HIT Policy Committee
Consumer Empowerment Workgroup and
HIT Standards Committee
Consumer Technology Workgroup
Transcript
November 15, 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 joint meeting of the Health IT Policy Committee Consumer Empowerment Workgroup and the HIT Standards Committee 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, the meeting is being transcribed and recorded, so please state your name before speaking. I'll start with roll for the Consumer Empowerment Workgroup. Christine Bechtel?

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
I'm here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Korey Capozza?

Korey Capozza, MPH – Consumer Engagement Director – HealthInsight
Here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
James Cartreine? Scott Fannin? 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
Katherine Kim? Sarah Krug?

Sarah Krug – President – Society for Participatory Medicine
I'm here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Rita Kukafka? Patricia MacTaggart?

Patricia MacTaggert, MBA, MMA – Lead Research Scientist/Associate Professorial Lecturer – George Washington University
Here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Beth Morrow?

Beth Morrow, JD – Director, Health IT Initiatives – The Children's Partnership
Here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Jan Oldenburg?

Jan Oldenburg – Vice President, Patient Engagement – Aetna
I'm here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Casey Quinlan?

Casey Quinlan – Chief Message Officer – Mighty Casey Media, LLC
Present.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Clarke Ross? Mark Savage?

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

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Alicia Staley? MaryAnne Sterling? Ann Waldo? Ryan Witt?

Ryan Witt – H4Y Corp
Here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Terry Adirim?

Terry Adirim, MD, MPH – Director, Office of Special Health Affairs – Health Resources and Services Administration
I'm here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Cynthia Baur? Bradford Hesse? Kim Nazi?

Kim Nazi, PhD, FACHE – Management Analyst – Veterans Health Administration
Here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Danielle Tarino? Teresa Zayas Caban? And is Erin Poetter on the line for the Consumer Empowerment Workgroup.

Erin Poetter Siminerio, MPH – Policy Analyst, Office of Consumer e-Health – Office of the National Coordinator
Yes I am, hi.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Hi Erin. I am now going to do roll for the Consumer Technology Workgroup. We know Leslie Kelly Hall is here. Brian Ahier? We know Christine Bechtel is here. Brian Carter? AJ Chen? John Derr?

John F. Derr, RPh – Health Information Technology Strategy Consultant – Golden Living, LLC
Here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Tonya Dorsey? David Harlow? Arthur Henderson? Susan Hull?

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

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Liz Johnson? Tom Jones? Mohit Kaushal? 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? Marsha Nizzari? Yair Rajwan? Wes Rishel? John Tritter – John Ritter, I'm sorry.

John Ritter, MS – Software Engineer – Co-Chair HER Workgroup and Volunteer HL7
John Ritter's here. Hi.

Michelle Consolazio – Interim Federal Advisory Committee Act Program Lead – Office of the National Coordinator for Health Information Technology
Anshuman Sharma? Fred Trotter? And Kim Nazi is here and Susan Woods? And I believe Ellen Meeker is on and so is Mary Jo Deering from ONC?

Ellen V. Makar, MSN, RN-BC, CPHIMS, CCM, CENP – Senior Policy Advisor – Department of Health & Human Services
I'm here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
So I will pass it back to Christine Bechtel.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Great. Well thank you Michelle and welcome everybody to our first I believe really, joint meeting of our Consumer Empowerment and Consumer Technology Workgroups. We've got a really exciting set of topics to cover today, focusing on patient-generated health data. So hopefully all of you are able to join online to see the slides. If we can get the agenda – there we go. So what we're going to do first is, the Consumer Empowerment Workgroup of the Policy Committee was asked by the Meaningful Use Workgroup to examine the issue of patient-generated health data and its readiness for Stage 3 in Meaningful Use, and to identify any other issues that we saw.

And so I think as you guys recall, because we had a joint hearing on patient-generated health data previously, we have come up with a series of recommendations based on that hearing and other work that we have done, and I'm doing to preview those today. As part of that work, we also made some asks of you all, our colleagues on the Consumer Technology Committee. And so I'm going to preview those and remind you of what they were. I want to give everybody a chance to ask questions about the recommendations that the Consumer Empowerment Workgroup has at least finalized preliminarily. And then we're going to hear from Leslie Kelly Hall, who is the chair of the Technology Workgroup. As you guys know, and we're going to hear all about the terrific work that you guys have been doing over the last several months, and talk about the recommendations you have. And then figure out how to blend them together for a presentation back to the Policy Committee and the Standards Committee, as appropriate. So, we've got two hours to do all of that and we're going to dive right in.

So, next slide, and keep going. All right, we'll skip this slide since you guys just heard the roll call and you have a sense of who is on the phone. But the workgroup charter for the Consumer Empowerment Workgroup is to provide recommendations on policy issues and opportunity for strengthening the ability of consumers, patients and lay caregivers to manage both their health and their care. Next please. So, and keep going. So, we had a listening session as I mentioned, on July 18, and you guys recall that and it was really around, how do we provide some input for Meaningful Use Stage 3 with respect to PGHD and what are the policy issues that we need to address to facilitate its more widespread use. Next slide.

And if you guys can put yourselves on mute, I know we have somebody paper shuffling and stuff going on and this is exciting stuff, no need to multitask guys.

Mohit Kaushal, MD, MBA – Partner – Aberdare Ventures/National Venture Capital Association
Sorry, this is Mo I just joined. I'll go mute, apologies.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Okay, thanks. All right, so the first thing that we started with, and we heard this from the listening session was that we needed a common definition for patient-generated health data and so you see that on your screen. So patient-generated health data are data that are health-related, things like health history, symptoms, biometric, etcetera and they are created, recorded, gathered or inferred by or from patients or their designees to help address a health concern. Patient-generated health data is distinct from data generated in a clinical setting because patients are primarily responsible for capturing or recording the data and also patients direct the sharing or distribution of the data to health providers and other stakeholders. So, it's a compliment to provider directed capture, if you will, but it is distinct. So that's the common definition we've been working with. Next slide.

It's not new; it's already valued and incorporated into the record today that was a really big takeaway. We hear a lot about patient reported outcomes, but frankly, patients provide an enormous amount of the data that ends up in their record in the first place. So, providers under Meaningful Use 3 draft recommendations would have the ability, and we're going to talk about this, to work with patients on PGHD, and I'll describe that more fully and there are lots of ways that we can capture patient-generated health data. In some work that was done earlier, the most common methods included through secure messaging, through structured and semi-structured surveys, through biometric and device data in the cloud and there were other ways. But those were really the primaries. And what we also heard, very importantly, is that there are four things that providers need to be able to do with patient-generated health data. They need to be able to receive it, they need to review it, respond to it and record it. And one of our asks to you guys on the Consumer Technology Workgroup was to help us make sure that electronic health records have those four capabilities. We think that we do, in terms of receiving and recording, but in terms of the review and respond, we asked you guys if we really needed anything else, so, we'll hear from you all on that.

Next slide. So, we also heard that when PGHD is implemented appropriately that a lot of the concerns that we commonly hear end up really being addressed, because they're thoughtful and they're counted for in the implementation process as PGHD use becomes routine to the provider. And that means that the providers are developing workflows and clear policies and procedures for clinicians and patients that help set those expectations and communicate those expectations back to patients and families. Next slide.

