



Health IT Standards Committee

2017 Interoperability Standards Advisory Task Force

Final Transcript

April 15, 2016

Presentation

Operator

All lines are now bridged.

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

Thank you. Good morning everyone this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Standards Committee's 2017 Interoperability Standards Advisory Task Force. This is a public call and there will be time for public comment at the end of today's call. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. I'll now take roll. 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. Kim Nolen?

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

Hi, Michelle, I'm here.

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

Hi, Kim.

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

Hello.

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

Christina Caraballo? Chris Hills?

Christopher J. Hills – Team Lead, Standards Engagement Team - DoD/VA Interagency Program Office

I'm here.

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

Hi, Chris. Clem McDonald? Dale Nordenberg?

Dale Nordenberg, MD – Chief Executive Officer – Novasano Health & Science

Hi, I'm here.

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

Hi, Dale. Dan Vreeman? 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 Heflin?

Eric Heflin – Chief Technology Officer –Sequoia Project/HIETexas

Hi, Michelle, I'm here.

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

Hi, Eric. Kim Wah Fung?

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

Hi, I'm here.

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

Hi, Kin Wah. Mark Roche? Michael Buck? Michael Ibara?

Michael A. Ibara, Pharm.D. – Private Consultant – Michael Ibara, LLC

Here.

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

Hi, Michael. Russ Leftwich?

Russell Leftwich, MD – Senior Clinical Advisor, Interoperability – InterSystems

Here.

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

Hi, Russ. Tone Southerland?

Tone Southerland – Director of Implementation – Ready Computing; Co-Chair, eHealth Exchange Testing Workgroup – The Sequoia Project

Here.

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

Hi, Tone and from ONC I heard Brett Andriesen and Stacey? Is there anyone else from ONC on the line? Okay.

Anastasia “Stacey” Perchem – Public Health Analyst – 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

Who was that?

Anastasia “Stacey” Perchem – Public Health Analyst – Office of the National Coordinator for Health Information Technology

That was just me, Stacey here.

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

Oh, okay, hi, Stacey.

Anastasia “Stacey” Perchem – Public Health Analyst – Office of the National Coordinator for Health Information Technology

Sorry.

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

With that I’m going to turn it over the Rich and Kim and if you aren’t speaking if you could please mute your line that would be greatly appreciated. Thank you.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

So, good morning, everyone, thanks for joining. We had a moment of humor right before the call began where we had noticed that geographically we’re probably more from the south than not and so a lot of good fun on that. I am personally from South of Montreal so I’m not sure if that counts, but in any event to get us going here the Interoperability Standards Task Force, Advisory Task Force, is charged with taking a look at the current Interoperability Standards Advisory and deciding what is needed on a going forward basis, making recommendations back to the Standards Committee and to ONC for, you know, further updates for next year.

And we will get into what the questions are and the charges are and all of that in a moment, but, you know, this group has been put together to represent industry, represent patients, represent clinicians and provider organizations and to really make sure that as we set the stage and the signals about what is important from the point-of-view of interoperability standards that there is clarity about, you know, which ones have maturity, which ones have relative levels of adoption and, you know, which ones are appropriate for different kinds of use cases all of which is part of the Interoperability Standards Advisory, which is called a sub-regulatory document.

So, it is not a required document but one which has, I believe, been influential and informative in its past versions and one where I think we’re at a fairly critical juncture to revisit and think further about the guidance that we need to offer.

I mean if you...we now have, with 2016, some visibility to what the future is going to bring in terms of an open API world and that may change some of the assumptions about what’s the best path forward from a standards perspective and I believe that this Task Force is uniquely positioned to begin to address and inform guidance to the industry, to providers, to everyone, App developers, everyone who is a part of the stakeholders in healthcare as to, you know, which standards they should be looking to for which purpose.

So, really appreciate your participation. The focus here will be towards delivering some recommendations back by about midyear, we’ll see the work plan in a minute, and we’re very appreciative, we’ve got a who’s who of folks on the call representing different kinds of expertise and

experience that we think collectively will really help us to get to an update to the ISA that will be helpful to a number of different stakeholders. So, with that let me turn it over to Kim for additional comments. Thank you.

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

Thanks, Rich, you summarized it well and we really appreciate everybody who joined this committee and help us develop out the ISA document further and thank you and as Rich said it really is a collective effort, everybody has different strengths and places where they can contribute to the document. So, we are looking forward to your feedback so that we can take that all in and help improve upon what we have so far. So, thank you.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

And we are supported from a staff perspective by both Michelle, who has introduced herself already, and Brett Andriesen who, Brett you're on the call as well?

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information Technology

I am here, yes.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Great, all right, so Brett will be going over the background and overview of this in just a moment. So, Kim do you want to walk us through the Task Force charge?

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

Yeah, were we going to go to the next slide where the...and let everybody introduce themselves? Is that what the next step was?

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Sounds good.

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

Okay, I can start with myself. I'm Kim Nolen, I'm a Pharmacist by training. I work at Pfizer Pharmaceutical and I'm the Clinical Informatics Medical Outcomes Specialist. I do a lot with primary and secondary use of data in the e-domain and one of the things for being on the Standards Committee is my knowledge around ePrescribing and all the functionalities so that is one of my areas that I work a lot in. And Rich, I'll turn it over to you.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

My name is Rich Elmore I'm with Allscripts, my role is corporate development and strategy for Allscripts which is a health IT developer and why don't we continue down the membership roster here. I'm not sure if I heard Mark Roche are you in/on? I guess not.

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

I was told that he joined now, but maybe he's not.

Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator

Yes, yes, I'm here, yes, sorry, I'm working off of my iPhone so I have to switch back and forth between applications.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Yeah, so maybe just to ease this process as your name...the member names are listed in order if maybe just you could pick up and introduce yourselves as we go down the list here. Thank you.

Mark Roche, MD, MSMI – Chief Medical Information Officer – Avanti iHealth

Sure. Sure, my name is Mark Roche, I'm a Physician Informaticist, I work as Chief Medical Information Officer at Avanti iHealth and I've been working on numerous initiatives with ONC for the past four years. Thank you.

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

David McCallie, I think I'm next on the list, I'm the Senior Vice President at Cerner an EHR vendor company and I just rotated off six years on the HIT Standards Committee working with a number of my colleagues here on the call.

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

I'm not sure Michelle, has Dan joined?

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

I haven't heard Dan and I haven't heard Christina either so we'll go to Michael.

Christina Caraballo, MBA – Senior Healthcare Strategist – Get Real Health

Oh, I'm on, this is Christina.

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

Oh, good.

Christina Caraballo, MBA – Senior Healthcare Strategist – Get Real Health

Sorry, I dialed into the wrong line. I'm Christina Caraballo, I am a Strategist at Get Real Health one of my many hats is leading our efforts as they pertain to industry alignment with standards and initiatives enabling interoperability and consumer access to meaningful data. I oversee our company's certifications and actively engage with our clients to better understand the challenges consumers face in not only accessing their health information but working to break down some of those barriers. Thank you.

