

HIT Standards Committee Transcript March 27, 2013

ATTENDANCE

The following members attended the meeting:

- Jonathan Perlin
- John Halamka
- Dixie Baker
- Anne Castro
- Christopher Chute (term expired)
- John Derr
- Jeremy Delinsky
- Floyd Eisenberg
- James Ferguson
- Lisa Gallagher
- C. Martin Harris
- Stanley Huff
- Elizabeth Johnson
- Rebecca Kush
- Anne LeMaistre
- Arien Malec
- David McCallie, Jr.
- Kim Nolen
- J. Marc Overhage (term expired)
- Wes Rishel
- Eric Rose
- Christopher Ross
- Walter Suarez (term expired)
- Sharon Terry
- Jim Walker (term expired)
- Andrew Wiesenthal
- Tim Cromwell
- Lorraine Doo
- Kevin Brady for Charles Romine

The following members were absent:

- Keith Figlioli
- Leslie Kelly Hall
- Nancy Orvis

Presentation

MacKenzie Robertson – Office of the National Coordinator

Thank you. Good morning, everybody. This is MacKenzie Robertson in the Office of the National Coordinator for Health Information Technology. This is a meeting of the HIT Standards Committee. This is a public meeting, and it's being held virtually over webinar and phone platform. We have one public comment built into the agenda. We only have one because there is a shortened agenda today, so that will be at the end of the meeting.

This call is also being transcribed, so for the sake of the transcript, please make sure you identify yourself before speaking. And I'll also just remind everyone that since this is virtual and over the phone, if you have to take another call, please don't put the call on hold. Your hold music will come through the speakers.

Lastly, for anybody tweeting, the hashtag for today's meeting is #HITstandards. And with that, I will go through roll call. Jon Perlin?

Jonathan Perlin – Hospital Corporation of America

Good morning.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Jon. John Halamka?

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center

I'm here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, John. Dixie Baker? Anne Castro?

Anne Castro – BlueCross BlueShield of South Carolina

I'm here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Anne. And new member, Jeremy Delinsky?

Jeremy Delinsky – athenahealth, Inc.

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Jeremy. John Derr? I'll just ask whoever's not speaking to please mute your line. Thank you. Floyd Eisenberg?

Floyd Eisenberg – Independent Consultant

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Floyd. Jamie Ferguson?

James Ferguson – Kaiser Permanente, Institute for Health Policy

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Jamie. Keith Figlioli I know is unable to attend. New member Lisa Gallagher?

Lisa Gallagher – HIMSS

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Lisa. Leslie Kelly Hall? Martin Harris?

C. Martin Harris – Cleveland Clinic Foundation

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Martin. Stanley Huff?

Stanley Huff – Intermountain Healthcare

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Stanley. Liz Johnson?

Elizabeth Johnson – Tenet Healthcare Corporation

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Liz. Becky Kush?

Rebecca Kush – Clinical Data Interchange Standards Consortium

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Becky. Anne LeMaistre?

Anne LeMaistre – Ascension Health

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Anne. Arien Malec?

Arien Malec – RelayHealth Clinical Solutions

I'm here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Arien. David McCallie?

David McCallie, Jr. – Cerner Corporation

Morning.

MacKenzie Robertson – Office of the National Coordinator

Morning, David. New member Kim Nolen?

Kim Nolen – Pfizer, Inc.

Hey, MacKenzie. I'm here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Kim. Wes Rishel?

Wes Rishel – Gartner, Inc.

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Wes. New member Eric Rose?

Eric Rose – Intelligent Medical Objects

Eric Rose is here.

MacKenzie Robertson – Office of the National Coordinator

Great. Thanks, Eric. Chris Ross?

Christopher Ross – Mayo Clinic

I am here.

MacKenzie Robertson – Office of the National Coordinator

Great. Thanks, Chris. Sharon Terry?

Sharon Terry – Genetic Alliance

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Sharon. And new member Andy Wiesenthal?

Andrew Wiesenthal – Deloitte Consulting, LLP

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Andy. Tim Cromwell?

Tim Cromwell – Department of Veterans Affairs

I'm here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Tim. Lorraine Doo?

Lorraine Doo – Centers for Medicare & Medicaid Services

Yes, I'm here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Lorraine. Nancy Orvis? And Kevin Brady for Charles Romine?

Kevin Brady – National Institutes of Standards and Technology

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Kevin. Okay. With that, I will turn the agenda over to David Muntz for our opening remarks.

David Muntz – Office of the National Coordinator – Principal Deputy National Coordinator

Thanks, MacKenzie, and thanks, everybody, for participating today. I am David Muntz. I'm the Principal Deputy National Coordinator in the Office of the National Coordinator, and it's my privilege today to kick off a new start. But I would like to at least say it's been quite an eventful month since we've met. HIMSS Conference was quite a success I think by all measures. More than 35,000 of our best friends gathered together in New Orleans, and I think if there were some remarkable things, probably the one that impressed me most was the interest in interoperability, and I think that's testament to what it is that this committee has done and the work of the people in the public who have started the adoption. So if y'all got a chance to walk through the interoperability showcase, I think you could notice the excitement and the reality of what is going on out there. So I think that's really remarkable.