We hear a lot about liability for reviewing patient-generated health data, but the way the meaningful use criteria is structured would help to eliminate that or at least reduce it, because the provider and hopefully in collaboration with their patients and families, they are determining what type of patient-generated health data they want to receive. And so they will be better prepared to receive it, it's not just turning the faucet on and seeing what comes out, they're really able to develop some clear policies and procedures around a specific data set that they're actually looking for that would be helpful and useful in care.

We heard about the fact that in terms of HIPAA, definitely setting a floor and not a ceiling and it establishes some rights around corrections. And as you may recall, there is a meaningful use criteria around amendments that we'll talk about. And then finally, we heard that frankly providers and patients really want to have accurate information that is high quality, in the record. And they're very aligned on that. We just frankly need to make it easier. Next.

Okay, so the original objective for patient-generated health data in the Meaningful Use draft is a menu item and it would provide – so in other words, people would voluntarily choose it. They could be an EP or an EH, and they would provide patients with the ability to electronic submit – electronically submit patient-generated health information through structured or semi-structured questionnaires for more than 10% of patients during the reporting period. Next slide.

We've done some work in the Policy Committee, just to update you guys, to try and make the recommendation framing more resonant with people and keep them from getting too into the weeds. And so in the middle column in green, and in the right column in green, you'll see that really what we've outlined is what are the overarching goals of patient-generated health data. So on the far right, it's really about providing the ability to contribute information to the record and having patient preferences recorded and used. And then in the middle column is a recapitulation of the previous slide, and there will be a threshold indicator, which would say the threshold would be low, we're trying to get away from an exact percent. Next slide. The other piece of it – let's just go ahead to the next one please, oh no sorry, previous. My bad, I thought we had another one. So, the other proposed certification requirement for Meaningful Use Stage 3 would provide patients with an easy way to request an amendment to their record online, okay.

All right, so with that as background, the next two slides cover our recommendations, and then we're going to do a Q&A, if anybody has questions or thoughts about these recommendations. So our first recommendation is that for provider organizations who choose the menu item to do PGHD in Stage 3, they need to establish clear policies and procedures, in advance of implementation for Stage 3. Including the content that they want to receive, the mechanisms by which patients and families can submit it, right, whether it's secure messaging or a survey, etcetera, how it's going to be received, reviewed, acknowledged and recorded, including provenance. And speaking of provenance, we also agreed that the sourcing of data should apply to the export of data for treatment, payment and operations as well. Third, providers need to collaborate with patients to ensure that the way they are proposing to collect and review and acknowledge and record the data actually works for patients as well as providers.

Fourth, we're recommending that ONC should work with federal partners, and of course itself, to really give providers clear guidance on how to implement the menu requirement, including the need for the policies and procedures. And tips on how to communicate the policies to patients and families in their preferred language at the appropriate literacy level, of course, and include information about their rights under HIPAA to amendments and corrections. And we've proposed a couple of ways that ONC and CMS might could do that, which would be the web sites, the Regional Extension Centers, the National Learning Consortium, at a minimum. And we've also said that guidance should really build off the work that's being done now by the technical expert panel on patient-generated health data that ONC has convened, and that we heard from, as you recall, in the joint listening session.

So, next slide, our remaining recommendations are that under Meaningful Use Stage 3 PGHD will be reflected in the record and HIPAA should govern that data, as it does other data in the record, period. People had asked if we need special privacy protections and we said HIPAA should govern it, but that in the future ONC and OCR should look at addressing data sharing by consumer devices and apps that providers might want and use in clinical care. So number six, work is also needed in the medium term to figure out the policies, workflows and liability issues around unsolicited PGHD. Number seven, that interoperable Direct email addresses should be made available to patients, in order to open up more options for efficient and effective collection of PGHD, and we would welcome the technical input from the technology group on that in particular.

Number eight; we support the Stage 3 requirements that address the capacity for EHRs to accept amendments and corrections. And number nine, that we need experience in Stage 3 around PGHD so we can figure out whether secure messaging content or other mechanisms like CDA headers, for example, have the capacity to receive and facilitate the review and recording of PGHD. And then finally, and this is really where we ask the technology group to weigh in, that additional work is needed to figure out how to summarize and aggregate biometric device data to show trends to providers. So, on the next slide were the three asks that we made to the Technology Workgroup, and I'm going to preview them now, but then we're going to do a Q&A around the recommendations. So maybe once I'm done with this slide, we'll go back two slides.

So our first ask to you guys on the Technology Workgroup was to look at the standards and the market around the feasibility of including consumer device data in Stage 3 of Meaningful Use. Our second ask of the technology group was to make sure that the functionality exists in meaningful use for receiving, acknowledging, reviewing and recording PGHD in Meaningful Use 3. And then finally, we asked you to identify any necessary standards to support PGHD including, but not limited to biometric and device data. Okay, so that's what we're going to talk about next, is we're going to hear about the work you've done in these areas. But let's back up two slides to the recommendations and ask if anybody has questions or reactions.

Ryan Witt – H4Y Corp
I have a qu – oh, I'm sorry. This is Ryan. I had a question for clarification on the recommendation number two. I just didn't quite capture what we meant by sourcing data should also apply to the export of data, like treatment, payments and operations?

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
That's a good question. I think what we were trying to say there is, it's not – that it shouldn't be the case that you only have PGHD sourced in the record, really that if you're going to move any data around, it should have a source with it. But I'd ask other members of the workgroup to correct me if I'm wrong on that; I could have that wrong, not being a technical person here. Anybody else want to weigh in or Erin or Mary Jo am I right on that?

Mary Jo Deering, PhD – Senior Policy Advisor, Office of Policy and Planning – Office of the National Coordinator
I think you were. This is Mary Jo Deering and I believe that in addition, the concept was that once PGHD has been into the record, it's going to be comingled with information that's going to be exported out again. And so that it would be very important when the receivers who are using it for treatment, payment and operations should know that among the data they've received, which elements carry a patient provenance.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Thank you Mary Jo, I did not have it right. So thank you very much, that's exactly right. Good memory.

Ryan Witt – H4Y Corp
Thank you guys. That helps.

John F. Derr, RPh – Health Information Technology Strategy Consultant – Golden Living, LLC
Hi, this is John Derr; I've got a couple of questions. I'm sorry, go back a little bit farther, but on slide eight, you said about the four things, I just wondered if aggregation of inputting information from the patient is part of one of those four things?

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
On slide four – oh –

John F. Derr, RPh – Health Information Technology Strategy Consultant – Golden Living, LLC
Providers need to be able to do –

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Um hmm, slide eight.

John F. Derr, RPh – Health Information Technology Strategy Consultant – Golden Living, LLC
Yeah. Would there be a – the patient be able to put information in or is that not germane?

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
I may not be understanding your question, but the whole premise that we're talking about is patient-sourced information, patient-generated health data. So the provider needs to be able to receive –

John F. Derr, RPh – Health Information Technology Strategy Consultant – Golden Living, LLC
Okay, I go you –

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
– so they're getting patient-generated health data and with that, they need to be able to receive patient-generated health data, review it, respond to it so the patient knows it was received once they've sent it or answered the survey or whatever it is, and then record it in their record and have it be sourced as patient-generated.

John F. Derr, RPh – Health Information Technology Strategy Consultant – Golden Living, LLC
Got it.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Okay. Thanks John.

Mark Savage, JD – Director, Health Information & Technology Policy & Programs – National Partnership for Women & Families
Christine, this is Mark.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Uh huh.