Michael A. Ibara, Pharm.D. – Private Consultant – Michael Ibara, LLC

Hi, I'm Mike Ibara, I'm currently privately consulting, I'm a Pharm.D. by training working closely right now with CDISC on developing out their digital health standards especially with healthcare link. I, until recently, actually was...I spent about 15 years at Pfizer so Kim I was on 42nd Street that place is neat. I was in the pharmacovigilance group, while there I created something called ASTER which was a study to take adverse events directly from the Brigham EHR and report them into FDA and so in that work for the last, probably about eight years now, I was focused on how best to take digital healthcare data from the electronic sources and move it over for research and regulatory purposes. Thanks.

Karen Nielsen, MPA – President – Nielsen & Associates, LLC

Small world.

Russell Leftwich, MD – Senior Clinical Advisor, Interoperability – InterSystems

Russ Leftwich.

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

Sorry, go ahead, Russ.

Russell Leftwich, MD – Senior Clinical Advisor, Interoperability – InterSystems

Yes, I started out a first career practicing internal medicine in Nashville, Tennessee for over two decades and then started my second career with the State of Tennessee as the CMIO for the Office of eHealth and six months ago I joined InterSystems which is a healthcare solutions company with database

platforms and health information exchange platforms where I am now based in Cambridge, Massachusetts.

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

Dale?

Dale Nordenberg, MD – Chief Executive Officer – Novasano Health & Science

Yeah, hi.

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

Dale?

Dale Nordenberg, MD – Chief Executive Officer – Novasano Health & Science

Hi, yes, this is Dale. So, I'm currently the CEO of Novasano Health & Science which is a healthcare technology services company with a focus on public health initiatives and in that role I co-founded and am now the Executive Director for the Medical Device Innovation Safety and Security Consortium or MDISSC which is about five years old, it is a not-for-profit public/private partnership with the large manufacturers in health systems and close relationships with collaboration with government agencies to look at how medical devices could be optimally secured both as devices and as medical device networks so that all of the data that we're are now sharing would be shared in a more secure arena and would promote patient safety and quality of care.

And prior to that I had been involved with...I was at the CDC as the Chief Information Officer for the National Center for Infectious Diseases where I was responsible for all the informatics for that center and was very involved with the laboratory domain where I was able to help launch some initiatives like the Public Health Laboratory Interoperability Program or PHLIP which helps public health laboratories across the country do standards-based data exchange for preparedness and response in day-to-day public health initiatives.

Michael D. Buck, PhD – Senior Director Biomedical Informatics – New York City Department of Health and Mental Hygiene

I'm Michael Buck, I'm from the New York City Department of Health and Mental Hygiene. My background is Senior Director of Biomedical Informatics and I work a lot with...I've worked with Rich and Kim with PCORI Health Project where...and I've been applying that work from ONC to my work with health information exchanges throughout the city to gather information for public health scenarios as well as...or continue to work with EHR vendors directly and gathering information to monitor disease throughout New York City.

Eric Heflin – Chief Technology Officer –Sequoia Project/HIETexas

Well, very good, I think I'm next, I'm Eric Heflin, I'm the Chief Technology Officer and CIO for the Sequoia Project which operates multiple initiatives including the eHealth Exchange forming a state-wide health information network and also Carequality.

And in addition I just want to say I'm honored to be part of this Workgroup or this Task Force, thank you for having me and look forward to providing some input. Formally both these organizations I work for now are non-profits, formally I used to work for vendors until recently so I have a strong focus on trying to really just get things done and make them work and focus on a use case-driven approach.

I actually am a Software Engineer by heart and Software Architect, I actually still program on weekends and evenings occasionally just for fun to keep my skills fresh in that regard. My really, standards activities include work for IHE where I co-chair a workgroup, all to HL7. I co-authored quite a few of the

specifications that we're actually using in production today for HIE to HIE data exchange and I'm really focused these days on production deployment and operations and use of many of the standards actually mentioned in the ISA.

I have a focus on security, I'm testing directories and patient matching, and I really do hope that on our work for this Task Force that we really focus on use cases and what we can do for patients and providers on the business side and also as well to use that to drive all of our technology-based decisions. So, thank you, again.

Tone Southerland – Director of Implementation – Ready Computing; Co-Chair, eHealth Exchange Testing Workgroup – The Sequoia Project

Good morning everyone, Tone Southerland from Ready Computing, I'm currently the Director of Strategic Consulting. By background I'm also a Software Architect Engineer so that's still kind of in my heart but these days I run a distribution consulting team we focus on healthcare IT interoperability strategies specifically as it relates to standards and I also am involved in a few different areas in the health IT standards space.

I Co-Chair the HIE Patient Care Coordination Domain. I Co-Chair the eHealth Exchange Testing Workgroup. I do a little bit of work there and others there and I've been involved just in general in various different standards activities over the past 10 years. So, thanks for the invite and I'm looking forward to the participation in this.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Susan are you on mute?

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

I believe Susan was on but Clem why don't you go and then we can go back to Susan.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

I'm Clem McDonald I'm the Director of the Lister Hill Center at the National Library of Medicine and I think I was working on medical records since I was born. We built one of the early record systems, we built the first health information exchange in Indiana and all of it made it so clear that you can't do it without message and vocabulary standards, it's just too hard. So, that's why I've been involved in them for all these years too.

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

Susan?

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

Okay, Kin Wah.

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

So, this is Kin Wah Fung, I'm a physician by training but I've been working in the medical informatics area for the past 15 years. I'm a Research Scientist at the National Library of Medicine and my work mainly involves medical terminology and vocabulary standards like SNOMED, ICD and also RxNorm, and I do mapping between some of these vocabularies so I'm looking forward to working with this Task Force.

Susan Matney, PhD, RNC-OB, FAAN – Senior Medical Informaticist – Intermountain Healthcare

So, this is Susan, I'm on, I just found about this meeting a half hour ago because I just started a new position. I work as a Senior Medical Informaticist at Intermountain Healthcare. My primary role is I'm working for Stan Huff and I'm ensuring that the clinical information models are standardized with content. I'm the current Chair of the Nursing LOINC Sub-committee, I'm a past Chair of the SNOMED CT Nursing Sig. I am a nurse and very proud of it. And I understand all the different nursing terminologies in the industry and I'm excited to be on here. Thanks.

Daniel J. Vreeman, PT, DPT, MSc – Research Scientist - Regenstrief Institute

Hi, this is actually Dan Vreeman I've been on but apparently was on maybe the public line so I couldn't say that I was on earlier and I'd like to introduce myself. So, I'm a Physical Therapist by clinical training, informatics researcher at Regenstrief Institute and the IU School of Medicine and I had a part of data standards work including LOINC and SNOMED and I'm happy to be on the committee.

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

Do we have Chris?

Christopher J. Hills – Team Lead, Standards Engagement Team - DoD/VA Interagency Program Office

Yes, I'm here, I was just curious if there was anyone else we had skipped. So, this is Chris Hills, I am a Computer IT person by training and have been working in the health IT background for the last 8-10 years. I am the Team Lead for the Standards Engagement Team inside of the IPOs, so I coordinate all of our standards releases and balloting across all of the standards within the DoD which tries to coordinate with the DoD and the VA. So, I'm excited to be here. I was on the last Task Force so I look forward to making more great contributions and working with all you guys.

