

**HIT Standards Committee  
Consumer Technology Workgroup  
Transcript  
August 28, 2013**

**Presentation**

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Thank you. Good afternoon everyone, this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Standards Consumer Technology Workgroup. This is a public call and there will be time for public comment at the end of the call. As a reminder, this call is being transcribed and recorded, so please make sure that you state your name before speaking. I'll now take roll. Leslie Kelly Hall?

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

Here.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Brian Carter? Arthur Henderson? Brian Ahier? John Ritter? Anshuman Sharma? Susan Hull? Mo Kaushal?

**Mohit Kaushal, MD, MBA – Partner – Aberdare Ventures/National Venture Capital Association**

Present.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

AJ Chen?

**AJ Chen, PhD – Chair, Data Committee – National Partnership for Action Region IX Health Equity Counsel**

Present.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Tonya Dorsey? John Derr? Yair Rajwan? Tom Jones? Liz Johnson? Christine Bechtel? Marcia Nizzari? Fred Trotter? 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**

Holly Miller, I believe that she's muted.

**Holly Miller, MD – Chief Medical Officer – MedAllies**

Here. I'm here.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Thank you. David Harlow? Wes Rishel?

**Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated**

Here.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Susan Woods? Kim Nazi? And are there any ONC staff members on the line? And I believe that we also have Lisa Nelson and Chuck Parker on the line as well. With that, I'll turn it over to you Leslie.

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

Okay, great. Well we have a very small group, but I'm hesitant to not go forward with the meeting because we've got a lot to cover and we do have recommendations around this that we will have to meet. So we'll have the meeting and we can transcribe – it will be transcribed and passed on to the others on the team. Go forward please. So just an overview of the charge, we are all familiar with this. Go again. And the members, we just went through the roll call. Next slide. So today, we're going to have two presentations and we're going to here from Lisa Nelson, who has been working very hard and very quickly on a patient-generated health data project and team within HL7, Co-Chairs that with Virender Batra from Intuit. And then we'll also hear from Chuck Parker from Continua Health, who will talk to us about device integration of patient-generated health data.

Our purpose today is to really talk through all of the options, all of the issues presented so that in our next meeting we'll be able to have a very good discussion and make our recommendations – preliminary recommendations to support Meaningful Use 3 and the Policy Committee. Next slide please. So we have several questions we've been tasked to answer. What are the standards that support patient-generated health data? We'd like to make sure we reference use cases as we go forward. And although we've been asked to take a look at vocabulary and content standards, we will not be doing that in the next few weeks; we'll probably go forward after our recommendations in October. Next slide. We will hear today about patient-generated health data standards that will support both Meaningful Use 2 and 3. Next slide.

So our next steps are to really confirm the standards, what's available now, what's missing and to make recommendations for a joint meeting in October. In September we'll go through each of our recommendations and also assign some maturity and adoptability indexes to each of our recommendations. Next slide please. So actually I'm going to reverse the order a bit. If we don't mind, I'd like to start with Lisa and we will then move to Q&A, followed by that to go on to Chuck, if that's all right. So, Lisa.

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

Thank you very much Leslie. I wanted to say that 50 years ago today, when Martin Luther King gave his "I Have a Dream Speech," I turned one years old, and that speech has always been a very inspirational part of my life, to be able to believe that we can dream big and make those dreams come true. And I feel that way about patient-generated documents; it's a big dream to believe that we can empower people in this way. But I believe that it is possible and that's why I'm so excited about having the opportunity to talk to you all today about the work that we have been doing in HL7, to create standards that enable patient-generated documents. So my name again is Lisa Nelson, and I have been the Author Co-Lead on this work in HL7. Next slide please.

Today I'm going to briefly talk with you about some background on that project and bring you up to speed on the current state of that work. We'll talk about some of the emerging issues that we've seen as this work has progressed, along with some opportunities for further harmonization and consolidation that I think would be important to think about as you are preparing your work. And then I'll give you some recommendations categorized in some areas that I think are things that you guys are already thinking about. Let's move to the next slide, please.

The patient-generated header document team was a very large group, very well attended by implementers and a variety of government and care level organizations, companies that are interested in patient education and very well supported by the standards group itself at HL7. This representation, I think, was part of what made it possible for us to do so much so quickly and we were very thankful for all the support that the project got. Next slide.

We began about a year ago, in August 2012, really motivated by the potential to do something that would help patients be more empowered to participate directly in their care and so we put forth a proposal that we would do this in a way to augment the work that was already happening in Consolidated CDA. And enable the templates that had already been designed and were coming into being, and allow all that work to be reused. We established our scope to focus our implementation guide as an informative piece of work concentrating on how to create headers for documents that would be authored by patients.

