



**HIT Standards Committee
Precision Medicine Task Force
Final Transcript
September 10, 2015**

Presentation

Operator

All lines bridged with the public.

Michelle Consolazio, MPH – FACA Lead/Policy Analyst – Office of the National Coordinator for Health Information Technology

Thank you. Good afternoon everyone this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Standards Committee's Precision Medicine Task Force. This is a public call and there will be time for public comment at the end of the call. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. I'll now take roll. Leslie Kelly Hall?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Here.

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

Hi, Leslie. Did we get Jon White yet? Andy Wiesenthal?

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

Here.

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

Hi, Andy.

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

Hello.

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

Andrey Ostrovsky? 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? David McCallie?

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

Here.

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

Hi, David. Eric Rose?

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

Here.

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

Hi, Eric. James Breeling? Josh Denny? Lisa Gallagher? Mary Barton? Mitra Rocca?

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

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 Uppaluru? Mazen Yacoub?

Mazen Yacoub, MBA – Healthcare Management Consultant

Here.

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

Hi, Mazen. Debbie Bucci?

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

Here.

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

Hi, Debbie. Okay, well with that I'll turn it over to you Leslie and hopefully a few more folks will join as we get started.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

That's great, thanks Michelle. Welcome everyone. We had some good discussion last week and I want to thank you all for participating and also for those who participated in public comment. As we consider the standards for PMI we need to keep in mind who we serve. Our immediate task is to serve the cohort of patients in this initiative. Our project is not centered around the provider or HIT vendors but the patient and the researcher in support of the patient as new participating members in data exchange. Recommendations should include standards to help facilitate the integration of these stakeholders.

As much as we know that standards are necessary for open exchange we know the wrong standard can prove difficult. There is tension in these competing ideas. However, we know for certain that the absence of standards make matters worse.

Proprietary standards evolve and data blocking can happen simply as a result of the lack of standards. And applying standards after the fact can prove more costly than having minimum standards today that industry evolves over time.

We need to provide direction imperfect as it might be. Necessity is the mother invention and government is pretty good at applying necessity and industry is pretty good at making what is needed innovative.

In the last meeting we briefly discussed privacy and how that related to aggregate data. I was struck by the public comments and these have caused me to rethink my ideas. The history of health data exchange has focused on a record of care that the data collected in the system are the observations, results and the record of care given it is data about us, our genomic and phenotypic data fundamentally defines who we are and what we are made of, it is us and therefore requires a more cautious approach.

Balancing the incredible gains research can make with the use of aggregate data while maintaining the individual's privacy is difficult but not insurmountable. For example, keeping key fields in the aggregate data that can be used to match patient identity from a separate database could be one approach. I'm reminded of the testimony given at the Standards Committee by NIST the encouraged good security practices including not putting all the eggs in one basket. Thoughtful consideration in this area is needed.

So, today the lens that we look through in our recommendations should reflect the urgency and needs of this cohort as if any of us or our loved ones are among them as we could be. So, thank you for your work today and we'll go on to discuss the preliminary standards findings.

It is important that we look at all of the discussions we've had, this has been a tough project to learn, I know for me, to learn all about some of these new standards and what this might mean to this cohort and so I really look forward to your discussion. Has Jon joined us? Okay.

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

Leslie?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes?

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

Would you mind repeating the first couple of sentences that you said about what you thought the target of this work was?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

It's just...

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

I was surprised with what you said.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Well, the target of the work, our immediate need is to serve the cohorts that has been put before us that is our immediate need. And...

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

And where do...where do they think that cohort data is coming from?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Both the patient, the researcher and to the EMR and out of the EMR. So, it's consistent with what we've been talking about.

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

But then you said something...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

It's just the urgency...

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

You said that the EMR was not our target. I'm just...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

It's a target of the recipient of data from the patients and the researcher, from the lab and then the extraction of that data from the EMR to the researcher for use or back to the patient. Those are still consistent. What we've been talking about is the use of those data in and out but also the cohort we're serving or the immediate need we're serving is this particular cohort.

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

Which they haven't even defined yet by the way, right?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

We have defined some definition around that which was presented to us about the cancer patient and I would have to go back and look and see more of the...

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

The...yeah, I think the working group is going to report out on the 17th.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes.

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

In other words the target is even unclear whether it's a large single trial or mini separate trials or...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

So, I just want to register that it's a bit of an underspecified problem.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

It is, it is and we have some initial recommendations and those can include further work.

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

Yeah and then, but go ahead...I'm still puzzled by...well, I don't know, let's just...maybe I'll raise the question later. It just...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

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

It sounded to me like you want data flows that eliminated what was in the middle which...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

No not at all, not at all.

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

But, okay.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So, shall we go onto the next slide? We know who we are and thank you for that. We can go on. So, a reminder is to enable this new era of medicine and I think we know our charge, go forward.

So, we're identifying opportunities for collaboration and pilots, and testing, and standards that support Health IT interoperability for the Precision Medicine Initiative. We're looking at existing standards, emerging standards and identifying gaps. Next slide.

We have a new meeting that we've scheduled for September 18th the time is to be announced but we will be looking at finalizing our recommendations. Next slide.

So, the questions that we gave the presenters were to look at the exchange of the data among the patients, EHRs, researchers and testing labs. What are the key problems or set of problems their organization was attempting to solve? What is the minimum interoperable dataset such as genome and phenome data and are there standards that can support this movement today? What are the gaps and what is needed in the future? Next slide.

So, we have a table attachment that I hope each of you received, we'll also be displaying it today but we're looking at three categories, readily applicable standards, so it's been previously discussed by the Standards Committee or the Task Force with the immediate potential to help PMI, promising standards, those with the potential but are not fully tested, gaps in standards and then accelerators. Accelerators could be resources or standards in development that could actually progress interoperability at the patient initiative or excuse me the Precision Medicine Initiative. So, let's think about all of these things as we review the table. Next slide, please.

So, when we were considering the findings and recommendations we looked at de facto standards, so are there overarching standards today that we have a bias towards using even if they're not fully mature. Mature standards that are...would pass the maturity test for HIT but hasn't yet been used for PMI. What have we not included here? Is there anything misplaced or missing and what are the accelerators?

So, Michelle, are we going to display the actual chart or are we relying on each person to pull that up on their own?

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

We can certainly bring it up if it will be easier...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay that would be great.

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

Okay.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Was that Jon that just joined us? Okay.

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

Lonnie or Caitlin can you bring up the spreadsheet when you have a chance?