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information Technology

Everyone, this is Brett Andriesen from ONC. I am in the Office of Standards and Technology in our HIT Infrastructure and Innovation Division. I have been with ONC for just about five years now. Before I joined OST I was part of our State Health Information Exchange Cooperative Agreement Program. I was the ONC lead for the ISA Task Force last year and helped process all the public comments and all the recommendations that many of you gave the Standards Committee and gave to ONC last year and drafted a couple of the different drafts of the ISA that we made last year. So, it doesn't feel like a whole year has gone by since we've been meeting last but I am excited to be working with you all again to get some good work done.

Nona Hall, BSN – Chief, Standards Adoption Monitoring & Reporting Division – DoD/VA Interagency Program Office

Stacey or Chris are you on?

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

Stacey and Nona do you want to introduce yourself? Chris has gone.

Nona Hall, BSN – Chief, Standards Adoption Monitoring & Reporting Division – DoD/VA Interagency Program Office

Thank you, so much, yes, if you can hear me this is Nona Hall, like Brett I was with the team last year supporting the Task Force and the actions that were recommended. I come from the IPO and right now I am by profession a Nurse Clinical Informaticist and I support, right now, through an ONC detail. So, happy to be back again.

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

Nona?

Nona Hall, BSN – Chief, Standards Adoption Monitoring & Reporting Division – DoD/VA Interagency Program Office

Yes?

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

Do you want to introduce yourself?

Nona Hall, BSN – Chief, Standards Adoption Monitoring & Reporting Division – DoD/VA Interagency Program Office

Can you hear me okay?

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

We can hear you.

Nona Hall, BSN – Chief, Standards Adoption Monitoring & Reporting Division – DoD/VA Interagency Program Office

I'm sorry, it's Nona, I work with the IPO and I'm currently detailed at the ONC and like Brett I supported the ISA Task Force and will do so again. I mainly have a background with nursing and have been with DoD and VA largely supporting their interoperability efforts and happy to be back again.

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

Thank you and I think we actually have a full list of members. So, everyone was able to join the call in the end so thank you all for being a part of the Task Force. Can we go to the next slide? So, Kim do you want to walk us through the charge? Did we lose Kim?

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

Sorry, I was on mute. Talking and on mute. Basically what the charge for the Task Force is, is to go through the ISA document, the 2016 document, and see what type of revisions or enhancements that we should create for 2017.

So, last year was probably a really big year for the document. We got a lot of really good feedback from the group on how to format the document, what its intentions were, because it was a new document and everybody didn't understand exactly what the intentions and the purpose of the document was and so what we want to do this year is, one, to relook at it, are we on track with what we had put together last year and are there any changes that we should consider to make the document better, and then also to review all of the public comments that came in regarding the document on how to improve it. Rich, any extra comments?

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

That's a good summary, Kim, thanks. So, at this point let's turn it over to Brett who is just going to give us some I think helpful background to just level set everyone on the ISA and where we're headed here.

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

Hey, Rich can I ask a question before we dive in because it might affect how Brett, what he covers?

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Sure.

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

Just on understanding the, you know, the problem that we're trying to solve as a Task Force, is it really focused more on the ISA as a vehicle and how it is structured and works or is it on the actual standards that are included in the ISA or both, or neither?

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

It's both and I think, you know, we want to make sure that we're validating that there is utility in what's being provided, so we want to make sure that we check that, but we also believe that the most important part of this is going to be, you know, the standards themselves, the signals that are being sent as part of this advisory and the information around the standards. So, you know, we expect this Task Force to get very specific about what changes are needed.

I think that last year's ISA Task Force did a really terrific job of improving over the year prior and, you know, just from a personal vantage point, and we'll obviously take everyone's input, I think we've got a great starting point framework to work from and we'll actually be able to, you know, work our way up the food chain of, you know, questions and new challenges and opportunities for all the stakeholders.

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

Thanks

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information Technology

All right so I will dive right in here, just so everyone is on the same page we thought it would be helpful to give folks some background recognizing that some folks have really probably read the document numerous times and given us public comment on it and know it inside and out and others may not have seen it before at all.

So, the Interoperability Standards Advisory, which we lovingly refer to as ISA, really was our first deliverable as ONC in support of the Nationwide Interoperability Roadmap. Its goal was really to provide the industry with a single public list of the standards and implementation specifications necessary to fulfill specific clinical health IT interoperability needs. We did specifically choose not to include many administrative standards that are in play for payment and administrative operations in healthcare.

Last year we really did, thanks to the Task Force, add many known limitations, preconditions and dependencies as well as known applicable security patterns applicable to reference standards and implementation specifications to help really give much more additional information and context to folks that are looking at the ISA.

As Rich mentioned before, the ISA is and continues to be a non or sub-regulatory advisory document in nature with a straightforward approach with an interactive process for getting stakeholder feedback and predictable annual process for getting updates. It is meant to prompt dialogue, debate and consensus among industry stakeholders when there is more than one standard or implementation specification that could be listed as best available. We really want to try to figure out what's kind of the best or multiple bests out there are not pick and choose.

It was initially published in January, 2015, at that point it was about 13 pages and over the course of the ISA Task Force and two rounds of public comment last year we really expanded it from 13 pages out to I think it landed at around 79 pages last year and really it's not the length but also the content within it that greatly expanded and thanks everyone for the comments that were submitted. Next slide.

So, in the ISA the list of standards and implementation specifications may be adopted in regulation, it can be required as part of a testing and certification program or included as procurement conditions. And it is hoped and thought that the ISA could be referenced by various funding opportunities or government procurements as well.

It is meant to provide stakeholders who administer programs, procurements and testing in those certifications with an advisory to help them achieve their interoperability goals and a place to visit if they have questions about how to achieve the clinical health IT interoperability needs.

It is meant to provide clarity, consistency and predictability for the public. And at this point it does not represent the full breadth and depth necessary for all purposes in interoperability for which stakeholders may seek to interoperate but will continue to expand incrementally as we continue to receive more input. Next slide, please.

So, just to give folks kind of an orientation to what's inside, we thought it would be helpful to kind of almost review the table of contents here on the next few slides and then we'll dive deeper into a few of the sections and show you some examples of what is within the ISA in case folks haven't had a chance to look.

So, it starts off with an executive summary and then details into the scope and purpose of the ISA, and again, the scope is really limited to clinical health IT systems interoperability. We are incrementally adding additional scope but really trying to remain focused on the clinical side of things as we feel there are other documents in other places where those administrative interoperability standards are very well detailed.

It does go into detail what we are considering the best available characteristics which include a number of different characteristics of where we are rating, so to speak, and providing additional really objective advise for stakeholders to be referring to, so that includes, you know, standards process maturity, whether a standard or implementation specification is in final or is a balloted draft.

It includes implementation maturity, so whether something is in production or in limited pilot. It includes an adoption level which tries to give a sense for whether something is widely adopted or is kind of really low on an adoption scale, whether something is utterly required so it's been referenced as part of a federal program requirement in regulation. If there is a cost or fee, or licensure involved for obtaining or using the standard and then whether there are test tools available.

Again, these characteristics really help provide stakeholders with more context regarding, you know, the relative maturity and adoptability of standards and implementation specifications, and also really help to set a baseline to allow tracking of industry progress over time as standards and specs get updated or retired, move from draft to final or from pilot to production and growth from lower to higher adoption over time.