Mark Savage, JD – Director, Health Information & Technology Policy & Programs – National Partnership for Women & Families
A couple of things, one related to the previous item; on the key takeaways on slide nine it mentions that MU Stage 3 sets up receive and record. And I was wondering if it's fair to say that with respect to amendments, there's also a review and respond element, it may not be built in generally yet, until we hear from the Consumer Technology Workgroup, but it's already envisioned that there would be a review and respond function for amendments and corrections?

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Umm.

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

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Yeah, yeah, I think we could be more clear about that, yeah.

Mark Savage, JD – Director, Health Information & Technology Policy & Programs – National Partnership for Women & Families
Okay. I'll wait until that stops.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Oh, thank you guys for mute, that was helpful. Okay, go ahead Mark.

Mark Savage, JD – Director, Health Information & Technology Policy & Programs – National Partnership for Women & Families
Then the other observation I had more on the recommendations is that, I'm not a member of the Consumer Technology Workgroup, but I've been following the meetings because I learn a lot from them. And I've noticed a lot that's already in place around patient-generated health data on care plans and care planning and maybe this will come up later in the session, but it looks like there's a huge amount, and it would be useful to weave that into our recommendations. I didn't see it mentioned here, so I just wanted to flag that.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
So that's a great flag. I think process-wise, these are the – these recommendations are what I had described as kind of initial final meaning, the policy related ones have been agreed upon by the Consumer Workgroup. But we have not yet heard from the Technology Workgroup and so, we want to have a discussion at the end of our time today to talk about what the core recommendations are that we should incorporate back here, and so that would be a very good time to raise that again.

Mark Savage, JD – Director, Health Information & Technology Policy & Programs – National Partnership for Women & Families
Great. Thank you.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Um hmm. Anybody else? Okay, so with that, what I'd like to do is turn it over to Leslie Kelly Hall, who is going to give an update from the Consumer Technology Workgroup and run through the work they've been engaged in. And I'll just say, in advance, on behalf of the Consumer Empowerment Workgroup, we are very appreciative of the hard work you guys have been doing over the last several months. So Leslie, take it away.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Thanks Christine. We're pretty excited. I challenged our group to say, we are the group of no excuses, there needs to be standards in place and a way to support these efforts and I think we all took that to heart, quite seriously. Next slide. So there's a wide group of people involved in this, and we've had pretty good attendance and a lot of thoughtful testimony and involvement including, I'd like to highlight Russ Leftwich who's really helped us to make sure that anything we do in patient-generated health data is a foundation for care plans of the future. Lisa Nelson from HL7 patient-generated health data team has been instrumental in advancing that agenda to ballot and ballot reconciliation within HL7 so that we would be timely for Meaningful Use 3. And also Dr. David Kibbe on Direct, talking to us about using Direct as a transport. And then Chuck Parker from Continua Alliance, who really informed the group about devices and device integration. So we've had some ongoing commitment both within the team and external experts who have stuck with us for these last few months.

Next slide please. So our charge was really to respond back to your request with the idea that we could help to build upon the momentum of patient-generated health data. Next slide. So we wanted to first confirm what's available and then take a look at what's missing, sort of the gaps, and what's the current level of maturity and adoptability. And these are all very important and I'll touch on them as we go through our findings.

Next slide. So some of the things we had, that we wanted to repurpose existing standards where possible. This was very important because when we bring in a new group to the ecosystem, bringing in new people and new technology and new standards would be completely disruptive and largely put everything off. So we felt, all right, what can we do to build upon standards that are already not only existing, but already named within meaningful use, can this inform our work? Now knowing that, we would inherit both the benefits and the problems of using existing standards, something that's mature in the provider world might be very new in the patient world. And the standards can constrain innovation or encourage innovation. So we were constantly looking at these natural tension items as we reviewed our work.

Next slide. What a big takeaway was, that when you look at consumer-friendly products and services, there's an app for that, there's a technology for that, but those standards are very, very likely to be presumed when data is coming outbound of an EHR, something similar to what we envision the Blue Button and the Blue Button Plus in the future. Those standards are around more generic IT, more generic consumer technology standards, things like OAuth, and partly it's because this is new technology and it's also because the patient assumes the risk. When you take something out of an EHR and it's now consumed by a patient to do whatever what they want, it's only their risk.

When data comes inbound to an EHR, the risk is the providers, not only because they have to act on data provided by the patient, but also allowing data to come into an EHR, you have to have a high degree of trust that that data is secure. That its consumable, that its involved in your workflow and not disruptive, because the risk is not just to the single patient's data, but actually to the entire EHR. If you bring in a virus, if you bring in something unfriendly, then the risk is the providers. So this was a way to articulate – but consumer friendly standards are highly likely for outbound data, but when we look at standards for inbound data, it's going to be about the EHR and existing HIT standards. And this was a way to address that natural tension. Next slide.

We also learned in our patient-generated meeting that we had several on, that there were some high benefit areas, things like safety related, where there's a medication, an allergy, an intolerance or barriers to care. Next slide. We learned that the patient and the provider also have to have care plan related information coming in, incorporate the patient goals and values, support your decision making, provider requested, long term data, enable data tracking, pre-visit preparation, history gathers. Next slide please.

Or it could be a new patient concern or patient reported outcome or administrative and important. And when we look at this and the request from the consumer empowerment team, we really see that this is about questionnaires. This is about asking for information in return from a patient, very much a patient response and so that helped us to put our arms around the constraint as we looked for standards. Next slide.

So we looked then for patient-generated data standards to capture the needed information during care. And the value of that is just as we've seen over and over again. Next slide. So, we also felt there were other types of considerations. When you look at standards for certification, that's one menu item is 100% for HIT. We also looked at the tension between episodic patient-generated health data and collaborative patient-generated health data. So an episodic information is many of the things I outlined above, what are your medications that you're taking? What's your weight? What's your pain? What's your patient reported outcome? What's your experience of care? These are all questions asked from the provider with a response expected. And it's generally asynchronous; it's generally a one-to-one relationship.

But as we move to the future of shared care plan, shared decision making and collaborative care, that's a much more of a complex environment and we're not quite ready for that. We can build to it, but there's a lot of work there. And then also I mentioned earlier the tension between provider-based standards and consumer product standards. And we think we've struck that by saying if it's outbound it's consumer friendly, if it's inbound, it's provider friendly. Next slide please.

We looked at the National – the NEM standard for maturity and this was a very important part of our work. The Standards Committee has asked that any standard being recommended consider this maturity type criteria and we asked for help from Dixie Baker in our interpretation of this because using existing standards, we can take, for instance the Consolidated CDA which is named in meaningful use, it's a requirement in meaningful use. It's also very high on the maturity and adoptability index for provider use; however, it is brand new for patients. So we have no maturity and no adoptability for patients, but as a standard, very robust. So when asking Dixie how do we score this, she said, it actually comes out right in the middle. So, it's – that really gave us a leg up in the idea of adopting these standards, because in fact, it is something already there we can repurpose. Next slide.

So we looked at the – from left to right is the evolution of types of data that's patient-generated data from secure messaging to a structured questionnaire, to an unstructured or and narrative or hybrid approach. The structured questionnaire is I'm asking you something, you're replying back and it might be a pick list item. It actually might be check your pain, check your weight, and check the meds you're taking. An unstructured or narrative or hybrid approach could have a very structured envelope or surrounding, but a section that is a narrative, that is actually patient-generated data that they're typing in their own words. We then looked at device data and we looked at care – plans of care and care planning. So plans of care are individual episodic-based care plans, how am I going to handle my wound after surgery? What's my care plan for that? Collaborative care planning says, it's an overarching theme and as an individual, I am planning for my care that could include many different providers and a care team that I designate. So when looking at what we thought might be ready for meaningful use, the yellow indicates that we're probably ready to identify a patient in a structured way, the providers of record and to begin to identify the care team, all the way through to that episodic plan of care. Next slide please.