Lonnie Moore – Meetings Coordinator – Altarum Institute

Okay, you want the summary?

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

The Excel document. Yeah. Thank you.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So, as we looked to create this graph staff went through all of the testimony that we received and categorized the data standards on the left side and then looked at what standards were readily applicable, previously discussed, the reference that was cited and the date it was discussed.

And so we want to make sure that we have all of this information noted. So, part of the discussion is what are the gaps, is there anything that's been misunderstood or needs to be clarified and we also want to make sure that as we go forward we have any additional information that the team has gleaned outside of these meetings that might be relevant to the cause. So, I think Lonnie we can't get the whole thing up right?

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

I...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay, so can folks read what we've got so far? Is there anything to the right of date discussed? I don't believe there is.

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

So...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

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

This is formatted; it's been turned into PDFs that aren't readable the way the PDF page divisions got done.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

On the screen versus on the...

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

Well the...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Excel sheet itself?

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

What I got was a PDF maybe there is an Excel that was sent out by e-mail or something, but...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Michelle was...

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

There should have been an Excel that was...

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

Yes.

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

So...

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

The only thing that...

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

I'll send it to you David.

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

The only thing I could download was PDFs.

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

Yeah, I have the same, this is Andy.

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

So...

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

No, I have the...

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

Michelle, it's Maya, perhaps we could just send the Excel sheet around to everybody again.

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

I'm just going to send it to the two folks that mentioned it.

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

There was an e-mail that went around. There was an e-mail that went around with the spreadsheet.

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

So, what we can do is on your screen, if you're following along via the webinar, at the top of the screen there is like four arrows that make a box, if you click on that you can...it's much more readable and we can try and zoom in a little bit more.

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

The problem isn't the zoom it's that the spreadsheet is cut in half such that the titles of the columns of the rows are invisible when you scroll down further or...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

If you bring that up in Excel, which is part of that same attachment, on the e-mail...well, she is sending it out now, but it was dated...was 1:28 on the 9th, you'll see the entire spreadsheet.

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

So, Leslie, this is Betsy.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes?

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

To start with a more substantive point or to get onto the substance of it, I understood in terms of what was discussed and that makes sense in putting this together, but I think when we had discussions for example when Josh Denny and others were presenting that there are...since we do expect that some of the data for the cohort will be coming from electronic health records and that certain key elements of the electronic health record, in terms of what Josh presented and what was important to emerge and would be important to this cohort, are things like the medication list and the tests, and the problems.

It seems to me that you would therefore say, for content, it's not that we don't have no standards for those things we have agreed standards for those. So, it seems to me that in the column when it says, existing standards that are applicable then we should list the standards that have already been...are already part of the Meaningful Use requirements and EHR certification for at least the problem list, the tests and the medications, which I think everyone would agree need to be part of the data that's available for the cohort.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Good point, absolutely.

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

Yeah.

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

So that would be usually SNOMED for the problem list, LOINC for the tests and RxNorm for the drugs.

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

Yes.

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

This is...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And then furthermore...go ahead?

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

This is Claudia I had the same thought and taking it one step further I've been trying to think of it as what are the things that we can expect certified electronic health record technology to be able to produce that could serve this and to me it's those categories but it's really the whole common clinical dataset and a question I had is if we put that forward almost as a standard that we know we can extract at a minimum C-CDAs or some kind of API and so data fields. Is that sufficient and what data fields might be missing.

So, I'd like us to do the work of thinking is that largely sufficient for what we would imagine being the phenotypic data other than kind of surveys and things that would be more tailored, one domain for instance that comes up a lot is notes and we don't have a routine expectation that those would be made available, that there is obviously a field within a C-CDA but I think it would be really useful to think about the common clinical dataset the standards that are embedded in that, like Betsy said, and then ask ourselves what's missing that might require additional collaborative work or work in the community to be sure that EHRs can routinely produce what might be needed from a research stand-point for PMI.

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

Well, but...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And when you're thinking about that Claudia you're also thinking about both the data that's existing in the EMR and the data that needs to be added to the EMR as a clinical...common clinical dataset because adding...it's not just the data but we're adding new cohorts or excuse me new participants in the exchange of the data as well. So, when you say common clinical dataset are you just referring to what we now know in the standards or also are you referring to new stakeholders added?

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

So, I just...in keeping with our conversation last time I would highly recommend that we think in stages. So, to me one of the first stages is the ability to get information out of the EHR and feed it into PMI. That could be done with a couple of mechanisms one would be patient mediated which I think is a pathway that NIH has already said they're thinking about.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

Another would be through an existing delivery system but I'm not sure that really changes what's needed from an EHR capability so I would still think of it as, is there a standard kind of expectation that an EHR be able to export these data, are those data fields right and what might be the gaps both in terms of completeness or quality as well as from a stand-point of data fields that might be missing.

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

So, this is David, I mean, not to be too crude about it, but what's missing is genomic data, right?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And phenotypic data from the patient.

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

Well, no, I mean...

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

No, phenotypic data is there, this is Andy I agree with David.

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

It's there.

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

It's there.

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

Yeah, we've got...we may not have the ideal phenotypic data but we've got an awful lot that's the stuff we just enumerated problems, medications, allergies.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right, right.

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

Yes.

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

I guess I was...David; I was talking specifically about the use case of getting data out of the EHR into the cohort. It sounds like you're talking about the round trip back of bringing the...

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

No, I'm...

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

Or are you talking about actually feeding data...

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

Yeah, so I'm talking about...I'm talking about two things; you know, first, well, three things, first totally agree with Betsy that we don't want to reinvent the wheel in those spaces where we've spent the past six years, you know, laboriously arriving at the standards that are now part of the Meaningful Use and Certified EHR Programs, that's a no-brainer, keep that, use that.

But what's missing, there are two things, one is we don't have standards for the capture and transmission of genomic data either via the EHR or directly from the lab to the research community.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Correct.

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

And B or C whatever we're up to, we haven't talked at all about how to get data out of the EHR and into the researcher's world. I mean, that subject hasn't come up to my knowledge, I mean, just generically, forget genomics, anything. Everybody solves that with ad hoc ETL tools today, right?

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

Well...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

We heard a little bit about that from Duke, but, yes, you're right.

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

So, I mean, I think there's some great ideas that we could put forward in that space, you know, leveraging FHIR bundles and stuff, that I think I mentioned in one of the previous calls, but we haven't really dove into that at all and the S&I group that has toyed with that idea a little bit hasn't testified to us, I don't think they've done much work on it frankly yet, I think it's on their agenda, but if they are still going, I'm not sure about that.