And I think the other thing that I found probably more telling was the lack of discussion about whether or not to do meaningful use, but the question of how to get onto and optimize Stage 2 activities. And so I look at that as a measure of success and the acceptance. And I think the other is the focus on the use of data. The number of times I heard the word analytics was extraordinary. So I think that was great. And then we also were able to celebrate the fact that we've reached more than the halfway mark on our distribution of the \$22.5 billion in incentive payments. So I thought that was pretty remarkable. And then just yesterday was actually the third birthday of the Affordable Care Act, which has had some remarkable successes. So I think it's been quite a month.

I don't want to ... anymore on those things, and I do want to go ahead and take some time to talk about the appointees. The ONC held an open call for nominees to fill the expired terms on this committee, past June, and the secretary announced the results of that nomination process last month in a press release, but I do want to go ahead and thank the reappointed member who signed up for another term, John Halamka, with – who everybody knows, and as somebody said I think during the Academy Awards, needs no introduction, so I'll skip on to Cris Ross, Mayo Clinic, serves as CIO representative, and he's continuing as the co-chair of the implementation workgroup. Wes Rishel with Gartner, who is certainly an expert in all things health information technology-related. Jamie Ferguson from Kaiser Health Plan representative is continuing as chair of the clinical operations workgroup. Charles Romine with NIST, Lorraine Doo with CMS, and Nancy Orvis with the Department of Defense.

The new members, this is the first meeting for those new members, and want to take a moment to introduce them and also express our thanks to them for joining. Lisa Gallaher with HIMSS will serve as the HIT security representative. I think it's Andy Wiesenthal with Deloitte Consulting serves as the HIT implementation and provider representative. Kim Nolen from Pfizer will serve as the pharmacy representative. Jeremy Delinsky with athenahealth will serve as the small innovative provider representative. Eric Rose with Intelligent Medical Objects serves as the HIT implementation and provider representative. Keith Figlioli with Premier, Inc., serves as purchaser and employee representative. And Anne LeMaistre with Ascension Health serves as the CMI representative.

And then we do have to take a moment to give I guess a virtual applause to the retiring members, and want to be certain to thank them for the work they have done. Each member will be receiving a certificate of appreciation from the Secretary for all the work they've done, and that's Walter Suarez, who served as the HIT security representative, and will continue to serve as co-chair of the HITSD privacy and security workgroup. Marc Overhage, who served as the vendor representative, will continue to serve as chair of the data intermediaries tiger team of the quality measures workgroup. Christopher Chute served as health exchange representative. Jim Walker, who served as provider representative, will continue to serve as chair of the clinical quality workgroup, and co-chair of the Policy Committee's vendor tiger team of quality measures workgroup. And finally, Kevin Hutchinson with My-Villages, who served as the vendor representative.

And then there are 14 additional members who are not mentioned above who are going to continue, were not part of the nomination process, but we certainly appreciate everybody's efforts. And I think the successes that we see are due in large part to the efforts that you've made on behalf of this committee and on behalf of the patients that are represented out there. So a significant and enthusiastic thank you, and I will turn this over now to Jon Perlin, who will review the agenda.

Jonathan Perlin – Hospital Corporation of America

Well, thank you, David, and let me join you, I know on behalf of John and MacKenzie and the ONC staff. Welcome, all the new members. Thank you very much for making a significant commitment. I am betting they may not know quite how significant, but it's in that regard that I want to thank those members who are continuing to serve, the 14 that David mentioned, as well as the five individuals who will be departing from formal service on the overall committee, but many of whom, most of whom, will be continuing service on workgroups. It is simply inadequate in words or by certificate to really be able to express the appreciation for the thoughtful and diligent effort.

I know that amongst those of us who have served together so far, we've joked about ONC standing for the Office of No Christmas. We know that the work has gone on around the calendar. And really hope that our new members are approaching not only with the skills and background that prepare you so well, but with the energy that will prepare you for the continuing hard and good work which is manifest in so many positive ways.

Indeed, HIMSS brought people together, as David mentioned. And it's really a great segue to our agenda for today. It's quite remarkable that our agenda is one that acknowledges, and in fact, it requires our continuing effort to be able to thread the different components of an ever-expanding ecosystem together through interoperable technologies. I know John Derr has really reminded us passionately about the need to assure that our frame of reference, our perspective, doesn't stop and start at the doors of the hospital or the physician's office, but includes those long-term care settings. Leslie Kelly Hall has reminded us that the ecosystem includes at the very center the patient, his or her lay caregivers and family and advocates.

And as a physician personally, it is certainly not lost that the pervasiveness of technology ties to an over-increasing number of devices, many of which are in fact information systems at their core, others of which are part of the ecosystem in terms of how we treat and care and interact in this healthcare ecosystem. And so I think this is really an exciting agenda, because it is focused on the expansion of capacity for interoperability within this ecosystem, as we work – as we look at the unique device identifiers and the long-term care coordination. In reviewing the long-term care coordination yesterday, it's clear that there's a lot to be proud of, a lot that is now possible, but it's also evidence that we have additional work to do, and look forward to this discussion really setting some of the trajectory for that work, just as it will set some of the work that's necessary to incorporate unique devices and their identifiers into this ecosystem.