So when we take a look at the potential use cases and what could be meaningful use ready, we felt that in messaging, both secure non-tethered with or without attachments were ready by adopting the Direct standard. In the structured questionnaire, any of these things could be met using the Consolidated CDA template – questionnaire template, and we have several already in there, I think there are four or five, but the opportunity to repurpose that for other types of questionnaires is very, very high. It also accommodates a – in the Consolidated CDA, it actually accommodates the provenance issues that have been brought up, and we have a very robust identification of provenance. The patient, the patient's care team, their family members, not only who the person is, but the role they play in care.

And this was crafted brilliantly by the HL7 patient-generated health data team, by Virinder Batra, gosh, there's a group of them, Lisa Nelson and a bunch of others, also harmonizing with the care planning team with Russ, to make sure that we could standardize at the header level. So rather than approaching this standard with, I've got patient-generated health data over here in a bucket and I've got physician generated health data over here in another bucket and we're all going to call it the same structure. We felt that that separate and equal approach was not sound so we actually took it to the header level.

What that means is that anytime someone looks at a Consolidated CDA structure or template, they are constraining the use of that by both the patient-generated and provider-generated. It becomes an opportunity for consideration for all future template development. So we don't end up with a separate but equal, we end up with parity in the standards for health generated data for any of the care team members. So this approach was quite brilliant and we're really – we really think we're right on. With this approach we can address the four areas that Christine outlined from the group.

As well we think that under the unstructured and narrative or hybrid approach, we're ready for structured templates with unstructured narrative, using again the Consolidated CDA. We don't think we're ready for consumer-centric standards yet, but we think there is a great market opportunity. So for instance, by naming the standard, organizations who – perhaps Microsoft or others or Apple who are looking at creating documents like Word, they could create a Word Wizard to translate that into a Consolidated CDA and upload to an EHR. So we do think there's great promise in the future, but we're not quite ready for that.

On the device side we looked at two opportunities. One was devices that are being prescribed for home, provider directed users of telemetry, biometric, mobile devices and apps, and we see them going home today already. When a device is sent to the patient, there's a high degree of acceptance of that device, the provider already knows it, and the provider has interfaces potentially. It's something – it's akin to a patient response, it's something directed. However, the consumer directed, consumer products for telemetry we really don't yet have standards on the consumer side that say hey, we're ready to provide unsolicited, unprescribed devices data back to the EHR. So if I decided to by – perhaps it's My FitBit. Today I've got great opportunity to use that, but I don't yet have mature standards that could be easily adopted to get that back in to the EHR today. However, if we named the standards under provider directed devices, which might include a FitBit, then we have the opportunity to get that data back in.

We felt that under the care plan, we really aren't quite ready yet. There needs to be some work on versioning, reconciliation and harmonization. So today when we think about data coming in to an EHR, we think about provenance and time/date stamp and we know who has created that document, authored it. We also might know who transcribed it. There are many different roles associated with that document and the Consolidated CDA standards structure helps us to inform that. However, we don't yet have, whether it's patient-generated or multiple provider generated, we do not have standards yet to accommodate multiple versions, reconciliation of multiple versions, harmonization of multiple versions and/or a collaborative document structure, or perhaps a wiki structure.

We're seeing things emerge in the SMART platform that's being talked about and things like using FHIR in that environment, but it's not yet there. And I think there's going to be renewed interest to look at versioning reconciliation, harmonization and collaborative care records as we go forward for Meaningful Use 4. And I would hope that under the S&I Framework we start to look at this big project, because we won't be able to do collaborative care planning until we have this structure. And moving to collaborative care planning, we see even beyond that document level structure, we need to take – have the ability to look holistically and integrative, horizontally across multiple care plans. And then we get into well, what's the governance and what's the curating structure of that. That's still yet to be worked out. But we're very excited, hopefully address the four things that the group asked for, be able to address structured questionnaires and hybrid approach, and also a recommendation on devices. Next slide please.

So these are the standards that we would recommend. We assume that the common meaningful use data set standards, vocabulary, device and technology are – that's assumed across the board. We don't have to name anything differently. Under messaging, we believe that Direct message for patients can be evolved. We also believe that the HL7 care team roster goes across all of these areas; we'll begin to expand the idea of who is on a care team and what their role is. Under the questionnaire, we would use the HL7 Consolidated CDA, again the care team roster. And then the device, we're actually recommending a Continua standard that adopts both the FDA requirements, it incorporates Direct, it can send a Consolidated CDA, it's all those things you see down the – on the side of this in small letters, all fall under the Continua Standard. The other thing that the Continua Standard has allowed for most recently is that it incorporates the idea of aggregate data and individual data. So something like a HealthVault has been – with a Con – using the Continua framework to actually aggregate data from multiple devices and then upload it in an – from a HealthVault environment. So we think there's great promise there.

In discussing this with others on the Standards Committee, this is the area where's the most concern, and this is the natural tension between consumer directed standards and provider directed standards, how would that work. We – the group feels pretty strongly that Continua was able to respond to all of the questions asked, but there's still some work to do. And then the HL7 care team roster. Next slide.

So we also felt that even though we felt very solid in being able to respond to the request from this group, that there also needs to be some future work. One is to create a collaborative care document structure overall, that includes the patient and their caregiver and anyone they identify in their care team, that will address versioning, expanded provenance, reconciliation, data governance and curation. We also believe there's an opportunity for consumer product and provider standards forum for alignment. Where can we bring those two communities together? To take a look at the Blue Button Plus and API approach to accommodate patient-generated health data in the future, so looking at an evolutionary approach to patient-generated health data. And also look at the Trust Framework to be expanded for consumer and patient adoption, like we've done with the Blue Button Plus and Direct.

To look at consumer vocabularies in the future, what would that role be? That's another area of tension, do we have a consumer friendly term that now are translated into medicine, just as we take today medicine and translate that into consumer friendly terms. There is great work being done there. Kaiser donated consumer vocabularies, I believe to the NLM and I think there are others interested in doing that, but that's still emerging. And then we also think there's opportunity for ONC to create a patient-generated health data guidelines and policies very much akin to the Notice of Privacy Practice that they did such a great job on. So all in all, we feel positive.

Now yesterday we presented to the Health Information Technology Standards Committee and I would invite my other team members to chime in. Where I felt the tension was, when is something an informing standard and when is something needed for regulation? We also heard concerns about is a use case – enough? I think it is when we discussed it in terms of questionnaires, both structured and hybrid approach. Then the question about devices somewhat came up, that's been more playing in the background. We – that the approaches we've taken by repurposing existing standards already named in meaningful use and allowing them to evolve for patient-generated health data gives us the highest and best likelihood of having a successful patient-generated health data integrated into the ecosystem. So I would invite Kim and John, do you have any comments from yesterday, or Mary Jo or Ellen?

W
I think you summed it up.

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

John F. Derr, RPh – Health Information Technology Strategy Consultant – Golden Living, LLC
Yeah, John, this is John, I agree.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Great. So with that, we'd love to open it up for comments or questions.

