



**HIT Standards Committee
Content Standards Workgroup
Final Transcript
March 23, 2015**

Presentation

Operator

All lines are bridged with the public.

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

Thank you. Good afternoon everyone this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Standards Committee's Content Standards Workgroup. 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 will now take roll. Andy Wiesenthal? Rich Elmore?

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Here.

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

Hi, Rich. Calvin Beebe? Charles Jaffe?

Charles Jaffe, MD, PhD – Chief Executive Officer – Health Level 7 International

Here.

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

Clem McDonald? Hi, Charles. Clem McDonald? David Dinhofer?

Christopher Muir, MPA – Senior Advisor – 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, David.

David Dinhofer, MD, MS – Chief Medical Information Officer – Infotek Solutions and Services

Hi.

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

Dianne Reeves or Larry Wright?

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

Dianne Reeves is here.

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

Hi, Dianne.

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

Hi.

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

Floyd Eisenberg?

Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC

Here.

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

Hi, Floyd. Grahame Grieve? Jamie Ferguson? John Klimek? Joyce Sensmeier?

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

I'm here.

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

Hi, Joyce. Kelly Aldrich? Kevin Kirr?

Kevin Kirr – Clinical IT Implementation Consultant - Dignity Health

Kevin is here.

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

Kim Nolen. Hi, Kevin. Kim Nolen?

Kim Nolen, PharmD – Medical Outcomes Specialist – Pfizer, Inc.

Hi, Michelle Kim's here.

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

Hi, Kim. Kin Wah Fung?

Kin Wah Fung, MD, MS, MA – Staff Scientist, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Present.

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

Hello. Marjorie Rallins?

Marjorie Rallins, DPM – Director of Measures, Standards and Informatics for the Performance Improvement Division – American Medical Association

Present.

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

Hi, Marjorie. Becky Kush? And Susy Hull?

Susan Hull, MSN, RN – Chief Executive Officer – Wellspring Consulting

I'm here.

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

Hi, Susy. And from ONC do we have Matt Rahn?

Matthew Rahn – Program Analyst, Implementation & Testing Division, Office of Standards & Technology – Office of National Coordinator for Health Information Technology

Here.

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

And 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

Anyone...oh, and Chris Muir from ONC?

Christopher Muir, MPA – Senior Advisor – 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

Thank you. There is someone on the line who we're getting an echo from so if you are speaking if you aren't speaking if you could please mute your line that would be wonderful. And with that I'm going to turn it over to you Rich.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Thanks, Michelle. Okay, so we had an HIT Standards Committee meeting last week if you haven't had a chance to take a look at the output from that it would probably be worthwhile doing. A couple of things I would note, one is there was an update from each of the Workgroups so beyond what you already know about the Content Standards there were some interesting feedback from Semantics and a couple of other Workgroups as well.

Also, Arien Malec and David McCallie did an update on, you know, the question about how do you have an open API approach using standards that can...technical standards that can apply across most of the platforms in industry today and that got, you know, kind of a strong endorsement I would say from the Standards Committee. There may be implications of that for this group. So, it is certainly worthwhile if you haven't already participated in or heard that conversation to go back over it.

Today we've got a fairly packed agenda we want to...as a follow-up from an earlier call, there had been a request to understand a little bit more about NIEM how it might apply. We also wanted to get a report back out on the research and clinical data challenges and kind of what recommendations or what the way forward is there and then finally to continue on the comments on the interoperability roadmap. We had some framing questions that we wanted to run by you and as we begin to move towards presenting back more specific feedback from this group to the HIT Standards Committee, which I believe Michelle is scheduled for April?

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

April 22nd.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Okay and so then I think we have this meeting and one more which are our times together between now and then. So, wanted to make as much productive use of the day as we can, get as much of your feedback as we can as we start to begin now to work towards that follow-up.

The update that we gave yesterday...the last week to the HIT Standards is more on some of the broad brush strategic feedback the Workgroup had provided a lot of the more specific comments will be part of our April 22nd report out. So, with that Michelle should I turn it back over to you?

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

Not me, hopefully, Matt?

Matthew Rahn – Program Analyst, Implementation & Testing Division, Office of Standards & Technology – Office of National Coordinator for Health Information Technology

Yes.

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

Or Chris Muir to walk through NIEM?

Matthew Rahn – Program Analyst, Implementation & Testing Division, Office of Standards & Technology – Office of National Coordinator for Health Information Technology

Yeah, we're going to move to Chris now. So, Chris if you are there? And operator if you could pull his slides, put his slides up please?

Christopher Muir, MPA – Senior Advisor – Office of the National Coordinator for Health Information Technology

All right, well, thank you Matt and as everyone said my name is Chris Muir, I'm from ONC. I was part of the team that coordinated the development of the roadmap and I've been asked to address you and tell you a little bit about the thought process that went into including NIEM within the roadmap and so the first couple of slides I have you're going to be very well aware of. They are slides you've probably seen before, you're very aware of the interoperability roadmap but the reason I included them is just to put some of my comments into perspective and so if we go to the next slide please.

And so I'm sure you've all seen this slide before. The roadmap came from the 10-year vision paper that we developed almost a year ago now and really in the vision paper and in the roadmap it's really framed in two ways. The first way is by time and so you can see here there are things that we hope to accomplish in the first three years and then in the following three years, and then by the end of a 10-year period.

And the different things that we hope to accomplish were built on building blocks and so we have the technical standards and functions, the certification, privacy and security, the business, clinical, cultural and regulatory environments and the rules of engagement for governance.

And if we go to the next slide, but we...in both of those documents the 10-year vision paper and in the roadmap we talk about the reasons why interoperability is so important and of course one of the top reasons is that individuals and providers need access to the information at the right time, at the right place, you know, regardless of geography or organizational boundaries.

The next reason is that because patients see so many different providers their care really needs to be coordinated to have the biggest impact on both cost and quality. The third bullet there really goes to the point that healthcare outcomes are...only 10-20% of healthcare outcomes are attributed to healthcare and so there is a lot of other factors that go into that including environmental, personal choice on things like exercise and eating, and those kinds of things whether they smoke or not those kinds of choices. It also goes to environmental, economic, genetics, you know, just other factors such as those.

And then the third or the last bullet I mean, information needs to flow inside and outside the care delivery system to support health and so when you look at bullet 1, 3 and 4 that really helps set the stage to why we, in the roadmap, considered putting NIEM in there. And so let's go to the next slide.

So, first of all what does the roadmap say about NIEM? In the first three years where we're targeting send, receive, find and use a common dataset it says within the standards and technology area states and other stakeholders across the ecosystem to further explore and determine the role that NIEM can serve with regards to supporting healthcare and health services interoperability. Let's go to the next slide.

So, what is NIEM? NIEM started out as a collaboration between criminal justice, the criminal justice community and homeland security to try to reduce redundant efforts following 911 on standards development, you know, they were wanting to be able to exchange information between the courts and the police and some of the homeland security agencies and so that's really where NIEM started from.