So, diving into some of the content we have, Section I is really around vocabulary code set and terminology standards and here on the screen you'll see all the different areas where we have kind of sub-sections around the vocabulary and code set standards so that would be allergies, healthcare providers, encounter diagnosis, race and ethnicity, family health history, functional status and disability, gender identity, sex and sexual orientation, immunizations, industry and occupation, lab tests, medications, medical references and values, clinical problems, preferred language procedures, imaging, tobacco use or smoking status, unique device identification and vital signs.

On the next slide here, diving into more of the content on Section II, this is really where all the best available content and structure standards and specs are so things like ADT, care plans, clinical decision

support, drug formulary and benefits, ePrescribing, family health history, clinical genomics, images, labs, patient education materials, patient preference and consent, public health reporting, quality reporting, representing clinical health information as a resource, segmentation of sensitive information and summary care record.

And then in Section III are really where many of the standards and implementation specs or services are so things like push exchange, clinical decision support services, image exchange, provider directory, publish and subscribe, query exchange and the resource location.

So on the next slide just to go through some of the sections beyond, in Section IV we have included this as a new section in the most recent ISA published in Fall of 2016 and that really is a section, which is all the interoperability needs that we had received comments on in the latest round but felt needed to be vetted further and are planning to at some point add them into the ISA but would really love your input on a lot of these.

So, there are a number of different interoperability needs related to healthcare providers, lab tests, a lot of stuff around nursing and research, care planning, a lot of stuff around medical device communication to other information systems and technology, data provenance, public health exchange stuff like that.

In further sections we have questions and request for stakeholder feedback which we are analyzing responses to from the most recent round of public comments and would also love input from the Task Force on as well.

And then a number of different appendices, so Appendix 1 we have the annual process to update the ISA which if folks are unfamiliar it starts with a publication towards the end of the preceding year, so to take this last year for example, we published our 2016 ISA in December of 2015. We then open it up for a first round of public comment through March and April.

Then we have a health IT Standards Committee Task Force, which is you all, that reviews those public comments, gives recommendations to the Standards Committee and gives recommendations back to ONC. ONC then implements those recommendations into a draft 2016 ISA which will be published around late summer/early fall. Opens up for a second round of public comments then we publish a vital 2017 ISA around December 2016 and start the whole process over the following year.

The next two is a new section that was added last year and that is a source of security standards that we grappled with on this Task Force last year how to includes specific security standards and ended up deciding it be kind of too onerous to maintain and update that because that can kind of really change overnight so we felt that it was more helpful to industry to provide a kind of source that folks can go to, to be looking at where those security standards are listed and can be more regularly updated.

We also include a revision history so folks can kind of track from version to version what has changed and then an appendix for, and this is an area where I believe we will have some homework for the group, we provided some responses to comments where there was a need for additional consideration so those were things that maybe we just didn't have time to implement in the short turnaround time from processing public comments to putting out the next version or maybe things aren't quite settled enough for us to make determinations and include them in the ISA, but these are areas where we did receive public comments and wanted to respond to them and just for various reasons weren't able to implement those into the previous ISA draft. So, would love some input from you all on what some of those priority areas are and I think we'll get to those when we talk about next steps.

So, before I jump into the next few slides, which does a deeper dive a little bit into some of the specific interoperability needs within each of the sections, I'll pause here and just see if there are any initial questions or comments before we move on.

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

This is David again, McCallie, just a clarifying comment, I'm not quite sure about the distinction between 2016 and 2017, and what is the substrate that we are focusing on? There's a published on the web 2016 document is that substrate or is there a not yet published 2017 that we should be focused on?

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information Technology

It is a published 2016 version, we haven't even started the not yet published 2017 draft at this point and we will wait from input from you all to be publishing that.

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

Okay, thanks.

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information Technology

Yeah.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

This is Clem McDonald, I just have a question to the whole group, you know, the challenge of communication networks and all the certificates and managing it I think is very high and hasn't really been a booming success yet. But I was just wondering if anyone thought this new technology with end-to-end encryption would simplify everything or whether that is something we should consider or talk about?

Eric Heflin – Chief Technology Officer – Sequoia Project/HIETexas

So, this is Eric, we actually are...part of our work for Sequoia actually manages a PKI including interoperability of federal agencies and private entities and we are actually using it in encryption now. And so I would be glad to talk in detail about that either now or in context of specific areas of the ISA.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Great, thanks.

Eric Heflin – Chief Technology Officer – Sequoia Project/HIETexas

The kind of bottom line it was designed for scalability and there certainly are challenges but I think it is working relatively well and, you know, I hope that we can continue something somewhere in the future as well.

Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator

This is Mark Roche, I have a question. Looking at the Sections I through III I'm wondering whether you're considering these standards topics to be revolving around the electronic health record or potentially also medical devices?

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information Technology

That's a good question. I think when we initially started we were envisioning electronic health records but I think we are open to more and more different types of health IT in general. There are medical

devices in some standards related to medical devices into the proposed edition to the ISA section, Section IV, so certainly I think we are open to medical devices being something that's included here.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

If I could weigh in just a bit, I mean, medical records are empty unless you have something to feed them and devices and people, and a variety of other systems feed them so I think it's kind of entwined already and IEEE which deals with a lot of devices actually already uses v2 and another standard to communicate between their devices and medical records. So, I think it is part of it but it's really all part of medical records in my mind.

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

I think, this is David, just another, you know, maybe question for the broader strategy about what we do with our Task Force, I mean, there are clearly some broad questions about what's the purpose of ISA and how it fits into the...how a sub-regulatory text fits into the regulatory process that I think some of us would like to discuss.

There is obviously a lot of questions about specific standards and whether they should be included or not and why we would, you know, why we would want to do that and then there's questions about the document and process itself just the mechanism of the ISA and I think we ought to work hard to keep those things straight otherwise it's going to be really challenging.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

I think that's good feedback David. We are at...once Brett finishes his update we're going to go through a list of questions to get the juices flowing and then we're going to ask the Task Force for feedback, give you some homework, some think time homework to help us set this up with the right questions and the right priorities.

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

Good, I obviously, haven't read ahead.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

That's fine, it's a perfect setup for where we're headed, thanks.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

One more piece on this. I think one of the things that's hard about the document is that, you know, you've got things like SNOMED for smoking, which is a teeny little one question and you've got other things that are huge spaces, so there is like...they're not all comparable in the sections.

And then the other thing is some of them I don't think the average person knows what it really is or whether it overlaps with anything and whether we could find a way to build in just a couple of lines of text to explain some of them and say how they may overlap would be helpful for making decisions.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Clem, I think that's a good call out and part of what we will be doing here...we have, you know, a short timeframe so we're going to...you know, pick the spots that the Task Force believes that we should concentrate on and address ourselves to the large priorities, I mean, that sounds like, you know, a really good goal.

And, you know, we're going to work to not only improve what's there but also to look to extend what's there and to refine where necessary with additional explanations potentially signals of, you know, where the puck is going, maybe the best available is pretty awful and maybe we need to make that

clearer. And so, that really will come back to you as Task Force members to help us make sure we've got the right priorities and focus for the 2017 recommendations.

