

**HIT Standards Committee
Joint Meeting of
Clinical Operations Workgroup and
PGHD Task Force
Transcript
January 25, 2014**

Presentation

Operator

All lines are bridged with the public.

Michelle Consolazio – Federal Advisory Committee Act 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 joint meeting of Health IT Standards Committee workgroup – the Clinical Operations Workgroup and the Consumer Technology Workgroup’s Patient Generated Health Data Task Force. This is a public call and there will be time for public comment at the end of the call. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. I’ll now take roll. Jamie Ferguson?

Jamie Ferguson – Vice President, Health Information Technology Strategy and Planning; Fellow – Kaiser Permanente; Institute for Health Policy

Present.

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

John Halamka?

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Present.

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

Donald Bechtel? Chris Chute? Jeremy Delinsky? Floyd Eisenberg? Marty Harris? Stan Huff? Kevin Hutchinson? Liz Johnson?

Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation

I’m here.

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

Hi, Liz.

Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation

Hey.

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

John Klimek? Becky Kush? Kim Nolen? Marjorie Rallins? Wes Rishel? Cris Ross? Joyce Sensmeier? Dan Vreeman?

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

Present.

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

Kevin Brady?

Kevin Brady – Group Leader, ITL Interoperability Group – National Institute of Standards and Technology

Present.

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

Jay Crowley? Clem McDonald? Nancy Orvis? Terrie Reed? Karen Trudel? I'm now going to go through the Patient Generated Health Data Task Force members. Leslie Kelly Hall?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Here.

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

Hi, Leslie. Dixie Baker? David Kibbe?

David Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.

Here.

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

Hi, David.

David Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.

Hi.

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

Russ Leftwich?

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives

Here.

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

Hi, Russ. Lisa Nelson?

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives

Hi.

Lisa R. Nelson, MBA, MMI – Co-Chair, Patient-Generated Documents Project – HL7

Here.

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

Hi, Lisa. Chuck Parker?

Charles Parker, MSHI – Executive Director – Continua Health Alliance

Here.

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

Hi, Chuck. And Sue Woods? And are there any ONC staff members on the line?

Farrah Darbouze, MPH – Program Analyst, Office of Science & Technology – Office of the National Coordinator for Health Information Technology

Hi, this is Farrah Darbouze from the Office of Science & Technology.

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

Hi, Farrah.

Ellen V. Makar, MSN, RN-BC, CPHIMS, CCM, CENP – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Ellen Makar.

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

Hi, Ellen.

Ellen V. Makar, MSN, RN-BC, CPHIMS, CCM, CENP – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Hi.

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

And with that, I will turn it over to Leslie and John.

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

I just joined this Stan Huff, too. Thanks.

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

Thanks, Stan.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Well hey, thanks very much and certainly look forward to this discussion today. It's a very important topic, I think we are all deeply concerned about patient and family engagement and as I've reflected with the Standards Committee many times, my own experience with my wife's breast cancer, my father's death 11 months ago, my mother's broken hip, all would have benefited with patient family engagement, patient-generated data and enhanced interoperability. And our challenge today and I'm really looking forward to reviewing the slides that Leslie and team have presented, is to assess as we hear about the use cases, the maturity of the standards and their suitability for purpose. Because as we provide advice to the Meaningful Use Workgroup and to the Policy Committee ultimately, they are going to craft some Meaningful Use Stage 3 recommendations.

And I think we have to be careful how we achieve our policy goals, try to set as many unambiguous standards with as little optionality as possible, but also recognizing where we are in the standards process. And we may not be able to achieve every policy goal with an unambiguous standard as we had to 2014 and 15 and it's going to be a fascinating discussion. I know Leslie has considered standards maturity and will hopefully give us a sense of where we can back her policy goals with standards that are good enough for purpose. Leslie, I want to certainly welcome your opening remarks.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thank you very much, John. I think this group has been working on this and done some amazing work over the last year and this task force was brought together in the last few months to address some of the specific questions that we heard. There is a natural tension between when do standards help innovation and drive use, when do standards stifle innovation and actually dissuade use. When can standards be used to advance a new purpose? And we are at the crossroads of that tension and today I hope that we can discuss all the pros and cons. The general feeling of the group was that because this patient today is so largely left out of the digital ecosystem that when patients are invited to the table, they have to be invited with all the appropriate utensils in order to be considered an appropriate guest. And I think that we've felt that absent standards, that it would be difficult to advance an agenda like patient-generated health data except for those organizations that have a pretty contained system.

We somewhat liken it towards in the early '80s, maybe late '80s when we all brought in email and email was inside our organization and we thought that was wonderful, but certainly quite limiting until we had gateways into other proprietary email systems. And now we couldn't imagine a world without that kind of interoperability. I think we're at that point here. So the theme of the group has been let's use standards as a way to help promote the policy agenda and invite the patients to the table with all of their utensils in place.

So, with that, I think we can go through our slides pretty quickly and what we hope to do today is discuss the Consolidated CDA release and our recommendations, Direct, the Continua Alliance and just the overall use of questionnaires, both structured and semi-structured questionnaires, which is the overarching use case given to us by the Policy Committee. Our – there are standards available to support the use of structured and unstructured or semi-structured questionnaires. Next slide please.

So the Task Force members have been working quite diligently and we invited Dixie Baker to help provide feedback and critique of the work being done, as well as Sue Woods. And got some great feedback and we're able to incorporate a large degree or answers to the questions posed to us. And I would encourage the group to look at the entire slide deck when they can; we have pared it down almost by half for the purposes of time. But there is some rich information in there as well. I'd just like to acknowledge Lisa Nelson's amazing work in getting us our strawman as we went forward. Next slide please.