Since that time, there, you know, have been numerous different domains that have been established which include human service, child youth and family services, biometrics, you know, just...kinds of things, just a variety of other domains.

It's really been looked as a way for the local, state, federal and tribal governments to share information with each other across the different domains. The way it's governed is they have an executive steering council which includes the CIOs for Homeland Security, the Department of Justice, Health and Human Services and OMB. It includes a few other not-for-profit organizations such as the National Association of State CIOs.

Under that executive committee, I mean the council, there are two committees, there is the business architecture committee and the technical architecture committee and then the domains fall under those committees. So, if we go to the next slide.

So, why is NIEM being considered, I'm just going to go back to a couple of the bullets that were in the previous...because healthcare outcomes aren't left just to healthcare, the health outcomes are not left to just healthcare because of the genetics, the social, the environmental, the different choices that we make and the economics, and because information needs to flow inside and outside of the healthcare, and there are, you know, a variety of federal, state, local agencies that, you know, really at some point need to participate in exchanging health information.

We look towards NIEM because NIEM is there, it has been established, they work with existing standards so they're not trying to replace standards that we already have in healthcare but in as much as that we need to interact with those other entities.

We think potentially, and, you know, we are still exploring it, we're asking for public feedback on it, but we think potentially, you know, it could be useful to bridge between health and the other domains. And so if we go to the next slide.

We know it's being used in a few areas today, there are some states who are using NIEM in pilot phases to do exchange between state PDMP registries and also at the federal level the CMS Federal Hub authenticates individuals for the health marketplace, you know, with the subsidies and everything, they're NIEM to exchange information between states, CMS, the IRS, Social Security Administration and the Department of Homeland Security.

And so we think there is some potential there. We are, you know, asking for public feedback on it. We ourselves internal to ONC are exploring it some more and that in a nutshell is why NIEM is in, you know, the roadmap. So, I'll go to my last slide.

Just so you also know, ONC actually owned the domain when it was first established and those domains are time limited, you have to renew them and we...ONC, you know, up until now really hasn't done very much with NIEM because, you know, we've been working with the health industry and developing, and, you know, improving the health standards that we already have and so there is a proposal that FHA, the Federal Health Architecture, which is a group made up of federal agencies, you know, they have a formalized group where they interact with each other and coordinate with each other and it's proposed that they take over that health domain since, you know, a lot of the NIEM interaction is really at the governmental level.

And so that is my presentation, that's why NIEM has showed up in the roadmap and I'm happy to take any questions about it.

Calvin Beebe – Technical Specialist – Mayo Clinic

This is Calvin Beebe, one question I might have is how developed is the healthcare topic area currently within the NIEM space?

Christopher Muir, MPA – Senior Advisor – Office of the National Coordinator for Health Information Technology

It's really not. There is very little that has been done with it to date.

Calvin Beebe – Technical Specialist – Mayo Clinic

Okay.

Christopher Muir, MPA – Senior Advisor – Office of the National Coordinator for Health Information Technology

And so, you know, again, you know, NIEM...well we would...we or the FHA would have control of what gets developed in there and it wouldn't be creating anything new, we could definitely leverage the things that we already have but we see it as more of a bridge to like the health services or criminal justice when those kinds of exchanges need to take place.

David Dinhofer, MD, MS – Chief Medical Information Officer – Infotek Solutions and Services

Hi, this is David, Dinhofer, I'm not so sure this is the right place for this question, but as much as I'd like to shared information between healthcare organizations I notice that the...there were a lot of organizations in that group you mentioned, I mean, there were in the past walls set up to block information exchange between government agencies to protect privacy, is there being anything done to protect it here?

Christopher Muir, MPA – Senior Advisor – Office of the National Coordinator for Health Information Technology

Well, you know, certainly there are numerous recommendations within the federal government about privacy and protection of data and, you know, so this would provide a way for the appropriate sharing of data and we're not talking about aggregating data or anything like that.

Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC

This is Floyd with a comment, I think for those who weren't participating in the Standards Committee meeting there were some comments from other Workgroups suggesting that NIEM may not apply here or be the best method.

I think Calvin's comment about not much being built out in the healthcare space is relevant. And I think there are specific healthcare related privacy issues that are just being addressed now about data segmentation that would need to be applied as well.

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

This is Joyce Sensmeier, just a question on slide seven, PDMP, I'm sorry, I'm just not sure what that is, that acronym?

Christopher Muir, MPA – Senior Advisor – Office of the National Coordinator for Health Information Technology

Oh, yeah, I'm trying to remember exactly what it stands for too but it's...

Matthew Rahn – Program Analyst, Implementation & Testing Division, Office of Standards & Technology – Office of National Coordinator for Health Information Technology

It's a drug monitoring...

Christopher Muir, MPA – Senior Advisor – Office of the National Coordinator for Health Information Technology

Where states are looking at who is using prescription drugs and, you know, making sure that they are appropriately used.

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

Prescription Drug Monitoring Program.

Christopher Muir, MPA – Senior Advisor – Office of the National Coordinator for Health Information Technology

Yes, thank you.

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

Prescription Drug Monitoring...thank you. And then I'm still struggling to understand how this would be applied so is it an exchange that we would adapt to healthcare or I'm struggling with what is the "it?"

Christopher Muir, MPA – Senior Advisor – Office of the National Coordinator for Health Information Technology

Oh, the "it" okay, well, so what NIEM does is it establishes the semantics and, you know, so like name, address, phone number, you know, is it alphanumeric or is it just numeric, you know, the different fields and, you know, what are the size of them and, you know, what are appropriate, you know, inputs and which aren't.

So, they get at semantics and syntax, you know, so they're like data attributes and then they're also...they also establish documents in which data gets exchanged so it's similar to like HL7 kinds of stuff, you know, this is my understanding not being a technologist in this area.

And again, it's really...it's really to exchange, you know, within certain domains that are not healthcare related and the way we see a potential use of it, we're not completely sold ourselves, that we could potentially use it for cross domain exchange.

So, if there is some information...for example, if a prison is releasing an inmate and there are some known health issues and they want to, you know, hand that off to, you know, receiving primary care physician or something there would be able to be a way in order to facilitate that exchange of information, you know, especially if it wasn't already in some kind of an EHR or some kind of a healthcare system, maybe it's in some kind of a prison system but they still want to, you know, provide us that information.

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

So, could I say then that it really provides a structure for what the data elements might be and how to...a structure for how to represent that data that could then be applied to the healthcare exchanges, is that a way to...

Christopher Muir, MPA – Senior Advisor – Office of the National Coordinator for Health Information Technology

Yeah and it could go the other way too, right, so we may find use cases where, you know, maybe, you know, on social service or some other entity that would have an appropriate use of the information, you know, and they would, you know, ask for the information in a certain way. And again, we're talking about only legal appropriate uses of doing exchange between these domains, we're not just talking about just opening the doors or anything.

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

Okay, thank you for clarifying.