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information

Technology

All right, well hearing no other comments or questions let's move on then and dive a little bit deeper into a few sub-sections of the document just to kind of orient folks to how it is laid out if they haven't seen it before, but hopefully everyone has read it and already knows what is going to be on the screen here. So, next slide, please.

So, in Section I, again this is all kind of...the vocabulary code set and terminology standards, wanted to call out just one example here, so to show folks the structure, so here we have our sub-section D here which is race and ethnicity and in this sub-section there is really only one interoperability need currently and that is representing patient race and ethnicity. You can see the type there is a standard, standard or spec is the OMB standard that is listed there. There is a URL link to it not as a final standard but it's in production.

ONC's best assessment is that is a four on the adoption scale. It is federally required there and there is a link to the regulation where it is required. It is a free standard to use or there is no license associated with it. There is no test necessarily available with it. We have a number of different kinds of limitations and dependencies and preconditions for consideration for stakeholders to think about as they are considering this interoperability need here on the left.

And then on the right for everything in Section I or for many cases in Section I, we've tried to add applicable value sets where necessary to provide some additional context for industry.

So, then on the next slide we have in Section II we decided to call out one of the interoperability needs for labs, this is receiving electronic laboratory results, there are a few other interoperability needs in this section but wanted to pull this one out because it shows off really that there is a standard and implementation specification and then an emerging alternative implementation specification that could be considered here.

Again, we have the standard, the base standard listed then an implementation guide for the S&I Framework LRI there both of those are final production. Standards and specs with a 4-5 adoption level, you can see the various different characteristics that are listed for each of them there.

And then an emerging alternative to that implementation specification, which is in early stages but it is something that could be considered best available and it's something to kind of have folks be keeping an eye on.

Some limitations, preconditions and dependencies are listed there again and then you'll see a number of the different applicable security patterns for consideration so thinking about things like secure communication, secure message routing, authentication, authorization, user role purpose of use things like that.

And then on my final slide here we'll move into Section III, this is just one of the interoperability needs within III-C image exchange versus exchanging imaging documents within a specific HIE domain and wanted to call this one out here because it does show, again, there is the emerging alternative implementation specification and then this one we've tried to attempt to show...and there are certainly probably better ways that we could do this, but this is one way place I think where we would love some input from you all on.

We've attempted to show that there is a relationship between several of these that's kind of what we're signifying with the 1, the 1, 2 and the 2 there, trying to show where things work together when there are multiple standards associated with a specific interoperability needs.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Can you take questions now about these?

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information Technology

Sure.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Sure.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Okay, so, on the laboratory one it wouldn't be obvious to people that the difference between the emerging one and the real one is like 20 words, I mean, it's really tiny differences they've restricted out some of the things in the 2.5.1 into the S&I Framework one. So, it comes across, some of the other emerging ones are like FHIR versus version 2, which are really big differences, but this is a teeny it'sy bitsy difference. I don't know how you can convey that.

And in terms of the imaging where does DICOM live in this? Are these also DICOM standards? Because that's what I thought was the big kahuna on the imaging exchange.

Eric Heflin – Chief Technology Officer –Sequoia Project/HIETexas

This is Eric, I also have a comment if I could on the prior slide 12, regarding the security standards. I think that there are probably some revisions there I would suggest. For example, authentication enforcer is tagged as being a centralized authentication process and I believe that probably...that and also the SAML comments for credential tokenizer and so on and assertion builder don't apply. This is actually, I believe, typically done using MLLP not SOAP and so those would actually largely apply for a SOAP-based transport as opposed to raw HL7 version 2 transports.

And I would be glad to provide...

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

Well, I'm going to...

Eric Heflin – Chief Technology Officer –Sequoia Project/HIETexas

More detail in writing or as our homework assignment if that would be appropriate.

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

I'm going to take it...this is David, I'm going to comment on these two questions as indicative of what I think is maybe a central issue with this ISA which is to say no nice concise, one page summary of these incredibly complex spaces can in fact capture all the subtleties and details and anyone who is going to actually implement something or service in one of these spaces is going to be deeply familiar, as Eric and Clem are both, with the actual standards.

So, I'm just not clear on what the purpose of the ISA is?

In other words if you're going to implement a lab HL7 system you're going to know this stuff inside out. If you're going to implement image sharing using any of the many approaches that have been tried or haven't been tried you're going to know it inside out. You can't get enough of that from the ISA, so

what problem are we trying to solve by listing these things here that's my fundamental issue. That will tell us what we should...

Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator

I...

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

Shouldn't list.

Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator

This is Mark, I actually worked with ONC on a number of previous ISA initiatives behind the scenes and with a lot of these standards as they were being developed, designed, developed and implemented, the problem is sometimes that the standards themselves are overlapping and there is a need for an overarching kind of like review of all the standards and how they fit together, so to put the pieces of the puzzle together so that both the standards development organizations and the users understand how different standards components fit together so that we can identify overlaps and gaps much more easily. To me that's the key purpose of the ISA.

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

But that...this is David, I mean, I think that's a nice goal to have, I'm not sure if this document can get you there. I mean, those are...each one of those is a fairly complex discussion in any one of the dozens of domains that the document summarizes. And, you know, just because the standard is listed on here doesn't mean it is any good. These are just lists of standards and many of them have never even been implemented.

Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator

Well...

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Actually, I think it's a great question. I mean, we spent, Kim and I, and Michelle and Brett spent some time with last year's chairs of the Task Force who now happen to be the co-chairs of the HIT Standards Committee and, you know, the very first thing, feedback and guidance that we got from them was, you know, to ask is, you know, the ISA format and approach useful to practitioners in the field, and, you know, a need to just revalidate the expected audience which as was described to us was health delivery organizations or providers that are...and tech developers, and federal providers.

So, there is, you know, a number of different constituents that they were trying to provide some overview to on standards and I think that is, in their view, a question that we should be trying to address, David, exactly the one that you're asking.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

This is Clem, in defense of ISA I think it could be useful I just think that it has to be...the difference between emerging standards and the next version, if we've got 8.1, you know, I mean, there's a whole bunch of HL7 versions and I kind of think the emerging one for the lab is almost the new...just a slightly different version and we should make those distinctions where it is not a leap that it would be trivial to implement it if you're already implementing the other ones, you may not want to.

And then regarding just getting it right, you know, what are the ones in this space that we should be looking at and I'm not sure...DICOM maybe mixed in with IHE I just don't know that space well enough, but to not have DICOM on that one really threw me off.

Eric Heflin – Chief Technology Officer –Sequoia Project/HIETexas

So...

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

So, that just needs more homework I think.

Eric Heflin – Chief Technology Officer –Sequoia Project/HIETexas

So, Clem, this is Eric, XDS-I is actually based on and includes elements of both DICOM and XDS so it's in there, the specification explicitly.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Yeah but it's not mentioned so a reader of that, from a radiology department, would probably revolt because they're sort of all tuned to DICOM. So, I think it's a matter of tuning the content with some expert input but it's difficult in a political arena and in a big committee, so I don't know if we can get there.

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

So, Clem and Eric DICOM is in here it's just in a different section. DICOM is an image standard not an image sharing standard so I don't think it's a big...that's a particular problem.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Okay, but they do...