So we sort of stepped into it in a backwards way, we began with the Consolidated CDA general header pattern, and from that, because that was already a US oriented piece of work, we crafted the US realm patient generated document header. So we knew for sure that we had something that would fit and be immediately useful. And then from there, we generalized that work in order to create something that was applicable in a universal realm. But this approach, I think, was a really important part of how the work came together so that you can see how we were able to deliver something right away that was immediately applicable in the United States, and at the same time, share a standard that could be used by the whole world.

So we submitted that work in December of 2012 and then proceeded to work through all of our ballot comments. And completed that reconciliation at the very beginning of this month, so that our new patient generated document header template could be included with – the US realm one, could be included in the body of work that is now being balloted as Consolidated CDA Version 2. And that is – was submitted on August 15 and that ballot process is going on right now, and will close in the middle of September and then patient generated document header will just be absorbed and go forward with that work as a part of Consolidated CDA Version 2. Next slide please.

Some of the use cases that we considered in developing this included topics not only where the patient may be the author of their own document, but also the case where someone else, a related party or a legally responsible party, might be the author for the patient. And so you see some of the things here thinking about how a patient might document their own health history, or keep track of their nutrition and allergy information. Document special alerts or care preferences that they may have or even provide updates to their health record-to-record changes over time that their care providers would need to be aware of. We also had envisioned the notion of like a pre-visit questionnaire that could be an electronic means of doing what you typically do on a paper documents on a clipboard in the waiting room right now. And then other types of screening questionnaires that could very much contribute information to the patient's clinical record.

There are times when it could be a parent answering these – this – providing this kind of information for a child or very much a case where an adult child may be providing this kind of information for their parents. And so going forward we're considering all of those possibilities, along with some traditional ones like guardians authoring notes for their children or healthcare power of attorney. These are examples where someone else may, in fact, be the author on behalf of the patient. The thing I wanted to point out on this slide is there's a third use case that people often ask about, which has to do with devices generating information for patients. And this is already a use case that is handled by the existing Consolidated CDA general header. Devices are already structured to be allowed to be authors of electronic CDA documents and so it isn't a specific constraint that we needed to invent to enable that if a patient's blood pressure cuff or weight scale were to be generating an electronic document and submitting that into the clinical record. Those devices are already – them being the author of a document is already accommodated for. Next slide please.

I wanted to give you a glimpse, for folks who don't spend their life living in the details of CDA the way that I do. When we talk about the header of a CDA document, what are we really talking about? I like to think of it as a formal letter, because we're working with that document paradigm, in a formal letter, there are very specific rules about how you would record at the top of the letter who the letter is going to, the date that the letter is written, who the letter is coming from, in a formal letter. Often there are four or five lines of information, your name, your position, your address, etcetera, that has to be structured into the top of that document before the body of the document begins. And in an electronic CDA document, we have something similar to that, only a few extra fields, so – because there are additional roles that need to be considered.

So think of it that way, as sort of the formal structure of the top of the document and the general header is already available with the guidance and the conformance rules for how to set that up and record that when clinicians are authoring these documents. That was sort of our initial use case. But now that we're also opening the possibility for patients, we needed to think through how these roles would be represented and we needed to add some additional conformances and guidance so that the patient, as you could see, could perhaps be represented – their guardian could be represented more clearly, that was something that we needed to improve on. The author could, in fact, be the patient themselves or a related person or a legally responsible party, etcetera. It's a little bit repetitive, but you can see that we went through thinking about each of these spots in the header and finding where would it be applicable that that role might also need to be able to be filled by the patient themselves or someone who's representing them.

And then the act relationship, this is additional contextual information about the document. Are there other related parent documents that came before, authorization consent? Is there a particular encompassing encounter that this document is a part of? Most of the rest of the structure here didn't need to be changed and it is exactly the same as it is in the general header for all Consolidated CDA documents. So you begin to see how it is that these two headers really work together, the general header establishing kind of everything that needs to be established and then the patient-generated document header augmenting that to make it possible for these special use cases that we're just beginning to explore. Next slide please.

The current state of things is that this new header template for expressing patients as the author, it is already a part of Consolidated CDA Version 2, which is out to ballot right now. Along the way we needed to invent a new value set that identified these personal and legal relationship roles that non-clinicians, just people, could be participating as in that role. And so the value set has not only the concept of self, but 99 other roles. It's pretty exhaustive, that have all of the kinds of relationships that you have within a family, the legal relationships from a healthcare power of attorney, guardians, there's about twenty different legal relationships. And it's a value set that is connected in a way that's dynamic, so that if we discover that there are additional roles that need to be expressed, we can very easily expand that value set.

This patient generated document's header can be used in conjunction with the general header in CDA. So this permits patients and their relations to be able to participate, and it doesn't exclude anything that was already done in the general header. So they're a perfect set. There's no new document types that had to be created in order to do this, we're not establishing sort of a segregated world for patient-generated information, this is an encompassing space where patients just simply – we have the technology to represent them within these documents. So if a CCD document is created and if a patient using those same sections, what was my – what are my allergies, what's my social history, what's my family history? All of those same sections in a CCD, what medications am I taking, can be populated and that kind of document can be generated by a patient simply – a person, simply by including not just the general header, but the general header plus this additional patient-generated document header.

