the Genomics Information Nondiscrimination Act, which provides a national framework for enforceable protections to advance both medical research and public health. GINA creates federal rules to protect insured patients from discrimination by employers and insurance. It is a milestone and a best practice for the rest of the world.

Moving forward we need to think about how can the US close the loopholes that were left in the act ensuring non-discrimination based on genetic information for things like mortgages, long-term care insurance, disability and life insurance markets, and coverage for our military men and women. There is still work to do in this area.

And then lastly, we believe the future is here. The research is ongoing and our challenge now is to integrate the new data into advanced clinical decision support software which can be connected to electronic health records with clinical training required to use the patient data. We need to bring this science into daily clinical operations.

Centers like the Cleveland Clinic are holding summits for clinicians to earn CME credits while building upon the genetic data that is familiar family history, migrating to pharmacogenomics more and more as clinicians begin to weave these additional sources of data into their workflows.

At the Mayo Clinic the goal is to get every physician to use personalized medicine in their practice starting with an alert system issued by the EMR. For example, when a physician prescribes an AIDs drug that causes severe reactions in some patients with certain genetic variance the EMR alert pops up and gives the name and pager of an expert at Mayo who the prescriber can call for advice. This clinical decision support tool combined with genomic data has the capability to change medicine today.

The challenges we need to address here are how we can change workflows and educational requirements to convince doctors to adopt personalized medicines within their practices. How can all sectors of the US government enable this personalized medicine approach by working together with DOE labs who have great expertise in computational science and HBC that can contribute here.

To wrap up, we believe that the 2008 President's Council on Science and Technologies prioritized priorities for personalized medicine which called for the federal government through the leadership of HHS to join with the private sector to create a private/public sector personalized medicine R&D roadmap to coordinate discovery and translational research in precision medicine was critical. The report focused on policy recommendations for technology, regulation and reimbursement. However, five years later many of the issues have yet to be addressed and remain unsolved and the roadmap is long overdue.

So, as we enter the next decade and focus on next generation sequencing we need to get the policy and the standards right to ensure that the benefits from this miraculous new science can provide individualized treatments for the patient at a speed that will dwarf Moore's Law. Thank you.

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

Thank you very much Ashley. I'd like to open this up to the group for questions. I have one, you mentioned the walled gardens as an opportunity and a hope to prevent the walled gardens that without standards you feel will be erected. Could you speak a little bit more to that and then also specific recommendations you have with regard to how standards will help any of the problems you've mentioned?

**Ashley Rees – Marketing & Business Strategist – Intel Corporation**

Yeah, so I think specifically on how the walled gardens get created I think the idea there is that technology is progressing quickly and the standards and policies that we have in the past may not really be as applicable or ready today. So, we need to develop new standards that folks that are developing these technology systems can use and so data is in a consistent format.

Until we have that each individual solution provider is often left to their own devices to create a specific...to create their own what we called "walled garden" and so I think that's what we're seeing today. So, we need organizations like the Global Alliance for Genomics Health, HL7 to work together and create standards that as systems are developed their built around those standards.

I'm sorry I think the second...what was the second part of your question?

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

I think you've answered it, thank you.

**Ashley Rees – Marketing & Business Strategist – Intel Corporation**

Okay.

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

Are there other questions from the group?

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

Yeah, hi, this is Christina Heide, you had mentioned briefly a multilayered approach to privacy and security could you speak a little more to that?

**Ashley Rees – Marketing & Business Strategist – Intel Corporation**

Yeah, so I think the idea is...and I can speak at a high-level I would need to follow-up for more specifics, but I think the idea is that there is not a one size fits all security or privacy model so there is the aspect where we need to have fully de-identified data but we also have to have other security safeguards things like debit encryption, tokenization and access controls that determine who can see what type of data.

It is important as we do these that they are user friendly and yet robust. I think one of the things that we've seen be a challenge for organizations is having these security solutions be so complex that end users seek work arounds to try and get around them which obviously compromises the security intent. So, those are the...that was what I was referring to.

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

Okay, thank you.

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

This is David McCallie, just to follow on that question. I appreciated your remarks about GINA and the need to close the loopholes that's a political big ask but I think it's the right ask, but I want to tie that back to the question of de-identified data and the notion of more wide scaled sharing of data.

I believe that it's essentially impossible to de-identify genomic data, you know, every patient has four million variants so the amount of DNA necessary to uniquely match to a particular patient is pretty small.

Does the combination of wider spread donation of data or wide spread sharing of data, given that it can't really be fully de-identified, conflict with your concern about the loopholes in GINA such that asking for more wide spread sharing is problematic. Is that...is it something that is...is the lack of the privacy protections...the lack of prevention of harms is that sufficient to disinhibit the wide spread sharing of data that you called for?

**Ashley Rees – Marketing & Business Strategist – Intel Corporation**

I think it's a really good question and I think it very much depends on how we share the data. So, as technology evolves potentially could there be a way where we...rather than sharing a cohort of patients raw genomic data could we share something like folks with this variation, you know, with this genomic variant respond well to this drug, which is fully de-identified but still allows the type of research and sharing that could benefit clinical and research efforts.

If the answer was that we're just sending back and forth significant amounts of patient data without their name but still with all of their genomic data then I think that does raise some concerns and we need to figure out a way to ensure that privacy so that it isn't at odds.

I think there is a lot that rides on how we share the data and exactly what type of data is shared and as we go down that path I think there will be a way that we can have wide spread data sharing in a way that still protects patient privacy.

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

Thanks, I have another question but I'll take my turn in line and let some other people ask.

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

Are there other questions? All right, David?