So the scope and the charge of this work was to really look at how standards could help promote and strengthen relationships with patients in our ecosystem, looking at a variety of different patient-generated data options and an emphasis on the questionnaires. And then also make sure we were touching back to different groups, like this one, as we go forward. Next slide please. So the standards we looked at were how could we promote patient-generated health data. We were looking at the availability of standards for the specific use cases. We did come to recommendations, which we'll go over today, but in the vocabulary and content standards area, we felt that there was not yet a standards opportunity for a consumer vocabulary. However, the existing vocabulary as reflected in SNOMED, had – and already stated in meaningful use, could largely meet the questionnaire and questionnaire response use case, simply because this is patient-generated data in response to a physician or clinician request in a questionnaire. Next slide please.

So we were hoping to identify different issues, which we'll go through today, I won't spend a lot of time here. Next slide please. So as we looked at standards, we felt that we were tasked with interoperability between systems and that tethered PHRs to EHRs will probably continue and in health systems where there is a large containment of patients, that that would flourish. However, where there is opportunity for non-tethered or consumer applications that are not necessarily provided through tethered PHR, there is an opportunity for standards. So seeing more consumer-friendly devices, consumer-friendly applications that might want to interact with that EHR, we felt was highly likely. And we felt the standards need to be consistent with EHR to EHR communication but simply expand to patient-generated data. We really constrained our view to existing standards that could potentially be repurposed and reused for patients. And we heard over and over again from people, hey, I don't want a bunch of PHRs, I don't want to have to go a bunch of places, how can I send my data, know it can get to everything and every place I need, or download data as I need it?

Next slide please. So the continuum of patient-generated data we looked at from the very beginning was from the left to the right; messaging, secure – it's structured questionnaires and unstructured or semi-structured questionnaires, device data and then going forward to plans of care or planning of care and then eventually collaborative care planning. So we looked at that continuum of patient-generated health data.

Next slide please. What we felt is that communication structure, as in using Direct for communications, already named in Meaningful Use Stage 2 and work being done to expand to patient use should be considered. We also felt that a strong cornerstone for care team and care planning in the future needs to be identified in the care team specifically. And so we are going forward as a recommendation on the HL7 care team roster and then expanding the Consolidated CDA as this work has been done in HL7 in the last year to include a very significant approach using changes to the header, which we'll go over in a minute. And then also taking a look at the Continua Alliance to support existing device standards. Next slide.

So a little bit about the Consolidated CDA, Lisa came up with this analogy and most of us are old enough to remember Garanimals where we would purchase anything for our child that would match with anything else. And really the evolution of the Consolidated CDA has done just that, where we have a set of templates and instructions and the ability to combine information from different types of documents and to include two header templates for providers and for patients and consumers. Next slide please.

The header approach really helps us to benefit all authors. There is no separate or equal approach for patient data, this is just data with authors identified, provenance identified, roles identified. This encourages innovation in collaborative records and it encourages the use of Consolidated CDA in any EHR. Next slide please. So this just goes into a little bit more detail about the document header, but the important thing to note here is the participant is the people that are active in care, the care team members, who receive the data and our updates. And then we also have the roles of the author, which can be anyone from the provider to the individual patient themselves or family members. So this type of a structure gives us the opportunity to really identify the entire care team and to make sure that we distinguish the act relationships from the participants. Next slide please.

As you know, the care team roster was mentioned in the 2014 criteria, but nothing really specified, so it didn't advance that agenda. The work that Russ has been doing and others on the care team roster helped to give us more detailed information about the individuals across the care team, including the patient. This has been harmonized at the RIM level and we feel is the pivotal starting point to get to eventual care collaboration and collaborative records. Next slide please.

The four use cases we looked at were patient-generated data is a patient response for a request for information or questionnaire. So providing updated medical history, access to the patient's advanced directives or patient's wishes, for care planning or any kind of care planning. A form and questionnaire that uses a Consolidated or standardized CDA and then device data from the patient. Next slide please.

So this gives you an overview of the actual use cases and the recommended standards. And these are all very much consistent with existing efforts in meaningful use. Next slide please.

This is an example of a non-tethered PHR, in this particular case it's NoMoreClipboard. But the patient is using a PHR, downloading that information and able to then use the standards to upload information in this simple way, import the entire document or consume data out of the document and into their system. So this is already being demonstrated and used in many of the non-tethered PHRs today. Next slide please.

We are also encouraged by the use of the Consolidated CDA not only for care planning and advanced directives, but the ability to acknowledge that within a document you might have an active link that takes us to the most current version. We've heard over and over again that getting to the most current version of an external document needed to be incorporated into any of the designer standards principles. I think we were largely informed by some of the work that's been done on the radiology efforts, and much of that applies, much of that kind of use case applies in this for advanced directives. Next slide please.

So we were all tasked with looking at maturity and this was a tough one to get to because something that is already a national standard and defined in meaningful use for the provider could be considered very high on that list. but for a patient, brand new. So under the recommendations of Dixie and others, we felt that it's a moderate, somewhere moderate, if something is brand new for patients but already been adopted by a national standard. Next slide please. So the Consolidated CDA then is somewhere above pilots and in national standards. And we hope to build on the current efforts for the care team roster, also to use it for devices and questionnaires. Next slide please.