But, so I think that, you know, the open questions for us is, okay given that we've got SNOMED and RxNorm and LOINC what are we going to do to capture the biomarkers of interest if somebody is BRCA1 positive is that just a lab test or is that a new thing with new data associated with it? Is it tied back to the sequence? Is it not tied to the sequence? Is it mapped to the SNPs that were present is it not? If it is mapped is it using the SNP db database nomenclature or HUGO, or all those things I don't think we have answers to, do we?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

No, I think what we want to do today is simply have we compiled the correct information here for consideration and then discuss it. So, right now what we're missing in that first section on the left in the green section is a list of all of the existing standards that would be applicable and that Betsy mentioned, and that you enumerated on as well.

And then the next is the area under the yellow which is promising standards but not yet fully tested. Do we have...have we listed those that were all...the information that we've received in our testimony or we've brought to the table, are there gaps there as well and is there additional information needed to assess this information. So, that would be the next area of focus.

Is there anything else beyond the existing standards that we want to call out under the readily available or applicable standards today? If not I think the majority of our conversation needs to go into the promising section of the standard.

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

So, can you explain how...

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

So, this is...

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

How the spreadsheet works? I'm having a hard time reading it.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay, have you been able to bring it up in Excel David?

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

Yes, yes, thanks I've got it.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

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

I had it I just missed it, that was my fault.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay, there...you should see on the left a beige column and across the top there are four pages in the first sheet and it's a green section, it's readily applicable, the yellow section, which is promising standards but not fully tested, the red section which is gaps in the standards and then the blue section which is accelerators that might be able to help promote or distill, or activate the standards work necessary to meet the objective.

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

Yeah and is each row...it's odd that the label of the row doesn't tell you about what the row is about, you have to go across and see, right?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes.

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

But there's things that overlap.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Correct.

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

I don't understand row 5, it has SDC lined up with microbiome data standards and those don't have anything to do with each other.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

They don't think of these as three separate distinct or four separate distinct columns or pages and so we probably should have had the label down the left down each of the colors, okay? So, I want you to read each section as an individual section. Does that make sense?

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

Well in that case let's take the green section, row 5, what does that say? It says None, N/A and N/A.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Because we're...if you go across the...and Mazen maybe I'm explaining this incorrectly, you could pipe in any time to help, so what we're saying is in this section we're really looking at content standards for interoperability in the yellow section only. So, I might be...I'm doing a poor job of explaining this. Mazen can you help?

Mazen Yacoub, MBA – Healthcare Management Consultant

Well, this is Mazen, yeah, I think what we can do to make it a little bit more clear in the first example that David mentioned where SDC doesn't relate to microbiome data standards, we can put those on separate lines just to make it more clear that...and then that also gives us the opportunity to note where if there is a gap and something that's promising that are related to one another then we can put them on the same line.

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

Yeah, I'm...this will have to be redone to be interpretable.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Point taken.

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

So, can somebody walk us through, forget the spreadsheet formatting issues in the green what are we saying? It looks like the only thing that we have listed in the green is SNOMED for family health history.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right and I think back to your point and Claudia's point we have not been...and Betsy's point, we need to go back and include all the existing standards that have already been named in Meaningful Use and their applicability to the content here.

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

Yeah.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So, that's some work to get done.

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

Yeah, I agree, that makes sense.

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

I agree.

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

Now, you know, SNOMED for family health history I would say that is underspecified. What do you mean by that? So, you're just saying SNOMED for the...what aspects of the family health history, the relationship codes, the diseases, the cause of death, I mean, you know, the data...you have to specify the data model into which these code sets apply.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And right now we're reflecting this as what is only articulated today in the standard underneath the referenced section. So, we know there are gaps there. So, part of our work going forward needs to take these, Mazen, is we need to get out the detail of these so that it's easier for the Task Force to see where the gaps are or what promising things can be applied here if there is work ongoing rather than just a referenced link.

Mazen Yacoub, MBA – Healthcare Management Consultant

Okay.

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

And folks, just a quick question, Andrey Ostrovsky here, I've seen under exercises like this one use cases referenced and I don't think we have time given our deadlines to come up with a robust use case and I'm sure a lot of us can think of lots of different use cases, but in making recommendations around or even in identifying gaps would it be helpful to have a very basic use case of how genotypic, phenotypic data and standards could be helpful or is that really too much work given the timeframe we have?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

You know I believe, and Claudia you might pipe in here, I believe that after the 17th we might have more specific information about definitions in the cohort and definition in the work going forward that could give us a use case is that correct?

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

Yeah, I mean, I can check into...yes the recommendations from the ACD should provide us a lot more context and from a...from a use to data stand-point.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Great.

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

Great, thanks, guys.

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

So, I would propose thinking about this maybe...I mean, I'm not sure how to say this, but, you know, for...we need to define the domains of data that are needed, you know, by a clinically meaningful almost a use case but you'd say for example, I'll just pick pedigree, we know we need a pedigree to interpret genomic data robustly and you need a family health history, and you need to decide whether that's the same thing as pedigree or not, and then you need the, you know, what we've been calling biomarkers which is to say the variants that are thought to be relevant to the patient, and, you know, we need phenotypic information which includes the problems, the medications, the allergies, the labs and documents, and forms that could be parsable, etcetera, maybe to be supplemented. And then for each of those categories say, do we have a relevant standard to transmit for example pedigree and then for each of those standards do we have value sets that are adequate, that populate that standard.

So, maybe you say, the HL7 v3 pedigree is adequate and you use SNOMED for the diseases and you use the role codes from the v3 role hierarchy for the relationships or something like that. That's a bad example because I think those are not good standards, but whatever, you see my point?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right and so...

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

Because I think that's what you're trying to do here but it's just...it's not easily assimilatable in this view.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So, it would be helpful even to have this categorized by the different standards layers that we've all been familiar with from the transport all the way through the content and the vocabulary data standards and such. Would that be helpful?

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

Yeah, I mean...

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

I...