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

So, this again maybe a little bit off the target of our focus on standards but I'm just curious to know what your assumptions are when you opened with talking about the widespread applicability of whole genome sequencing. Is it your belief that this will become a routine test that is used frequently in care, you know, well I'll just leave it at that. Whole gene sequencing or whole exome either one do you think that will become a routine test?

**Ashley Rees – Marketing & Business Strategist – Intel Corporation**

I think we do see it becoming more and more common. I don't know if I can say whether or not it would be routine, but I know in some of the partners we're working with we see that whole exome sequencing especially for folks with cancer or other diseases that's becoming increasingly an aspect of the standard of care. So, I think we expect that to increase going forward as patients are able to see the value and physicians are able to see the value associated with that exome sequencing.

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

Yeah, so that's a nice clarification. I think that...just my opinion is that for something like cancer where you have a very clearly defined benefit from the study it makes a lot of sense, but most patients will have, if you just do a whole exome sequencing just randomly on the patient you'll find lots and lots of very low predictive power markers that don't mean very much.

**Ashley Rees – Marketing & Business Strategist – Intel Corporation**

Sure.

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

And you will create a lot of iatrogenic intervention that somebody goes chasing down potentially dangerous markers that turn out to be irrelevant to that patient. So, I think you clarified that it's use case specific, you have to have a reason to go do it but if you do have that reason then it needs to be done.

**Ashley Rees – Marketing & Business Strategist – Intel Corporation**

I think that's what we're seeing right now. I can't speak to...I can only really speak to the examples that we're seeing with our partners but I think the point you raised is one that is shared by some of the organizations we're working with.

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

This is Leslie I have one other question. You mentioned the computable consent and do you know if Global Health Alliance or HL7, or other groups have done some work that identifies what's specifically unique about a computable consent that would be required for any sort of genomics or genome data?

**Ashley Rees – Marketing & Business Strategist – Intel Corporation**

Yes, so the Global Alliance for Genomics and Health is working with the International Rare Diseases Research Consortium on a task team to determine what should be part of those machine readable consent forms and what are some best practices there. So, right now they're exploring machine readability of consent as well as the impact on data use and accessibility.

So, I think the current task team has been tasked with creating two deliverables, one which is a basic set of metadata that would be needed to describe common variations in existing consent agreements that could facilitate some of this work.

And then also a report that would detail the potential of machine readable tools and this includes things like how smart contracts might impact consent over time. So, I think that task force is currently under way.

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

Thank you.

**Ashley Rees – Marketing & Business Strategist – Intel Corporation**

In addition I think the Texas Health Information Exchange has developed a White Paper on how this could...a machine readable consent process could be used into their local and statewide medical network so I think they may have some best practices and what that might entail in that document.

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

Super, thank you. Any other questions of the group?

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

Leslie, this is Michelle, I think we need to go on...

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

Go on.

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

To our next presenter.

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

Okay.

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

Sorry.

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

Let's go, thanks, Michelle.

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

Thank you.

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

Thanks very much Ashley.

**Ashley Rees – Marketing & Business Strategist – Intel Corporation**

Thank you.

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

Appreciate it.

**Ashley Rees – Marketing & Business Strategist – Intel Corporation**

Thanks.

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

Next up we have Intermountain Healthcare with some very friendly and known faces to the standards group for sure. Welcome.

**Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare**

Yeah, thank you, so this is Stan Huff I'll do a little bit of an introduction and then give Grant some time to talk to the slides. So, we took a little different approach to this than exactly the question outline you have but I can address, I think, the context of, you know, what we're interested in and what we see the problems as.

You know as a healthcare provider what we're really interested in is how we can improve the quality of care that we provide to patients and how we can decrease the cost and that takes, you know, thinking about the precision health area and genetics more generally that means that we're interested in many aspects of this. We're interested in cytogenetic testing, you know, the kinds of things that are done in pediatrics that detect Down Syndrome and, you know, all of those kinds of things.

We're interested in DNA variance and how that affects then the drugs that we can prescribe and the effectiveness of the drugs. We're interested in precision medicine relative to oncology doing genetic testing on the tumor tissue to understand the susceptibility of the tumor to certain kinds of therapies or medications and chemotherapy.

We're interested in the genetic data in terms of providing genetic counseling to families and understanding of the impact. We know that many of the things that we're doing have to do with family history and that there is, you know, a lot of data in family history and then finally we do have a set of researchers that are pursuing research questions where we're trying to understand new associations between the genes and the patient's outcomes.

So, that's the general context and then before I turn to Grant just a couple of comments on things that have been said already. One thing, I have a different perspective than Dave on what HL7 is doing. I think HL7 has actually focused on getting lab tests into EHRs but it's not at the level of moving full sequence data or the FASTQ files and other things.

HL7 is really focused on how do we get the DNA variants and the coded and structured genetic results when you do gene specific testing and ask, you know, does this patient have one of the variants that leads to cystic fibrosis. Those are the things HL7 is really focused on not on standardization of a lot of the activity of things that are coming directly off machines and sequencers and other things. So, I would make that clarification.

And then the other thing is, you know, I would argue that there is actually a cost case...you could justify the cost of doing full genome sequencing on every baby that's born because during the lifetime of that individual, you know, you don't have to have very many things done to justify the cost of that sequence. So, you look at the number of women who at some time will be tested for the BRCA genes, the fact that...it might be on anticoagulants and you want to know whether they're a fast or slow metabolizer.

I mean, you just look at...somebody ought to do, you know, a formal study but my intuition would say that, you know, every individual during their lifetime now would benefit from knowing that genetic information and the cost of doing full gene sequencing is going to be less than targeting individual genes and the earlier you do it in life the more opportunity you're going to have to benefit from that information.