Appreciate both that the leadership of David Muntz and Judy Murphy – we've heard from David and look forward to Judy and Doug Fridsma updating on a variety of topics later in the agenda. And I want to thank Liz Johnson and Cris Ross for your continuing work, bringing increasing practicality and internal consistency into testing scenarios that are more beneficial to the safe and effective and efficient use of health information technologies. And indeed, not only for the end users, but also for the manufacturers, and look forward to, as our second action items today, reviewing your recommendations. Indeed, the committee, which has asked in the past to be reminded of what are the action items, not that everything isn't action-packed, but that one of our action items is indeed approving a transmittal to the National Coordinator on the recommendations of the Implementation Workgroup.

Our first action item is to approve the minutes of the previous – of our previous meeting, and as always, many thanks to the ONC staff. They're just thoughtful, comprehensive, remarkably succinct, given the amount of information. And I'll ask that if anyone has any corrections or amendments, I'd ask that you state those now. Hearing none, we will assume consensus on those and accept those minutes into the record.

Just by way of process for the new members, in many ways, a teleconference is more difficult than being there in person, but we want to be sure to be able to recognize you, so do please identify yourself if you want to comment during one of our discussion periods. We'll probably define those a little bit more sharply, given the format. If there's an urgent clarifying question, go ahead and insert that, and as well, the reminder that if any of us aren't speaking, we'll put our phones on mute, not hold, so that it's as clear as possible for all others.

With that, let me turn to John Halamka for additional details on the agenda, and John, as always, appreciate your terrific leadership and guidance.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center

Well, thanks very much, and some very brief comments. Recognizing that Beth Israel Deaconess, where I work, will be doing a certification of all of its IT systems this summer, I am of course very desirous of getting the test scripts and processes as robust and straightforward as possible. Maybe it's a Microsoft term, the programmers, they get to eat their own dog food; that is, they use the products they create. So the work that Liz and Cris is doing is essential not only for the country, but for me personally, and so I very much look forward to their thoughts.

I'll also be involved in doing the certification of our state healthcare information exchange this summer, and so certainly all interoperability testing and the scenarios we have to go through to prove robustness are going to be key. So Liz and Cris, thanks for your work.

I'm being asked as a CIO to more and more incorporate patient-generated data into our systems, and especially in a world of healthcare reform and wellness and preventative care, making sure that I understand what devices are at the other end of the wire is key. Is this a device that is generating robust data, or is it a device that is consumer level with questionable data? Today, I don't know. So Jamie Ferguson and the clinical operations workgroup have described how essential it is to get the universal device identifier, unique device identifier, completed for all types of devices. So look forward to that.

And then long-term care coordination. I think you'll find most interesting the notion that our C-CDA standard is only a subset of those data elements that are perceived as required for transitions of care between hospitals, LTACs, and SNFs. And certainly as we think of what is that summary that's good enough, we want to make sure that there are templates that can be easily listed and used for a variety of transitions of care. And so Larry Garber and colleagues will show us where the templates exist and where the templates don't exist. And I certainly have watched the CCR, the CCD, the C-CDA evolve, and I think you'll see that their work, as well as the work that HL7 is doing on standards simplification, the FIRE Initiative, is going to be foundation for what I'm going to see as the next stage of interoperability and Meaningful Use Stage 3.

So look forward to our robust agenda. And of course, also the work ahead, we can't forget that all of our workgroups are busily focused on continuing to drill down on the Meaningful Use Stage 3 questions that they have been asked over the last several months, and I know there are going to be many phone calls in the next couple of months. And certainly welcome our new members as participants in that ongoing effort.

Jonathan Perlin – Hospital Corporation of America

Well, thank you, John. Let me – let's proceed apace to our first formal topic, presentation today, the implementation workgroup update on testing scenario presentation and posted test scenario materials. Again, the action item is approval of the transmittal letter. And let me turn to Liz Johnson and Cris Ross, with thanks for your work and presentation this morning.

Elizabeth Johnson – Tenet Healthcare Corporation

Thank you, Jon, for that. Can we go to the presentation, please? So this morning, we're going to talk about the 2014 edition test scenarios, and what we've been working diligently as a workgroup on is to provide you with visual depictions of how those test scenarios would work. And so that will be the intent of this meeting, and as John referred to, we want to transmit this to ONC following your input into the process. Next slide, please.

So from an introduction perspective, and I do want to make a call out to the workgroup, and especially to Wes Rishel. This has been many, many Mondays for particularly our California folks, at 6:00 AM in the morning, to get where we are today. And I think the work that has come out of it is outstanding.

So when we go back and sort of set the stage for what we were trying to accomplish, it was clearly to put scenarios in place that were clinically plausible, that we were ensuring the use of data store, that the data was being stored and moved from scenario to scenario. And the, you know, ultimate goal being that we would increase the value and the efficiency and the consistency of testing. When you do unit testings one at a time, we weren't able to depict how that would be really replicated in a clinical environment, and that is part of the purpose of today, is to show you how we would show that to the public and begin to work with the testing centers and folks like John, and then those who actually ... commercial vendors, to move this process forward.