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

You know I think that what we do...you know what we've worked on historically has been, you know, moving data across boundaries...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

And we're talking about the boundaries of the lab, the EHR, the researcher and the patient/consumer and we're going to move data across those boundaries and in order to move the data across the boundary you need transport although that's probably the least interesting here. You need a data structure.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

And then you need value sets within the data structure. So, I would enumerate what are the boundaries that we want to move data across? What are the data structures that we think are most appropriate for each one of those boundaries and then within that data structure what are the value sets that we might need, you know, to either accept or say it needs more work, you know, so we could say for example, in the biomarker space the FHIR genomic concept, I forget what they call it, I can't remember right in front of me, I've got the paper but I'll have to pull it up, is the data...is the definition of the resource that moves that biomarker from the lab to the EHR or from the EHR to the researcher but you've got to specify the value sets for each of those complex fields in there. So, do you use dbSNP numbers or HUGO numbers, or OMIM numbers or do they all get remapped to LOINC before you use them, etcetera, those are the questions that we could then say need to be addressed.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And in that we would also be identifying where there could be competing standards that needed to have some sort of reconciliation and/or mapping recommendations.

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

Yeah, exactly, so for example, the IGNITE group, is that their name? The IOM group? You know they've done mappings back to HL7 v2 to move some of these biomarkers around and we could say that's an existing approach that's useable by a lot of people today because v2 is widely supported but in the future if we want to move it to FHIR we would restructure it and, you know, change it in the following ways or that works needs to be done to map it to an equivalent in FHIR which is what I think that paper that we circulated around was essentially trying to do, although I'll have to admit I didn't do my homework to actually go and do the detailed cross walks to see, but I think that's what needs to be done. So, that's a case where, you know, there may be an existing standard v2 that's adequate for certain progress today but we know in the future we want to go beyond that with a more powerful API.

And then on the question of dumping the data out to the researchers there's, you know, a broad question of how do we get Meaningful Use encoded data out to researchers and, you know, the only realistic choice today is the Consolidated CDA and we know what the limits of that are so we could list that as, you know, that's a step in the right direction but we probably want to go to FHIR bundles or something like that that's being defined or worked on by the Data Access Framework S&I Group as a part of their research support effort.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right, so it's the readily applicable and evolving standards that we need and understand that the readily available might be used for a long time or periods until the others are more mature and readily available.

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

Yeah.

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

This is Claudia, I really like...I think we're all struggling to make meaning of this in the context of the cohort and the relationship and exchange of data across the boundaries. So, I really like that kind of clustering of what information needs to move from where to where and what are the...you know, what are the standards we have on this sheet as well as existing laws of doing that which we've heard about and on top of that I might say we can then prioritize which of those exchanges is past critical in the next year to actually get the cohort up and going versus things that are going to be needed longer term, for instance bringing some of that science data back into the EHR I would argue is longer term. But, so, I really like that kind of framework and I think it would help us organize our thinking a lot better.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I think that's great feedback.

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

So, and Claudia...to Claudia's point that list that I just, you know, sort of enumerated randomly off the top of my head is actually driven by EHR considerations independent of the cohort. So, I think those align pretty well. The emphasis maybe different and the emphasis on getting it into the researcher's hands is going to be higher in the cohort, but the vendor community needs to be able to incorporate this data anyway. So, there is not a conflict here it just maybe different priorities for different subsets of the community.

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

Great point.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And the dependencies might be different for each of those.

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

Right.

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

Yeah and, you know, if something is going to get built into the certification test for EHRs than obviously it's going to have a very different priority for the vendor community than, you know, something which is in support of research. On the other hand if it's not a certification requirement and it's just something that we'll do more experiments with before we turn it into a regulatory requirement then, you know, the priorities might shift in the direction of trying to support that research focus. You know vendors are going to respond to what they need to keep certified.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

And that's the whole point...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So...

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

Of the program, right, I mean, that's...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

Why we did it. Anyway, so...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I'm sorry, who was that?

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

This was David, I'm sorry, I had a thought but I didn't finish it and I need to think more before I say anymore so I'll shut up.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay, I think...so what we've heard is this needs to be organized better, we need to have across boundaries indicated, timely lines or sense of urgency that data is moving between those boundaries articulating the existing standards that are already named and the applicability for this use, further definition of the use case after being informed by the report on the 17th. And then going through and getting to the specific detail of the gaps and the standards that are not yet fully there but can help inform this work that's what I've just heard. Did I miss anything?

Does the group feel confident that we have...if we move into the yellow section, if we have listed all of the standards that have been named and in our testimony, is there additional information that we're missing here back to I think David's point of should we name where standards in this area might actually be in conflict with existing standards or competing, are there other kinds of reference information you would like to see here as we go forward with recommendations?

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

This is Eric, so we're on the yellow section now right?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes.

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

Yeah, okay, so the two that I thought or actually the three that I thought we might want to include there are first of all OMIM, O-M-I-M, which hasn't really come up too much but the nice thing about OMIM is that it actually has...it has codes that represent phenotypes and codes that represent genotypes and a link between them. So, you know, for sickle cell anemia there will be an OMIM code for sickle cell anemia and there will be an OMIM code to represent the specific...the various mutations that can lead to sickle cell anemia and, you know, whether it's somewhat recessive, dominant that sort of thing.

So, I think OMIM may be a potential terminology that allows bridging between the kind of data that's going to be recorded in patient records and the kind of data that might be in genomic testing.

The...you have HPO, HUGO probably merits mention in that it's the sort of de facto standard on the naming of genes themselves and or HUGO produces a terminology, HUGO's an authorization, produces a terminology that sort of is the official naming of genes.

And the other one that I think we might want to mention at least is...that we heard about in testimony is dbSNP and, you know, dbSNP is an enormous database and I don't think anybody would suggest that it be sort of somehow represented in the database of every installed electronic health record system, but there may be a role for some kind of service that can consume dbSNP data and maybe spit out something that is, you know, represents something that can be consumed in some other manner that's some synthesis of, you know, indicating the clinical significance of a particular polymorphous.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Great.

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

So, this is Josh Denny and I'm sorry that I was late joining...I wonder in this discussion have you talked about ClinVar or ClinGen?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Not yet.

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

Those are the two resources that has...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Please elaborate, okay.

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

This data. So, in dbSNP you're going to have, you know, your SNP information and location, and then it's linked to...there is linkage to other resources such as the, I'm forgetting the name of the acronym, but it's a phenotype/genotype linkage that is NCBI maintained with all the GWAS catalog findings and things like that and then there is ClinVar which is capturing particular variants the their clinical significance linked to, you know, particular phenotypes and a level of evidence.