So, that might be a radical view but I think you could actually do the cost analysis and find that it would be cost-effective to just do a full genome sequence on everyone and basically the earlier in life probably the better for the outcomes and for the economics.

So, but with those kinds of radical statements I'll let Grant talk more about what we see as sort of current barriers to accomplishing our goals and some suggestions about things that we think might help as we move forward. So, Grant are you there I hope? Are you on mute?

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

I don't think we got Grant actually.

**Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare**

Why don't you do it Stan?

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

So maybe Marc can dance for Grant or maybe...

**Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare**

Yeah, I think we'll have Stan dance for Grant.

**Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare**

Okay, well, so that's...yeah somewhere Grant is going to be really disappointed too or something I don't know. But okay first slide, I'll do my best. I think I'm a poor substitute for Grant in this.

So, you know, challenges that we have in implementing precision medicine is that one is just competition for resources, you know, we have a lot of things going on, we're installing EHR systems, we're working on how we do accountable care, we have, you know, Meaningful Use requirements that are related to reporting and quality measures that we need to report and all of those things compete, you know, it basically just competes in resources for...there is a set of resources and the sort of precision medicine part of this competes in that same pool with all of these other activities and, you know, you could go on with, you know, implementation of ICD-10 and all of those other things. So, that's a challenge just the share number of sort of things that are going on related to electronic health records and things.

So, the second thing is storing and using family history data as part of the electronic health record.

**Grant Wood – Senior IT Strategist – Intermountain Health Care Clinical Genetics Institute – Intermountain Healthcare**

Stan?

**Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare**

Yes?

**Grant Wood – Senior IT Strategist – Intermountain Health Care Clinical Genetics Institute – Intermountain Healthcare**

I'm sorry but they finally connected me through.

**Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare**

Oh, there we go.

**Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare**

They got you out of the penalty box.

**Grant Wood – Senior IT Strategist – Intermountain Health Care Clinical Genetics Institute – Intermountain Healthcare**

Yeah.

**Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare**

Grant take it over.

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

Welcome Grant. Welcome Grant, thank you.

**Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare**

Nice dancing Stan.

**Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare**

Yeah, so, Grant have you been able to hear at least where we got to here?

**Grant Wood – Senior IT Strategist – Intermountain Health Care Clinical Genetics Institute – Intermountain Healthcare**

Yes.

**Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare**

Okay, so, I just barely starting talking about family health history so take it away.

**Grant Wood – Senior IT Strategist – Intermountain Health Care Clinical Genetics Institute – Intermountain Healthcare**

So, yeah, with the challenges we had as Stan of course covered that first bullet, the second one, how to get family health history and genetic genomic data in the EHR, it is supposed to be EHR not HER, I think maybe since auto correct always does that to us why don't we just give in and call it the health electronic record and just give in to auto correct, but anyway, we especially are looking at the challenges of getting patient entered family health history into the EHR.

So, when you have those first two bullets, especially in the first bullet where you talk about creating the omic repository and clinical genomics platform and getting family history data and all this genomic data into the EHR that's what was required for the third bullet and that is developing the infrastructure to support molecular clinical decision making and that is the goal of all of this.

And so we have to figure out how to solve those first problems before we can get to that final goal of molecular decision support.

And some of the other challenges are with creating the data interfaces with labs and the fact that a lot of times the source of the data does not come in a structured format and of course there is some work with the IOM digitized initiative that's trying to solve that I'll mention it a little bit later.

The last item on this slide is really trying to achieve true interoperability is always a difficult process, you know, trying to standardize on terminology or information models but also going through the processes of creating the standards and then really the biggest problem and barrier is the adoption of those standards and especially historically for the genomics standards, the adoption there has been difficult and hopefully I think now that everybody is coming together in this space we might solve that problem. Can we go to the next slide?

So, I want to mention what work HL7 has done in this space and we've been working on developing these standards since 2007 when we first created a version 3 standard for family health history and a pedigree, but since 2009 we've also created standards for reporting genetic test results from the lab to the EHR. We started with a version 2 standard because back then and even still today HL7 version 2 is the laboratory interface that every EHR uses and every lab uses.

So, we did create an implementation guide that if this group was to review it at some point, and I suggest you do so, it is fascinating reading, but it shows that we've created over 40 different data elements and panels and codes for all of those to really report all the different ways you look at genetic and genomic data, we've created over 15 different coded answer lists for that and just as an example we have data elements that talk about allelic state, amino acid change type, drug efficacy, drug metabolism, genetic disease analysis over all interpretation and it goes on and on. So, it's quite comprehensive.

And because CDA or Clinical Document Architecture was being mentioned in Meaningful Use requirements we created a version of that that's based on CDA. Once again, both of those are available but they just have never been adopted. So, once again adoption and trial of these just has never been done.

Now HL7 is of course moving to the FHIR, the Fast Healthcare Information Resource, so we're taking all of that work that we've done previously under version 2 and CDA and we're creating FHIR resources for genomic information those are still under development.

There are some other standards that we can build on so Stan Huff works, of course, with the Healthcare Services Platform Consortium that allows us to build applications regardless of the data source or regardless of the system platform those applications can run everywhere. I'm already working on, with my new friend David from Cerner there, on looking at how we can do a family health history SMART on FHIR application.

There are APIs to genomic databases that are being developed, the Global Alliance for Genomics & Health is focusing on this, they are working with Google and there are some other folks that are working on these APIs to genomic databases.

The IOM digitized effort that I mentioned previously is focusing on can we agree on a data standard, a minimum data standard to transmit genetic test results from the lab to the electronic health record. We do have representatives from several major labs and representatives from major EHR vendors that are part of that and we're going to start with a pharmacogenomics use case and expand beyond that.