When we talk about unit-based testing, we'll show you that that's already currently implemented, and it's required, and we'll show you how individual unit tests work. And that works for both the 2011 and the 2014 test procedures.

And then we'll move into the scenario-based testing, which is where we'll spend the bulk of our time today, and we'll really look at that as a future implementation. It's optional at this point, but it really gives us the opportunity to link our unit tests and to thread our data throughout the scenario. The first scenario that we'll actually show you that we're ready to go live with, so to speak, is the EHR interoperability or the intake. And as I listened to Dave and Jon and John talk about the criticality of interoperability and the interest in that, I think this is another step in that direction. And then, you know, finally, of course, once it's submitted to the ONC, we'll be seeking further public input on that.

With that brief introduction, I'll give it over to Scott, and he'll go through the actual scenarios themselves. Scott?

Scott Purnell-Saunders – Office of the National Coordinator

Good morning. Thanks, Liz, and thanks, everybody, for being on the call. Next slide, please. So this just goes over the content that we'll be discussing today, as Liz discussed in the introduction slide. This provides a little bit more detail. So we'll start with unit-based testing, go into description and depiction of one unit test, discuss the purpose of scenario-based testing, and then go into further detail of scenario-based testing with two unit tests and then a scenario-based testing sequence. We'll then follow it with a multi-test scenario and some optional testing. So we'll depict how those are shown in detail. And then we'll go into the summary of what the testing scenarios will do and look like. Then we'll move into the actual depiction of an EHR interoperability intake test scenario procedure that has been developed by ONC, and has actually been published on our website. And we'll talk about a clinically plausible workflow. I'll go over the testing scenario diagram, explain the narrative, and then go back through the summary. And we have a glossary of terms that are frequently used throughout the presentation. Next slide.

Just to start, this is what unit-based testing currently looks like in the current 2011 and 2014 edition testing and certification program. You have three individual tests depicted at the bottom of the screen, unit test A, unit test B, and unit test C. The big black lines that are depicted here kind of show them in isolation, so any information that's passed or sent through unit test A does not touch unit test B or unit test C. They are required for the current 2011 and 2014 edition testing and certification programs, and they're succinctly independent tests. Next slide.

This is a detailed blowout view of what one unit test looks like. So if we start with the diagram moving left to right, you'll see that at the beginning of the test, the test is set to an initial state where it can be tested and used. Data is entered during the test, which is depicted by the red box and diagram and document data at the top, then through the unit test, and then data is then verified at the bottom as the – from a on screen output or by a test proctor.

And at the end of the test, you have a group of information that comes out of the test. The test is then set to an end state. You have the testing results, which are depicted by, you know, a yellow circle, which we'll continue in the other diagrams, and then any individual data that's coming out of that particular test. And as I said before, this is what testing currently looks like in the 2011 and 2014 edition testing program. Next slide.

So here's what we'll talk about with the purpose of scenario-based testing. As Liz mentioned in the introduction, it's to make clinical plausible scenarios and to align with something that actually does occur in the clinical environment. We do understand that everything can't be exactly as depicted in every clinical situation and environment, but we try to make this as adaptable as it can be, so it does make sense to those who use it and do this work every day.

We're ensuring the ability to use the data across systems and within systems, which is depicted by the diagram below, with the information and the dots passing inside a circle and then between two independent circles as depicted below. Ideally, this increases the value of testing, improves efficiency, reduces setup, and it makes testing consistent and replicable.

What we heard from a lot of the testing labs as we started to work through this process was that they at times are able to link individual unit tests together in a string. That string was not consistent in testing between different test labs, so our goal was to develop a situation where the testing scenarios could be used and standardized across all testing labs to improve efficiency in testing, and actually improve the speed of individual testing directly. Next slide.

We'll talk more about scenario-based testing. First and foremost, it's an alternative to unit-based testing. It is not required for the 2014 edition test method. It is optional. And just to kind of keep that in mind, this is our first attempt at this, and we will try to improve this as we move forward. Testing based – testing based – scenario-based testing, excuse me, means dependent tests. You're linking individual unit tests one to another, and the output of one test becomes the input for another. Scenario-based testing will be clinically plausible, and it represents, as we're showing, one possible clinical workflow. That could link unit tests. I mean, it doesn't represent every single possibility. So we've gotten some feedback during our revisions to this process to try to make them a little bit more setting generic so that they could be adaptable in all different clinical environments.

And it will test all the capabilities of the criteria in a particular scenario and allow the technology to be tested in a clinically plausible way, and do not imply any requirements on how eligible providers should use EHR technologies to attest to meaningful use. And additionally, they don't add any additional rigor or requirements that are not directly stated in the rules and regulations as have been established by the Office of the Secretary. Next slide.

So here's where we'll show two unit tests. Basically, the depiction here is exactly what we showed before with a single unit test, but they're happening in sequence. So test one occurs individually, as we talked about before, to attest to initial state. Operations happen in the middle. And the information is sent out as a test result. What's depicted in the red box on the bottom of the screen that is outlined is that you do not see that data being passed into the next step in test two. That's what's depicted by the red box and the set to initial test state in unit test two. So in this particular piece, everything that happens in test one is independent of everything that happens in test two. Next slide.