David Dinhofer, MD, MS – Chief Medical Information Officer – Infotek Solutions and Services

Hi, this is David Dinhofer, again, sorry to belabor this issue, but when you aggregate all this information from, you know, CMS, IRS, SSA and DHS and you put it with healthcare it's really hard to protect individual privacy, this is...I mean, I know you mentioned there were safeguards but, you know, there was a case in Massachusetts where they had safeguards and the governor's healthcare was able to be identified, you know, so I am concerned about these safeguards and when we exchange information between all these groups it seems to me that the privacy is going to still have a problem here.

Christopher Muir, MPA – Senior Advisor – Office of the National Coordinator for Health Information Technology

Right, well, I mean, it certainly is something that we really have to pay attention to. I just want to clarify something, you know, we're not talking about an aggregated database where all this information just automatically gets, you know, added together or any...you know we're not talking about any kind of a wholesale aggregation of data, it would be for very specific appropriate uses of course and a lot of this stuff, you know, often times is really to provide patients access to certain kinds of information of the patients to share certain kinds of information, you know, that helps them or helps their providers make, you know, better informed decisions, you know, so it's within the context of the learning health network that we're trying to get to the 10-year goal.

In the first three years we're just wanting to explore and find out if it makes sense or not, right, I mean, you know, again we haven't made any decisions we want to explore this area to see if this would help, you know, as we work towards that learning health system and when we're talking about sharing and receiving information from different sources what would be the best way to do that and is NIEM a potential way to help us accomplish that?

Susan Hull, MSN, RN – Chief Executive Officer – Wellspring Consulting

This is Susy Hull I just want to thank you for the presentation and it's interesting to think about are there any benefits directly to the consumer who, you know, we're trying to continue to build these cycles of learning around in the learning health system.

Some of the consumer-facing kind of consumer-family, patient/family network solutions that I've been involved in are exploring use of like local registries or meals-on-wheels or other social services that individuals or families could connect to as part of their health exchange, but I'm not really quite seeing the connection of how this kind of a network would support those more consumer directed efforts or the consumer directed efforts that are perhaps like part of a larger disparate project where they're trying to connect both traditional healthcare providers, payers and these consumer health services that are not typical, they're more of the social services, again, like meals-on-wheels or ride sharing efforts.

So, can you make any connection at this point or are you just hoping to explore what those benefits would be.

Christopher Muir, MPA – Senior Advisor – Office of the National Coordinator for Health Information Technology

Yeah, no, we were just hoping to explore, I mean, you know, I'm certainly not an attorney and I don't know what appropriate uses would/wouldn't potentially be with those different groups, but, you know, we hear of small markets, you know, sharing information between providers and people who, you know, they need rides to the doctor's office and so, you know, there is some exchange of some basic, you know, basic information, some, you know, demographic kind of information, things that might at a certain level be protected but maybe not, you know, a complete health record, you know, with some of those kinds of programs and making sure that they get a proper diet, you know, if they're home and, I mean, you know, they're just different, you know, social services that could support the health outcomes that the providers are trying to achieve.

But, yeah, I don't have, you know, a lot of detail on those kinds of things or what would be appropriate, you know, what specific things would be appropriate to share in those circumstances.

Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC

This is Floyd Eisenberg again, I think what's concerning me is the individual privacy concerns for data segmentation that often in text that might get shared or the context of even why there might be transportation required might require specific privacy segmentation to avoid the wrong people learning the information and I think that's being identified and somewhat more sensitive for healthcare that I'm not sure that I'm...that's there in the NIEM infrastructure.

Christopher Muir, MPA – Senior Advisor – Office of the National Coordinator for Health Information Technology

Well, I think that's something that certainly is a legitimate concern and something that, you know, we would definitely need to think about and address if we were to go forward in this way. I'm not a NIEM expert, although I do know within the domains there is a lot of flexibility on the kinds of things that are developed, but I don't know if they have anything like it or not at this point.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Hey, Chris, this is Rich Elmore, it seems there are so many interoperability demands and challenges and opportunities out there that I think that nationally we're going to be confronted with deciding which ones return the most value in terms of safety, clinical care, etcetera, cost.

What are the high impact use cases of connecting healthcare in NIEM which is I think what you're saying you want to explore?

Christopher Muir, MPA – Senior Advisor – Office of the National Coordinator for Health Information Technology

Well, that's exactly right, I mean, you got it exactly right, that's something that we need to explore, I mean, you know, we can kind of imagine some things but, you know, we don't know for sure and, you know, as we put in the roadmap we were really just doing kind of an investigation and exploring how it might be helpful to achieve the learning health system that we want to.

We hadn't really, you know, decided on or proposed anything specific at this point, you know, we're really looking for some ideas and it may not fit and that's okay too, but, you know, in the first three years we want to explore it.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

And it would seem like that would be, you know, the place you would want to start before, you know, you spend any significant cycles on this is that you've got, you know, a real pressing problem that needs to be solved and, you know, if NIEM is the best way of, you know, connecting with, outside of healthcare, because that's part of the solution to the problem then great, but I think you've got to start with that don't you?

Christopher Muir, MPA – Senior Advisor – Office of the National Coordinator for Health Information Technology

Well, before we start spending any money you're absolutely right. Now I will have to say because NIEM is a governmental kind of thing it's used to, you know, exchange data between federal partners and between states and states in the federal government and, you know, local government and you know, other governmental entities, we were encouraged to take a look at it and to put it within the roadmap and to explore ways in which...if there were ways in which information were shared across the domains particularly among the federal government entities and, you know, again with other governmental entities as well that NIEM be looked at as a way to do that.

So, right now I admit it's kind of like a solution looking for a problem, it is a little bit like that, I completely agree, but because of the encouragement of, you know, the different...and we heard this from the states as well it wasn't only the federal government they encouraged us to put NIEM into the roadmap as a potential way of exchanging data if it needed to be exchanged between, you know, the health domain and like for example the human services or the criminal justice domains.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

So, just to further clarify then, are you in fact considering NIEM not as a way of kind of extending healthcare standards but as a way of thinking about how to interoperate, you know, the other hand clapping outside of healthcare?

Christopher Muir, MPA – Senior Advisor – Office of the National Coordinator for Health Information Technology

Yes, exactly.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

So, you're not...so the maturity of the healthcare model in NIEM isn't what you're trying to develop or further develop?

Christopher Muir, MPA – Senior Advisor – Office of the National Coordinator for Health Information Technology

Right, no what we're really looking at NIEM to do is help us to bridge between healthcare and the other domains such as the human services or criminal justice.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

So, in terms of recommendations from the Content Standards Workgroup on this topic Matt or Michelle what...how do you think we should go about getting that feedback?

Matthew Rahn – Program Analyst, Implementation & Testing Division, Office of Standards & Technology – Office of National Coordinator for Health Information Technology

...

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

Thank you, Matt.

Matthew Rahn – Program Analyst, Implementation & Testing Division, Office of Standards & Technology – Office of National Coordinator for Health Information Technology

We can go to what we have right now in this slide deck which is on slide 28 and kind of...wait, sorry, not 28, let me see, let me find it. We can do that now or we can just look at that when we get to it towards the end of the discussion where we're going through and discussing the specific issues that people have with any comments. Okay?