Katherine Kim, MPH, MBA – Health Equity Institute Professor in Residence – San Francisco State University
Hi, this is Kathy Kim. I had a question about the use of Direct for consumers, and I think we had a conversation in the Empowerment Workgroup about this as well. My understanding is that even on the provider side there's not a way for reconciliation if a provider has more than one Direct address, right, it's sort of affiliated with each provider organization, and they would have more than one. And that needs to be addressed, but then when we talk about consumers, what if they have more providers issuing those Direct addresses? Has the Standards Committee thought about how that might work and whether we can avoid that situation?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Well, I think it's going to be up to the individual, just as the provider might say, I want a general Direct address from my inbox and I would like a specific, unique address that I really only want to give to my colleagues. And then I have another Direct address that I will use for the patients, because it's really just – it's secure messaging. I think that patients will be able to have a choice, do I want to have this Direct address issued from my provider at present, and then every time I go to another provider, I can just simply give them that address. Here we are benefited from the ruling that states that a patient can say, send this to any place I want, and so there is nothing that requires a provider to issue an individual Direct address for its patients only. The patient has a right to say, send it to this address. So, we do think there's actual better opportunity for a patient to end up with one, than there are for providers.

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives
This is Russ Leftwich. I – at this point, I don't think it's envisioned that provider organizations in general will be issuing patient Direct addresses. The ones that are available at this point mostly come from personal health record vendors, if you will, who are issuing patient Direct addresses.

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

Jan Oldenburg – Vice President, Patient Engagement – Aetna
This is Jan Oldenburg. And I just had some conversations recently with some of the ONC staff members regarding HISPs seem to be interpreting the Direct standard as that they would each issue Direct standards – I mean Direct addresses that are in effect linked specifically to that HISP. And that then say where the email or the message should be directed. So similar to if I have a g-mail address and a Comcast address, it tells the system where to send that message and so as we talked, it started to feel as if both consumers and providers might end up with a plethora of Direct addresses with no clear ways of harmonizing them or reconciling them.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Yeah I think Jan, this is Leslie, and I think it – we have opportunity to influence this as we go forward. And I think this is where the market will probably tell us a lot of how that adoption is taking place, how are those being issued. But, I think it will be – it'll be interesting for a while. There is no clear, absolute direction.

Jan Oldenburg – Vice President, Patient Engagement – Aetna
I mean the question I think that that surfaces is, should we be setting one or should we be building some indications of how we think it should evolve as a way of eliminating the interim confusion that might slow down adoption?

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives
Well, this is Russ Leftwich again. I think to a significant extent this is part of the ongoing work of DirectTrust.org to try to provide some governance and guidance around those issues. The other thing that may help to alleviate any problem is the development of provider directories, which DirectTrust.org at least envisions will also be patient directories that would enable a cross-linking of Direct addresses, if you will, if an individual, provider or patient, has more than one.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Yeah, it think it's really being discussed in earnest right now. Thanks Russ. Other questions or comments?

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
So Leslie, this is Christine. This is a really terrific – of work and boy it's a lot. I want to come back to what I think were the – that was the impetus for asking you guys to do some of this work and that was the three requests that we had. And so, I just want to kind of come back and make sure I understand the answers so that we can figure out how our recommendations might change here, or what recommendations that we need to add from your group.

So the first was to tell us about the feasibility of including consumer device data in Stage 3. If I read your slides correctly, it looked like since this is a menu option, if a provider chose device data, that it would be essentially provider directed, but maybe that should be an option for them and they –

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
I agree.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Okay, so we would say provider directed device data or whatever.

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

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Okay. So that gets to the second kind of add on question which is, the way the, and maybe we can go back to slide – probably the easiest slide to look at is, I think it's 11, it's with 204B on it.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Say that again.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Slide 11.

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

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
So hold on, we're going to get it up here, keep going. Yup, that one. All right, so the way the meaningful use recommendation was originally drafted, only focused on structured or semi-structured questionnaires. So I think you're saying, yes we're ready for that, but we're also ready for secure messaging and a provider – we know secure messaging, and provider directed devices. So if an EP or an EH chooses this, I think your group is saying, we're ready and they should get credit if they decide to do – to collect –

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

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
– PGHD via those other channels.

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

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Okay, great. So the next ask that we had was to ensure that the functionality exists in the EHR for receiving, acknowledging, reviewing and recording in meaningful use. Is that –

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Correct, because we've used the Consolidated CDA, everything that's in the Consolidated CDA is inherited for the patient. So if it's coming from a lab company in a Consolidated CDA or it's coming from a chiropractor or if it's coming from a cardiologist or it's coming from a patient, all that provenance data goes with it. So you know who it's from, it can be recorded, it can be kept in place, when you go to download it again, all that provenance stuff comes with it. So, we are inheriting all of the benefits that come with using those existing standards.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
And would the CDA always be used for these different channels that we just described, for a structured or semi-structured survey instrument or for secure messaging?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
So secure messaging itself, the message transport layer could be Direct, the actual payload would be, we're suggesting a Consolidated CDA for structured and semi-structured questionnaires. The Continua standard for devices, the device itself can – standard, can support a transport layer of Direct, it can support many other – there are many other standards for transport within the Continua framework. Additionally it can support a Consolidated CDA also within its payload, depending upon the device type. So, there's a lot of flexibility within that.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
So, I wonder – that takes me to thinking that maybe secure messaging should be different; it should not be included in the menu objective because a device for a questionnaire is a thing, but a secure message is the transport mechanism? So maybe –

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
No, I – we heard from Arien Malec yesterday and he gave some quite insightful comment and his comment was that secure messaging, because it's easy, has huge opportunity to be a great way, and is a great way to get clinically relevant information. And where the provider might start with things like appointment scheduling, but then move quickly into gathering care information within a message. Now it takes more to then get that message data into the record, so for instance –

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Yeah.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
– if I had a message, I can't immediately click a button and consume it, but I can say, okay, I'm going to copy this forward, I'm a front desk person, I'm making a note into the record. It's me, Leslie, making a note into the record. I heard from Christine, here's what Christine says and I've cut and pasted that into the record. It takes time, but it's very relevant and the folks around the table yesterday who are involved in this believe that secure messaging actually evolved on its own to clinically relevant data. And so you would not have to have a secure message that had a Consolidated CDA named in it, Consolidated CDA could be attached to a secure message for ingesting. So we have almost an evolutionary approach to patient-generated health data that is very, very complimentary from secure messaging using a Direct transport with just narrative inside of it to a Consolidated CDA that can be attached to a Direct message that can be attached to a device upload, it can be part of the patient's portal.

So we think that this approach gives a lot of flexibility, but the secure messaging we heard yesterday from I think at least 4 team members, they felt that the – we should not discount the clinical relevance of it. Nor should we demand that inside a secure message we require specific structure, because the workflow today, although quite laborious, accommodates this and is prevalent. John, did I get that right or Kim? I guess so.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Thanks Leslie, I think – I mean that makes a lot of sense to me.

John F. Derr, RPh – Health Information Technology Strategy Consultant – Golden Living, LLC
Yes, you did. John.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Other questions from folks?

W
Just, can I ask one –

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Go ahead.