Eric Heflin – Chief Technology Officer –Sequoia Project/HIETexas

Yeah.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Some web-based image sharing, no?

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

Well, there's tons of ways to do it. I mean, there are lots of real world implementations that aren't anywhere on this list that are solving, you know, problems every day and they're not using any of these technologies. That's, again, back to the question of what's the point of this sub-regulatory publication? Is this a staging ground for a regulatory candidacy in which case it matters a lot? Is it just an FYI in which case maybe the Wikipedia is a better approach? Or is it something different?

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Let's use that as a segue to the questions and what we've done is to...if we can go to the next chart, please. We've put together a list of questions that we think are important for the Task Force to address and we're going to want your feedback on these because these questions will guide our work over the next couple of months. So, if we could go to the next slide, please?

So, we've set out on this chart and the next one a few questions for your consideration, when we get to homework, you know, kind of what we're going to try and prep for, for the next meeting, it really will be to get your feedback on these questions it doesn't mean we can't talk about them now, but to get

formal feedback from you on what questions we should be addressing and that will guide a lot of the work of the Task Force and what are the priorities.

So, just with going down the list here, so with respect to 2017 I think this is really the one that we've been talking about or some refinement on it. Does the ISA contain information and criteria that makes it a useful tool for the industry and what additional content or criteria should be added to improve its utility? So, that's the first question and let me just go through the whole list and then we'll open it up to discussion around these questions.

The second one is, you know, what gaps exist and I think, you know, some of Clem's commentary and some of Eric's commentary were towards this question, you know, where are there gaps in the ISA that the Task Force should try and address this year?

We know of some various category areas like population queries or distributed queries, or research broadly. We know a lot of work that is going on in terms of value set harmonization for quality measures that this will be an important area that is not necessarily being picked up adequately in the ISA today and then representation of other standards that exist to offer context and kind of clarity around the relationship of LOINC and SNOMED for questions and observations.

So, again, these are examples, they're not meant to be suggestions as to what the Task Force gaps are that we should address but just to get the thinking going on what those gaps might be. If we can go onto the next chart and then we'll come back to this one and have some conversation.

So, the next one is, are there better ways for the ISA to show relationships across various programs/initiatives? They have an example of MACRA, Meaningful Use, precision medicine, you know, the list is fairly broad and are there ways to kind of create an understanding of the connection of standards to their use in various programs.

The next one is what standards become, I mentioned this earlier, more or less relevant in an open API world? You know I think a good example of this might be, you know, dynamic care planning across settings of care. Does an open API world suggest that we should be thinking differently about standards than we have up until now and if so how do we reflect that back into the ISA, you know, to make sure that we're not...I guess I'm explaining a prejudice, but perhaps adopting into something that is more rigid or less flexible than is really needed to, you know, support a dynamic care plan. So, that would be an example there.

What's the importance of, you know, SMART on FHIR work that's been done on decision support. Another, I think great example in this area where there is actually some development work going on and, you know, what is the evolution of, you know, SOAP-based web services compared to FHIR and, you know, what should be getting done and where.

There are a number of questions that can be asked in this area, again, these are examples that really say, does our view on standards and the way forward change as a result of this and is there a way that we want to reflect that back in the ISA?

There was some critique last year...of last year's standard that the measurement of adoption was too subjective. So, is there a better way to measure that? Is there a better way to show the trajectory for a standard? Is the adoption increasing or waning or what might we forecast in that regard?

And then finally, we did get some guidance back from the ONC Health IT Standards Chairs that there is probably some overlap with the Interoperability Experience Task Force and some alignment setting that we should be striving for so we'll try and make sure that we ask those questions and see what kind of feedback or kind of cross pollination is appropriate with that Task Force effort.

So, let me stop there. Those are the questions that we came up with to, you know, start the conversation and again, the point here is to give you examples, we'll try and finalize these as a result of your feedback post this meeting but let's get into some of that conversation now.

Eric Heflin – Chief Technology Officer –Sequoia Project/HIETexas

So, this is Eric...

Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator

I...

Eric Heflin – Chief Technology Officer –Sequoia Project/HIETexas

I think this is a great starting point. I really like Clem's comment as well to whether we would consider adding devices to scope or not as an explicit decision and the other thing I would offer in addition to what's on slide 15 and 16 is also I think kind of the, in my mind, big question of what needs to be updated in the existing ISA to reflect progress in the industry between now and last year.

Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator

This is Mark Roche, I think there is one question that would be interesting maybe, how can we improve or feedback of the variance of these standards to make sure that we thoroughly understand how they're actually being implemented in reality the consistency and the level of consistency of their implementation so that we really know what's happening with these standards in the field whether they are working or not.

I'm also an HL7 member so I know that there are a couple of ways that the industry can provide their feedback but so far I haven't seen any consolidation of, I would say, feedback and infrastructure or feedback architecture where any user in any hospital that implements any of these standards can simply go to and say "hey, this particular aspect of C-CDA needs further consideration."

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Could I just to weigh in, this is Clem, on the issue of measuring, Hewlett Packard did a survey maybe 10 years ago through I think CEOs or CIOs and got some data about the usage of some of the standards and I don't know whether that's something...if ONC has any resources they could generate a survey to some targeted group or some random group of people who might know just if they're using it or not using it, that would be helpful.

And the other groups, the insurance companies are asking for data to be delivered, it's probably just a few domains, like United Healthcare and now they're asking for lab results to come from a least the referral labs, and whether they would provide some feedback about how well what they've dealt with are being implemented, the standards have been implemented, just a thought.

And then the idea about APIs replacing messaging, which is sort of hinted at, you know, you've got to realize it took them almost 10 years to make an NPI work, the one single code, so these things you can't...these are like big heavy oil ships you can't change direction quickly and I think we'll expect to see...for ordering and things I don't know how you're going to do it without messaging.

So, I think that the APIs are going to be an additional thing a little bit like radio versus TV, I don't know who is going to be the radio and who is the TV they'll both be there and I don't think we should plan on redoing everything because it just takes too long to get the boat turned around.

M

Could the...

Michael A. Ibara, Pharm.D. – Private Consultant – Michael Ibara, LLC

This is Mike Ibara, just...I'm sorry, just a follow-on to what Clem said. It seems like the general question in this unfortunately goes back to a more general question overall for the group that was asked is, so rather than talk about is, you know, should it be SOAP or REST, or something shouldn't we be talking about which standards fit which situations now in healthcare or are we trying to predict also and then that just basically takes us back to, is this...the most important question seems to me, having just come into this now, not having been on other ones, is this a staging ground for regulatory consideration. It seems like if it is that complicates it and makes it much more difficult and if it's not what exactly is it?

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

Yeah, this is David McCallie, again, I'm curious if ONC staffers have any sort of user stories about how people have used the standards advisory? Have you gotten feedback from, you know, people or entities that have found it helpful and if so what parts of it they found to be helpful? That would be...that's nothing to answer right this minute, but that might be interesting to go back and pull something together because it's not clear to me who benefits from this.

I mean, we all know that, you know, the standards groups are always waring with each other to be the standard and so we've got lots of standards wars captured on these pages but if you're trying to use those standards to solve real problems you already know about that and this isn't, you know, settling the argument because it's not regulatory. So, what is it? That's still what I'm struggling with.

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

David...