The same could be said for Direct. We know that this is a named national standard, still very much new and emerging even in the provider setting. However, as we worked through things in DirectTrust, we've come to realize that many of the same issues apply for any participant, so what is the privacy? How are the directories handled? How is acquisition of the Direct address actually achieved? This is work to be done. We hope that by naming the standard we can help to drive solutions in the market to some of these issues, but we do see that already starting today. Next slide please.

So we talked about devices and the Continua Alliance. And the Continua Alliance is really much more about a group of industry leaders coming together to define particular group of standards and setting implementation guidelines specific to devices. And so we – Continue is looking at underlying standards, making specific recommendations including the device data, the security, the connectivity and certification. Continua is quite actively engaged in international efforts and today the association really promotes and repurposes or defines standards to be used across the country as well as the world. Next slide please. So Continua is more like IHE than it is HL7, I think. There are implementation guidelines driven by use cases, driven by submission process and all guides are published to the public. It's important to acknowledge that as devices are brought to market, they have a two to three year process just to be FDA approved, prior to then adopting standards. So that there is a natural lag time and expected lag time when we look at maturity.

Next slide please. So as we look to the specific use cases of device data and active link or device data and emailed information, you can see that the recommendations are very consistent with the other patient-generated health data, simply constrained further for device use. Next slide please. So today the specifications that have been completed are quite a few, and very much aligned with things you would see in the home for personal use. Next slide please.

So one of the questions we received at the Policy Committee and at meaningful use is how will this support both the use of individual data coming from an individual device and aggregate data. And the actual connectivity model accommodates both, so there could be a personal area network manager, there could be individual device linkages or there could be a health record aggregator, something like a HealthVault, providing information using the same alliance of standards. Next slide please.

We have a high degree of interest across the industry in patient reported outcome measures and these measures both can come from a structured questionnaire that appears to the patient perhaps through a Direct message through their PHR or on a device itself. And so we hope to advance the capability of patient reported outcome measures to support all of the use cases outlined here, as well as the emerging work being done in PCORI. Next slide please. So we – the patient reported outcome measures, we have the ability to, by using the standards, respond with numeric or free text, analog slider, discrete data, pre-conditions and so forth, a great deal of detail that can be provided back into the EHR using the named standards. Next slide please.

So the structured/semi-structured under the Consolidated CDA, we have the ability to define multiple choice, numeric free text, again analog, discrete sliders, decide – we can also define templates for pre-conditions to ask a question if the previous question was yes and also we have the ability template for copyright info related to patient reported outcome measures. So accommodate the industry in every way. Next slide please. It's important to note with our header approach that for the patient-generated responses, we make use of the Consolidated CDA patient-generated header template. And for clinician-generated responses, we use the Consolidated CDA header template. And the templates for capturing patient response to questions are in the actual patient reported outcome measure. Next slide please. And this is just an example of a form definition and how that might create a form-based questionnaire.

So there are another 25 slides in your background material that we would be happy to take questions on these and any others. I purposely went through quite quickly so that we can move to question and answers and discussion. And I would invite each of the team to answer questions and I'll hopefully facilitate those where they're not obviously going to an individual. So, there you go.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Thanks so much for a tour de force presentation, very, very efficient with our time for those 30 slides. And Jamie and I, representing the Clinical Operations Workgroup I'm sure will have some initial reactions, and certainly seeking initial reactions from others on the workgroup. So of course we recognize that CCDA is a standard, which is required in Meaningful Use Stage 2 and is required from a certification perspective for both transmission and receipt, and has certain templates, such as medications, allergies and problem lists, which are well understood. And so I think there will be very little controversy about saying, you know the notion of a CCDA container being used to transmit such information, whether it's a patient or whether it's a provider, work equally well.

I think there will be some interesting dialogue, as we talked about before the call began the fact that Kaiser has a fully integrated, shared record rather than two separate records. So in effect, the patients are doing their problem lists and medication list reconciliation without the requirement of doing a CCDA transmission across two disparate applications. So I think from a meaningful use certification attestation perspective, it'll be interesting as we craft language to say, CCDA is mature and good, it is suitable for purpose for medications, allergies, problems and you may, or may not, need to use it, dependent upon how you do your patient and family engagement, interfaced or integrated.

And then I think we'll all discuss the maturity of the device interoperability standards. You presented Continua quite well, showed the IEEE 1173 standards quite well and if you were to go down to CVS today, chances are, you would be buying products that probably don't use those standards. If you go buy a Withing scale, it's a very effective instrument; it just doesn't use those standards. So, as we talk about maturity of standards, those true are mature and good, but we look at the maturity of the marketplace, it's still rapidly evolving. So that's going to be our interesting tension as we think of certification and attestation.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Um hmm.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

And so Jamie, certainly welcome your comments.

Jamie Ferguson – Vice President, Health Information Technology Strategy and Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

Yeah, thank you John. So I think you nicely encapsulated a couple of things that I think are important to talk about. So it does seem to me, and I agree with your characterization that of the use cases that were presented, I think the med list is one that does make sense, where the standards are mature. I'm not sure the same can be said of advanced directives, where even though the structured document standard that underlies it is mature. The implementation guide and it's use is, I think, not at the same level of maturity, but certainly for the med list portion of the CCDA, all of the different transport standards that Leslie I think you listed on it was slide 16, certainly are easily things we could agree on recommending.

But I have a couple of other concerns; one is something that I think John alluded to about the applicability of these standards. So the very notion that there's a huge ecosystem of fragmented systems actually is counter to the trend of ACO integration and it really serves to perpetuate the fragmented fee-for-service model as opposed to the integrated ACO model. And so I think that we do need to have recommendations that can account for the actual integration across ACOs that is going on and that don't unintentionally inhibit actual integration of patient and provider together in common shared systems. And so that's – I think that's one thing.