This opens up the possibility for additional documents to be created, which are designed specifically with patients in mind, but it doesn't require it. So for example, one of the first standards that we've seen come out now has been right on the heels of patient generated documents header was work that you'll be hearing from Chuck about that has to do with a standard to define forms and then create electronic responses to those questionnaires. And that standard is already set up to take advantage of and to work with the patient generated documents header. So you see, you can either use existing documents or new document types are now possible to be created so the world of patient generated documents is really wide open at this point. Next slide please.

In going through this process, we have identified some emerging issues that we just thought would be important to think about together here. There's quite a lot of work that had to do with maintaining and dealing with this body of templates and the associated value sets, which create the semantic meaning for the data that is encoded in those templates. And so we are finding that there's an evolution that needs to happen around building up our capabilities in terms of how we will maintain and govern these templates and these value sets. So that's something that's important to know about and be thinking about.

The next three bullets, I'll sort of take a little bit – at least the next two, a little bit together, and this has to do with establishing the context for the information. So a CDA document is a snapshot in time and the snapshot includes a full representation of the context that makes that data have meaning at that point in time. And so in order to make this work, we really need ways to have trusted representation of the parties at play that establish that context, so that we can understand the data and who contributed and in what capacity. This concept is often discussed now in terms of this notion of data provenance, which means the ability not only to encode that context in the data when it is captured, but to preserve that context with the data over time, so that as longitudinal records begin to accumulate, the context of the data travels with the data. So those kinds of issues are things that we always knew they were out there, but I think we've reached a level of maturity where they are on the top of the list of things that we need to be focusing on developing greater capability around.

And then as patients and as people begin to get involved in working with these documents and creating them, there is going to be additional pressure on developing standards that allow us to segment and control this information, so that it is ensured to have the level of privacy that matches with what has been consented. There's good standard work going on right now, I don't Leslie if you'll be having a presentation about the data segmentation for privacy standards, but note that it's an important standard that is in ballot right now and something that certainly will be applicable as you think about Meaningful Use Stage 3.

Generating documents is not very helpful if you cannot share them. And so – and a really big emerging issue is the notion around how we will do bi-directional point-to-point data sharing so that the data. As we begin to articulate it and capture it in documents, that we immediately have got the capability to very easily, without barriers to sharing, we can immediately begin to share that information with our care team as patients become a part of – an important part of contributing to that care team notion.

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

Lisa, I need to interrupt, this is Leslie, a bit, because we're on a time schedule, so I need you to move a little bit quicker –

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

Sure.

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

– so we can get to discussion. Thanks.

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

Sure thing. Data reconciliation is an important issue as longitudinal records come together and also the notion of the balance between narrative text and structured data. The Health Story Project is taking on this issue and that would be an important place to watch as the balance between narrative text and structured data comes together. Let's see, I think there's one more slide to go quickly through this so that I can land on recommendations for a second.

There is an opportunity to do future consolidation, you can read these bullets for yourself, in the space of templates, value sets and transactions and processing. The important point is that we thought of consolidation as a point in time piece of work that happened and finished and that's not really the way that we need to be thinking about it. Consolidation is an ongoing process, a kind of a continual improvement process that needs to be ongoing and we need to be looking all the time, as these standards evolve. There will always be places where we can say, two things could really be simplified and become one, or five things could be simplified. So, I think we need to think of consolidation as an ongoing need that needs to be built into our system as we go forward. And let's now go to recommendations.

So in order to have these documents, patient-generated documents, be able to have an impact and be able to begin to contribute, we have to focus on how we were get our secure messaging strategy together so that patients can easily become a part of the communication stream. The documents that allow surveys, a very effective way of doing question answer sort of dialogue between clinicians and patients, those standards exist and are ready to be used, and they should be promoted in their use. We need to adopt a notion of ongoing or sustainable consolidation techniques that give us the ability to build upon the work that we've already done on a regular basis. And then do further work, which really requires some investigation, around how we achieve some lofty goals that were set forth in Stage 2 around reconciling and being able to simultaneously display and look at multiple sources of information. And maybe even sources of information that accumulate at different points in time, so that we can get better at a standard way for building longitudinal records. So that's the end of my presentation. I welcome questions if there still is time for them.

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

Great. Thank you. Yes, we have time for a few questions. Are there questions in the group?

**Thomas M. Jones, MD – Chief Medical Officer – Tolven Health**

Yeah, this is Tom Jones. It would be really wonderful if, and I know we don't have time today, if we could re-examine that emerging issues slide and contrast that with what has got to be a parallel set of emerging issues as far as clinician-facing CDA is concerned. Just to make sure that we're on the track which you admirably pointed out is, we don't want to sequester patient information from the broader healthcare information. Second comment I make is I see you have deferred discussions of vocabulary, yet we kind of keep coming back to value sets and value sets. And if, in fact, we're going to be serious about semantic interoperability, we need to make some kind of equivalent statement between standard vocabularies and value sets, just so we know what we're talking about. Finally, with data reconciliation, and thank you for going through that, I just wanted to make sure that that's encompassing what folks normally call update semantics in healthcare information. So those are my only comments. Thanks.