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Okay, that's fine.

Matthew Rahn – Program Analyst, Implementation & Testing Division, Office of Standards & Technology – Office of National Coordinator for Health Information Technology

I'm just trying to find where it's at in our comments here. I don't see which slide it is.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Okay, well if there are no other questions on this then Chris thanks so much, really appreciate the update I think it's very helpful to us to understand the context around it.

Christopher Muir, MPA – Senior Advisor – Office of the National Coordinator for Health Information Technology

Well, thank you. And thanks for inviting me, thank you.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Thank you, the next item is a follow-up on the challenges of interoperability of clinical and research data. There were a number of sub-teams that were following up. Matt you had put a note out, I don't have that in front of me, do you have that? Can you just kind of bring that back up for the group?

Matthew Rahn – Program Analyst, Implementation & Testing Division, Office of Standards & Technology – Office of National Coordinator for Health Information Technology

It should be...can you go to the next slide, please? Let's see, next slide, yeah, so quickly I'll just go through this. Today's meeting we're just going to finish or try to get through as much as we can of the comments and then spend a little bit of time at the next meeting finalizing those and then we will transition to the NPRM after we get a chance to speak with Rich and Andy to see how we're going to kind of tackle the NPRM.

Then April 22nd we'll report out, as people have said, on those interoperability roadmap comments and it looks like we'll have four...like 3.5 to 4 total meetings to be able to get some commenting on the certification rule. The next meeting we'll have a better idea on how we're going to do that so we'll just kind of table that until then. If you can go to the next slide, please?

Okay, next slide, all right. So, Rich can you see this one?

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

So, you point out where it is, I have it...I'm not on line.

Matthew Rahn – Program Analyst, Implementation & Testing Division, Office of Standards & Technology – Office of National Coordinator for Health Information Technology

It's slide five.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Yeah, yeah.

Matthew Rahn – Program Analyst, Implementation & Testing Division, Office of Standards & Technology – Office of National Coordinator for Health Information Technology

So, if you kind of want to just give a little update or like speak through that slide on kind of the...where we see the comment is and kind of discussion and give a little bit of background on the Sub-Workgroup and then we have some...the next slide we have some action items that we can follow-up on.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Yeah, I think we had a really good conversation with Becky Kush, I mean, I think there had been hypothesis that perhaps we could, you know, use SNOMED instead of MedDRA, I think she was pretty clear that because of some of the international kind of aspects of this that probably wouldn't happen, but there was a need for, I think as Kin Wah put it, you know, an open and authoritative and a maintained mapping between SNOMED and MedDRA that could go a long way to try and promote better understanding, I know there were some concerns in the Workgroup about, you know, yet another map to maintain. So, we can certainly talk about the impressions that other folks had at our last conversation of the Sub-Workgroup.

And then there were basically a set of action items where we saw both the need for clarity and maybe an opportunity, so those included...maybe we can just go to that next slide of the action items. You know the first one was exploring MedDRAs terms for adverse events for which there is kind of a reasonably manageable set and see if there might be a path to alignment with SNOMED.

And then there was also going to be some work done on the text definition side of SNOMED to make it potentially more usable and useful in research also considering response time.

And then finally, there was an opportunity we thought to maybe align better drug naming perhaps in early stages of their lifecycle now kind of, you know, post...once the drug is out in the market it's RxNorm, but before that it isn't and so, you know, kind of trying to understand how that naming is working today was yet another action item.

So, those were the...kind of the report outs which again we'll hear from each of the individuals that helped with that, but first let me just ask where there any general impressions, different impressions about the conclusion that a mapping approach as opposed to a, you know, kind of subsuming MedDRA with SNOMED was the right path and is there any kind of differing opinion on that conclusion?

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

This is Dianne Reeves, that may be the...the mapping approach may be the best one but again, we are very concerned about maintaining all these maps, as we all know, I'm just saying it's not a great solution if we could think of something better that would be much appreciated.

Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC

And this is Floyd with a comment on that and is there a way, and I apologize for my lack of detailed knowledge on how IHTSDO would approach this, but is there a way that IHTSDO could work with MedDRA to incorporate some of that rather than a map but to incorporate some of the concepts or classifications that MedDRA has rather than creating a map for individuals in the US to specifically have to implement.

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

Yeah and Floyd it really is a great deal of international but in the US I think that would be a great thing to do.

Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC

Now I understand that's a lot of work.

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

Sure.

Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC

But I'm just wondering if that would be a better approach.

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

I think so.

Kin Wah Fung, MD, MS, MA – Staff Scientist, Lister Hill National Center for Biomedical Communications – National Library of Medicine

This is Kin Wah Fung and I think that it's a worthwhile goal to explore to how to align better MedDRA and SNOMED but in the end whether...it definitely takes a lot of work on both sides if eventually that can be done and also it takes a lot of commitment from both the IHTSDO and MedDRA's side to make that work.

And also if any of that is realized in the end and also due to the requirements of reports not just in the US and internationally whether that can...I mean, if one can substitute for the other for all the requirements is still questionable.

So, I think in both...in terms of delivering value and also in terms of the timeframe and then having a map is probably the near or medium-term goal that will give us some results or use in this activity.

And I'm still checking with IHTSDO whether...what kind of collaboration is going on or whether there is any collaboration that is going on between MedDRA and IHTSDO and I'm still waiting to hear back from them.

But meanwhile Dianne and I have already thought of some interactions to look at specifically item A and B the smallest subset of terms and from a very preliminary analysis there is a lot of overlap between the 790 MedDRA terms and SNOMED. So, it is quite doable probably to explore them further.

And also we are also working on adding some of the text definitions that NCI already has on these MedDRA terms to SNOMED because SNOMED is very receptive and if there is some text definitions already in use from alternative sources they are very receptive to add them to SNOMED. So, some work...I mean, we were already planning to work on that in the short-term.

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

Right.

Charles Jaffe, MD, PhD – Chief Executive Officer – Health Level 7 International

Hi, this is Chuck Jaffe, having lived in both worlds the absolute framework by which MedDRA is predicated is inconsistent with patient care. I think we're going to end up with a mapping solution whether we want it or not and pay the price of the overhead and the resources. I think we have to come to grips with that and if my understanding of my vocabulary colleagues is correct it's much more difficult than perhaps it appears to be on the surface. So, I think it will be more of a challenge than you suspect.

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

Chuck, this is Dianne again, what do you mean when you say it's inconsistent with patient care? Because we've been talking about it in terms of description of adverse events but what do you mean when you say that?

Charles Jaffe, MD, PhD – Chief Executive Officer – Health Level 7 International

I don't think clinicians describe adverse events the same way investigators do. I think in terms of the syntax, the terminology, the application to the adverse event, I think they're quite different.

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

Okay.