Another thing in particular for the devices, recently, actually just earlier this month, FDA published draft guidance for over the counter blood glucose devices, which includes literally hundreds of detailed data specifications for the data that are output by these devices, if they're to be used or marketed with FDA approval. And so of course those data specifications are brand new, literally I think just released on January 7 and certainly not in any way integrated into the existing device data specifications that we would think of from HL7 or Continua or IHE, etcetera. And so it seems to me that where we consider the growth of over the counter devices integrat – providing data that patients wish to share with their providers. We have to be very careful not to end up in a situation where the ONC related requirements end up being in any way different from the FDA regulations, as well as the sub-regulatory guidance of the FDA. So that's a particular concern that I have about moving forward with a lot of standardization on the device side at this point.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Great, well thanks. And so, I – Leslie, I'm sure we want to open it up to your team and others to react.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Well I'll first take a first pass. I appreciate the comments on the Consolidated CDA. I think that there is little argument and the header approach allows the market to drive which templates go with – are adopted; however, the use case that's always recommended is the medication, allergies and also the just update of my history, my demographics and so forth. Those seem to be mentioned over and over again, so perhaps we can look at a recommendation that would include that as an example.

The other comment that I'd like to respond to is the idea of the maturity of standards and specifically around the consumer devices. And we struggled with this a lot, honestly, and where the team landed was that we felt when data is downloaded from an electronic health record, it's likely to be downloaded to – in a way that can be repurposed by the patient and reused on devices and how the market might drive that particular use case, much more consumer centric. And we've seen that with the Blue Button. But that when data goes inbound to an EHR, it is highly likely and actually possibly not – it's not possible to do without having standards that are going to be more centric around the EHR, at least for now, because the inherent risk of data inbound for accuracy, provenance and so forth, the risk is at the provider level. So the literacy of the people doing the configuration, the people doing the work, is much more apt to be around healthcare provider standards than consumer standards.

We even discussed, well, what consumer standards are out there that could be used. Well, PDS is a great standard. It certainly isn't consumable in any way, but it is a consumer driven standard. So we really went back and forth as a group around this all the time and felt that in the policy recommendation of using devices selected or endorsed by the provider would help to drive the use case to more provider centric devices or prescribed devices versus, I want my FitBit to upload. So, that's why we landed on a very provider centric approach using the questionnaire and response so it addressed the fact that it was in response to provider request for information. Inherently that information then is going to be incorporated into the EHR that is assumed with that use case. And so with those constraints in mind, that's why we landed here.

And then I guess this good caution, Jamie, on the alignment with ONC on the FDA. And maybe Chuck has further comments on that, I know I don't have an update, but I know that the Office of the National Coordinator is to do just that, coordinate things nationally.

Jamie Ferguson – Vice President, Health Information Technology Strategy and Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

Sure.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So I'm hopeful that we can. So those are my comments, oh, just another on the Direct standard. We do know that there's work to be done, however we feel the work being done already in DirectTrust is quite meaningful and applicable to the patients participating. So, with that I will turn it over first to see if Lisa Nelson, do you have any comments that you'd like to add? Lisa, are you there?

Lisa R. Nelson, MBA, MMI – Co-Chair, Patient-Generated Documents Project – HL7

I am three buttons away from unmuting myself. Thank you very much Leslie for doing such a great job of getting through all that material very quickly. I'm very pleased to hear that there is strong agreement about the maturity and the suitability of Consolidated CDA templates to make it possible for patients and providers to be utilizing the same information, sharing information in the same way, which certainly will do a lot for interoperability. And certainly put us all on the same footing right to begin with, so that as these standards mature for providers to improve their communication with each other, it will simultaneously and sort of scale right at the same rate that patients will be benefiting from all of the work that's done to improve and evolve this standard going forward. So I think that's a really – I think it's great that there's clear agreement in that area.

I think the only thing that I would add, based on maybe to clarify here. I spend a lot of my time as Janie Appleseed out in the real world, talking to patients and making – explaining how this technology is coming and how it will change the way we live ourselves and for our families. And over the past two years I've done – I've talked to hundreds of people. And anyone that you do talk to directly about this, they see the need. When you're not asking directly about whether or not you need it, if you just don't go there, it's impossible to hear people express their needs. But when you are out explaining that this possibility is coming, everyone is very anxious to have it happen. And so I just, from my point of view, I would like to share besides the technology maturity, suitability, there really is a need for people taking care of children and elderly parents, while we continue to try to work and make our lives go without technology to facilitate good communication with our care team, it's just not possible.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thank you Lisa. And I'd like to see if David, would you like to add some comments?

David Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.

Sure, thanks everybody and thanks for doing such a great job, Leslie, presenting the slides. And I would say, with respect to provider-to-provider communications via the Direct protocols, we're – we've done a very significant amount of laying of the groundwork. There are currently 15 service providers who are fully accredited and whose trust anchors are interoperable with one another and are currently starting to test and that's pretty robust system. There's a lot we need to do to sort of fine tune it, but the fiber has been laid, so to speak, and with respect to EHR-EHR interoperability, I think the standard and the surrounding policies and framework for security, such as encryption, have been laid and are in place.