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

Thank you Tom. Lisa, did you want to comment back on any of those or continue with questions.

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

No, I would – I thank you Tom for underscoring the importance of thinking about vocabulary and value sets. They've been kind of a – just sort of a tag-along, and not really a primary focus and if you are watching anything that's going on with standards, you see that we have pushed the pain point from figuring out what do we do about structural interoperability. And we are at a place where semantic interoperability requires us to totally focus now on how we work with vocabularies and how we align and match up value sets, so that this data can be meaningful in multiple places and for multiple uses.

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

Great –

**Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated**

Wes Rishel.

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

– other comments? Yes Wes.

**Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated**

Leslie I have several and feel free to use your prerogative to cut me off based on time.

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

Okay.

**Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated**

The first comment is that this is an important piece of the work, but absent companion work on the body, we don't yet have something to judge in terms of its suitability for being required in Meaningful Use Stage 3 or not. That's not a criticism of this presentation, it's just pointing out that it's a piece of the puzzle. The second comment is that the – on the one hand, the context issue that was raised is extremely important because clinicians will reject information sources if they cannot clearly see that it's patient or caregiver generated. An A1c, a patient says, well my A1c was 7.5 last quarter, is a lot different than seeing a lab result for 7.5 with a data and all that. So the use cases that get to being regulation and certification rules need to be sufficiently explicit around that issue, to avoid a backlash.

I have a concern that, I'm going to express it in the big sense of, when we look at the actual use cases that become meaningful use requirements, what will we define as success, and by that I mean, will it be the capability to receive the document in the EHR, which is what we get to measure? Or will it be having received so many documents? It's likely that that's a two-step process, if we're allowed to think about multiple stages, first the capability and the – but it's a really fundamental issue because I'm not sure we have representation from the data sources, and I don't mean the consumer. I think we're doing better, this committee and this effort is doing better to get consumer representations ever had before, but I mean the developers of products that consumers use in order to enter information that would be a target for being sent to the EHR. And that has proven to be a critical issue in other areas, in part because the ways of thinking are different. For example, the vendors who are for example, selling personal health applications now, tend to think in terms of specific statements rather than documents and they don't think about a document lifecycle signature and they tend to have developed protocols that look more like FHIR than like exchange of documents. I'm not saying one's right and one's wrong, I'm saying that a standards process that doesn't involve a stakeholder that is actually required for there to be success in terms of actual data transfer, has concerns about risk at the time of roll out.

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

Um hmm. So Wes, I'm going to ask you to cut there –

**Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated**

Yeah, that's fine –

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

– and offer –

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

Leslie, can I respond –

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

Yes.

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

Can I respond to one thing? So Wes, thank you very much for your thoughtful comments. I noted one of them that I just wanted to go back to in the beginning and it had to do whether or not work on the body was requ – on the body of the document was required to make this work suitable for Meaningful Use Stage 3. And I wanted to point out that the – while Consolidated CDA did do work on document bodies, Meaningful Use Stage 2 did not incorporate at the document template level. They used all of the sections that are in the repository of sections that are available in Consolidated CDA and basically invented documents like a view, download transmit ambulatory or inpatient summary.

And Meaningful Use Stage 2 invented that document and simply said in order to meet the requirements for this, you would need to include these sections in a document, and it could be a CCD, it could be whatever, but these sections need to be present in the document. And so Meaningful Use Stage 3 would have the opportunity to utilize any of the existing sections in Consolidated CDA and could establish if there are certain levels of communication, the documents that would meet Meaningful Use Stage 3's requirements – it's all of the templates that are in Consolidated are available. And the important thing was that the header work be done so that the appropriate guidance around how do you represent patients, that all that was in place. But then any of the templates can make up documents that could be used in Meaningful Use Stage 3 for patient generated documents.

**Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated**

Leslie, may I respond?

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

And I – I'm concerned about time for Chuck to get on, but –

**Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated**

Just real quick –

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

Okay.

**Holly Miller, MD – Chief Medical Officer – MedAllies**

Leslie, I also had a quick comment.

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

Okay.

**Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated**

I mean, I can – if you want, I can respond to the group via email instead, but I think Lisa's statement's about 90% accurate, but the 10% is important.

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

Okay.

**Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated**

So as I understand Meaningful Use Stage 2, it requires the ability to extract information from various document templates as opposed to simply saying, we've defined a new template. And it makes us of the modularity of CCDA in order to be able to do that. My concern with regards to consumer documents is that the existing sub-templates that are used to describe specific things that the patient described, may need work in order to match the consumer's conception of what the data is and so forth. And absent a process of putting something together and using it in production, we stand the risk of taking something – the standard to requi – to full requirement in Meaningful Use 3, that's not actually usable by patients.