In this depiction, we're starting to show what would happen in the scenario-based testing sequence. What we'll show here, and it kind of is very clear by the big red X and large arrows here, that the test results that come out of test one, instead of being stored and sent off by themselves, they're basically continued through as the input for data in unit test two. The box that shows set initial test state for test two is not done. That's done in the process of the data coming out of test one, and the process through which test two would continue, continues as normal.

And the big callout at the top of the box basically says excludes data carried forward from test one. Ideally, there is input that happens during every individual test. The idea with the scenario-based testing is there's a reduction in the amount of information that would need to be put input manually in every individualized test, so that some of the information that comes from test one will be ... carry through for test two and the other tests as will show in the next few slides. Next slide.

So here's a depiction of a multi-test scenario. It repeats all the same processes we talked through before, but the big thing here is the volume of the flow-through data is compounded within each test in the scenario, specifically meaning that if, you know, you have four tests as depicted here, by the time you get to unit test four, there's a lot larger bolus of data that's been added throughout the testing process than it would be if you simply had two unit tests strung together, as we depicted in the screen before.

The note at the bottom basically indicates that there can be two – there can be two testing scripts for tests two, three, and four. One instructs the tester to enter all of the data, and one instructs the tester to enter only the incremental data that is needed or required for that particular test.

I'll take a step back for a second. So in the development of this testing scenario process, we've noted that we had to specially develop data sets that were different and unique for the testing scenarios. The hope was that, and the hope is that we can build data sets that are adaptable to both unit-based testing and scenario-based testing, understanding that they have different needs and requirements. For data to be passed through several individual unit tests, you have to have data that can then be linked in both. So we spent a fair amount of time developing those sets of information that can be used in the one that has been developed currently. Next slide.

So this starts to introduce the direction of optional testing within the scenario-based testing sequence. The idea was that – in our development of testing scenarios, that you would have the option of removing a test if need be, or if it was not necessary for the particular product that was being tested at that point in time. So for example, if we started to walk through, you'll see that in this particular example, that everything's set to initial state. You continue through test one and then through test two. In this particular instance, test three, which was depicted previously, is skipped, which is why it's been grayed out, and you don't show data inputs at the top or bottom, and the black arrow continues directly from test two through test four.

At the top, you'll notice that additional data has been added, because it's necessary when test three has been removed, and then the incremental data that is typically added during test four is added there as well. The same data verification is continued, and then you continue the test through the post-test state.

Notation at the bottom, the flow through data here includes not only information that would have otherwise been reentered during subsequent tests, but also other data that would be created by this unit test. The understanding here is that there's information that is needed at every step of the process, and in building an optional route or path for scenario-based testing, that data has to be represented in some way, shape, or form. So you have to ensure that that data goes back into the testing sequence so that the validity and the process for test four can continue as needed. Next slide.

So here's where we'll take a quick review of the 2014 edition testing scenarios, the components. Basically, the 2014 edition test method and the consistent and threaded data, as we've kind of discussed and depicted through these first three or four diagrams. We have a very focused scope and a directed, clinically plausible work flow. Specificity, we're not developing these as clinically location specific or testing data specific. The idea that they are general and adaptable enough so they can be used in multiple settings, as needed. And the unit tests determine the clinical locations. So for example, you can add or remove tests depending on the location and the need of that particular area.

The scenario details are determined by patient test data. You know, for example, pediatric versus geriatric. That was something that was called out during several of our meetings, to ensure that we could represent all of a particular patient population with these particular tests. And the documentation which will follow is a testing scenario diagram, the test scenario procedure, and the test scenario data. Those three pieces have been added to our website, and we have or there are links contained in this document that will lead directly to that, and that will ensure everybody on the workgroup is able to see those. Next slide.

So this is the depiction of our first testing scenario, EHR interoperability intake. So it basically shows the links to the testing materials, which are directly linked to our website. The draft test scenario includes the following pieces of information, the list of the criteria that are covered by the scenario: (a)(4), which is problem list, (a)(5), which is medication list, (a)(6), which is medication allergy list, (b)(4), clinical information reconciliation, (b)(1), transitions of care: receive, display, and incorporate. And then the draft test procedure has all the capabilities outlined in this criteria as linked together, and the draft test scenario data contains the data set that is able to depict all this information tied together.

And there's overview materials, which includes this particular slide deck, along with a narrative to explain it and walk everything through that. In the next three slides, we'll go through that – this particular draft test scenario procedure we developed it thus far. Next slide.

Here's our clinically plausible workflow that walks this process through step by step. You would start at start A, which is at the very top of the screen. You know, a patient is seen by a provider or admitted to a hospital. During the next step of the process, the visit, the patient is – patient data, including the med list, the med allergy list, and the problem list, is recorded, changed, and accessed in a particular EHR. That's represented by the three certification criteria listed on the right, so 1a through 1c, which is the medication list, the medication allergy list, and the problem list.