I have to mention other groups that are looking at standards for precision medicine, so WEDI and ASCO Health IT Workgroup, I work with both of those so I know that they are focusing on that and trying to promote that. And certainly there are NIH multi-center grants, I listed two that I know of and work with the eMerge Network and IGNITE, that are working in this space already and there might be some others but they should be participants in this discussion on standards as we go forward also. So, the third slide, please.

So, there were just some questions that Maya sent to us in preparation for this and I just want to address those questions here quickly. So, there was a question as to whether or not Intermountain was involved in some sort of a pilot that was incorporating genomic data in our EHR and I think that was in reference to, once again, this IOM digitized pilot, as I have been participating in that I raised my hand several months ago and said, well, I'm going to volunteer Intermountain and I'm going to volunteer our new EHR platform, Cerner, and a couple of our labs that we work with ARUP and Invitae and we're going to volunteer to do a pilot.

There are going to be other folks that will be doing pilots too, I know that Partners Healthcare will be doing a pilot with EPIC. And so those pilots haven't started yet, hopefully we might have something going in a couple of months we're getting really close to agreeing on that first pharmacogenomics use case and then we'll start the pilot at that time.

But there is one thing to do that pilot but it's another thing...because that pilot just transmits data from the lab to the EHR, but once the data gets into the EHR how are the clinicians going to view that data and this IOM pilot doesn't really address that so that's another thing that needs to be addressed and especially since there are all of these interpretation services that are available like Omicia and two genomics where if a clinician orders a whole exome or whole genome they can use these interpretation services to get a report back and how that is going to be viewed and included in the workflow and in the EHR we haven't addressed quite yet.

So, there is a comment that HL7 genomic standards were probably not adequate for the Precision Medicine Initiative. I'd like to maybe suggest that we have sometime on a future call a discussion with the HL7 Workgroup and really discuss that and maybe identify if there is a gap in our standards and also talk about the FHIR standard that isn't quite finished yet, but, you know, that also raises the question, even if the FHIR standard was available today there aren't any systems out there that could consume that data. So, that's one of the questions we have to deal with.

There is a comment about is dbSNP a standard for genomic and proteomic data and I'm not sure if I quite understood that question because dbSNP is really just a database that stores SNP data and doesn't store any proteomic data, but, you know, it stores data like the chromosome and the gene, and the position, and the, you know, allele and the submitter of that SNP and the date submitted, etcetera.

And I also know there are 14 different HGVS names for that to identify that SNP which is a problem with HGVS and there is a group called ClinGen that is hoping to solve that issue and in fact I should have mentioned ClinGen on the previous slide as one of the different groups that are working in this space because it is important what they are doing.

The last comment here was somebody said, can we try to solve the challenges of getting family history data in the EHR which I think is fantastic, I've been working on that question for a very long time and I'm happy to hear that it still maybe something that we can solve.

There are groups out there that have been talking about this for a very long time. There is a group called the Federal Non-Federal Group of, you know, DoD, VA systems and people that are outside of government that are interested in how to get family history into the EHR and so that group would want to continue working with us, the Genetic Alliance would want to do that too.

I do see that you are talking with Dimitry on the next call so certainly we want to solve that issue too and I think working with the standards that HL7 has done we can achieve that and once again that's something that we're going to be starting to look at with my friend, David, there at Cerner. With that I'll stop.

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

Thank you and we have time for just a few questions before we move on.

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

Leslie, it's David, can I start?

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

Absolutely.

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

Okay, Stan just a comment on your...your comment on my comment about HL7's focus. What I was referring to was the most recent slide deck from the clinical genomics group downloaded from the HL7 website just a few weeks ago Amnon Shabo's work and what I expected to find in the slide deck was a lot of information about how to transmit biomarkers from the lab to the EHR, the stuff that you focused on as being a critical need, and what I found instead was a whole bunch of work on how to build a data model for genotype/phenotype inter-relationships and that's what my comments were based on.

But regardless of whether that's a red herring or not I totally agree that the real challenge is getting the data out of the lab, into the EHR in a succinct and clear enough form so that the EHR can do something interesting with it such as decision support and so to that end my question, and it's really to you and Grant or to Marc if he wants to speak up, is given all of these different groups sort of wrestling with this big elephant of naming and standardizing the biomarkers how do we make progress? Who should drive that process so that we have something equivalent to I don't know like LOINC names for lab tests otherwise?

**Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare**

Well, you know, I think the groups are working together and certainly we could think more about how we could make that even better, but, you know, the IOM group, I mean, the very first meeting they said "oh, well, you know, we can describe sort of what the requirements are but then we need to go to HL7 to get the standard." And the HL7 guys say "well, you know, we're setting up this structure but we recognize we need LOINC codes" and as a Co-Chair of the LOINC committee I can tell you we spend a bunch of time, you know, getting in the genetic result codes.

So, I think they're all working together and we could work faster, you know, I'd have to think about it, you know, if there was some...maybe even just project management people who could help.

But to go back, so, I couldn't agree with you more. Whatever slide deck you got I think is not representative of the work that's going on. So, I've been even a stronger critic than you probably of the detailed modeling which is actually, you know, if you go back to the SAT exams you would mark it as true but irrelevant in terms of moving data, it's like modeling, you know, the heart and all of the chambers of the heart and the conduction channels when what you want to know is what's the cardiac output and how many beats per minute, you know, you would have to know all...you don't have to have a detailed conceptual model of all of the system in order to...so, I'm with you there. So, if that's what you were referring to I'm with you.

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

Yes.

**Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare**

But that's...there's a lot of work that's been done there but that's actually not what I...I would think that's not representative of the work of HL7 nor the value that they're bringing in terms of standards.