I do think that there are still significant challenges as bringing the patient and consumer population on board to that network of Direct exchange. And I'm very, very optimistic that we can approach that 2014 and make real successes, but I want to caution everybody that there's still a lot of work to be done to make sure that we don't raise expectations about Blue Button and Blue Button Plus, beyond those capabilities that are still building. For one thing, many of these conversations we're having are based on the ability of provider organizations to be able to receive and not only send messages via Direct. I think we're still pretty early, the electronic health records are just now rolling out their 2014 edition certified and therefore Direct enabled products. Some of these are, quite frankly, very good with respect to Direct, some of them are disappointing and border on unusable. So I just want to say that while I'm very optimistic, I also want to caution that we take things one at a time and build towards full patient and consumer participation in Direct. Thanks Leslie.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thanks. Chuck, do you have any comments?

Charles Parker, MSHI – Executive Director – Continua Health Alliance

Sure, yes, a couple of things I'd like to say. And thank you very much as well again, Leslie, for presenting that. First off, let me start with a couple of points that were raised with the FDA components of that. One of the things that we have been doing with the FDA is working very closely with them and many of you may have realized back in August that the FDA began to initiate guidelines on F...that they're issuing for what they consider interoperability standards. And of those applicable standards that came out for device standards, all of those are Continua derived standards as well. So, we worked very closely with the FDA to understand where they're going with this particular activity. I've had a close working relationship with them for the past 4 years on this particular area as well and are feeding them information about what are considered to be some of the standardization activities. So we're staying very closely aligned to what they're trying to accomplish from the FDA perspective on standards.

Another point that was brought up was about devices today and why you can't go to the store today. Really some of those are very low-end devices that have absolutely no way of connecting today, at this point. So if I went down to the typical CVS corner store, most of those blood pressure cuffs or weight scales that you're going to find don't have no connectivity, they have no real way to actually even assimilate data and pass it on, other than the end-user having to collect that data and enter it manually. As John mentioned, the Withings activities, there are certainly – they are certainly available for connectivity, but they're not scalable beyond their own infrastructure, so you're stuck with the Withing architecture and I think that's why we're seeing today the desire to have these sort of standards implemented in the market space. Because it helps drive the market to a common platform of how you're going to implement that technology so that you can put it on the store shelves.

And secondarily, how you can move beyond proprietary architectures to make that scalable across the entire industry so that you end up with a common platform that all the industry can connect to. The one thing that we've always said is that it's not – these companies are scaled to deliver tens of thousands of units; we actually need tens of millions of units to be able to place in the market space to be able to connect today. And that's just something that we're not seeing from an individual company to be able to supply that type of capability without interoperability. So I think those are some areas that we're seeing here today.

Just a point here within what we're doing with Continua is that we try to make this as open as possible and make this a process to incorporate as many of those resources and companies that certainly have interest in this area to communicate and participate in this. And we are starting to see that begin to shift in the market space where we now have almost a hundred devices that have been certified in the industry today and those markets – and those devices are now coming to the market. Thanks Leslie.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thanks Chuck. Russ, would you like to add any comments? Okay, I know Russ is also at an airport, so we might have lost him. So I think that – Russ, is that you?

David Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.; Senior Advisor, American Academy of Family Physicians

Leslie, this is David, can I make one more short comment?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Sure.

David Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.

I would – I do want to mention that among the 115 members of DirectTrust, approximately 10 or 12 of those organizations are planning to offer patients Direct addresses and accounts during 2014. So the market is already presupposing that we've solved these problems and I think it's an important point to make.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yeah, I think that largely we're looking at these standards for the timeline of – well, for Meaningful Use 3, so we're looking at a 2017 timeline. And this is somewhat the chicken and the egg; do you name a standard while it's still emerging, understanding that it's already been adopted in the provider setting and that many of the issues would be resolved by then? Do you remain silent on this and then have a happenstance situation or perhaps no involvement of patients in secure messaging beyond tethered devices. Or do you set a stage that allows for much more highly interoperable systems and to include new players to the market and not just the traditional proprietary EHRs. So these are discussions we've had for about a year, off and on, and yes, there's cautious optimism on Direct. I think we were further along with the Continua than we thought in the beginning of our evaluation and we're very encouraged to see that. And then with the simultaneous efforts on the Consolidated CDA and the care team roster, we felt boy, we were just ready for primetime. So it's with all those cautions and hopes that we brought forward these recommendations.

Lisa R. Nelson, MBA, MMI – Life Over Time Solutions; Co-Chair, Patient-Generated Documents Project – HL7

Leslie, is there time for my LOA free story?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Oh, yeah, I think it's – let me – how about if I just highlight it really quick and be mindful for time, but –

Lisa R. Nelson, MBA, MMI – Life Over Time Solutions; Co-Chair, Patient-Generated Documents Project – HL7

Lisa challenged us all and said I need to go find a Direct address. And so she decided that she wanted to do that with a high degree of level of assurance, at a level of assurance 3. And went to the post office, I believe, and received a notarized letter validating who she was. She was able to send that letter to a HISP and have a Direct address issued. And so the idea of having an individual go to a government agency, or an agency with a notary and validate who they are, is something we already have in the framework, we just haven't applied it to healthcare or yet to Direct addresses. But we didn't believe this was insurmountable and don't believe it's insurmountable.

Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation

So Leslie, this is Liz and I'm going to rain on you for just a second.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation

So we have now 77 hospitals in 23 states. We surveyed the first 50, we asked them to survey the main folks that they sent people to following their acute care. And when I'm talking about those folks, I'm not talking about the physician offices, that's a whole different story, but the home health, the rehab, the SNF and the assisted living.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Hum hmm.

Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation

So we get all of those folks and I have to tell you that the response we got, this is a 100% survey and a 100% response, was not one single Direct address existed.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Um hmm.

Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation

So –

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I think that's absolutely true and where we should be at the moment, we are in developing DirectTrust. I mean we are at the point where it's emerging and it's named in Meaningful Use 2 and we're still in the beginnings of the implementation. I don't think there's any argument there.

Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation

Okay, so what we're saying here is that the discussion for today is not around our readiness for 2 but will we be ready by 2017 for patient-generated data in Stage 3, is that –

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Correct.

Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation

All right. All right. Thank you.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

And just a general question actually for Dave Kibbe, which is that I hear that Cerner has, for certain types of transactions such as imagine a provider asks for a Direct address when the patient registers for care and then the provider sends a summary to that Direct address, and doesn't really require a level of assurance 3. It's more of a, I have an established relationship with you, you have, I don't know, a driver's license or something like that or LOA 2, that level of trust for the certain types of provider push to patient transactions is okay. I just – I hear this from Cerner and I think they're actually working with a different organization than DirectTrust on that, I'm not really sure.

David Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.; Senior Advisor, American Academy of Family Physicians

Yeah, I think to be clear about that, the DirectTrust policy on outbound messages to patients via Direct email address is guided by HIPAA. If a patient of mine says, I want you to send my clinical summary to David.Kibbe@gmail.com, I'm obligated to do so. The same thing would be true if the Direct email address, DavidKibbe@ let's say, HealthVault – Direct.HealthVault.com or an LOA1, that is essentially a non-identity verified Direct address. I would still – and the HISPs and service providers in DirectTrust have agreed that they would always send the outgoing message. Providers may require a disclaimer, say, we're not real happy about doing this, but the point is, you're really obligated to do so. It's a completely different story in accepting an inbound message because at that point you want the person or entity that is approaching you to send information into your system to be identity-verified. And within DirectTrust, the current level of assurance for that, between providers and providers is LOA3, which is a fairly strong level of identity verification or identity proofing. Is that helpful?

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Yes, very helpful. So let me summarize what I've heard thus far, Leslie. That – I think the notion of the CCDA as a container for certain kinds of templates that are well understood will not have much controversy. Then we get into areas where, as Jamie said, although it's true that a CCDA could be used to represent an advanced directive, that that is a use of the CCDA, which is not widely adopted at this point and so, –

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Let me clarify⁷ that a little bit though, John, and I think the advanced directive example we used could apply to any care plan. And so it's – I would use those as synonymous and we actually are seeing it being picked up in the market with people like MyDirectives.com, so we do see it being adopted specifically in that, and then also generally in care planning.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Right. And what I mean by this is a structured advanced directive or a structured care plan. I mean, certainly – I mean again, look to the wisdom of the crowd here. I have seen CCDA used as a means of describing free text care team, free text care plan –

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Um hmm.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

– but I haven't sort of seen vocabulary controlled, richly structured care teams or care plans yet used widely. I'm not sure –

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Um hmm.

Jamie Ferguson – Vice President, Health Information Technology Strategy and Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

Yeah, in other words – this is Jamie, I'll just jump in to say, in other words while it can be used and we expect it to achieve that level of maturity in the future, it's not at the level of maturity for structured data for care plans, including advanced directives, that's needed for interoperability today.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Um hmm, however, we feel as a place to start, the care team roster identified and named gives us that beginning phase so that by the time we are working on the next level of meaningful use, when we're looking at collaboration and collaborative care, we have that pivot point we have that starting point.

Jamie Ferguson – Vice President, Health Information Technology Strategy and Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

Well, and again, so that's where it's needed in fragmented team situations.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And I – Jamie, I just would – I agree with you, and they are often fragmented. The average Medicare patient has 14 physicians. So there is fragmentation –

Jamie Ferguson – Vice President, Health Information Technology Strategy and Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

I agree, but let's not fix that fragmentation into regulation while ACOs are evolving with greater integration.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

But the ACOs that are evolving are also evolving in environments with several different EHRs. There's no system direction that is implied, inferred or directed because someone is coming up with a financial or –

Jamie Ferguson – Vice President, Health Information Technology Strategy and Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

Well I think we may – know we may have to agree to disagree on that because ACO integration is very much evolving in the direction of sharing of systems. And so – whereas I think it's true that – including sharing of EHRs, and so I think it's true that within a situation where you do have multiple systems, you're not dictating any one system, absolutely true. But in essence what you're saying is that the solution set only works where there are multiple systems and not where there's really a single, shared system.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And I think that there needs to be perhaps a nuance. The assumption is that this is an “or” and not a “both,” but there – every market will – I talked to a critical access hospital today that’s forming an ACO with a tertiary hospital that’s 300 miles away, and they’re all on two different systems and they’re going to use the local HIE as a way to communicate. They want to include patient questionnaires for quality issues and patient reported outcome measures. They’re going to do that purely through the state HIE, because it’s the lowest cost potential for them. And this is in a geographic area that’s quite diverse, coming from Idaho that would be the norm that would not be the exception; so that there are different players involved, using different mechanisms.

I think where the group stands is that the – we don’t want to presuppose a closed system that further keeps the patient away from participating, but have an assumption of interoperability from the get go, of the patient’s participation in the ecosystem. And to – so that we are not inhibiting that yet just with one other thing. So I think it really depends on, again, your frame of reference in Idaho, Oregon, North Dakota, California – we have many, many systems, many people, people move and the idea of interoperability only benefiting the provider and not benefiting the patient, I think is a mistake.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Let me just ask this question, Jaime, maybe a subtlety of the recommendations we make to the Meaningful Use Workgroup, which is to say, where there is a need for payer, provider, patient data sharing where the patient generates information and its sent to others, we believe the CCDA is suitable for purpose. However, I mean, it’s going to be interesting, Kaiser probably should not be given an attestation criteria that requires that Kaiser patients use the CCDA as the means of getting their data in, because they’re actually going to be using HTTPS over a Kaiser provided shared record portal –

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Um hmm.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

– or something like that.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right. And we put that in the very beginning of the slide that we assume that tethered PHRs would continue and potentially flourish with patient-generated health data.