Charles Jaffe, MD, PhD – Chief Executive Officer – Health Level 7 International

And when you set them up so that you can compare I think then it becomes more obvious particularly adverse events, but I suggest that this group look at some of the written work or even ask Chris Chute about his efforts to accomplish this and get some feedback from someone whose significant body of work revolves around this and see what he says.

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

Okay.

Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC

Yeah.

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

That's a good suggestion.

Kin Wah Fung, MD, MS, MA – Staff Scientist, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Yeah, just, I think there is some...I think what Chuck said is probably right because the two models probably cannot be totally harmonizing to one and there are definitely some perspectives in which...in the way that MedDRA looks at things and SNOMED looks at things they could be very different, but, I mean, of course there are other areas in which I mean...for example just like the description of a particular disorder like anemia, I mean, there will be no difference in some areas.

Just like in a lot cases with mapping you can find some degree of exact overlap but then in some areas...and the problem is always in those areas that you don't align completely what so you do.

So, I think, I mean, a map is a practical solution and it will deliver value I think but looking for a total concurrence of a model probably is...at least it's not realistic at this point is my opinion. So, I agree with you Chuck there are some areas that it's very difficult to align between the two.

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

But...

Charles Jaffe, MD, PhD – Chief Executive Officer – Health Level 7 International

It seems like a first step, in any case, would be a map to deepen the level of understanding.

Kin Wah Fung, MD, MS, MA – Staff Scientist, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Yeah.

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

Yeah.

Charles Jaffe, MD, PhD – Chief Executive Officer – Health Level 7 International

And maybe out of that...and maybe we could put this into our guidance, you know, once we have, you know, an authoritative and maintained map maybe the next step in a subsequent 3-year period is to evaluate whether or not there is the opportunity to align subsets of MedDRA and SNOMED for example, adverse events.

Kin Wah Fung, MD, MS, MA – Staff Scientist, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Yeah.

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

But, isn't the issue larger than this though? I mean, we're talking about MedDRA as an example of a terminology that researchers use and then we're talking about how clinicians in a care setting would describe things. If the roadmap is really looking at how to bring the two communities together it seems like that's the question and there is going to be more and more examples like this, this is just one.

Charles Jaffe, MD, PhD – Chief Executive Officer – Health Level 7 International

I think you have to be careful how you use the expression researchers. If you're talking about regulated clinical research you're talking about MedDRA but the people who are trying to bring a learning health community together around this process realize that an automobile accident is not an adverse event, because...

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

Right.

Charles Jaffe, MD, PhD – Chief Executive Officer – Health Level 7 International

That when you ask someone about their smoking history you don't say, have you smoked within the past five years...

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

Right.

Charles Jaffe, MD, PhD – Chief Executive Officer – Health Level 7 International

That's about inclusion and exclusion criteria that's not about getting a history of smoking and so the fundamental processes are meant to achieve different things and that's why there is such a challenge in my mind.

Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC

Yeah, so this is Floyd, I don't disagree with anything that's been said, I agree with Chuck's comments too. I guess what concerns me though is I was hearing a few times, even on this call, that MedDRA is used commonly in Europe but not in the US and so is it used by clinicians in Europe, because that's not...that wouldn't be my understanding.

Charles Jaffe, MD, PhD – Chief Executive Officer – Health Level 7 International

I don't think so.

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

No.

Charles Jaffe, MD, PhD – Chief Executive Officer – Health Level 7 International

MedDRA is used extensively in the US...

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

Yes.

Charles Jaffe, MD, PhD – Chief Executive Officer – Health Level 7 International

For regulated clinical research.

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

Yes.

Charles Jaffe, MD, PhD – Chief Executive Officer – Health Level 7 International

That's the way the FDA expects adverse events to be reported because the FDA is a signatory on the ICH which is a loose collective of federal regulatory agencies and so the FDA expects MedDRA to be used.

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

Yes, you're correct.

Charles Jaffe, MD, PhD – Chief Executive Officer – Health Level 7 International

It's just a different environment and that's what the challenge is. So, can we please everybody when we come to this conclusion, no I don't think we can.

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

But can we negotiate a middle ground where we can agree?

Charles Jaffe, MD, PhD – Chief Executive Officer – Health Level 7 International

I hope so.

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

Yeah.

Susan Hull, MSN, RN – Chief Executive Officer – Wellspring Consulting

This is Susy Hull, I just have a brief question and perhaps it's appropriate today or it needs to be tabled, but if you look at the consumer trying to consolidate their health records and integrate what's the professional health data and then their own patient generated data over time I think this is, as Dianne said, this is kind of one example of many.

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

Yeah.

Susan Hull, MSN, RN – Chief Executive Officer – Wellspring Consulting

But, what would this...how could we look forward to anticipate what both researchers and clinical providers need but, you know, eventually and hopefully sooner than later what consumers might need to have shareable exchangeable data around some of this...these periods of time where they're both involved in active clinical care and active research studies that could be US or internationally-based.

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

Yes.

Charles Jaffe, MD, PhD – Chief Executive Officer – Health Level 7 International

Again, let me caution you about the way you use the term researcher. So, public health researchers don't use MedDRA it's for regulated clinical research. And so the issue is, for patients, is, you connect the way patients connect, the way patients speak, the way patient level data is exchanged and so I think that's a different issue.

Susan Hull, MSN, RN – Chief Executive Officer – Wellspring Consulting

I'm not sure I understood that, but...

Charles Jaffe, MD, PhD – Chief Executive Officer – Health Level 7 International

Okay, let me say...I'll say it in a different way.

Susan Hull, MSN, RN – Chief Executive Officer – Wellspring Consulting

Okay.

Charles Jaffe, MD, PhD – Chief Executive Officer – Health Level 7 International

The structured vocabulary implicit in MedDRA is different than the way patients talk to their doctors and doctor's record data specifically when it comes to adverse event reporting.

Susan Hull, MSN, RN – Chief Executive Officer – Wellspring Consulting

But there is...

Charles Jaffe, MD, PhD – Chief Executive Officer – Health Level 7 International

But when you said researcher you conflate the research that's done for, let's public health or community medicine or whatever you want to call it and the regulated clinical research for drug submissions not the same. Not the same vocabulary.

Susan Hull, MSN, RN – Chief Executive Officer – Wellspring Consulting

Right. There is also a patient reported version of the MedDRA terms that is being validated now through NCI that is more the way that an actual patient speaks to a clinician.

Charles Jaffe, MD, PhD – Chief Executive Officer – Health Level 7 International

A patient reported outcome side of this always has been, it's now that they're coming to grips with it.

Susan Hull, MSN, RN – Chief Executive Officer – Wellspring Consulting

Right.

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

Right.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

So, as a group recommendation, what do you think of the kind of guidance that a map should be developed and maintained and be openly available and that based on that map being completed that we should look for opportunities to align or otherwise, you know, move towards...I guess just align the vocabularies used by SNOMED and by MedDRA.

Charles Jaffe, MD, PhD – Chief Executive Officer – Health Level 7 International

I think aligned is a better concept than mapped because again, I'd like you to get some input from Chris Chute amongst others about what mapping entails between MedDRA and SNOMED because there is not a one-to-one concordance except for things like falling hemoglobin, but for other things it's really slight convoluting.