On top of ClinVar is something called ClinGen which is being developed which will have really more firm recommendations on kind of the clinical action ability whereas ClinVar will aggregate up all the different genetic variants and what was found and make a call but we don't really know at that level whether or not this is for sure going to be a variant of unknown significance or it is pathologic, we're just bringing these collections together and then ClinGen is going to try to...will have a layer of more certainty on top of that.

And in terms of how they're representing the phenotypes I'm not exactly sure I think some of these have used...may have used SNOMED to some degree but I'm not 100% sure what they used.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Great, thank you.

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

So, this is David, I'm curious Josh if you looked at the paper that we discussed in one of our previous sessions from Gil Alterovitz and Jeremy Warner, and Zak Kohane, and some others where they proposed some FHIR resource definitions for what I would call the biomarkers, they call it a genetic observation and if you look down the list of things, the fields that they suggested should be included in that it mentions most of the nomenclatures that you just described adding HGVS for if you describe the amino acid change in COSMIC, I don't know what COSMIC is but, I like...

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

It's a cancer variant.

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

Okay, good, so...

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

Somatic variants.

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

So, they've got a pretty concrete proposal coming from some people who I think know what they're doing. Is that something we could start with and suggest that we think this is a good starting point and the community should refine it?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

We certainly can consider that. I think that as we initially...let's make sure that all of that table in that...there was a very detailed table I believe in that article...

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

Yeah.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

That described definitions. Mazer that needs to be included in this section under the standards that are promising because I think there was very specific recommendations as part of that article that we should consider.

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

Yeah and so I would go back to the, you know, notion that we list, you know, the places where we want to move data across boundaries and what we've been calling biomarkers, which admittedly is a bad term, but just a placeholder until we get a better name, you know, this particular proposal of a genetic observation is a pretty good candidate for that and we might say, you know, this is a proposed but not yet mature standard and here are the fields and the value sets in some cases they'll probably be no-brainer value sets in other cases we might suggest that, you know, work needs to be done like dbSNP versus ClinVar is that a settled space or should we keep that open.

But I like you know...I would do that with the same for the pedigree work that's under way in the FHIR community, we had a call about that yesterday, unrelated to this Task Force, but Lloyd McKenzie has rounded up all the current best specs for pedigree and I'd be happy to circulate those and add them to the list of either, you know, this is good enough to use or still needs work...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

That's great.

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

I think we can get pretty close with stuff that...I don't think there's much stuff to say it's settled but I think there's a good nidus of things we can say, this is very promising work that just needs to be pushed forward and piloted.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I have a question for Andy. Andy you pushed back on the, we have enough phenotypic data was your response to the patient generated health data and I have a question around that because what I heard often in the testimony is that without the rich response from the patients, more detailed information, that there wasn't enough context and so you just mentioned that you felt there was enough to begin with in the EHR.

The folks from Duke even in their primary care model mentioned that they did questionnaires with patients themselves, I think we heard that on every single testimony except for the one that was taking the data directly from claims I believe and I can't remember who that was.

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

Yeah, so I think that...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So, Andy can you comment more on that?

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

I would be happy to comment a little. I think that the EHRs are likely going to store increasing amounts of phenotypic data. The questionnaires both ones the physicians, in other words, or health professionals administer and ones that might be administered on an ongoing basis by patients and families, and the problem is going to be that the core problem that we have all the time with a lot of what's in EHRs and that is that we don't have a standard data model and we don't have standardized categorical responses for some of even the most basic questions so that what we will have is...we can extract things using whatever ETL strategy we want to use but there's this mess because while we have vocabulary standards, you know, in terms of SNOMED and LOINC, and RxNorm, we have a number of other standards that we've established.

If you want me to tell you the gender of somebody who is contained in any cohort I would have a tough time being absolutely certain that I could describe gender with any specificity because of the way the data models are in the prevailing EHRs they are very, very alterable, not...or more importantly if we're looking at genome and we're trying to relate it to some concept for example like race and ethnicity what are our categories? If somebody self-reports that they are in some ethnic group what does that really mean?

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

Well, so Andy...Andy?

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

Yes, Sir?

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

This is David here.

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

Yes.

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

I mean, one of the reasons to push for FHIR bundles as a way to do these exports is to take advantage of the fact that mappings to the FHIR profile will have to be done in order for FHIR to be useful for anybody. So...

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

Right, so I agree with you David, I support it; it's just not something that anybody has done.

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

Right, right.

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

In the meantime, you know, we have increasing numbers of US citizens who have huge amounts of data, I mean petabytes of data stored in prevailing EHRs enterprise level and other systems and we're creating a big problem for ourselves if we don't do some work either on the FHIR side or on, you know, standardizing self-aspects of the data model so that we can make sense out of all of it.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So, last week...

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

Because...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

At the Standards Committee...

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

And I think...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

This was Steve's recommendations on the Interoperability Advisory specifically around some of the issues you mentioned gender, I think they recommend the Fenwick Institute definitions of gender.

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

Right.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

They had further recommendations coming forward that I think we could pull from those minutes to also add to this for consideration.

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

Yeah and Leslie I...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And like health I...

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

I think we just have to highlight it as a problem.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

Because genomic data is so...

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

Yeah.

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

So specific that if we have all these broad variability in the way people report information about themselves or the way their clinicians record information about them even though it's all digitized we will have a nightmare in terms of understanding it whether it's for clinical purposes or research purposes.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So, that's a big gap and the other one that I think you began to touch on was the versioning problem as we bring in new participants where we have many people perhaps asking the same information over and over again or different questionnaires being used, or different laboratories or research data. So, I think that is another sort of overarching problem that could impact this work, how do we manage version control across this, our existing group let alone adding now the researcher and the patient to the mix.

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

Right.

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

But so this is David, I mean, you know, again, at risk of going pedantic, there's no magic solution to these problems the best standards-based approach that we have today is to use FHIR resources, which are simple in their definition and FHIR profiles which allow for very specific constraints to be put on the range of choices for any profiles resource such that if people want to share data in an interoperable way they have to map from their internal structures to those profiles before they do the sharing and there's no other choice, practically, you can either share the data unmapped and let the researcher do the mapping which is what happens today or you can map it to the standard and then share it which is I think where we'd like to be in future and Meaningful Use is a powerful driver of pushing us in that direction for other purposes, so, you know, these mappings were unheard of six years ago and now everybody's knuckling down and doing them because they have to, to be a meaningful user.