W
Just, I didn't really capture the term you used, Leslie, when you talked about secure messaging evolving into clinically relevant – you used a term that –

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

W
– into a clinically relevant tool? Is that an appropriate way to refer to it or –

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
It is and that's probably – I'm probably being too strong. But what we heard was that although secure messaging in its beginning stages provider to patient, often starts with appointment tasks, from more administrative function, it quickly moves into clinically relevant dialog, how are you feeling? Or hey, I took a drug last night and here's a reaction that I had. And although it's not consumable immediately like a Consolidated CDA result or observation, it's relevant to care and does require intervention by that front desk person or that nurse to say, boy, how important is this, do I need to get on it right away? It's still meaningful in care. So we didn't want to have messaging mo – or the team, I think, heard loud and clear that we shouldn't discount messaging.

W
Okay. Great.

Jan Oldenburg – Vice President, Patient Engagement – Aetna
This is Jan Oldenburg and I want to move back to the question of the approach to the provider directed device data. And I'm wondering whether we could just adjust that wording a little to think about provider approved device data so that it doesn't exclude the potential for evolution of consumer devices into things that providers are both willing to accept and have the means to accept.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
That's great.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Yeah, so what was the – it was provider approved?

Jan Oldenburg – Vice President, Patient Engagement – Aetna
Yup.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Great. I like that, I was worried about provider directed, and I think that's great.

Jan Oldenburg – Vice President, Patient Engagement – Aetna
Yeah, I think we'd get some heat from the Consumer Empowerment Group, appropriately so.

Susan Hull, MSN, RN – Chief Executive Officer – Wellspring Consulting
This is Susie Hull, just a follow on question. It sounds like we're not going to recommend in the Meaningful Use 3 recommendations to look at consumer directed device data, but I'm wondering if we're considering kind of encouraging that, because it's such a give and take between consumer directed and whether it's provider directed or provider approved. And I'm wondering how we're planning to position that?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Well I think that – go ahead.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
No, I was just going to ask you what you thought.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
So, it's hard – it's a good question. I like the way that Jan has phrased it, because it allows for evolution. And so, hmm – can you rephrase that again?

Susan Hull, MSN, RN – Chief Executive Officer – Wellspring Consulting
Yeah, thank you Leslie. I think that – I guess what I'm starting to see in the marketplace is that consumers are ahead of providers right now and consumers are starting to play with their own device generated data actually quicker than providers are. So I question whether we're going to, for the Meaningful Use 3 recommendations try to focus on just the provider directed device data, but also are we going to encourage the consumer? And then I have a follow on question related to the term approved. There is another whole subject we haven't really talked about which is prescribing of apps.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Right.

Susan Hull, MSN, RN – Chief Executive Officer – Wellspring Consulting
And who can prescribe apps, it's again it's the provider directed apps and consumer directed apps, but anyway, we might want to – that into a future meeting.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
So on the first question, I think we were trying to distinguish, if a standard is named for consumer – for device data coming into a record, that that's standard is going to be more aligned with provider, whether it's approved or acknowledged or used or prescribed devices. Because that's where their interest lies. So when a provider sends you home with a cardiac device, that's where their interest lies. By naming standards that might be too consumer focused, like My FitBit or something else, that could generate noise and its – the providers aren't ready for that. So from a standards point of view, if we name a standard or recommend a standard for device data, it's going to be much more aligned with that provider centric approach. So, and I don't know if the right word's approved or acknowledged or prescribed, but it's just if you choose to get device data, the standard named would be named that was aligned with HIT technology versus consumer technology.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Leslie, I wonder if this is a place where your group wants to create a recommendation around future work for consumer directed or consumer initiated or whatever we call it.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Yeah. It is in one of the – fact our recommendations it said, we really need to figure out how we're going to marry these two worlds, and that's some future work to be done.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Yeah.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
So yesterday we really did an update only, we didn't – we got feedback from HIT Standards Committee, we didn't make formal recommendations, because part of it is we wanted to talk to this group and then we have to set a date to come back to the Standards Committee. But to answer your question, yes, we do have recommendations that the standards would meet the questions you've asked. Then the question comes from, is that a – is a regulatory requirement or is it an informing standard? That we don't have the formal recommendations in the Standards Committee as yet, that would be our next step.

Mary Jo Deering, PhD – Senior Policy Advisor, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology
This is Mary Jo and I just wanted to add something to what you said, because I thought that you did lead a really good discussion yesterday. And one of the things that I think that did strongly emerge, and I don't think it was wishful thinking on my side, which is that paradoxically I sensed that the Standards Committee was going in the direction of doing sort of a minimalist approach to what goes into the regulation. Precisely because they are very interested in how dynamic this field is and in not constraining innovation and so –

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
(Indiscernible)

Mary Jo Deering, PhD – Senior Policy Advisor, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology
– so while they may sound conservative, keep it as narrow as possible to get something started, it was from a very positive and affirmative point of view, that given their experience with what happens once you start certifying technology around this, that you may do more harm than good. So I think that definitely opens the door to the type of a recommendation that Christine made, to actually say that – about the work that needs to be done and the great interest. And possibly you might even, I say this with a great deal of trepidation, but you might explore with other ONC people and the committees whether you can say something to the effect of, providers are encouraged to experiment or to explore these. But again, that would certainly not be an official requirement through any of the regulations that might come out.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
And this is the natural tension and difficult, right? So, I'm going to put on the hat of a small company and when we go to look at how we're going to integrate something, our core competence is what we do for a living. And interoperability and interchange is one of those things where just tell me the rules and I'll play, because you only have – you have finite resources, how do you develop an ecosystem for other people to adopt? It's not going to happen, it has to be done with some sort of standards body or regulations.

And so there is really this tension about when is it necessary for regulation and when is it necessary for informing the industry. We don't want to have a mess, like we've had for years now on the provider side with nobody knowing what to do or how to interoperate. And look what it's taken within meaningful use to get us to the point where we could get something to allow for interoperability. You don't want the patient to be as hamstrung or left out in the cold because there isn't that agreement. This is a really big policy question. From a standards point of view, we wanted to make sure that there was not – we weren't in the way, so what we're stating is, there are standards that can be applied and work effectively in these areas. The question then becomes are these informative standards or are these regulatory standards, and there can be arguments for both. And – but, the good news as Mary Jo said, there was really no argument about the need for patient-generated health data, that didn't come up.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
And I think we don't have to fight the battle of regulatory or voluntary right now, and this isn't the – these aren't the workgroups to do it anyway. I think our original charge was a request from the Meaningful Use Workgroup of the Policy Committee to look at patient-generated health data and figure out, are we ready? Did we construct the draft criteria correctly? And I think we have a good answer to that, which is, yes we're ready and you constructed generally correctly, but there's more you could add to it to give people additional options for getting credit under this menu item. So I actually think we have what we need, then we subsequently asked you guys, are we ready for device data, and we're like half-way there.

So I think there's a couple of recommendations that are apparent to me from the technology group, which really center on the future work that also needs to be done in both consumer device stuff – consumer directed or whatever, and in care planning. I mean that's huge, like we're close, but not there and we've got to be there in collaborative care planning ASAP.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Well, we can start it with the HL7 Care Team Roster, because in first – when you first start talking about collaboration of any kind, you have to say, who are the players, what are their roles and how can we define them. And Russ has done a great job with that and we think we're very much ready to do that. It's also already been harmonized with the Consolidated CDA So we're ready there, and so those are some good foundational – I think. Russ, do you agree?