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

I also think, Wes, it's important – you made another point earlier about what is a measure – is a measure defining success and I think with this potentially going forward as a menu item, in the past what's come out is a request that something happen once, just that the capability exists in the certified – and that it happens once. And I believe that's where the group is leaning right now. But I wanted to get Holly's comment and then back – then get to Chuck, but I also have a question for Michelle, because Michelle, so much of our recommendation's going to be around patient-generated health data. We have a deadline at the end of September, if there is an opportunity to meet again for the group, so we get larger participation and we can do more discussion on the patient-generated health data, because that will be such a material part of our recommendation.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Yeah definitely Leslie. I think there's time now to – if you need to go out a little bit further –

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

Okay.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

– we can certainly schedule more meetings.

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

Okay, super. So I don't want to table this forever, I want to come back, because there is so much opportunity and equal concern about going forward, but we would like to make sure that we support the policy recommendations coming forward that include patient-generated health data. So our job is to say then what's the minimum necessary, what can we do to reach that. So, Holly, one comment and then we'll go on to Chuck.

**Holly Miller, MD – Chief Medical Officer – MedAllies**

Great. Lisa, I wanted to thank you and congratulate you and the committee on really some excellent preliminary work in this area and I really appreciate the committee's getting it ready for ballot. So thank you.

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

Thank you.

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

It has been an amazing journey and very quick. So thank you very much Lisa and can we call on you again if we have another meeting, if you're available to also provide consultation to us during that time?

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

Certainly, it would be my pleasure, thanks.

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

Okay. Super. Thank you very much. Chuck, I'm sorry, but I think we – we do not have another meeting after this in the group, so we can go over time for those of you who can stay. We had talked about the need for having device integration in patient-generated health data and Chuck is from the Continua Health Alliance. He's going to talk a little bit about what his group has been doing and we'll open that up for time for Q&A as much as possible as well. So Chuck.

**Charles Parker, MSHI – Executive Director – Continua Health Alliance**

Sure, thanks. And I'm going to go pretty quickly here, so we'll try to get through as much of this as we can. So next slide please. So what is – we define personal – this area as personal connected health and it's really about how do you start to instrument the individual and bring an individual's measurements on a more regular basis back into the healthcare environment. Unlike telehealth, it actually is – allows providers and patients to employ data communications independently at their convenience. It's a non-linear approach, so in essence, like telehealth where you're having to set up independent visits with a physician at one end with video at the other, this allows the patient to take their measurements and then the provider community to interact with them at the workflow appropriate times in their days.

Really the patient's personal connected health here allows the providers and the patients to use technology to collect the data conveniently and securely, communicate more frequently with manual intervention. And I think that's an important point that I want to make here is that it allows little to no requirements of the individual to have to manually enter the information. So, the data can be trusted at a higher level because it's coming directly from a machine at this point and the information has been documented as part of that overall process. Next slide please.

This is just some background, I will skip this particular slide, but obviously these were the pressure points in the industry as to why we're doing this. There's an increase in chronic disease, higher healthcare expenses are continuing to burden our systems and we're seeing a need to push individuals out of the hospitals into the – back into the community earlier to provide for lower – where there's actually a lower cost of care and a higher quality of life and recovery period for these individuals as well. Next slide please.

So, what are some of the benefits here? When the patient/consumer they remain/return to home, as I mentioned earlier, the quality of life and time and cost savings are better because they're at home being able to be monitored now. They have a new awareness of their health status, which creates understanding and engagement, so now we have a little bit clearer understanding on a daily basis, if you will, about where their health status is, and so it does provide an awareness for the individual. The automatic nature allows for ease of use and better retention, so you don't necessarily have to have the individual making complicated either calls or measurements. You basically can stand on a weight scale, that information will be collected and away it goes. Provides an improved collaboration with the health care provider on this data element as well, and helps the avoidance of unnecessary office and ER visits, which have already now been documented in several reported cases, both from Partners and also outside of the US in some disaster recovery areas as well.

In the provider community it provides the automatic updates and alerts on the patient's status. The data can be trusted coming from a device rather than the patient, there's less interpretation here and directly going into the individual record. Allows for maximal time of preventive action too though, because now we have a much clearer picture of what's going on with the individual where you can start to see the trend line happening well before the patient becomes ill or becomes at a point where they have to require emergency care at that point. Next slide please.

This is just basically the value of interoperability saying, we've seen examples of this in the past with the cellular networks as well as with the ATM networks. As we move towards an interoperability model, it became much easier for us now to use any ATM machine and we can basically purchase a phone today, for the most part, and know that it can work on the networks that we're going to be implementing or that we – the network of our choice, in this case. Next slide.