So, I'd say, you know, we have to identify what do the resources look like, what are the value sets that we think should constrain those resources and gender is one that needs to be constrained obviously, race and ethnicity need to be constrained and then say that leaves us with a big mapping problem and, you know, it's up to incentivizers to figure out how to get people to go do those mappings.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Is there an advantage for isolating our recommendations to only one type of technology option like FHIR versus a document exchange or is this an "and" rather than an "or?"

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

Well, I mean, you know, the nice thing about standards is you can have as many as you want to keep everybody quiet, right, so what have you accomplished, you've just, you know, exploded the number of standards to keep everybody happy with their space. This was kind of Betsy's point on our call last time is we don't want to do that.

So, you know, the FHIR as an API technology is sort of a don't care but a FHIR resource, the definition of the fields and the value sets that the profile attaches to those fields it's hard to get any more basic than that. It's a lot less complex than the v3 model because you don't have to go through all the RIM shenanigans and it's a lot less complex than some of the NIH current or the NCBI current models where they just go into, you know, excessive detail. So, it's the best compromise we've got but it's not about...

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

And...

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

It's not about the API design it's about the resource definition.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right but I'm struck by a comment you made a couple of meetings ago where you said when FHIR was created we asked if we had to do this all over again to solve these problems would we come up with a document exchange system or would we come up with a create-based system and so the answer was "no we'd come up with this. This is something that's evolved and grown out of it." So, is there merit in then saying that in this new application for this cohort it's worth leapfrogging to these newer standards and resources...

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

I see what you're saying.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Rather than back pedaling back, because the fact of the matter is the data, with the exception of the phenotypic data, it really doesn't exist in an EHR today we're talking about new movement in, at least in a standards way, new movement in and out, new cohorts being added, new use cases for retrieval of data into research and back again, and so therefore by nature, by adding these new constituents and adding this new data we actually have...a new ecosystem that we're adding.

So, is it worthwhile to apply the new ecosystem to this new technology versus retrofit. Is that something we want to consider?

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

So Leslie, this is Claudia, I think one thing to think about, and Josh can weigh in here too, if we're talking about wanting to potentially start a PMI cohort over the next month's not years.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

A question is how do we get going in the space of let's say 9 to 12 months and it's an open question to me whether the...so from the stand-point of getting phenotypic data out of the EHRs it would be amazing if we're ready to do that...and I think there might be promise in that, I guess I'd leave it up to folks who can represent sort of how ready we will be from a deployment stand-point as to whether that's really a realistic proposition over the next...so I think...I guess I'm anticipating we'll need a phased approach given that we have to get going and I doubt we'll have broad deployment of the APIs release...as a sole response. I don't...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And...

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

I'd be welcome to other people saying that's not the case.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And perhaps is a boundary question, something coming from the labs into the EHR has a more traditional use case to our existing HL7 messaging and document exchange, data coming out of the EHR in this new ecosystem might be more applicable to use a FHIR resource. Does the group have comments about this?

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

This is Mitra...

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

I think too you can think about, in terms of the near-term, you can think about this in a few cases, you know, the clinical data which already has a variety of structures and we need a transport, you know, some sort of common standard or standards for transport and sharing, and, you know, enumerating what the value set could be, but, you know, for the genomic data that's not necessarily going back into EHRs in the early part of, you know, PMI and the generation of genomic datasets integrated with EHRs is sort of a little bit of a...sort of two independent data streams. So, we have to think about standards for both, but the timing of them probably gives us more leeway in terms of what the standards used could be.

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

And this is David, I think that there's a reason to believe that we'll have to backport some of these new domains into the v3 data structures. So, I can imagine a point where the Consolidated CDA will have new templates and new sections to accommodate some of these new domains but I would do that as a backport of a much simpler FHIR-based negotiation of what the data should look like rather than go through the v3 machinations which is a pain and...

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

Yeah, I like...sorry go ahead.

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

Leslie...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So, back to Claudia's point, let's say if we had...even if we had something right now today ready for discussion and then balloting in that normal process what is the cadence of that deliverable being balloted accepted and tested? Is that a one year process? So...

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

Well, you know, the...I mean, you're talking about FHIR? Balloting FHIR standards?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I'm talking about document exchange versus FHIR. There is a cadence in the standards development themselves...

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

Yeah.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And so what does that...how does that match the sense of urgency we have in this to...

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

Well...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Exchange data for pilots?

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

None of the current cadences line up with the urgency...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Correct.

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

That Claudia was describing that's just...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

It is just not in anybody's time table either way. I mean, I think that's a very big challenge. Now if the goal is to get the existing phenotype data that is captured by problems, medications, allergies, observations, etcetera in a Consolidated CDA well that's doable today.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

And I think that's where you have to start, you know, the research community will probably gaggle to the thought of parsing CDA structures but so be it, you know, that's the best exports that we have today that are standards-based.

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

In some ways though...

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

So, we're talking about the future.

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

The getting a standard that is parsable, you know, and having it, you know, once you have it even if it's not what people are used to its doable.

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

Yeah, yeah, absolutely and then...and people have begun to figure it out, I mean, you know, there's code out there to parse a CDA.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

I just...I wish this would not use the CDA process as a way to invent these new spaces. I would backport once the new spaces have been tested and settled on with much easier technologies like FHIR.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So, the green section...

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

Leslie, this is Mitra from FDA, so there are actually two clinical genomic workgroups of HL7 have been working on this problem for many years and they have two implementation guides, one is based on CDA on genetic testing reports and that is to get genetic testing lab data into EHRs and PHRs. And then they have another one for a biomarker called gene expression release 1. I mean, we can start...and they have passed the DSTU, they have been working on it for four years.

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

And I'm...but I'm getting a sense in the community that people aren't real happy with that and I don't know...I'm puzzled about that. When we talk to people nobody mentions that work.

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

Oh, yes, we are always...like at the FDA we always review it, these two.

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

Yeah, I just...

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

Because the use case is like the pharma company working on like colon cancer and they want to do the clinical trial on a sub-population with a specific genetic biomarker...

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

Yeah, so that's what...

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

And then send the data to...

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

I think that's what that IOM group was attempting to standardize. It's odd to me that this clinical genomic workgroup's output has not gotten lot of traction. I don't understand why.

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

Yeah, that's strange, yeah, they actually have just finished a DSTU the second time that they finished a DSTU.

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

Well, we know that a DSTU doesn't mean much if it wasn't balloted by people who are going to use it. So, I mean it could be very important or it could be an irrelevant detail. So, that's...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So, it's something that needs to be in our consideration and under the green section as an existing standard, whether or not...