If we go down to start B, a patient is referred to a provider upon discharge from a hospital or directly admitted to the hospital from a provider. And in this particular case, the transition of care occurs, where a referral summary or C-CDA is received, displayed, and incorporated in the receiving EHR, and that's represented by 1d at the bottom, the certification criteria, which is the transitions of care, receive, display, and incorporate.

At the next step, data is then outputted either from the start A down into the EHR, or from start B up into the EHR, in the form of the C-CDA. In step two, the clinical information reconciliation occurs. So during incorporation of the C-CDA, clinical information reconciliation is performed between the medication, medication allergy, and problem lists stored in the EHR and those contained in the C-CDA. All that is then combined and reconciled and then stored back in the patient's – excuse me, in the physician's or hospital's EHR system. In this particular case, that's where this particular scenario would end. Next slide.

So here's the actual diagram of what's happening and what we just described in the workflow document. It basically shows the three individual certification criterion, 1a, medication list, 1b, med allergy list, and 1c, problem list, as individual pieces of the particular testing. You'll see data that comes out of the medication list and into the clinical information reconciliation piece in step two, out of the medication allergy list, and then out of the problem list at the top. And you'll also see data going out of the C-CDA, which is stored at the bottom.

Big note on the side. You know, tests 1a through 1d are unit tests, and can be tested in any particular order. In test two, the clinical information reconciliation test, interoperability of all these pieces together, the idea is that any of those can occur in any particular order as necessary. It's just that step two, which is the information reconciliation interoperability test, much be second and follow all of those individual tests. Next slide.

So this slide basically shows the narrative component of what was just depicted in the testing diagram, and tries to explain it in, you know, normal words, in case people need to have a better explanation, versus seeing all the different certification criteria connected and the data sets that are moved between the three of them. So for example, in steps 1a through 1c, in an ambulatory environment, a patient is seen by a provider during his ambulatory visit. Medication and medication allergy and problem list are recorded, changed, and accessed in the EHR.

In the inpatient environment, patient is admitted to hospital. During hospitalization, medication, medication allergy, and problem lists are recorded, changed, and accessed in the hospital's EHR. What you'll see next is that medication, med allergy, and problem list are stored and then pulled to do the clinical information reconciliation, which is shown in step two. And the same procedure occurs in step D, 1d, depicted below, for the transitions of care summary at the bottom, where a patient is referred to a provider upon discharge from a hospital. During the transition of care, a referral summary or C-CDA is received, displayed, and incorporated into the provider's EHR.

In the inpatient environment, a patient is directly admitted to a hospital from an ambulatory visit with their provider. During that transition of care, a referral summary or C-CDA is received, displayed, and then incorporated into the hospital EHR again. And as we talked about before, all that information reconciliation is done during step two, and in this case, incorporation of referral summary, the C-CDA, clinical information reconciliation is performed between the medication, medication allergy, and problem list stored in the EHR and those contained in the C-CDA. And upon completion of that reconciliation, the reconciled medication and medication allergy lists and problem list are stored in the particular EHRs, and that's where you'll see the arrow coming out of that box into that particular computer there, whether it's the physician's EHR or the hospital EHR, depending on the care setting that has been depicted. Next slide.

So to go back again, the purpose of scenarios was to make something that was clinically plausible and can ensure the use of stored data within an EHR and increase the value, efficiency, and consistency of testing of EHRs. One big thing we tried to do here was to ensure that we could build some interoperability into testing. We know that that is a huge savings in testing, and is the next step of the certification program, and also the EHR abilities moving forward in the future.

Unit-based testing is, again – it's a currently implemented format, and is required for 2011 and 2014 testing, and it tests individual unit tests and data, meaning they're isolated and not linked to one another. And the scenario-based testing, as I just said, is a future implementation. It's something we're trying to build. For now, it is completely optional. And it links unit tests and threaded data. The EHR interoperability intake is public and is available on our website, and we would encourage, you know, you guys to look at that and provide us any feedback that you see so we can improve this. We certainly thank the implementation workgroup for all those Monday meetings, especially those of us on the West Coast, for providing input early in the morning and getting this back to us. It's certainly been great thus far. Next slide.

And here's a glossary of the terms that we used during the presentation, and some that can be – that are actually used in the narrative and the diagram and the test scenario procedure that has been drafted and is up on our website. And I'm sorry I didn't introduce myself completely. I'm Scott Purnell-Saunders from the Office of Certification at the Office of the National Coordinator for Health IT. I guess I'm so used to being on the implementation workgroup calls, that I haven't had to have a formal introduction, but wanted to ensure that people do know who I am on the call.

Jonathan Perlin – Hospital Corporation of America

Well, thank you very much, Scott. Let's go back to Liz for additional comments.

Elizabeth Johnson – Tenet Healthcare Corporation

Good morning. The – I think what we want to do at this point is Cris will –

Christopher Ross – Mayo Clinic

Yeah.

Elizabeth Johnson – Tenet Healthcare Corporation

– move us through questions and that sort of thing.

Christopher Ross – Mayo Clinic

Yeah. So this is Cris Ross. I'm co-chair with Liz of the workgroup. And Scott, thank you very much for your report. A tremendous amount of work went into this, and Scott, you've been terrific with this.