Kim Nolen, PharmD – Medical Outcomes Specialist – Pfizer, Inc.

This is Kim, I agree with what Chuck is saying. I would like to understand it a little bit better because I think there are going to be implications for people and industries that may not know how to handle this if we don't get it right, you know, with how we state it.

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

I agree.

Kin Wah Fung, MD, MS, MA – Staff Scientist, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Yeah, I think, I agree also, so it is also important and that's why it's so important that we do it in an open way and so that people when they use the map they understand, I mean, the principles behind how we align the two, the contents for MedDRA and SNOMED so that they understand or if they don't agree they can have a channel to say that, okay this doesn't look right.

So, I think an open approach is much better than say somebody just developed their own map and used it without disclosing how they do it. So, I think I agree with Rich I think that to strive for an open and authoritative and in maintained manner I think probably is a worthwhile goal to pursue between SNOMED and MedDRA.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Okay and then in terms of the suggestion, follow-up with Chris Chute are there some folks on this call that would like to participate in that?

Charles Jaffe, MD, PhD – Chief Executive Officer – Health Level 7 International

I'll be glad to contact Chris.

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

Oh, good.

Kin Wah Fung, MD, MS, MA – Staff Scientist, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Yeah, that would be useful.

Susan Hull, MSN, RN – Chief Executive Officer – Wellspring Consulting

Thank you.

Kim Nolen, PharmD – Medical Outcomes Specialist – Pfizer, Inc.

I would like to participate.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

And Chuck maybe if you could coordinate with...thank you for that and maybe coordinate with Matt Rahn and we can...

Charles Jaffe, MD, PhD – Chief Executive Officer – Health Level 7 International

Oh, absolutely.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Arrange that call.

Charles Jaffe, MD, PhD – Chief Executive Officer – Health Level 7 International

So, I just will contact Chris and ask him to make some recommendations about when this group either individually or as a whole he can share his ideas.

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

Okay, that sounds great.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Okay.

Kin Wah Fung, MD, MS, MA – Staff Scientist, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Yes.

Marjorie Rallins, DPM – Director of Measures, Standards and Informatics for the Performance Improvement Division – American Medical Association

This is Marjorie, this is Marjorie, I would like to participate.

Charles Jaffe, MD, PhD – Chief Executive Officer – Health Level 7 International

I would like to try and negotiate with him, just find a time where he is available.

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

That would be great.

Kin Wah Fung, MD, MS, MA – Staff Scientist, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Yes.

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

And just one little word here on the slide, sometimes it says MedDRA and sometimes it says MADRA, we should be consistent. It is MedDRA.

Matthew Rahn – Program Analyst, Implementation & Testing Division, Office of Standards & Technology – Office of National Coordinator for Health Information Technology

Okay, we'll make sure to, this is Matt, we'll make sure to fix that.

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

Great, thank you.

Matthew Rahn – Program Analyst, Implementation & Testing Division, Office of Standards & Technology – Office of National Coordinator for Health Information Technology

So, as far as the meeting with Chris, do you guys...is that something that Rich are you thinking happens very soon or is that just...

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Yeah, I think it has to. Let's find out what Chuck gets back and Matt maybe if you can figure out with Chuck what's the best way to get feedback to this...maybe a Subgroup, maybe, you know, at our next meeting depending on availability, if you can figure that out. I mean, I think that's going to be central...it's a really good thought and will probably play a role in how we fine tune a recommendation here.

Matthew Rahn – Program Analyst, Implementation & Testing Division, Office of Standards & Technology – Office of National Coordinator for Health Information Technology

Okay, yeah, I was just thinking timing wise it's got to happen soon.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Yes.

Charles Jaffe, MD, PhD – Chief Executive Officer – Health Level 7 International

Yes. So, Chris has a new job of course.

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

Yes.

Charles Jaffe, MD, PhD – Chief Executive Officer – Health Level 7 International

And so that may be a limiting factor but I'll pick up the phone and call him when this call is over.

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

Oh, that's so nice, thank you.

Kin Wah Fung, MD, MS, MA – Staff Scientist, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Thanks.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Okay and then on the other action items any additional report out on those?

Matthew Rahn – Program Analyst, Implementation & Testing Division, Office of Standards & Technology – Office of National Coordinator for Health Information Technology

Kim?

Kim Nolen, PharmD – Medical Outcomes Specialist – Pfizer, Inc.

Kim?

Matthew Rahn – Program Analyst, Implementation & Testing Division, Office of Standards & Technology – Office of National Coordinator for Health Information Technology

Yeah are you on?

Kim Nolen, PharmD – Medical Outcomes Specialist – Pfizer, Inc.

Yes, I'm sorry, I can give from one perspective, the employer that I work with, so we do name our products at a molecule level and that goes through the clinical trial phases that same name until the FDA submission. I can't verify that for all the other pharma companies but for our pharma company that's how we do it. And there is not a standard, I mean, you name it on your own. There is not a standard naming convention as far as I know.

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

Is there any central registry that's used to collect up all those very beginning names?

Charles Jaffe, MD, PhD – Chief Executive Officer – Health Level 7 International

Yeah, the FDA maintains it. There are certain names you can't give it. So, that's their caveat is what you can't do.

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

Okay.

Kim Nolen, PharmD – Medical Outcomes Specialist – Pfizer, Inc.

Well and there was a certain place where you get the generic naming convention but that is after the molecule name.

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

Yeah, yeah.

Kim Nolen, PharmD – Medical Outcomes Specialist – Pfizer, Inc.

So, there is the molecule name and so I don't know, Chuck, do you know if the FDA keeps that molecule naming versus the generic naming? Because there are naming conventions with that. I'm not sure about the molecule.

Charles Jaffe, MD, PhD – Chief Executive Officer – Health Level 7 International

I don't know where they keep it if that's the question, but they do keep it.

Kim Nolen, PharmD – Medical Outcomes Specialist – Pfizer, Inc.

Okay.

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

Okay.

Kim Nolen, PharmD – Medical Outcomes Specialist – Pfizer, Inc.

At the molecule level or when they get to the generic name?

Charles Jaffe, MD, PhD – Chief Executive Officer – Health Level 7 International

I don't know when it changes.

Kim Nolen, PharmD – Medical Outcomes Specialist – Pfizer, Inc.

Okay.

Charles Jaffe, MD, PhD – Chief Executive Officer – Health Level 7 International

But they keep it all because if you look at the structured product label you can see all the ways to express the same name.

Kim Nolen, PharmD – Medical Outcomes Specialist – Pfizer, Inc.

Right.

Charles Jaffe, MD, PhD – Chief Executive Officer – Health Level 7 International

Or the same item.

Kim Nolen, PharmD – Medical Outcomes Specialist – Pfizer, Inc.