**Grant Wood – Senior IT Strategist – Intermountain Health Care Clinical Genetics Institute – Intermountain Healthcare**

And I can do a quick clarification there, so what you were looking at David I think is what we call a domain information model and that was an exercise to look at, from a very high-level, the whole process from...with clinical workflow, the clinician ordering the test going through the sequencing, going, you know, through the data coming out of the lab into the EHR, decision support, clinician interpretation reports in the EHR. So, that particularly...what you looked at was looking at that from that whole high-level, but HL7 does have these standards that just focus on transmitting the data from lab to the EHR in a format so you can do decision support.

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

Yeah and that's what I think should be a priority for us, you know, because if we can't get the data in a consumable way there is nothing much we can do with it except store it and that's not very satisfactory. There is a terrific Vanderbilt paper from a couple of years ago, Josh Denny isn't on our call today but Josh was the co-author of it, describing how they decided to deal with the biomarkers associated with pharmacogenomics and I think it probably predates some of your current work but they just had a very thoughtful approach that kept track of both the biological provenance of the data as well as the most likely useful clinical meaning of the data so that a clinician who wasn't familiar with the marker could at least see the clinical interpretation and have a clue, you know, that he needs to pay attention. So, I hope that work gets factored into the HL7 thinking.

**Grant Wood – Senior IT Strategist – Intermountain Health Care Clinical Genetics Institute – Intermountain Healthcare**

And it will David, in fact I can alert you to a paper that just came out in the most recent JAMIA publication, once again, Josh was part of that, it talks about that same work but how it's going to be done in FHIR. So, I think that would be a very interesting paper for this group to look at.

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

Was that the one on...

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

That's...

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

The SMART genomics platform or was that a different one? Because there was also a fairly recent JAMIA paper on SMART, SMART platform as applied to genomics.

**Grant Wood – Senior IT Strategist – Intermountain Health Care Clinical Genetics Institute – Intermountain Healthcare**

This one didn't mention SMART as much as it really just focused on the FHIR version of genomics.

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

Okay.

**Grant Wood – Senior IT Strategist – Intermountain Health Care Clinical Genetics Institute – Intermountain Healthcare**

Yes.

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

Good I'll go track that one down.

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

Are there other questions for this group?

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

This is...

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

Yes.

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

Sorry.

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

Sorry, go ahead.

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

This is Eric Rose, can you talk just a little bit, orient us to IOM digitized? I had not heard of that previously and to what degree are the standards that are being identified through that effort the same or different from what HL7 is identifying as part of its work on this CDA implementation guide?

**Grant Wood – Senior IT Strategist – Intermountain Health Care Clinical Genetics Institute – Intermountain Healthcare**

So, the IOM digitized is...the first pilots are going to be based on our HL7 version 2 work that we've done. We decided to do that because once again if we want to pilot it our systems still use HL7 version 2. So, it really is taking...if you were look once again at that version 2 implementation guide what we're doing with IOM is we're taking a subset of that, a minimum subset of that just to do this pharmacogenomics use case.

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

Okay, so it sounds like those efforts are being coordinated?

**Grant Wood – Senior IT Strategist – Intermountain Health Care Clinical Genetics Institute – Intermountain Healthcare**

Yes, they are.

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

Thank you.

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

Quick question here from Andrey Ostrovsky.

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

I think...

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

Oh, sorry, go ahead?

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

This is Leslie, just a follow-up question on that, I'm intrigued by your idea you mentioned to work faster, perhaps project management coordination, because it does sound like there are several groups involved and working together but there may be a need to have some help across all these groups specifically to get to the minimum dataset required to get the family health history into the electronic health record and to get the lab data into the electronic health record. Did I understand you correctly Grant or Stan and if you have specific recommendations to how that work could be accelerated and coordinated better. Can you provide those please in just a written comment back to the group?

**Grant Wood – Senior IT Strategist – Intermountain Health Care Clinical Genetics Institute – Intermountain Healthcare**

Oh, definitely would be happy to, sure.

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

Thank you.

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

Great...

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

Other questions, one...

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

Yes.

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

We have time for one more question, go ahead.

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

Quick question from Andrey Ostrovsky here, so I guess I'm here in two capacities one as a software company but also I'm a pediatrician and I found something that the first speaker said kind of interesting, you know, we should test every baby and do a gene sequencing.

I think there is a lot of value and clearly a lot of value in testing for, you know, genetically derived or detectable and intervenable problems like metabolic disorders and that is done I think pretty well with the newborn screen and there is a lot to be improved on that, but when I get a patient that I'm suspecting has something either genetic, metabolic or otherwise something amenable to genetic testing basically what I have at disposal is chromosome analysis and a micro, right, and there is a lot more sophistication we could be doing, but in the setting of primary care what are primary care physicians really capable of doing within their current bandwidth of practice given that we have so many patients to see and so much work to do already.

So, I'd be curious to know if Intermountain Health has addressed that issue with any new more sophisticated approaches to using genomic data to kind of drive value in the primary care setting and then also from a consumer or patient perspective don't we introduce a risk of creating undo, uncertainty and anxiety for the family when they just had this genetic testing done and now they're just sitting on it not really knowing necessarily what to do with that information.

This may be out of the scope of an interoperability or standards discussion but I think guidance on those questions would be really interesting and important when we do take into account how we set things up from a user and most importantly patient, and also provider-centered approach to design and how standards support that design. So, we don't necessarily need an answer to all of those things now but something sort of to consider.

**Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare**

Yeah, the mental model I had in saying that is that you would do the sequence and then you don't try and consume it, you know, at the time but through the lifetime of that individual what's going to happen for instance is, you know, more information is going to become available and at some point somebody is going to say, well what frequency should we be doing, you know, colonoscopies on this person or is this patient at risk of breast cancer based on family history. This patient is now going to be placed on anticoagulation because of atrial fibrillation, you know, what's the genetic status for the prescription of that drug and so it's there and as clinical questions arise that have genetic potential then you can answer the question and create appropriate risk and therapy based on that.