So Continua is a not-for-profit organization. We've been working in this industry for a little over seven years now, roughly 200 member organizations throughout the globe. And it's not just technology organizations, it's also telecoms, healthcare service organizations and healthcare industry leaders, as well as governmental bodies as well, such as in the US, NIST, HHS, the VA, the Department of Defense, all participate with Continua, as well directly. And then we also have on an international scale basis organizations like the NHS of the UK, who are participating with us. Next slide please.

What we do, we are not a standards body per se, we work as a guidelines publishing body, overall develop and publish design guidelines that combine and apply existing standards. That's an important note here is that we're using existing standards in the industry today to implement and publish these design guidelines. What we do is that there is no single standards body that allows for an end-to-end architecture to take the information from a sensor device all the way back into the EHR systems, the electronic systems. So what we do is integrate those multiple standards requirements. In this case we're working with approximately nine different standards bodies, that define clearly – these guidelines, how you implement those. So it's very much so a prescriptive methodology in design – how you implement the overall underlying standards in this case.

We do certify products and systems and services for compliance with those design guidelines to ensure that that interoperability is being met. And it does – we also then take a role in promoting a favorable operating climate for personal connected health through advocacy and coordination. We would work very closely with the FDA as an example, on how you begin to use and push the concept of interoperability into the FDA to understand how that begins to change the models on how they look at device connectivity and ensuring that a blood glucose meter that connects to a cell phone doesn't now inherently make the cell phone a Class II device. And we're starting to see some evidence of that rollout and that capability with some of their guidance that has been coming out over the last few years. And then it's also really understanding on how to engender a global market for personal connected health.

And that's an important key factor is that we've been very intentional about ensuring that the standards and underlying activities that we do select have an international approach as opposed to a single country by country approach, which allows for scalability on an international level. And really avoidance of having to create individual country standards for device architectures. So it allows us to build a highly scalable and drives the cost down of sensor devices on a global basis, in this case, as well. Next slide.

So we are the only organization convening global technology standards in personal connected health. We work very closely with IHE on connecting these particular areas and how we actually integrate into the systems of care that are based in the hospital and physician office. We're uniquely focused on end-to-end plug-and-play connectivity. We have a wide based consortium of healthcare, device manufactures and governmental bodies and we can hand data off into, now, through our defined mechanisms, through the endpoints to EHRs, PHRs and Health Information Exchanges, or we can run local apps run by the consumers, all with the same infrastructures device architectures. That's an important key factor is that we designed the overall architecture intentionally so that you can integrate these data elements and have a single form of output that goes to both EHR and PHR. Next slide please.

These are some of the standards bodies; these are the primary ones that we're currently working with, with 11073 being the primary device sensor architecture from IEEE. This is important because two weeks ago the FDA released to a federal register some adoption in the standards that are based upon those existing items that we have selected as part of our 11073 device sensor architectures. And moving forward in that area, we've worked very closely with these standards bodies to ensure that we – actually had improved on some of their activities. So an example of this when Bluetooth met – the existing level of Bluetooth was not secure enough to meet the HIPAA requirements, nor the EU Directives on Security. So we actually worked – took and worked with the Bluetooth sig on creating a new health data profile under Bluetooth, to ensure that the right level of security was implemented in this case. And we're a very close partner with IHE on how this data and the domain – information flows out. Next slide please.

This is sort of our use case process, so that you understand how we actually create this. We do use a use case driven process. There's a submission of ideas, use case development, and we go to a use case commenting period that has an open process for commenting. We then go to balloting at that point. Then from a use case sponsorship, we decompose these into work items, take a look at the gap analysis, match those out to existing standards. Then we create a set of guidelines development and where necessary, constrain those guidelines down, and the underlying standards down to develop a true interoperability model. That then goes to balloting, which is another open process point, and then we have approval, testing. And then we have – once the testing process is completed, then we release a full public version of this that then has a testable module behind it as well with, in some cases, the neighborhood of 80-100 different test cases to ensure that interoperability has been met. Next slide.

This slide here is important, and there may be some build to it that is not quite showing everything here from the device architecture perspective. But, just to say that here again, this is where I'm getting to the point of, there's no international standards body or single standards body that can integrate from the device sensor perspective all the way over to the data repository model, which is where the health records are in this case. So you have to have a model where you take the sensor information and collect it at a hub, whether that be a classic device that has been out there in the market in the past. Today it could now very easily be a Smartphone or it can actually be an embedded device that now will be – transmit data directly into a medical record system. That information can be and can flow directly from the device then back into the electronic medical records using HL7 technologies. And as you heard Lisa mention, we're very closely working on expanding this. To date the architecture's been sort of one way, but we're now actually working very closely on the – with HL7 on the bi-directional capabilities, in particular the patient questionnaire component of that. But we are incorporating and building towards a highly mobile architecture as well. So there's a historic component of it where we've come from the industry and bringing that industry forward into an interoperable component architecture, so that we want to make sure that we're bringing the existing infrastructure into interoperability.