But that happens after approval the structure product label. Let me...I have a couple of names because it has taken me a while to figure out the right person to talk to, I have a couple of names in the queue to follow up with so I'll follow-up some more to see if I can get some more detail about those questions that were just asked with the naming convention at the molecule level to the generic name...pretty much from the SPO on is more understandable to me than the molecule and the generic naming piece.

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

Yeah.

Kim Nolen, PharmD – Medical Outcomes Specialist – Pfizer, Inc.

I don't know that much about that personally myself, because that's not the world I work in with my job. Is that what y'all are looking for?

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

Yeah, from the very beginning before the product label information definitely.

Kim Nolen, PharmD – Medical Outcomes Specialist – Pfizer, Inc.

Yeah, so it starts with a molecule naming and then it goes to the generic naming.

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

Right.

Kim Nolen, PharmD – Medical Outcomes Specialist – Pfizer, Inc.

And that molecule name is the one that follows through.

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

Yeah, we start to track it from the molecule level forward through multiple names, additional names, etcetera.

Kim Nolen, PharmD – Medical Outcomes Specialist – Pfizer, Inc.

So, here was my e-mail that I got back is, assigned a code for a molecule but this is done in research and stays unchanged through the development although in later clinical stages the USAN assigns a generic name, drug name, which has been generally used. Each company follows their own naming convention-based on their system.

Dianne Reeves, RN, MSN – Associate Director for Biomedical Data Standards, National Cancer Institute – National Institutes of Health

Yeah.

Matthew Rahn – Program Analyst, Implementation & Testing Division, Office of Standards & Technology – Office of National Coordinator for Health Information Technology

Hey, Kim, this is Matt Rahn; can you just keep me in the loop on what you find?

Kim Nolen, PharmD – Medical Outcomes Specialist – Pfizer, Inc.

Yes.

Matthew Rahn – Program Analyst, Implementation & Testing Division, Office of Standards & Technology – Office of National Coordinator for Health Information Technology

And then we can report it back to the group probably via e-mail.

Kim Nolen, PharmD – Medical Outcomes Specialist – Pfizer, Inc.

Okay. All right I can do that.

Matthew Rahn – Program Analyst, Implementation & Testing Division, Office of Standards & Technology – Office of National Coordinator for Health Information Technology

Okay.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

So, we've got about a half hour left and there is no way we can cover what we'd like to cover in that timeframe. So, Matt maybe let me just ask you how you think we should best proceed through the next steps on the commentary? Would you like me to go through the questions that we've come up with for the group or what do you want?

Matthew Rahn – Program Analyst, Implementation & Testing Division, Office of Standards & Technology – Office of National Coordinator for Health Information Technology

Yeah, I think that would be good. I think, you know, as long as we can get through, you know, most of it that's why hopefully people reviewed the slides and if they have any issues with a particular slide comment then they can bring that up, but why don't you go through that, those questions.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Okay, so Andy was unable to make it today and he and I did connect on Friday and we had four different questions that we wanted the Workgroup to think about in addition to whatever other commentary you might have, but the first one, is there anything in our collective commentary, which Matt has included as part of what was sent out to the group, that you're very uncomfortable with?

So something in there that has been written that, you know, you just utterly don't think is right and it needs either to have some balanced alternative opinion or whatever, I mean, I just want to make sure that if there are any kind of big issues and that we make sure that you've had an opportunity to flag those.

The second one is kind of related, are there any serious gaps in the commentary?

And the third one is, to ask for which ones are the most important to accomplish now? And you can look at the SGR doc fix, you can look at, you know, the Meaningful Use Stage 3 goals and objectives, you know, there are a number of different approaches to try and accelerate improved interoperability and content standards are going to have a lot to do with the success of that.

So in terms of the here and now, interoperability by 2018 or whatever you want to call it on a national scale can happen in, you know, in a reasonable timeframe, what is it that we should be calling out in terms of priorities for content standards?

And then the last question is, are there content standard implications of the move to a cross platform-based open API standard, this is what was proposed by the API Workgroup that Arien and David reported back at the Standards Committee. So, those were the four questions we wanted to get some feedback on, you might want to...Matt do you want to kind of take them one at a time and just kind of go through them?

Matthew Rahn – Program Analyst, Implementation & Testing Division, Office of Standards & Technology – Office of National Coordinator for Health Information Technology

Yeah, one at a time would be good I think.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

So, the first one was, is there any commentary in here that you're uncomfortable with?

Matthew Rahn – Program Analyst, Implementation & Testing Division, Office of Standards & Technology – Office of National Coordinator for Health Information Technology

That seems good.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

I'm more likely sensing a mad scramble to read through commentary.

Matthew Rahn – Program Analyst, Implementation & Testing Division, Office of Standards & Technology – Office of National Coordinator for Health Information Technology

Yeah.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

And perhaps what we need to do is to give you a chance to consider these questions in light of the material that's been sent out and then maybe we can collect feedback as a follow-up, so if you don't know it now that's okay, but we do need to know it very shortly so that we can pull together finalized commentary for ONC and for the Standards Committee.

Matthew Rahn – Program Analyst, Implementation & Testing Division, Office of Standards & Technology – Office of National Coordinator for Health Information Technology

Yeah that would be good, I mean, this is Matt, so just to be clear, hopefully our next meeting will be focused on providing kind of the structure on how we're going to respond to the certification rule. So, hopefully we can get most of this stuff done and use only a minimal amount of the next meeting to finalize all that. At least that's what I'm hoping for but things can change.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Well in the interest of constructive use of the time here if folks understand the questions that we outlined do you have thoughts on, you know, any of the above that you'd like to get out in front of the group here in the time we've got available?

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

So, this is Joyce Sensmeier, just to clarify, I want to make sure I'm understanding what you would like us to do, if we haven't already and I'll admit I'm one of those that hasn't already, is review the slides as were circulated and then respond based on the questions that you asked first of all do we disagree strongly with anything in there or if we...and if we do tell you why, gaps identified, what is the most important priorities and then there was the thing about APIs that I didn't fully understand but I'm sure you'll restate the questions when we're ready.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Yeah, so I think that's a really good summary Joyce and the last one is a recommendation from the API Workgroup, there is some good, I think, material context for that which is part of the HIT Standards Committee material. I think that would be a good place to start. There was a presentation later in the day on that by David McCallie and Arien Malec and that will give you some context.

Now basically their recommendation...I guess I'm trying to abstract from their specific recommendation, but their recommendation is around, you know, how do you implement an API that's going to be as useful as possible across all the different kinds of technology platforms you can think about when you apply that lens to it the idea of using kind of a RESTful approach, technical approach to how that API is constructed is the...really the only solution that meets the definition.

And so they basically made a recommendation around that, you know, you can extend that to a recommendation around, you know, FHIR as a set of...FHIR resources that are associated with that API and so on and get into some more specifics.

But really the question is, if you have that kind of standard developing what do we think are the applicable changes to content standards or adaptation of content standards that are necessary to maintain relevancy to help with that interoperability in that new world. Does that help with the last question?

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

That was very helpful, thank you and I'll definitely get that presentation and review it, thank you.