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
So –

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives
I agree and I think that the care team roster has a number of uses, I call it the cornerstone of care coordination. One thought came to me a few minutes ago that the problem of which Direct address do you use, my – certainly my vision is that the care team roster would include an electronic endpoint address, if you will, for each member of the care team. That would probably be a Direct address for many of them and that would enable the whole care team for an individual patient to recognize that the direct address that is associated with them on the care team roster is the one they want to use.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Oh yeah. So –

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives
And for the who – and for the other members of the care team as well, this is the Direct address and I'm saying Direct because I think that's the logical place we wind up, this is the Direct address for this member of the care team for this patient that we're all going to use on the care team.

Susan Hull, MSN, RN – Chief Executive Officer – Wellspring Consulting
Russ, this is Susie Hull, just a follow on question. Those – the care team members and that roster will dynamically change over time –

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

Susan Hull, MSN, RN – Chief Executive Officer – Wellspring Consulting
– do you think that we're prepared for the updates and pushing out those updates back to the patient, so that the patient, as the care team changes and reconfigures over time, they've got new addresses?

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives
Yes, because I think those addresses for the professionals, those addresses would be tied to their NPI number, and –

Susan Hull, MSN, RN – Chief Executive Officer – Wellspring Consulting
Um hmm.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Can I interrupt on that it's Christine? Is there a plan to issue every provider a Direct address in combination with their NPI yet? Is there an official plan yet?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Well, every EHR is requ – go ahead Russ.

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives
No, it's probably going to work the other way around that every provider will register their Direct address, and I mean provider in the broadest sense. As you may know, anybody who's in the healthcare field can have an NPI number –

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Um hmm.

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives
– so that those health professionals would register their preferred Direct address with their NPI number, and you can only have one NPI number, so that would mean one-to-one.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
So, the reason I ask is because this is from a policy perspective, I think Leslie this obviously sounds like a recommendation from the Technology Workgroup. What I need to know is whether there's a policy implication, so in other words, if we were to – if this standard for the care team roster were to become part of certification in Meaningful Use Stage 3. Does it mean that we should change any meaningful use policy criteria around the care summary, care plan or around information exchange because suddenly it's easier if we have this? And I think what I'm hearing is maybe not yet, because it's really great to put this in but from a policy view, we need those Direct addresses to be issued to be tied to the NPI, etcetera, and be able to be updated. And then once that occurs, we might be able to increase some of the information exchange requirements or do other things, but right now, we just need to get the standard in to meaningful use. Is that correct?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Yes, the Direct for providers is already in Meaningful Use 2, and so that then is a requirement.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Okay.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
So it's now.

W
Got a question here, is who's version of the care team is it? Is this the consumer's version of these are the people on my care team, or is it the provider's version of, these are the people in your care team, because those two might not match.

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives
It's – to me, it's a patient-centered care team, it's the patient's care team.
Christine Bechtel, MA – Vice President – National Partnership for Women & Families
I think in reality it's going to be either the providers or the payer's view of the care team, because patients – so, it's Christine again, sorry, from National Partnership. So patients view the care team much more broadly than the primary care partners and my cardiologist, right? They think pharmacist, they think nutritionist, they think trainer, so I think it's probably closer to the provider viewpoint. But for now, I think you guys, the technology group can make a recommendation around the care team roster standard, but in terms of policy implications, I'm not hearing an until – many more providers have Direct addresses, I think is what I meant to say earlier.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
So the design of the care team roster accommodates all, the non-traditional, the family, the caregiver, and the professionals. So we're talking about who sources it? So is the source of the initial care team generation the provider or the patient? It probably will start with the provider and then move to the patient, but the structure – the design structure does not impose that.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Okay.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
And what we are hoping for, for this advanced work in the future, is to get to things like reconciliation, governance, curation and versioning. That's not been done, even from provider to provider care plans, so that's a body of work to be done. But in the meantime, by using the care team roster for patient-generated health data, we have the ability to start to influence the ecosystem to say, hey, there are many other players here. And the patient has generated this data and also has cc'd this person and this person, hmm, we've got opportunity to start to integrate, because it's the first step. It's like the ABCs of anything, you have to know first who the people are, and so that's why we wanted – we felt strongly that we could do this now as a first step.

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives
And this is Russ Leftwich again. From the standpoint of the HL7 Patient Care Workgroup and the Consolidated CDA update, the care team roster is the patient-centered, everybody that provides care to the patient, professional, family member, community member, at least that framework is there to have that comprehensive care team.

John F. Derr, RPh – Health Information Technology Strategy Consultant – Golden Living, LLC
This is John Derr, I just want to put my pitch in for the non-incentive care providers and the people in nursing homes and the ones that go through nursing homes for rehab and also home care agencies and how we ultimately, I would assume the standards and all that. Because we're working on Consolidated CDAs and that somehow we would get incorporated into this, especially when it concerns people in nursing homes and have family members that want to contribute patient-generated health data.

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives
Right. And another reason for the care team roster to be that inclusive so that the receiving members of the care team of patient-generated data know, in terms of provenance, who that submitter of that information is, as a family member or community caregiver or the individual patient.

Patricia MacTaggert, MBA, MMA – Lead Research Scientist/Associate Professorial Lecturer – George Washington University
This is Patricia MacTaggert. The only thing I think we also probably need to clarify as we look at the expanded care team, because a lot of the service some of these models are going to more expanded, is to link to the HIPAA and the Privacy and Security – as well, so everybody knows who is really working with the patient for purposes of treatment. And where that line is, otherwise there's going to be a lot of fear of breaking those lines and that may become an unintended barrier.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
So, Leslie, I don't know if you're ready to kind of talk about next steps and try to wrap some of these comments into that context?

Susan Hull, MSN, RN – Chief Executive Officer – Wellspring Consulting
This is Susie Hull, I have one more quick question. I was in a building with a fire alarm so I may have missed it, but where did we land Leslie on the care team members with the header approach for the CCDA to be able to have the patient-generated CCDA?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
We had landed – at the header approach we harmonized the care team roster at the Consolidated CDA at the long-term care – continuing care group, we were informed by some of the work CDISC has done on research so, that, to my knowledge and Russ can speak up, that has been harmonized at the header level for the Consolidated CDA overall.

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives
And that is part of the current update ballot for the Consolidated CDA that's in process in HL7 right now.

Susan Hull, MSN, RN – Chief Executive Officer – Wellspring Consulting
And when is that expected to be concluded?

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives
Umm, optimistically the end of the year, the first of 2014.

Susan Hull, MSN, RN – Chief Executive Officer – Wellspring Consulting
Okay, thank you.

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives
Another note on Consolidated CDA, if you're not aware, the 2014 ONC certification criteria require not only that certified systems be able to generate and receive Direct messages, but that they do so with a Consolidated CDA document in the message. So it is a certification requirement that those two things are actually together, the CDA document and the – in the Direct message. And the implication of that is whether receiving a Direct message from another system or from a patient-generated doc – CDA document in a Direct message, the system should be able to consume it.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
It's really dramatic guys that we've got all of this aligned at the same timing and that taking the header approach gave us this ability to be ready for Meaningful Use 2 and beyond.

Mark Savage, JD – Director, Health Information & Technology Policy & Programs – National Partnership for Women & Families
I second that. It is great that this is aligning this way. This is Mark.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Yeah.