So I think we want to take questions. I actually want to start with one perhaps to get the process rolling. So Scott, this question would be to you. You know, you ended with requesting public input, and that we posted one test scenario, which is on intake. So would you mind just commenting a bit on what kind of input we are seeking from the workgroup today, and just some brief thoughts about where do we go to develop additional scenarios, since that's the next work we're heading into?

Scott Purnell-Saunders – Office of the National Coordinator

Certainly. So the EHR interoperability intake has been developed and the draft is available on our website. That's HealthIT.gov/certification, and under the link that says 2014 edition test method, you'll find this information listed there.

So we are – we are seeking input on that – on that individual test scenario draft procedure. We have posted that and it is available certainly right now. It has been a – been developed as a first pass. We took the individual test procedures that were developed for, in this particular instance, the five tests that were shown before, with, you know, test 1a through 1c, 1d, and the two, the clinical information reconciliation, and put them together in such a way that it made sense, but certainly we can, you know, use some input from a clinical standpoint to ensure that it does make sense and it kind of works together.

Certainly at this point there has not been a huge reduction in the size – when I say the size, I mean the volume and length, of that draft scenario procedure. For example, each individual test procedure was say 10 to 12 pages, and this current one is about 60, so we didn't improve efficiency there. So if, you know, folks are able to look at that and see ways to improve the efficiency and the way that it's presented, that makes a little bit better sense to them, that would help.

Certainly moving forward, our goal is to pilot this out to some vendors within the very near future, so that we can get some real life feedback on how this works and how this may impact operations directly. We have also contacted and alerted folks that the – this testing is coming down the pipe as well. And moving forward, we will be working on developing other scenarios as this process continues. The idea is that we can build a bolus of data that can be used in multiple scenarios as well. So as we improve and broaden out the developed testing scenario procedures, we can broaden out that data set as well.

Christopher Ross – Mayo Clinic

All right. So let's open for questions.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center

Cris, this is John Halamka.

Christopher Ross – Mayo Clinic

John.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center

And of course, Wes Rishel does have his card up, so we'll get – we'll get to him, Jon Perlin, in just a second. So two things I've heard from the field. There have been reports that some of the testing tools themselves have lacked robustness, and so I guess the question would be, as we finish all of these scenarios and we pilot these, how do we ensure as a Standards Committee that we have oversight tools that we are inflicting on the environment, are themselves good enough. That'd be question one.

And then question two, I've heard that in some early vendor experiences of certifying for Stage 2 that there has been an extraordinary amount of time spent doing things that are sort of silly, like manually entering all the data that is necessary to demonstrate interoperability. And so, you know, also I would ask how do we ensure that we really have what I'll call value-added testing? You know, come on. If you want to have 20 hours of keystrokes done behind the scenes and then show the interoperability over a 15-minute demo, sounds a whole lot better than having a certifier watch you key in John Doe, birthdate, 5/23/62, etcetera.

Christopher Ross – Mayo Clinic

Those are great questions, John. I'm sure others are going to have a response. Let me try to on behalf of the workgroup. The second question, around manually loading data and so on, if we could switch back to slide 9 in the presentation, it would be helpful. One of the goals here is, as we get that back up – two more up. That one. Thank you.

You know, the goal here is to try to reuse data from one unit test to feed into another unit test, as part of scenario-based test sequence. The real goals here are two things. One is to make testing more efficient, and the second is to increase clinical plausibility. As you well know, John, in Stage 1 Meaningful Use, we had some instances where the tests, you know, didn't have clinical meaning, which caused problems.

So at least the goal here is to make the load lighter on those being certified. Specifically, as we walk through this, we were looking for input particularly from the vendors or representatives of the vendor community, around, you know, would this make things easier for them? And at least the intent is to do so.

With respect to your first question around, you know, the lack of robustness of testing tools and problems in the field, the sort of second charge of the implementation workgroup, in addition to this, is to gather feedback from the field around challenges in implementation. As you know, we've been looking to schedule some hearings for this spring, and that sounds like a good topic for us to raise.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center

My understanding is substantial progress has been made, and the tools are actually now much, much better. But just, you know, recognizing that there's a lot of ambiguity in Meaningful Use Stage 2. This is new stuff that we want to of course have good oversight. So I think a hearing is very reasonable.

But I would just encourage the workgroup, to the extent that you can, is to ask really do you need manual data entry witnessed by a certifier, if in fact the intent is interoperability, not the capacity to determine if an EHR can store name, gender, date of birth.

Christopher Ross – Mayo Clinic

That's a good point.

Lisa Gallagher – HIMSS

Yeah, and John, we would – this is Liz, and I would add to that. As Cris said, we've started now to look at actual testing – that's the next step, is to actually look at the testing tools that are being used, as well as the data entry, and we've heard exactly the same thing you have. And so we know that some critical attention needs to be paid to it. And, you know, because what we were hearing was, you know, seven and eight hours to do data entry, which is still not acceptable, obviously.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center

Right. I heard the exact same thing.

[Crosstalk]

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center

We are aligned. Now Jon Perlin, Wes Rishel did raise his card first.

Jonathan Perlin – Hospital Corporation of America

Which is amazing, given they are in California. So thank you, Wes.

Wes Rishel – Gartner, Inc.