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

Yes that is what...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Going...

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

Yellow section. So, the clinical, the gene expression is in DSTU, the other one, the gene...genetic testing report is a normative standard.

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

Yeah, again, a standard is not useful unless the people that are going to use the standard were involved in the creation of it and I'm skeptical simply because people aren't talking about that work and I could be...just I'm not looking in the right places and I'm perfectly willing to back down and say it's widely accepted but in the conversations that I've been in nobody seems to bring it up which implies to me that it hasn't passed the muster of practicality or something even if it is normative. Normative just means...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Maybe...

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

It's been balloted.

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

Yeah, but, I mean, for Leslie for her list we can add this too.

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

Yeah, absolutely.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes.

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

We need to figure out why...

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

But I know that actually they are working on a FHIR, creating FHIR resources based on the work they have done with the CDA genetic testing.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Perhaps we could take a few minutes at our next meeting to hear from that workgroup chair to describe what they're doing with the FHIR resources...

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

Okay, yes.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And where they are in the normative standard. Can we do that Michelle?

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

Well, we need to make sure we have the right people and that's the real question, who the heck are the right people, this is so fragmented right now.

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

Maybe we need to...David maybe you could ask around, this is Betsy or maybe I can too, to see, because Mitra it sounds as if the workgroup that is certainly interested in it is, you know, people who are running trials and on the pharmaceutical side, is that what you described as the use case?

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

Oh, that was one of the use cases and they always ask FDA to review the material, but they also have individuals from Partner's Healthcare System who use it for clinical research.

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

Okay.

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

They have five...the workgroup has five co-leads or co-chairs.

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

That could be part of the problem.

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

Someone from Boston's Children's Hospital is on it too.

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

Yeah...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And...

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

I thought...I have sort of heard reasonable things, my general impression of this work has been sort of positive but David from what I've heard from people, but let me see who I can find.

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

Yes, I can...

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

Because I think...

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

Yes, I can do the same.

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

It is absolutely true that sometimes you have a group that's very interested in something and thinks it's great and then there are a bunch of people in the broader community who feel...

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

Yeah.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Everybody mute? Yeah, I think it would be interesting to know if this is generally pharma led that just gives us an idea that the lens they're looking through when making these recommendations if there is a significant provider involvement, research involvement and HIT involvement then it can give us a little bit more comfort that there's a broader group of stakeholders, because I think David's getting to, are the right people involved to make a recommendation that would impact this work or is it making recommendations to things that aren't related to the work we're on right now...

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

Yeah and I...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Just by the nature of where they are, right?

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

Yeah and I...you know, I sound too harsh, I just...I'm cautious because when I ask my colleagues in HL7 they don't point me to that work and it just...it seems odd. So, I'm just trying to figure out, you know, is there is a disconnect there, is it just that the work is targeted to a different use case or is it just a visibility problem and we need to just surface the good work that's ready to go.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes.

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

I...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And Mitra maybe it would be worthwhile...

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

I can...yeah, I am a co-chair of another HL7 workgroup so I can reach out to these co-chairs and ask them to present to us.

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

Is it...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

With an idea of its applicability...

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

Yes.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

With this work at hand...

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

Yes.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Versus a justification of the existing use case.

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

Okay.

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

That's a...

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

Well, yeah, and of the other work that's under way. So, why did the researchers from Boston Children's...

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

Yes.

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

And Vanderbilt publish a different model two weeks ago that doesn't reference that work? I mean it's...

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

I know.

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

Was it ignorance or did they think that it needed to be done differently?

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

When they have someone from Children's Hospital on their co-chair at least.

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

Yes.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay, thank you very much Mitra.

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

Yes.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Other comments, items that are not here or in the red section gaps that we already know even given the fact that we don't have a complete inventory in the yellow section?

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

Quick note, Andrey here, I've referenced it before but I think it's important for everyone here as well, H6 references family history, I think this is an important opportunity to look far beyond just the immediate information that can be gathered in EHRs even if it's a little bit out of scope for this work looking at more upstream health determinants even if it's a placeholder for gaps to be addressed in the future not necessarily in the immediate term, things like built environment, access to care, access to housing, adequate nutrition, etcetera, etcetera, even...it is important to call out recognizing that data isn't even collected in EHRs in a systematic way in many cases.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

All the psychosocial as well as determinants of environment, correct?

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

Exactly, yes.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Other items that folks would like to make sure are called out even as a placeholder?

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

Yeah, this is Eric, we're on the red section now right?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes.

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

...knuckled headed primary color...so I think one area against that should be called out is with regard to the genetic variants among infections, among infectious organisms causing chronic infections particularly hepatitis C and HIV those are two good examples where currently precision medicine would consist of, in many cases, analyzing the genome not of the patient but of the infectious organism and making treatment decisions based on that because it can tell you things about the likelihood of response to different, you know, antivirals for instance.

And I think that aside from maybe dbSNP which covers non-human organisms I think that maybe to some degree a gap in availability of...there is some coverage in LOINC, there may be some coverage in SNOMED but I think it should be called out.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

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

So, I didn't express that in a very elegant or simple fashion but hopefully you get what I'm talking about.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

All right. Thank you, no I got it. Others? So, I'd like to move quickly to accelerators and these are items that can, through improved process or convening of groups, can get to consensus greater. David has mentioned recommending that FHIR resources be accelerated in this area. We've heard about family health history being accelerated. Who would we convene and how would we motivate that acceleration?

So, this example on the sheet is just for example purposes, we heard a lot about HPO and perhaps a specific...I think the article we read it was maybe SNOMED only represented 30% of what was already in HPO, as I understand those groups are working together, Betsy provided some additional information to us, but is there a way that through recommendations of this group we could accelerate those groups coming together in order to come to resolution or consensus earlier? What kinds of...

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

Leslie?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Accelerators do you think...

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

This is Andy, I think there is a process accelerator that David suggested an hour ago that I don't want to lose and that is that trying to make sure we focus most of our attention on what's relevant now. There are specific genomes or genetic conditions that are well described that are clinically important today that we can make sure we have the capacity to do all of the things that are necessary from both clinical care and research perspectives.

If we try to, use the tired metaphor, boil the ocean, and do everything for all genomics it's overwhelming. But if we focus on the top 20 conditions for which genetic information is crucial in terms of clinical decision making and really make sure we've fleshed out all the information needs for those I think we will have made headway in areas that matter to patients and clinicians today, and we will have set process standards for how to do that and sort of content or parametric standards for how to lay those things out in EHRs and in research databases that will be useful for genetic information to come. I don't know, David, if that...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So, that recommendation...so you would be recommending that the top 20 there be consensus across that top 20 if there wasn't any already.