Kim Nazi, PhD, FACHE – Management Analyst – Veterans Health Administration
And this is Kim, I think the timing is good.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Yeah, I agree. I think that your workgroup has done a really terrific job overall on everything. So thank you very much guys, that's really terrific. It's very helpful. Leslie, do you want to try to summarize some next steps or do you want me to do that?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Why don't you start.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Okay. So I think from the policy, the workgroup Consumer Empowerment Policy Workgroup, I think we will revise our recommendations to clearly say that we are ready for PGHD in meaningful use and we support that objective, period, full stop. Then the second addition would be that we – that the Meaningful Use Workgroup should consider adding secure messaging and provider approved devices, in addition to the structured questionnaire. I think our third clarification that we need to make is around amendments and how – clarifying that these recommendations apply to the meaningful use criteria on amendments and that providers do need to have the ability to receive, review, record and respond to amendments. And I think we can do that by really framing the fact that amendments are a form of patient-generated health data and therefore, they need to be included in that. But that – or looked at in terms of the workflow implementation, but that I think it makes sense for them to remain two separate items in meaningful use.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
The – the amendment structure would work within the questionnaires, so if you said do you have a change, you – have a change, what is it? You can use the hybrid structure questionnaire and we could look at a template development in the Consolidated CDA work team to address that. So I think we're very – position for that.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Okay, terrific. And then – so those would be the, I think, top three recommendations. And then I think one of our groups, or maybe both, or maybe we should just do a set of joint recommendations, needs to say that there is future work to be done, and I think it's in the technology arena more than the policy arena. Well, it's both, and we have a recommendation around the policy side, but that there's more work that needs to be done around, in particular, care plans and collaborative care plans and consumer device data. That those are two really hot button areas that are getting closer and closer, but that need some attention in the short to medium term in order to really drive some progress in the field.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
I agree. And then I think you captured also the care team roster as part of the recommendations for the Consolidated CDA. I just want to make sure that – because that really is a building block for our future.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Right, and so I was going to say, we can work with the staff offline to figure out how we do these recommendations, if they're joint or whatever, but I think you guys had more recommendations. You're recommending a set of standards, for example, or you're recommending that we're at least ready in those areas that are reflected by the yellow highlighted box, that includes the care team roster, but includes some other things. And so, I think there's kind of a broader set of recommendations that are really coming out of your group that you guys haven't probably articulated yet, and we can figure out the best way to do that.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Sounds good.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Any reaction from the workgroups?

Katherine Kim, MPH, MBA – Health Equity Institute Professor in Residence – San Francisco State University
Yeah, this is Kathy Kim, I just wanted to make sure that I understood what you said about the recommendations and moving forward on the – of care plan. Were you saying that that needs to be done in future, not in Meaningful Use 3 or are you saying that some workgroup or some Standards Committee needs to actually adjust that in Meaningful Use 3?

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
What I heard, this is Christine again. What I heard from Leslie's presentation of the technology group's work is that Meaningful Use 3 – we're not ready for collaborative care plans in Meaningful Use 3, but we need to do some immediate work to get ready for future stages, Stage 4 and beyond.

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

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
I wish that was something other than what it is, but I think you guys will have a recommendation around the care team roster that will perhaps explain in more detail the advantages of the care team roster standard and what kind of behaviors it would support. I think that would be helpful.

Mark Savage, JD – Director, Health Information & Technology Policy & Programs – National Partnership for Women & Families
Christine, this is Mark. If I can just second the recommendations that say, we should tee up the forthcoming work, because we have another stage coming, and to get that on the agenda and not lose the momentum would be really good.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Yup. Great. Any other reactions to the sort of recommendations and next steps as either I framed them or as Leslie's described them? Because if not, we may have some found time for you guys.

Jan Oldenburg – Vice President, Patient Engagement – Aetna
Actually, I have one question regarding the intersection with the HL7 standard – this is Jan Oldenburg – around care team. And I believe that they are proposing some additional standards that would include more specificity about what a care plan is, going into the CCDA standard. And as I looked at them very briefly, it looked to me as if they were quite absent any consideration of the patient's input. Is that something that we could at least accommodate or think about or start preparing the way for?

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

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
(Indiscernible)

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives
Well, this is Russ Leftwich. So the Consolidated CDA does include the care plan, which with respect to how its labeled, a plan is a plan, whatever it gets called, that has health concerns or problems, interventions and goals in it. The HL7 standard really doesn't speak to whose input is included, but in that the care – in that the patient and the family members are part of the care team by design in that model, then they would have the opportunity to provide input to the care plan as well. That's part of the model, the governance or process, if you will, is not really part of an HL7 standard, but the data framework, meaning those individuals are part of the care team and therefore part of building the care plan. That's all part of the currently being balloted Consolidated CDA update.

Jan Oldenburg – Vice President, Patient Engagement – Aetna
Okay.

Susan Hull, MSN, RN – Chief Executive Officer – Wellspring Consulting
This is Susie Hull. What I'm starting to see in the innovation marketplace is innovations where when a care plan gets changed over time, whether it be by a member of the provider team or the patient, there's sort of an update and the patient accepts the new care plan, but that could go either way. So I think this is an interesting part of those changes over time and who's making the changes to the shared care plan and then is there acceptance reconciliation, those kind of things, happening.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Yeah, that's all the work to be done, reconciliation, harmonization, governance and we're talking also about curation as a separate concept. So, that is a big body of work that we would encourage in our recommendations – it could be taken on to Mark's point, so that that momentum is not lost. And there's already work being done on this under the SMART platform –

Susan Hull, MSN, RN – Chief Executive Officer – Wellspring Consulting
Um hmm.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
– so there's things being done on it that we can take advantage of.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
And Leslie, I'd like to follow up offline, too about how we can support your continuation of the advancements in care planning. We had a terrific hearing in the Policy Committee around care planning. There are a set of consumer principles on what real collaborative care plans should be, that I believe are going to be released next week, and so I think we can circulate those to the group and use them as a guide. I mean this is a terrific group, a very patient and family centered professionals, so it would be nice to –

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

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
– for your guys to take on them as well. So –

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Yeah, that would be great. We did – we were really lucky, the HL7 Long-Term Care – not the – Longitudinal Care Team that Russ leads, we were able to have Erin Mackay from the National Partnership present to us the principles of shared care planning and that really helped to inform the group. I think that would be great to also discuss with this group. Thanks.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Terrific. Any other comments or questions before – we do need to go to public comment before we hang up? Okay, hearing none, Leslie, any closing remarks before we do public comment?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
I just would like to say thank you for those of the people on the team, really appreciate the work. Russ's work, Lisa Nelson's work, have been and Virinder Batra from Intuit, have all been fundamental in making sure that we were ready, when you guys asked the questions, we were ready with opportunities to review the technology to meet the needs. So I was very, very thankful for the group.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Well, and likewise, I'd say all – on behalf of the Consumer Empowerment Workgroup, thank you guys very much for your hard work and thank you to the members of the Empowerment Workgroup themselves for really coming through. This is a really terrific stream of work, so thank you. So we'll go ahead and open the lines for public comment.

Public Comment

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Operator, can you please open the lines?

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. We have no comment at this time.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
All right, terrific. Well thank you again everybody for your time today and for some really productive work over the last several months. We appreciate it and we will be back in touch about next steps. I do know that the Meaningful Use Workgroup meets November 21 so I would expect that we will discuss these recommendations then as well, and again, thank you guys so much and have a great rest of your afternoon. Happy Friday!

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Thanks guys. Bye.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Thank you.

Public Comment Received During the Meeting

1. Consumer devices and apps may not be devices/apps that are approved devices -- FDA approved as medical devices

2. In writing the policy, we could leverage the patient portals to let them patients create their patient-centered care team.