But moving forward, we're also integrating now the mobile infrastructure and the highly portable capabilities that these sensors can have in basically a cellular enabled world in this case. So we're incorporating mini-modules and furthering that work. Continua just at this point, as a note, Continua guidelines are released on an annual basis and we continue to improve upon those on a regular basis, so while we've been at this for seven years, we're now on release five of our guidelines and we'll have release six here within the next three to four months. And available for the public at that point to consume and begin to implement. Next slide please.

This is just to highlight that interoperability actually lowers design costs for organizations and participating and using these device architectures. We've actually seen this and proven this in the case. It helps them faster to market because it really decreases integration time. From an interoperability perspective, you now no longer have to, per the FDA or actually, per the market itself, have to implement and integrate with every single device that you're going to perhaps – that you might know about at that point or want to integrate with. By having a true interoperability model, which we defined, you can have blind plug-and-play, meaning that you don't know what the next device needs...is, nor do you have to know, the models actually clearly allow you to have the plug-and-play. And it provides an increased efficiency for quicker, less expensive integration to the electronic medical record because now you have a single model channel using the CC – the Consolidated CDA architecture to pass data directly into the electronic medical record in this case, as well. Next slide please.

Just one thing to note here too is that the certified devices are guaranteed for forward and backward compatibility with all Continua products. This makes it easier for industry standards than to be – and industry devices to continue to move forward in the industry at this point as well. Same use devices are completely interchangeable, so it means if I have a blood pressure cuff from Company A, I can replace it with Company B if I like the user interface better. But because they're certified or they've met the requirements of the interoperability components, then we – it makes it plug-and-play in that environment.

One thing I will note here too is that the HRN interface is standardized Consolidated CDA document and then interoperability has been already shown at this point with HIMSS, IHE Connect-a-Thons and directly with NIST over the last 18 months. So this is something that we've been working with NIST on. With HIMSS we've actually been showing this connectivity for the last 3 years at the interoperability shows at their international shows. So this is something that is now – we can demonstrate – has been directly demonstrable over the last 18 months with NIST. Next slide please. This is where we are, so this is something that we're seeing here, there is global adoption starting to happen at this time, where countries now are picking up the Continua standards and requiring them as a major rollout of their next level of care with dealing with the individual, whether that be through an ambient assisted living eldercare sort of a model, or through a chronic disease management model. We're starting to see this actually take place at this point. Next slide please.

Just sort of, this is where we are right now with national adoptions by Denmark and Singapore and regional adoptions by Abu Dhabi and NHS in the UK, and commercial deployment in Japan already at this time. Next slide please. This is just also state that we're on track now to also be integrated into the ITU as an international standard as well. So we expect this to be part of a global perspective in roughly November-January timeframe. The submission's already been made; we're just working through the details now to have Continua – the Continua model actually adopted by the ITU as an international global standard. Next slide please.

And this is just an example of a solution that was implemented post the tsunami and earthquake in Japan and how that actually using interoperability considerably reduced the overall time to deploy the devices, as well as the overall cost to deploy the devices in the refugee camps that were created in particular areas of Japan where they had elder individuals who had to be moved from their home. Next slide. And I think that's it. I tried to make the timeline as quickly as possible so I'll take questions at this time.

#### **Leslie Kelly Hall – Senior Vice President, Policy – Healthwise**

So Chuck, this is Leslie. So you're product or your recommendation of standards in Continua include both a hub-based approach that takes devices to a hub that's then transmitted to an EHR. Can you speak a little bit about how you also work in more of a consumer model, like a HealthVault? Or what kind of varying technologies that you might support?

**Charles Parker, MSHI – Executive Director – Continua Health Alliance**

Sure. So, that's – the HealthVault falls in the PHR side so we can still work with an existing hub model in this case. So you can take multiple sensors, so I may have a blood pressure cuff, a weight scale and a glucometer that I'm using to collect data and that may go to my hub. And my hub may actually be a device as we may have been familiar with in the past like a Honeywell HomMed device, it could be a Smartphone today, we actually have many deployments of Smartphones and apps that are currently running and collecting that type of data. In the future it could be a Smart TV for example, that collects that data.

But the hub device itself is then collecting that data from multiple sensors in the home and then transmitting it using a single standard, whether that be CDA, in this case it's the primary model that we use, is – can go – the CDA can handoff to whether it be an electronic medical record or to a PHR. We've already demonstrated this capability with HealthVault, and actually it's a part of our consumer model demonstration for the last three years with HealthVault. So, HealthVault directly accepts the CDA documents that we hand off and you can import those or – really, it's not really an import, it's just a direct handoff of data into their system. It makes it easier for HealthVault because it's actually only one single connection as opposed to them having to maintain a connection for every single device that's in the market space.