And the cost of doing the whole genome and then just asking those questions as those come up through the lifetime of the patient I think is less of a cost than if you attack it one gene at a time or one question at a time.

And then of course it would be harder to put a dollar amount on it, but having all of that information now available to do new correlations and new research I think is an undervalued proposition from that testing as well.

And so, you know, the genome would be there and, if you will, it's a like library that when I have a question I can go to and ask for this individual patient what is the risk, what are the pharmacogenomics impacts, what...there were be a lot of questions I think in the pediatric environment, you know, just things, you know, a number of things that would go undiagnosed probably for a number of years because it takes that long for us to sort of build up the clinical case.

But I wasn't proposing that...and I think you're exactly right, there wouldn't be...the fact that you did that sequencing I wouldn't propose that we now had to try and explain to the patient all of the ramifications of that at one point in time or anything else, but again, it would come back into play in genetic counseling between, you know, as couples marry look at things where, you know, they might both be recessive carriers of cystic fibrosis, I mean, I just see over the lifetime you don't have to, you know, especially with the cost of the full genome sequencing coming down, you don't have to have very many clinical questions that you answer against that data to justify the cost of doing the sequencing.

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

So, Stan, I'm going to interrupt there, I would think it would be very helpful if you could expand on those ideas of how a primary care physician might use this information and how a patient might use this information further perhaps in writing would be very, very helpful. And thank you for your discussion today and I think we need to move to our next speaker. So, Betsy I believe you're with us or is Jim presenting today?

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

I sincerely hope that Jim is presenting.

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

Okay, Jim?

**Jim Ostell, PhD - Senior Investigator, Information Engineering Branch – National Center for Biotechnology Information**

Yes, I heard I was presenting.

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

Great, well, welcome and thank you.

**Jim Ostell, PhD - Senior Investigator, Information Engineering Branch – National Center for Biotechnology Information**

All right, thank you, so I heard a pretty broad set of things that I was asked to cover I was told that a number of the people on the committee may not be intimately familiar with how genomics is done so I should say something about that as well as cover the several dozen resources at NCBI that might be relevant. So, this is a bit of a scatter shot and I intend to go through these slides pretty quickly. And I'll just say, next, to go onto the next slide and hopefully it won't be too confusing. Next.

So, when you do what's called the sequence there are actually a number of steps, the top two steps in this picture, and it's going to be a little hard not being able to point here, is actually getting the DNA sample and then breaking it up into lots of very short pieces maybe even just a few hundred base pairs long and collecting all those little fragments of sequence.

Once you have all those little fragments of sequence at this point it's not possible for humans to effectively do a de novo assembly that is actually create a sequence of the genome of the person that you just sequenced because it's too difficult given current technology. Instead what you do is you take all those short pieces and you align them to a reference genome which means that you're comparing them to sort of an imperfect representation of the person and what you choose as that reference genome makes a big difference and I'm going to talk a little bit about that later on.

Once you've done that alignment though you look at the differences between all the little pieces that you collected against the reference to try to find the differences and a challenge is to distinguish the genuine biological differences from the reference from, for example, noise in the sequences that you got or errors, or even more problematic, errors in the way that you placed that read against the referenced genome.

Once you've called those variants then the next step is to decide whether they are associated with a condition or a disease and how much evidence there is for that connection. And NCBI is involved in all those steps and builds resources at all those steps. So, in the next slide I'm going to try to quickly walk through some examples and name those resources without going too far in depth. Next. Next.

So, first the big data problem, the big data problem is actually all those little pieces of sequence because you have such a high redundancy but we've faced big data problems before, this slide is from science in the 90's showing the growth of the sequence databases and talking about the catastrophe that was facing us. Next slide.

This is the database today and you can see the danger sign and it's actually not even visible on this graph. So, I think the volume while it's a problem and we have to deal with it, the volume of this data isn't the main issue. The main issue is, understanding it and understanding the quality of it and appropriate use and inappropriate use. Next slide, please. I'm just going to skip this one this just shows how huge the new things are. Next.

Okay, standards about how we store the data, a common form for this data of the short reads align to a reference is called BAM like many formats that are standard within research bioinformatics this is actually a very ad hoc standard.

In the short read archive, which is the US archive at NCBI where we store this kind of data, we can compress it to less than half the size with no loss of the content of the data but now it is an engineered format not some of the words you might hear commonly used for the files. But it's still an important decision as you can see because when you talk about very large data you're talking about millions of dollars in hardware just to store it and you're talking about very large network transfer times when you go between resources or communicated around and so that difference does translate to millions of dollars or hours of transfer time.

In the second SRA-8 version if you were willing to make decisions about the quality of the information, for example, if you have deep enough coverage lots of reads piled up in the same place you can drop precision in the accuracy of each space and if you do that it goes down even further to SRA-8, you can get it down further by reads only once the reads are very high quality and one would expect to go there.

And then the last slide here is if all you did was store the differences from the reference it becomes tiny and actually the big data problem disappears it is not big data anymore. However, to reach this point you have to trust the analysis that led to that set of variants.

While with current technology, and I'm going to show, in just a minute, that you probably shouldn't trust that yet, if we're really going to use this for clinical practice I would hope we could trust it and in fact maybe we should only be using the subset we trust.

And so I'm going to make a proposal here that you basically do best quality calling of the variance and really that's what gets shared around but you hold in reserve perhaps a compressed version of the original reads so that you can recalculate those variants occasionally, but that isn't really what you're transmitting around and operating on in your system. Next slide.