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

I'd be curious to know how people have used it?

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

David, this is Kim, I would like to provide an example of how it may be used, like in my role I'm not a software engineer where I'm implementing all these standards and know the details inside and out, but I am a user of the data and sometimes, and not so much now, but in the beginning I needed to know how certain things were identified or represented in the electronic domain and being able to go back and find out what vocabulary is used, how it's been transported, that content, could help me figure out, okay, how can I get the data that I need that is in these electronic systems so that I can accomplish some of my business goals.

So, the company I work for probably doesn't implement any of these standards, but we definitely use the data. So, as a user of the data the standards are very helpful and this document wasn't around when I first started doing this but it would have been very helpful for me to have a place to go to, to see what they are and to figure out...start putting those puzzle pieces together to get the information I needed for what I was trying to do either for primary use or secondary data use. So, that's one case I would like to share.

Susan Matney, PhD, RNC-OB, FAAN – Senior Medical Informaticist – Intermountain Healthcare

And this is Susan Matney at Intermountain, I have a use case when it comes to nursing, there are 12 American Nursing Association recognized terminologies that currently don't speak to each other and because of these initiatives and what its saying in the standards advisory that we use SNOMED for the problems the nursing terminologies that have nursing diagnoses in them have been mapping to SNOMED so they can be messaged in a C-CDA. So, I think that these have had a big impact on nursing to

get it. They're still going to use the nursing terminologies in their systems but when it comes to sending between systems they are all really rapidly getting their mappings done to SNOMED and LOINC for outcomes and assessments.

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

So, I...this is David, let me respond to that, I mean, I think that's a...those are both good stories, my concern is that the decision to use SNOMED in the CDA for communicating problems was not a side-effect of the standards advisory that was a side-effect of long and complex deliberations over the last six years of figuring out the certification standards for Meaningful Use. The ISA merely documents the outcome of that.

So, I think as an informational tool for somebody who is coming into the field new and wants to understand, you know, what's the current snapshot that makes good sense but the ISA was not a forcing function at all and if we want to turn it into a forcing function so that it becomes a staging area for regulatory then I think, you know, that's a...that could become a very important function but it changes, you've got to have a process around that and I don't think we're there at the moment.

Dale Nordenberg, MD – Chief Executive Officer – Novasano Health & Science

This is Dale Nordenberg, I just wanted to quickly express support for the notion of including medical devices, they're clearly the source of so much of the data that's being exchanged in the healthcare marketplace today.

And then the second notion is, and I'm sure many people on the phone have seen this already, is that as we increase the amount of interoperability that we're all experiencing it doesn't necessarily express the quality of the interoperability or quality of the data and the data is increasingly being used, at least inside the fed, is the basis for delivery of care. So, I'm just wondering what we might do to engage, you know, the concept of quality, the quality of the interoperability and the quality of the results of interoperability which are, you know, these data assets.

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

I like that point, I second it.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Oh, I have to weigh in, first, I worry about defining devices as being part of our goal per se. We're worried about what you said interoperability between whatever and I don't think...we can't standardize devices but we should be able to standardize what they send so if that's what you're talking about I'm 100%.

And then the best quality actually is getting the darned stuff, you know, I'll tell you what it was like when we couldn't get it at all, so getting it is really a great step up in quality versus not having it.

Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator

This is Mark, actually I'd like to qualify one comment on the phone that I made, I didn't only mean medical devices I also meant wearable devices, I meant consumer devices that are being adopted at a staggering rate and they're collecting the data from everyday life and at some point, you know, patients, especially in millennials and younger generations are going to start wanting to...for that data to be easily integrated into electronic health records.

So, I think that while I don't think that we should be mandating these standards but at least if we give some guidance to the entrepreneurs on what standards they should be looking at as they develop these wearable devices would be I think very good.

Dale Nordenberg, MD – Chief Executive Officer – Novasano Health & Science

This is Dale, I think I'd echo both of those two points and the notion that it may not make sense to call out medical devices or call out, you know, outpatient related wellness devices at the end of the day, in today's world, interoperability really covers all of that and I'm just wondering if we should be calling out anything specific or if we should be looking at the use cases and addressing them?

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Could you just clarify that last question? I just want to make sure I understand what you were asking.

Dale Nordenberg, MD – Chief Executive Officer – Novasano Health & Science

Sure, so earlier in the call there was a distinct mention to the notion of including medical devices, I'm just wondering why we should discuss whether to include medical devices or not? There is so much interoperability that's going around medical devices and as one of the last, you know, people said, even around, you know, the homecare based devices or wellness devices, are we supposed to really identify each and every kind of data exchange that's happening and say "okay, we're going to think about interoperability for these and not for those." Or do we basically say, interoperability is about exchanging data in today's healthcare environment and that's a very, you know, broad, you know, broad environment.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Let me do this, we have about 15 minutes left here and I want to make sure we get through the agenda with everyone on the call and I think partly your question will be addressed in the next steps conversation. So, would you mind just holding that for a minute and let us go to the draft work plan, I think Brett is going to take us through that, and then from there we'll move onto the next steps and if your question isn't addressed please raise it again.

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

Brett, do you want me to do this?

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information Technology

Sure go for it Kim and I can provide some clarity, I mean, I think, ultimately we put this together very much as a draft and some of the conversations that we will have today and, you know, over e-mail the next couple of weeks between now and May 6th will certainly define a final or more final draft work plan but Kim why don't you walk us through it.

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

Yeah, so this is something we just put together before our discussion and it definitely has flexibility so don't look at it and think that this is the exact structure and I've been taking notes, I haven't talked a lot, I've been taking a lot of notes and I typically put these together at the end of the call for everybody, but some of the things that I've heard along the way, David you had mentioned early in the beginning, like three key points to focus on, like what is the ISA purpose, which standards do we use, which ones and why and then the ISA document itself.

So, it seems like that first ISA characteristic structure, etcetera kind of goes along with the ISA document itself and then the Section I, II, and III probably goes into the standards which ones and why.

And then we have had a lot of discussion about some other details with things to focus on. So, with the discussion and what we've just mentioned how would y'all like to see this move forward with the agenda so that we can cover the critical key points but at the same time, I believe, one of the things that we have to do is get through the public comments, is that correct?

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information Technology

Yeah and we will provide some summary of those, of various...

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

Okay.

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information Technology

Sections of public comments for the group to respond to.

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

Are y'all in favor of how it is structured now? Do you think we should modify it a little? I know last year we did do an ISA purpose, we could revisit that maybe on the next one because that was brought up, like what is the purpose and we may want to redefine that a little.

We also had some guiding principles, I was pulling out all my notes from last year, so those are some things that we could consider and it fits into some of the conversations. The ISA characteristic structures, etcetera, is something that came up, Russ had written an article around some of that so we were thinking that might could be a small group that could work on that and then to go through each of the sections.

Tone Southerland – Director of Implementation – Ready Computing; Co-Chair, eHealth Exchange Testing Workgroup – The Sequoia Project

Yeah, this is Tone Southerland, I would agree, I think, I mean, just from listening to the conversation and from what I've skimmed of the previous ISA version, I mean, we need to know who are target audience is, right? Because we want to deliver value and the only way we can really do that is if we know who we're talking to. So, I would just second that we spend a little time, you know, adding to the purpose section maybe to talk specifically about target audience there or something to that nature.