Jamie Ferguson – Vice President, Health Information Technology Strategy and Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

But that doesn’t apply to us; we do not have a tethered PHR.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I’m sorry, Jamie, I’m using that as a term to reflect whether you’re using a web portal, whether you’re using tethered PHR like a MyChart or – but a contained system is a better way to look at that.

Jamie Ferguson – Vice President, Health Information Technology Strategy and Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

So, what we have is we have a shared system that is a single shared system that is shared by the entire care team and the patient and their designated family members.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Um hmm.

Jamie Ferguson – Vice President, Health Information Technology Strategy and Planning; Fellow – Kaiser Permanente; Institute for Health Policy

And that’s obviously a situation where the fragmented approach of files flying around is really counterproductive.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

It is, but the – it's exception rather than the rule, outside of your market area. And so –

Jamie Ferguson – Vice President, Health Information Technology Strategy and Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

I'm sorry, again, I'm just respectful again, I have to say, we'll agree to disagree on that because this is the direction of evolution of ACOs, under the ACO initiative and so saying that the primary thrust of things is to perpetuate fragmentation, I think is counterproductive.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Umm, okay. Well I think – I think we do disagree because of our different frame of reference.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

So one wonders, though, as we craft regulatory language or – not we, but as we as a Federal Advisory Committee, recommend regulatory language, I mean I think the answer, of course, is a policy goal that we wish to achieve, and that is, patient and families being able to generate data that is used by providers. And we recognize that when there are disparate systems that require a bridge, that there are standards that we would like to recommend; however, there may or may not be disparate systems. I guess –

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I agree.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

So I think we can get around both of your points by just crafting the measure appropriately, so to speak.

Jamie Ferguson – Vice President, Health Information Technology Strategy and Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

Yeah, and if I could switch gears a little bit and back to the devices, so first let me couch this by saying that I am one of the founding members and initial funders of Continua and have maintained a membership since its inception. And so I'm proud to say that Continua is very well supported here and I'm a huge supporter of the adoption of Continua specifications as standards. At the same time, the – I just had a chance to review, in the last couple of days, the FDA guidance on over the counter blood measurement devices that include – incorporates, as I said, literally hundreds of detailed technical specifications for data outputs of those devices that is not currently contemplated by the standards that are being used.

And what we're talking about is detailed content specifications, so I think that in essence the containers for content, the methods of data flow and so forth, the specifications are, I would agree are mature. But as FDA comes out with increasing sets of data output requirements for over the counter devices, we have to make sure that we have a mechanism that can ensure sort of flexible adoption of those within the framework that we're talking about here. So – and there is no device that currently incorporates those because they were just published.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right. And so what the – what would the language be that would both promote adoption of standards for those that are ready, specifically more often than not those that are prescribed by a provider or given by a provider? Because remember, this is a questionnaire and a response from a device that has been, I think its provider selected is the words in policy. How do we match that need and that paradigm?

Jamie Ferguson – Vice President, Health Information Technology Strategy and Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

Yeah, no, I don't know. I mean, I think this is a tough problem because before January 7, I would have said, oh, blood glucose, no problem, and then we got this several hundred-page document from the FDA. So, I don't know when that's going to happen next and certainly don't want to get sideways with respect to that guidance.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

And this is probably, of course, a question for Michelle, and that is, ONC has a sort of somewhat unique role as Geneva and that is, it has to ensure that HHS, CMS, FDA, FCC, all these other government entities tick and tie their various efforts. And so I think Jamie's point is well taken, that is, we believe the IEEE 1173 underlying standards are good and suitable, but it would be strange for us to recommend something and then have the FDA say, oh no, no, no, no, we're using Morse Code and smoke signals – I made that up, of course. And so Michelle, I think –

Jamie Ferguson – Vice President, Health Information Technology Strategy and Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

I think – if I could just clarify John. I think what's more likely is it's particular constraints on the methods that devices have to use that have an input on the data, it's parameters and ranges and the way things are represented on the outputs. So it's – essentially what they're doing is they're issuing a large number of additional constraints. And I don't know how we can account for that.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Right. And so I think that certainly we would work with our ONC colleagues, reminding everybody we're a Federal Advisory Committee, and so we don't write regulation, we just offer advice. And so maybe Jamie our advice is, we believe that the Continua standards are directionally appropriate, but, we must of course, align that direction with the FDA standards and advice, to ensure that as a regulation is written, we don't constrain the marketplace in such a way that is, if you comply with this, you don't comply with that.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Um hmm. I think that's reasonable.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

But I think our challenge – Paul Tang, has asked that we as a group of – a joint set of committees here, make some recommendations to advise the Meaningful Use Workgroup in its deliberations.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Um hmm.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

And what I've heard today is that I feel like we're all fairly comfortable in suggesting the CCDA over Direct, is probably a reasonable way of getting data in and out of EHRs to PHRs or other patient facing types of applications with a proviso that that may or may not be an architecture that a given ACO decides to use. But the last thing we would want is to see, as both Jamie and Leslie have said heterogeneity and fractured applications coming up with a thousand different ways to send data to and fro, if that is what is required by the nature of the healthcare system in their area.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Um hmm.