This is about the reference sequence that you call it against. NCBI is the lead partner in the International Genome Reference Consortium which decides what the current public human reference genome is and also analyzes it for problems, directs sequencing centers to make corrections and fixes, and participates in this international consortium and then releases the version of the genome.

The first thing I would point out is that this genome is changing over time, it has accessions and versions, and yet you still see in large sections of the research community they simply say, we call variants against chromosome 1 and that's far too ad hoc we're going to have to get much more rigorous about exactly which version of which reference genome the calls were made against. Next slide, please.

The genome itself is imperfect. It's actually a chimera made from multiple different people. So, the reference genome we're calling against actually represents no real human genome. So, right off the top we're faced with a problem of interpretation on a biological basis. Next slide. Next slide, please.

The other thing is...so one consequence of this is the picture you see in the top this is showing release 38 and chromosome 9, this is the ABO locus, so this is blood type and in an older version of the human genome because it's a chimera that gene is actually partially ABO, it's O Type and it's partially A type and that's because it comes from two different people.

And in terms of short of the research issue of getting the gene for the ABO locus, there is one, but if you're actually caring about medical interpretation this is no blood type that any human has and so one of the fixes that went in was to do targeting sequencing in this area and put in one full length legitimate A1 blood type gene and then create what are called alternate alleles which is other little chunks of genome for the other blood type alleles.

And so that means that the sort of cartoon that most people think of the human genome that it's sort of a black line with coordinates on it and genes is not really true because there are places where it fans out into multiple alternatives.

In addition, there are genes that only certain subsets of the population have so there is no living human being who has every human gene instead you've got to make sort of alternate sets to cover all known human genes. Next, please.

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

Jim, it's Leslie, I'm just doing a time check here, so we need to move pretty fast in order to have time for public comment. Michelle, can we go over?

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

We have to check and see if we can go over.

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

Okay, thank you. Go ahead Jim.

**Jim Ostell, PhD - Senior Investigator, Information Engineering Branch – National Center for Biotechnology Information**

Okay, sorry we started a little late, but, okay, this is just another case of a gene that's involved in disease that had a gap in it and was missing a piece and was corrected later. Next one. Next, please.

This is an important case, this is a case of a tandem duplication of a human gene where two very close variants should have been next to each other but instead were all collapsed as one, a correction was made to add the other variant of this gene and make an accurate human genome.

The danger of it, if you look at the next slide, please, is that because there's only slight differences if you have reads from the other copy of the gene aligned to this one it looks like SNPs, it looks like variants which are those red boxes, because it's the same sequence except for one base difference or two base differences.

And so particularly in areas of the genome with repeats, which also tend to be areas with diseases, it's easy to confuse this sort of repeat structure with variants and so there is going to be a continuous development of the genome and the calling algorithms which is going to change those calls you made at different points in time. Next, please.

There are a number of variation resources at NCBI among them dbSNP which was mentioned earlier. Next slide. dbSNP is basically positions on the genome where a variation has been detected each one of those positions gets an identifier, can I have the next slide, and those RS numbers are a world standard for how you identify that a known variation occurs at this point even as the reference genome changes and evolves over time that RS number will be moved around so that it always points to the same variation even though the background genome changes and so that's important to have that be independent of the reference.

The thing is that this is just all observed variation not just pathogenic variation which is why in this example, which is just against the cystic fibrosis gene, you can see that there is almost 3400 reported variants or 34,000 variants in that one gene. Next slide, please.

That is why ClinVar was developed which is a database which is about pathogenesis it's about the interpretation of those variants so the variant itself is referencing dbSNP but then it also collects information about what condition this has been associated with, the evidence supporting that association whether it's pathogenic or non-pathogenic. ClinVar is collaborating with ClinGen which was also mentioned, people get confused between the two resources.

ClinVar is a comprehensive set of these assertions from lots of sources. ClinGen is one source which has active experts curating this information but it also collects the assertions from other sources such as ACMG practice guidelines, OMIM, GeneReviews, PharmGKB and other authoritative sources and puts them all together in one place for rapid computation against the genome, and each of these assertions also gets a ClinVar accession number and a version so it's citable, you can say this variant was called and interpreted with this ClinVar record, this version in time so that when there is later versions if the interpretation changes you can track back to the basis on which you made your judgement. Next.

This is more ClinVar, next. And just showing that in fact this makes an important change in the cystic fibrosis gene. Next. dbGaP was mentioned, dbGaP is the research database that combines phenotype information in some cases derived from EHRs with genetic variation. Next. It has lots of studies in it. Next.

We collect these supporting study materials and those red dots link it to summary of the phenotype information. Each one of those elements is tracked and versioned, and available for download. Next.

This is just showing that the genetic associations are also there and can be tracked and searched globally and this actually in the animation allows you to see sort of ways that one could imagine dashboards looking at available large quantities of genetic information. Next.

The Genetic Testing Registry, GTR, is sort of the end game, it's a registry of tests which is a laboratory offering to do a test by a particular method against specific named genetic regions and as an interpretation of a specific disease.

For the GTR we're using, for the genetic information genes from the referenced genome, SNPs from dbSNP, and for the disease and condition names we've been collecting vocabularies out of UMLS in particular SNOMED CT and we did talk about using...we are using OMIM and gene reviews all of which by the way are still inconsistent with each other, that's a bigger topic. Next.

Okay, so that's the end of what I was trying to present at this one. The additional slides have to do with some of the issues that were raised about tiered-access to the data, the Beacon Project with the Global Alliance, easy ways of providing secure access to human data over the Internet for example to Amazon for computation, but I'm assuming we don't have time for all that. So, I'll stop there.