Eric Heflin – Chief Technology Officer – Sequoia Project/HIETexas

And this is Eric, I strongly agree, it's hard to write a document without really having a clear picture to answer that question of who are target audience is.

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

And target audience and what problem we're trying to solve. This is David. I mean, if you don't know what problem you're trying to solve you're probably wasting your breath...

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

I have a question to the ONC staff on this. So, is there...I'm not sure, I haven't looked at the public comments yet, so I don't know if it's clear there or if not is there a way to ask a question for public input about, you know, we had some suggestions of use cases of where the value was and should we be asking for where value has been found or, you know, kind of separate from public comment? What would your thoughts be on that? Would that be helpful to the Task Force?

Tone Southerland – Director of Implementation – Ready Computing; Co-Chair, eHealth Exchange Testing Workgroup – The Sequoia Project

This is Tone again, so, you know, when I think of use cases I also start thinking of workflows and clinical workflows and in my experience in the industry it's one of the things they're trying to figure out in the standards space, right, how do we pin standards to certain clinical workflows and how do we allow that to happen in kind of a dynamic nature instead of a static nature, meaning that if you have a patient that crosses multiple medical verticals like cardiology, radiology and so forth how do you handle that with standards and interoperability?

So, I think the use case aspect is important. I do think we have to be careful to keep our focus on use cases that are relevant right? Like pick a few and try to focus in on them if we're going to go that route but, you know, in general I agree that use cases are very important to make sure that whatever it is we're recommending or researching, or what have you, you know, lines up to something that's going to impact end users and patients.

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

So, this is David, Tone, let me respond to that because I think there are two uses of the use case phrase in this last couple of questions. The one I was worried about is not so much the use cases of the standards themselves but the use case of ISA, in other words, who is using it and why, what purpose does it serve as a document published by ONC?

Is it regulatory pre...is it sub-regulatory pre-staging, is it to keep track of the winners of the debates, is it to just be informational links to the ongoing debates?

You know who is using it and why and is it the best place to solve their problems or I don't know people that want to know what...how to encode smoking maybe they should go to the value set authority, why is that stuff in ISA for example.

I mean, what...those are the levels of use case questions that I was worried about not so much how the standards themselves are being used. I think that's down deep in the standards work itself and it will differ obviously by the standard.

Tone Southerland – Director of Implementation – Ready Computing; Co-Chair, eHealth Exchange Testing Workgroup – The Sequoia Project

Yeah, I agree, I agree with that 100%, I mean, this gets back into, you know, what's the purpose of this and who is our target audience. So, yeah, from that perspective I agree we should figure out...

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Okay, so...

Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator

This is Mark, I actually think in terms of specifically smoking, smoking history there are more innovative ways to capture the smoking history such as the type of the tobacco, the frequency, the duration basically adding more clinical components that are more meaningful as opposed to adding the SNOMED CT codes with existing value sets.

So, I think that one of the things that this group can focus on is rethinking whether the way we capture the data in a structured format today is actually sustainable over the next 5 or 10 years. I can tell you from a clinical perspective that the current smoking status value set has a very limited value in clinical medicine.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Could I follow-up on the decision, what this document is for, and I don't know what it's intended for but my guess is how it's really used is by people within organizations to get their management to go a given direction and they look for things like that and then the question then is, we just have to get it right and there are a lot of things to worry about including like one little tiny variable like smoking history, if we spent time on that we'll never get done.

And I agree with Mark, there are better ways to say it, but, you know, LOINC has going on 80,000 variables, we can't talk about them one at a time, we've got to deal with the bigger issues I think. But I do think that people would like to have something that they could wave at their administrator to say "this is what we should do" and then if we do that we at least have to get at the committee thinks it is right.

Russell Leftwich, MD – Senior Clinical Advisor, Interoperability – InterSystems

This is Russ Leftwich, I have chaired the HIMSS ISA Task Force the past two years and in terms of the value of the document the broad range of individuals who participated in that were I would say both commoners and the audience for the document, and one observation I would make is that as representatives of many different domains most of the individuals knew their own domain very well but didn't know much about the other domains covered by the document and the standards for those domains and there were not many implementers but there were many individuals who had some relationship to a product that used standards and were presumably...their clients were mostly end users who I can imagine found the document valuable in terms of understanding the standards that were in the products they were purchasing, you know, as purchasers not as implementers.

Daniel J. Vreeman, PT, DPT, MSc – Research Scientist - Regenstrief Institute

Hi, this is Dan...

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Let me just kind of jump in for a time check. Kim do you think we should maybe get to next steps? I know Michelle you probably want to have some public comment time as well.

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

Yes.

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

That sounds good, so, I think what we will need to do is kind of regroup with all the comments. Rich and I can get together, we can set out an agenda of things that we need. I think Rich brought up a great point about having to figure out the users and Russ I appreciated your comment because that was an interesting part to it also if your purchasing products are they using standards that can be interoperable with other places that you may need them to be.

So, I think we have started some good dialogue and I think we probably should focus on that on our next call to finish up with the purpose and we can send that out to everyone for review and finalize for our May 6th call. And Michelle, I'll turn it over to you for public comment unless Rich you have one more comment?

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Kim, just before we jump off of next steps I still think that the questions that we're asking of the Task Force are relevant here and I agree with the next steps you just talked about Kim, but just what we'd really like this group to do is to take some time to take a walk through the ISA and to think about the

questions that the Task Force needs to address. We've provided you some examples. You've come up with some other ones on this call which have been great additions or great clarifications. And we'd like your help in prioritizing what you believe to be the top areas of focus that we should be seeing through. So, we'd like to get that feedback by e-mail by April 22nd, Brett would that go to you?

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information Technology

Yes, to me is great.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Great, thanks. And then ONC is also going to provide some level of information on the public comments that we've received also in advance of the May 6th meeting and we'd like you to have reviewed that and be prepared to discuss the public comments as well. I think it will be helpful for us to be, you know, well informed not only about the 2016 ISA but also the feedback that's already been collected through the formal ONC process.

So, I think that plus what Kim spoke to will constitute our next steps and we'll really begin to address, you know, one of the questions that was deferred earlier about, you know, how we're going to proceed forward and which questions and which problems do we want to try and solve for within an admittedly short time that we have the Task Force to take this fresh look at the ISA.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Does anybody know whether the comments really will focus us? I mean, is there anyone on the call who have seen them?

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

We'll know better after we've taken a look at them. So, I think we've only got a minute left I want to make sure we leave time for Michelle for closing and comments.

Public Comment

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

Yeah, thank you, Rich. Lonnie, can you please open the lines?

Lonnie Moore – Meetings Coordinator – Altarum Institute

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

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

And it looks like we have no public comment. So, thank you all for joining our first meeting, this was a lively discussion, we appreciate all the feedback that we received and as Rich said, you know, if you have any feedback most of you have my e-mail address, this is Michelle, and I can make sure it gets to Brett. And we will be in touch and talk to you all on the 22nd.

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

Thank you.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Thank you.

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

Thank you, have a great weekend.

M

Thanks.

W

Thank you.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Bye.

W

Bye-bye.

M

Thanks.