Jamie Ferguson – Vice President, Health Information Technology Strategy and Planning; Fellow – Kaiser Permanente; Institute for Health Policy

And if I could also add – this is Jamie again, that I'm not saying we shouldn't have standards in these areas, I'm saying that their application should be constrained to the cases where they're needed and they're useful. In other words, there may be some – there may be a recommendation that we would make that well the standard should be "X" but the threshold level for its use should be zero.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And that actually was discussed in the Meaningful Use Workgroup as a certification only requirement. And so that is an option.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Right, but I – we do want to be very, very careful, as I wrote in my blog recently, about certification only requirements, because in effect what you have is EHR vendors now creating software and going through sometimes extraordinarily painful, expensive and rigorous processes. And so by doing such a thing, it would require – I mean Jamie, let me just use an example, EPIC to create a set of CCDA exchange mechanisms that EPIC users would, in fact, probably never apply.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

John, how do we rationalize that in the provider setting world where we have named Consolidated CDA being used, or Direct being used for both – for certification and use, in Meaningful Use Stage 1 and 2?

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Right, and so, this is of course where the brilliant people at ONC who craft the regulatory language. You'd hope could put in something to the effect of, where an ACO exists with a fully integrated, shared medical record, there is the requirement that the function, the outcome is that patient's families and providers can share data, and that's not only read, it's write –

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Um hmm.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

– in the following domains problem list, medication list, allergy list, whatever. But of course, if there is not a fully integrated, shared medical record, then the EHR must be able to receive a CCDA containing the following templates, to accomplish that goal, that outcome, the policy that patients and families should be able to participate in problem list, medication list and allergy list reconciliation. And Steve Posnack, of course, is the master of writing these kinds of items.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

He is I think that's very reasonable. And so that would be on the Consolidated CDA, its Direct and the care team roster. And on the device, as you indicated earlier John, you had some language around that as well, which allowed for the evolution that Jamie's concern was included.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

And we just have to be very careful, given FDA, FTC, IEEE, Continua that we don't in – and this is again the delightful role that ONC gets to play –

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Um hmm.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

– is trying to consolidate multiple federal government regulatory requirements, sometimes which don't align.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Because I don't think we as a committee want to step on the FDA –

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

No.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

– so if we say, we think this is directionally correct, but must be coordinated with FDA standards. And then, of course, we have this tight timeframe of needing to make recommendations by February 4 to Paul.

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

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

But we will also have an in-person Standards Committee where we can present all these thoughts to the more global committee and get further input from them.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I think that's great. I'm – Michelle, I would ask that we can get the transcriptions of what language that John put forward and maybe incorporate those in our slides for recommendation.

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

Hi Leslie, this is Michelle. Just so you know, we don't transcribe workgroup meetings, but we do record all of them, so we can always go back to the recording, which I will share with everyone.

Caitlin Collins – Project Coordinator, Altarum Institute

That's actually incorrect; all of the workgroup meetings are transcribed.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Wow. And so, Michelle, and of course as you know I am very happy to work with you on making sure that what I've said is actually coherent and that we will circulate and get feedback and then get to Paul in a timely way.

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

Thank you.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

That's great. I want to ask my team any – if they have any further comments to add or questions and then also John, anything I can do to help, and I really appreciate the robust dialogue and also the work of this team has been quite profound. So, thank you.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Wow, have we stunned them? Have we achieved consensus? Is there peace in the Middle East?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I think we've achieved consensus. We have peace in the Middle East.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Okay, and Jamie, any other refinements you would add?

Jamie Ferguson – Vice President, Health Information Technology Strategy and Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

No, no, I think you did a great job, John. Thank you.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Wow, well hey, what that implies is Michelle, if we have achieved a set of recommendations that this group believes is reasonable to forward to the Meaningful Use Workgroup, then of course we can gather public comment and hear from anyone who may have joined our meeting as to any refinements they might suggest.

Public Comment

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

Okay. Operator, can we please open the lines? And thank you John, Leslie and Jamie for – and the whole workgroup, for all of your –

Ashley Griffin – Management Assistant – Altarum Institute

If you are on the phone and would like to make a public comment, please press *1 at this time. 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. It appears we do have one public comment.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Well then, let us go ahead.

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

I think they're trying to get them through, so, we'll have to wait a second.

Ashley Griffin – Management Assistant – Altarum Institute

Correction, we have no public comment at this time.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Okay. Well and Michelle, from an administrative standpoint, was there anything else on the agenda that you wish to cover?

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

No, I think we're good. Oh, I'm sorry; it looks like we do have a public comment.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Okay, well we – public comments are important and we wish to hear any public comment.

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

Oh, okay, John Travis did – maybe he'll submit something in writing. It looks like he changed his mind.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

And so Leslie, since you and I were listed on the agenda as the initial conveners of this, any final words of benediction, other than an incredible thank you to the team that has worked so hard and done so much in such a compressed timeframe.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I –

Jamie Ferguson – Vice President, Health Information Technology Strategy and Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

Yeah, I want to thank Leslie for leading the group to this really good outcome.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thank you very much, it's been a great team and we look forward to doing more work because there is no healthcare without a patient.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

That's true. Well good –

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

All right then, thank you.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

– well Michelle, I think then that concludes our call and we will work together on written recommendations to Paul and the Meaningful Use Workgroup and we will look forward to further discussion as a whole committee and moving forward on this very important patient and family engagement topic.

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

Thank you all and have a nice weekend.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Thank you.

Jamie Ferguson – Vice President, Health Information Technology Strategy and Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

Okay, thank you.