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

Thank you, very much, Michelle, a time check?

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

Yeah, so we can go a few minutes over maybe we could take one or two questions and answer them quickly and then open up for public comment.

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

That would be great. Any questions?

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

So, David, has a question. I think you...that was a brilliant summary by the way, I think you hit the nail on the head when you raised the question of whether this data is reliable enough to be used for clinical purposes and I think it's also fairly clear that at the EHR level we're probably not going to save the raw data and reprocess it, that would be the purview of the lab maybe someday it actually it just disappears inside the instruments so the lab so doesn't have the CLIA issues associated with it.

But my question is do you foresee that we will get to a point where storing the VCF file or whatever is the successor to the VCF file along with a reference that the VCF is computed against would be sufficient to persist the majority of the useful information at the EHR level?

And I'm assuming the VCF is a couple of hundred megabytes not much bigger than a full blown MRI scan and therefore manageable? Are we likely to get to that point? I get a sense that we are when I talk to Illumina and other companies like that, but what's your take on that?

**Jim Ostell, PhD - Senior Investigator, Information Engineering Branch – National Center for Biotechnology Information**

I think it's a matter of practice and what I mean by that is if what it's used for is to give you a clue that is it looks like this person has this variant and that's followed up by confirmation that is so then we get another DNA sample and we do targeted sequencing to prove they really do have it I'd say "yes."

If we're talking about believing that answer for all time, say the next...the lifetime of the person I think we're not there yet.

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

Yeah, that's very, very helpful insight, thank you.

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

Other questions? I had a question...I had one question on the dbGaP you mentioned that phenome data as well, the work that they were doing for both family health history as well, is that the group that's trying to coordinate both the genome and the phenome data for the most part?

**Jim Ostell, PhD - Senior Investigator, Information Engineering Branch – National Center for Biotechnology Information**

Is dbGaP?

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

Yeah.

**Jim Ostell, PhD - Senior Investigator, Information Engineering Branch – National Center for Biotechnology Information**

No, dbGaP is a resource it's a database here.

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

Okay.

**Jim Ostell, PhD - Senior Investigator, Information Engineering Branch – National Center for Biotechnology Information**

It's not a group.

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

Thank you. Thank you.

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

You're probably thinking of OMIM.

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

Yeah.

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

And others...

**Jim Ostell, PhD - Senior Investigator, Information Engineering Branch – National Center for Biotechnology Information**

Yeah, OMIM is doing some of that. There are a number of different groups trying to do that.

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

Okay.

**Jim Ostell, PhD - Senior Investigator, Information Engineering Branch – National Center for Biotechnology Information**

I think that's probably a process not an end point.

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

Thank you, it sounds like it. Other questions?

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

This is Eric Rose, real quick, this is hugely beneficial and I might not be the only one in the Task Force for whom this is not already background knowledge and since the slides were more supplementary to the verbal explanation maybe off line if the presenter is able to point us towards some kind of introductory, you know, genomics for dummies type resource that covers the information that was provided here that would be enormously helpful.

**Jim Ostell, PhD - Senior Investigator, Information Engineering Branch – National Center for Biotechnology Information**

Yeah, I'm actually not good at coming up with those sorts of things, but I will ask people here for suggestions and send them onto you.

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

Okay, or maybe write it.

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

In his spare time.

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

Other questions if not we'll be going to public comment I think?

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

I...

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

We have to go public comment, we can do that and if there aren't any then we can open for one more question maybe.

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

Okay.

**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**

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**

Okay, while we wait for our commenters there was a question if you want to quickly go ahead.

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

This is Betsy, I just wanted to make a comment and that is that our discussion...if we have a public commenter they can go now of course.

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

Go ahead Betsy we're waiting to see if we have one.

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

Okay, I was just going to say that our comments from David and Stan, and others have focused on matters which are dear to my heart which is how are we going to integrate this in a way that it's going to be very useful in the clinical environment, but I think that our task as in this PMI Workgroup is actually broader than that because we're supposed to be making recommended standards that would be useful for the PMI effort and I think in the context of the PMI effort we may want to call whatever we think is the current best practice for starting out and actually having the whole genomes of people because I think that's expected isn't it in the context of that project?

**Jim Ostell, PhD - Senior Investigator, Information Engineering Branch – National Center for Biotechnology Information**

I'm not sure of the question.

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

So, Betsy are you asking whether the...

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

Oh...

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

Project at hand is the one million cohort project needed to have the entire genome sequence as recommended by Stan?

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

What I am just saying is, I believe that this Workgroup was put together to provide advice that would be useful in the context of that initiative and so therefore...

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

Correct.

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

I think we are interested in obviously the exchange of data and how, you know, efforts related to EHR data and the relevance of that to this project absolutely, but I think we are also interested, to the extent we're able to do it, in providing advice on any standards for the project as a whole which will of course include the gathering of data for research, current and future research purposes which may or may not ever logically be actually integrated in an EHR in a clinical setting. And I want to make that comment.

**Jim Ostell, PhD - Senior Investigator, Information Engineering Branch – National Center for Biotechnology Information**

Yeah, so, I think you're right.

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

Thank you.

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

Okay, thank you, we have no public comment, but thank you everyone for bearing with us as went a little bit over today. Thank you to all of our presenters we greatly appreciate you taking your time and sharing your expertise with us. And I'll turn it over to you Leslie for any final comments.

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

I think that Betsy's reminder is a good one and we do have a particular task and it is in support of this project and I thank everyone that participated. I look forward to the follow-up responses we asked for in writing to further inform our work in our next session. So, thank you, very much and with that we'll adjourn the meeting.

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

Thanks, everyone.

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

Bye.

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

Thank you, bye-bye.