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

This is Michelle, we can send it out when we remind everybody of your homework.

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

Oh, even better, thank you.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Thanks, Michelle.

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

Yes. Maybe before we let everyone go we could look at the NIEM comments since we had that presentation from Chris today and just look at those today before we close or do you want to give that for homework?

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

I think that's a good idea.

Matthew Rahn – Program Analyst, Implementation & Testing Division, Office of Standards & Technology – Office of National Coordinator for Health Information Technology

No that's good.

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

I think it's on slide 31.

Matthew Rahn – Program Analyst, Implementation & Testing Division, Office of Standards & Technology – Office of National Coordinator for Health Information Technology

Yes.

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

Mine might be different though.

Matthew Rahn – Program Analyst, Implementation & Testing Division, Office of Standards & Technology – Office of National Coordinator for Health Information Technology

You're good there it is 31 I believe, yes, all right. So, states and other stakeholders to further explore and determine the role that NIEM can serve with regard to supporting healthcare and human service interoperability. So, in light of Chris's presentation do you guys want to move forward with commenting here or if you have any further comments to add?

David Dinhofer, MD, MS – Chief Medical Information Officer – Infotek Solutions and Services

This is David Dinhofer, we did bring up the privacy issues and I don't see that mentioned here.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Privacy, relative maturity of the healthcare domain.

Matthew Rahn – Program Analyst, Implementation & Testing Division, Office of Standards & Technology – Office of National Coordinator for Health Information Technology

Anything else?

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

I mean, I guess I'll just speak for myself, you know, I'd like to...if there is going to be such an assessment of use of NIEM I think it really needs to start because there is a particular high priority, no use case that requires interoperability with other, you know, key stakeholders in NIEM, that building out NIEM for healthcare doesn't make sense, it's not mature, it just becomes yet another standards but if there is a need to figure out how to interoperate whether it's those stakeholders and it's a national priority that then it would make sense to look at NIEM as a way of supporting that interoperability to and from that other stakeholder.

Susan Hull, MSN, RN – Chief Executive Officer – Wellspring Consulting

This is Susy Hull I was just going to say I think that's an excellent addition and there could be some priority use cases perhaps around violence either domestic violence or childhood violence, or something like that which is a priority use case where the data would be valuable to have and might, you know, even link to some of the new work we're trying to do on social determinants of health. But I do think having very specific use cases to drive the exploration would be helpful.

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

This is Joyce Sensmeier, I agree the one word that I heard folks say before was high impact use case so maybe there is a way to weave in that word in addition to priority but also impactful.

Matthew Rahn – Program Analyst, Implementation & Testing Division, Office of Standards & Technology – Office of National Coordinator for Health Information Technology

Okay, so I have those down and I can update that slide for that comment, is there anything else?

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Matt when would you...let's just put a time on getting comments back so that we have adequate cycle time for you and the team and just to try and polish this off.

Matthew Rahn – Program Analyst, Implementation & Testing Division, Office of Standards & Technology – Office of National Coordinator for Health Information Technology

So, our next meeting is next Friday, it would be helpful if we could get comments by the end of this week at least.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

All right, great so we'll send an end date of Friday to get comments back to you or do you want them sooner than that so you can pick up some time on Friday. Is the end of day Friday soon enough?

Charles Jaffe, MD, PhD – Chief Executive Officer – Health Level 7 International

What is the time and date of the next call?

Matthew Rahn – Program Analyst, Implementation & Testing Division, Office of Standards & Technology – Office of National Coordinator for Health Information Technology

It's April 3rd at 11:00 a.m.

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

Eleven.

Matthew Rahn – Program Analyst, Implementation & Testing Division, Office of Standards & Technology – Office of National Coordinator for Health Information Technology

Eleven to 12:30. Yeah so...

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

So, why don't we say they're due Friday the 27th by close of business that means they'll probably trickle in over the weekend and then Matt will have most of the week next week to aggregate comments in preparation for our meeting on Friday and hopefully we'll be able to pivot to the NRPM, at least start talking about it then.

Matthew Rahn – Program Analyst, Implementation & Testing Division, Office of Standards & Technology – Office of National Coordinator for Health Information Technology

Yeah, thanks, Michelle, that works.

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

So, I will remind you in an e-mail and we'll send out Arien and David's recommendations as well.

Matthew Rahn – Program Analyst, Implementation & Testing Division, Office of Standards & Technology – Office of National Coordinator for Health Information Technology

And I will update the comment for the NIEM section and we can resend those slides.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Great, well I think it sounds like we're done for today. Any closing thoughts Michelle or Matt?

Public Comment

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

Let's open up for public comment and then we can come back and wrap up if that's okay? Lonnie, can you please open the lines?

Lonnie Moore – Meetings Coordinator – Altarum Institute

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

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

So, while we wait for public comment, as you all know the NPRM was released on Friday, we appreciate all the time that you've dedicated to us, I know this is a busy time for the Workgroups. We tried to set expectations in advance that this really would be the busiest time, so you'll be getting homework to wrap up the interoperability roadmap and then your other homework will be to start reading the certification rule, this group along with others will be assigned different sections of the rule.

I can tell that this group does have a lot of work to do so we are going to work with the Chairs off-line to develop a process and think about the most efficient way to get that work done and we'll share that during the next call so that you all know exactly what sections you've been assigned so you can focus your reading. And we will work through it and hopefully it will be a painless process, so busy time and it looks like we have no public comment.

Matthew Rahn – Program Analyst, Implementation & Testing Division, Office of Standards & Technology – Office of National Coordinator for Health Information Technology

So, Rich, quickly, I know you had asked about...to ask this to the group, Rich was wondering if there is an opportunity at HIMSS for the group to kind of get together maybe you guys can kind of reach out off line and kind of discuss a time, I don't know if you wanted to speak to that Rich?

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Yeah, just if folks are interested and if there are members of this Workgroup that are going to be in Chicago and/or at HIMSS and you'd like to just at least put faces with names and voices we can certainly try to arrange an informal get together. So, not a formal meeting of the Workgroup but just more of an opportunity for some in person social interaction if that would be of interest.

Matthew Rahn – Program Analyst, Implementation & Testing Division, Office of Standards & Technology – Office of National Coordinator for Health Information Technology

It sounds good and we can remind you again at the next meeting as well.

M

It sounds good, so I'd be happy to meet you.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

All right so if you have an interest maybe just get back to Matt and let him know and if so then we'll try and figure out a way to coordinate a time and place.

Matthew Rahn – Program Analyst, Implementation & Testing Division, Office of Standards & Technology – Office of National Coordinator for Health Information Technology

Yeah, that works.

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

Okay, well, thank you everyone and have a wonderful rest of your day.

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

Thank you.

Matthew Rahn – Program Analyst, Implementation & Testing Division, Office of Standards & Technology – Office of National Coordinator for Health Information Technology

Thanks, everybody.

M

Take care.

M

Bye.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Bye-bye.

W

Bye everybody.

M

Thanks.