The other component of that, from a consumer market, is that we're now seeing embedded devices, meaning that in some cases we're directly embedding 3-G or 4-G chips – chip sets in the device itself so the device itself doesn't have to even know that it's connected to a hub. Basically it collects the information and then transmits the information automatically to a backend facility as well. So that's a new model that's also emerging from the device architectures and we're seeing that – it's somewhat similar to like what you might have seen with a Wi-Fi based network, but this is directly connecting and sending and transmitting data.

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

Are there questions from the group?

**Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated**

Yeah, Leslie, I just – this is Wes. I'd like to comment that that last point that Chuck made is extremely important, I think, to the future of what we're doing and we should get more information about it. I would like to ask Chuck, has this entire picture on your architecture slide been implemented anywhere? Is there any place in the world where devices are using a continuous standard to go to hubs that are using the continuous standard to go to EHRs with or without the telehealth service center?

**Charles Parker, MSHI – Executive Director – Continua Health Alliance**

Sure. Yeah, so there are at least two instances of that today, one is in Japan as the case example that we used and demonstrated there, that was used, and still is actually in use now with the refugee camps in Japan. That's one of the instances and then there are currently deployments taking place in Denmark as part of the rollout there. There is a demonstration project that is actually taking place starting next week with a bike ride from – that will be taking place from Brussels to Barcelona using Type 1 diabetics that will actually be monitored and measured the entire ride and be deployed throughout the week that they're actually doing the ride itself. So, there will also be another project that's kicking off and well, they're actually underway now, they're doing some pre-measurements this week to measure the individuals pre-race, so they'll be doing the race next week and then they'll be measuring one week post-race as well.

**Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated**

So when we talked about Japan before, it wasn't that they required IHE – continuous certified devices, it was that they recommended the use of some of the standards from Continua. Has that changed or is that still the situation?

**Charles Parker, MSHI – Executive Director – Continua Health Alliance**

It has changed. So in the deployments that are taking place now in Japan, for example, NTP – is requiring Continua compliance.

**Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated**

Okay, requiring compliance, not necessarily requiring certified products.

**Charles Parker, MSHI – Executive Director – Continua Health Alliance**

Well, it does mean certified products, I'm sorry.

**Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated**

Okay, all right. Good. Thanks. Because the United States we sort of – around – compliance differently, but that's a good point. Thank you.

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

Other questions from the group? So Chuck, in summary what I hear you say is that there is opportunity – there is a standard that can be used to support device data through the Continua Alliance that you've named, for both an environment where the provider might prescribe devices to go home. Or a patient might buy their own devices and want that information to be consolidated into a PHR and/or emerging from the mobile devices that are actually embedding compliant chips. Is that a summary of what I've just heard?

**Charles Parker, MSHI – Executive Director – Continua Health Alliance**

Yes it is.

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

And yet we're still emerging everywhere in consumer generated data to see places where it's been widely adopted, we're still somewhat in that pilot and demonstration phase of that, but with it sounds like huge adoption or at least consideration of the standard throughout the country and the world. Is that a fair representation?

**Charles Parker, MSHI – Executive Director – Continua Health Alliance**

Yes it is.

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

Are there other comments or questions, concerns from the group? I know we've gone over time. Okay. Well thank you very, very much Chuck and Lisa and with that, I think we'll turn it over to public comment. Oh, before we do that Michelle, and for the group, we have meetings scheduled on September 7 and 10. On September 7 I'd like to see if we could regroup around the patient-generated health data issue questions, discuss the points that both Wes and Tom and Holly all brought up, emerging issues, vocabulary sets, some data reconciliation issues, suitability for Meaningful Use 3 and have a richer discussion around that in our next session. Did I have the dates right Michelle?

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

No, its September –

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

The third and the seventh –

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

– September 3 and the tenth.

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

Okay, so the third we'd like to dedicate to that and see what we can do to recruit more people in. So with that, I'll turn it over to you Michelle for public comment.

**Public Comments**

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

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

**Caitlin Collins – Project Coordinator, 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. And we do have a comment.

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

Great.

**Operator**

The comment is from Mark Savage.

**Mark Savage, JD – Director of Health Information & Technology Policy & Programs – National Partnership for Women & Families**

Hello this is Mark Savage at the National Partnership for Women & Families. I listened to the presentations at the last meeting and this meeting and I've got to say, I'm very excited to hear about some of the possibilities for patient-generated health data. One question or observation about the discussion on PGD headers, it will be useful from the patient perspective to also see how this can be used. I thought I hopefully discerned in the discussion there that care planning might be a possibility here with the recognition of the different kinds of individuals that might be involved. So, teasing out some of those examples will help patients and families also appreciate the good work that's happening here. Thank you.

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

Thank you Mark, and I think that that's a great comment and something that the committee had discussed before in care planning and appreciate the reminder.

**Caitlin Collins – Project Coordinator, Altarum Institute**

We have no more comments at this time.

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

Okay, with that, we will adjourn and I hope everyone has a great Labor Day Weekend. Thank you.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Thanks Leslie.

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

All right. Bye, bye.