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

Right.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And that this 20 would be used across each standards organization named as one of the yellow or those working on the gaps...

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

Right.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

To focus their attention and constrain their attention around those top 20 so a deliverable for us or recommendation for us would be convene the following stakeholders to gain consensus on the top 20, publish those top 20, those areas of interest for more urgent or acceleration and standards development. Would that be...

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

Exactly and then I would say we have a further potential convening role once we've identified the top 20 and who needs to participate in standards development is actually forcing them to agree on a deliverable date and getting them together so they can meet that deliverable date.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Great. That's really helpful.

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

One thing, Andrey here, that would be interesting and this maybe a little bit downstream, but actually going to accelerators in the sense of digital health, technology or otherwise entrepreneurship or innovation accelerators, so organizations, standalone or as part of other institutions that help to nurture the innovation ecosystem. I think if that innovation ecosystem were made aware that there are efforts to coordinate standards creation and that innovation ecosystem can then guide all of the innovators toward a common set of standards or emerging standards, I think that level of education will streamline a bunch of innovation efforts so that there isn't silo'd innovation happening.

And then also an outreach in a similar sense but to consumer groups. I think we need to really make sure that even though we're focusing a lot on technology and standards, and somewhat technical esoteric concepts to an average consumer of health or healthcare, informing consumer groups and engaging them really early on actually is probably really important to make sure that we clinicians or we technologists, or we policy makers aren't alienating or not alienating but ignoring the most important folks which are the consumers and the patients.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I would agree with that and maybe in support of all of the themes here is, as Andy recommended, the top 20 areas of disease or conditions, I think there is a convening effort across getting consensus around family health history, pedigree and such maybe patient generated health data included in that so that we have that as another accelerator.

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

This is David, I'd be leery of the top 20 a little bit in that, at least from the genomic perspective it's a long-tail problem the things that are of most interest tend to be the things that are fairly rare because that's where the breakthroughs are going to come and the deepening of our understanding, you know, common variants are common and don't have probably a whole lot of manipulable effect.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Is that the same...would that apply to the new use cases of existing drugs David? Does that apply as well?

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

Well, I just...I'm leery of anybody...of a workgroup setting priorities and I mean, I understand where Andy's coming from and we don't want to get bogged down in details so that important things get ignored, on the other hand, you know, kind of by definition genomics is about a long-tail.

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

Yes, David, I know and I'm going to push back though, we have to start someplace. We can't operate in the tail.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

Yeah, but what does this group have to do with that? Isn't that a market decision? Isn't that, you know, some...

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

No, don't misunderstand what I'm saying, I think that if we work on the common things people will perceive them to be valuable and put their energy into it and we will set a process in place for then dealing with the larger volume of more uncommon things so that we'll do it the same way.

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

Yeah, well and that's why I think that, you know, getting...if we can get pedigree right and get people to adopt it and support it, and capture it then everybody benefits the common and the rare.

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

Right.

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

If we get, you know, biomarkers or gene expression or gene facts or whatever we want to call it correct then, you know, labs can start sharing structured data instead of just gibberish reports. So, I think we're on the...I think we are addressing the fundamental problems at least from a Task Force of a Standards Committee anyway.

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

Yeah.

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

The cohort workgroup is going to define their priorities and those will be driven much more by clinical facing considerations and underserved population concerns, and what is the federal government interested in addressing those things but that's their job. We'll sit back...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And that might give us the roadmap then to have the constraints that Andy talks about so that we are in fact working across different standards organizations or technology alternatives towards that constraint.

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

So, this is Claudia, and I'm not as educated about the various standards efforts as many of you are, but that maybe gives me some ignorance that's helpful, it feels like this is an ecosystem of standards organizations that's not necessarily the typical ones that ONC interacts with, I'm thinking about the Global Alliance Group, and I'm wondering if we need a really thoughtful review of where each of those organizations is in their kind of scope, because what I wouldn't want is for ONC to take on a set of activities that are actually already being well addressed elsewhere or where the ONC credibility maybe doesn't extend.

So, being really thoughtful about the scope of activities that makes some sense for ONC to lead and maybe that is focused more on bringing genomic information back into clinical practice and exporting phenotypic data from the EHR for use in PMI, right? Maybe it's some way to narrow it.

Because it just seems to me like one could easily wade in and not be seen as the credible entity to make decisions for other folks like researchers that are already out there doing stuff. So, I...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And I think when we're advocating for accelerators does not necessarily mean that ONC is the recommending body but that we are recommending these different bodies march to this drum and whether it's a constraint technical definition, whether it's taking the existing use case and saying we're going to constrain around those only, whether it's some broad reaching or swaths of information like the pedigree data, the gender and such that would benefit no matter what condition, disease we were looking at. That's I think where we can provide help.

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

Well, and this is David, again, you know, we are fundamentally focused on EHRs and EHR related HIT, right? I mean, that's who we're drawn from the HIT Standards Committee so our expertise isn't in any of these genomic spaces with the exception of Josh.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

None of us have even done research in it to my knowledge.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

So, I think what our job is to do is to call attention to the stuff that needs to be pushed forward with respect to the space where we are authoritative which is HIT technology and, you know, we can be informed by the experts like Josh on our workgroup here, but, I mean, we wouldn't know a dbSNP if it bit us.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Maybe if it did twice. That's good caution and I think we had some really great discussion. We have a lot of work yet to do before our next meeting I think to re-organize the table as was discussed, to add the additional information and then I think there's some significant analysis that's going to have to be done going forward. So, our recommendations will probably be very broad initially with recommendations on further work. So, with that I think Michelle we have to have public comment.

Public Comment

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

Thanks, Leslie. Lonnie can you please open the lines?

Lonnie Moore – Meetings Coordinator – Altarum Institute

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

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

It looks like we have no public comment but we also are having technical difficulties. So it looks like no public comment. So, thank you everyone.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thank you, Michelle. Thanks, everyone.

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

Have a great rest of your day.

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

Thanks, bye.

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

Bye.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thank you, bye-bye.

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

Bye-bye.

Public Comment Received During the Meeting

1. Andrey Ostrovsky: Quick follow up question: are we limiting to EHR or HIT more broadly? I think this needs to be stated explicitly because EHR focus is really limited and may set wrong expectations