Well, speak softly and carry a long card. I'll be happy to defer to the chair, Jon, if you'd like to comment.

Jonathan Perlin – Hospital Corporation of America

No, no. I'm – we're recognizing you, Wes.

Wes Rishel – Gartner, Inc.

Oh, okay. All right. Okay. So I want to – I have a clarifying question, but first, I want to sort of continue on the conversational thread that we've had. The specific issue that we addressed in a lot of the slides that Scott presented today was effectively not reentering data that had already been entered in a previous test step. When you're using testing to test software, rather than to verify its functionality for certification, it's an important premise that each unit test be independent. And so you – and in fact, a lot of testing tools deliberately run the tests in random order to make sure there aren't any dependencies among the unit tests. That's not a requirement for certification, where all you're attempting to show is the happy path. You're attempting to show that there is a way that the system meets the certification requirement.

The – that – simply not having to re-enter the same patient over and over again, or an equivalent patient over and over again, to be part of multiple tests on the function, should be a really substantial savings in data entry time. I hear another point in the discussion today. There may be times when we want the test capability to have more than the minimal number of patients. Perhaps we want to see a – or other data ... perhaps we want to see a patient whose medications run on to over a page, so that there has to be some folding, or perhaps we want to see a list of patients that runs on to several pages. Perhaps we want to create an interoperable output document with that many patients' data on it.

It does seem as if it would be overkill to require the system to have witnessed data entry of that longer list of patients. Perhaps there's a way to say – to specify that the people with the system under test here do a local procedure of their own control that adds a list of patients to the system without it being witnessed, but then it's verified with a spot check.

It is important in all of these issues that the data not be known to the system under test the day before they're being tested. It's just a – we just want to avoid a temptation to fudge an output in order to – in order to meet the test, because of a last minute bug or something like that. But that doesn't mean that we have to have witnessed data entry to get the data in. So I think – I think we can work on that issue. And for all I know, they have, but it just wasn't covered in this presentation.

The clarification that I wanted to ask, Scott said that the unit testing approach was mandatory for 2014, and we were working on an optional scenario testing approach. Does that mean that it – that each of the testing bodies will offer vendors or self-developers who request is testing using the scenario approach for 2014? Or does that mean we'll continue to use the unit testing through 2014, and at the next iteration of certification, scenario-based testing will become an option?

Scott Purnell-Saunders – Office of the National Coordinator

I'll take that. Once developed and approved by ONC, the scenario-based testing will be an option for 2014 edition testing. That's one of the reasons why we tried to expedite getting these materials developed and published as quickly as we can, to seek output – excuse me, seek input from the public to ensure that it's going to work properly. We've heard definite requests for this, and trying to get this out as quickly as we can, so that we can get it to the testing labs for use in this program as quickly as possible.

Wes Rishel – Gartner, Inc.

That's great. I would hate to think I was doing 6:00 AM calls for a 2016 deadline.

[Laughter]

Scott Purnell-Saunders – Office of the National Coordinator

No, we would have told you that a while ago, Wes.

[Laughter]

Wes Rishel – Gartner, Inc.

Thanks.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center

Surprise.

Lisa Gallagher – HIMSS

Cris, I think that Carol Bean has some information for us.

Carol Bean – Office of the National Coordinator

May I?

Christopher Ross – Mayo Clinic

Carol, yes, please.

Carol Bean – Office of the National Coordinator

Great. I just wanted to address the comment about – or the question about the data loads. As we all know, these test procedures, where we can, after they've been deployed, we want continued input as to how we can improve them. And one area is in this issue of preloading. You know, the initial intent was to demonstrate the loading, because there are some criteria that do require, you know, to demonstrate how these things can be – you know, how data get into the system for the test, as well as if a unit test doesn't have the data, you know, from a prior testing – a prior test procedure, but what we have done is in response to this concern and our own concern, you know, feedback from the vendor community, the tested community as well as the testing community, rewritten or revised some of the test procedures to allow flexibility with respect to data input.

So where – so some of the public health data, so the clinical quality ... data, public health testing criteria, are the areas where this was a particularly sensitive issue, where the amount of time required for loading of data was very sensitive, that we have revised some of the text procedures to allow for preloading of some of the data sets, and to allow for observation of a subset or one set, say, out of seven, to really cut down on the amount of time.

Our initial feedback on that is that this is successful, and, you know, the eight, 10, 12 hours of, you know, watching somebody enter data is a thing of the past, unless somebody wants to do that. And so just a plus for continued input, feedback, and that we are hearing and listening and responding to these things. But sometimes it takes a little time to figure out how to do this and then to go ahead and implement and deploy within the testing environment. So we continue to improve, and that's one of the issues that we have already begun to address.

Christopher Ross – Mayo Clinic

Thank you, Carol. That was really helpful.

Judy Murphy – Aurora Health Care

Cris, this is Judy Murphy. I'm going to just ask for another point of clarification that hopefully either Cris – not Cris. You're Cris. Either Scott or Carol could answer. What percent of the testing that is done by the ACOs today uses automated test tools and prescribed test data? Because I know it went up significantly from Stage 1, and so I thought that was another point we could clarify with the group, that there's really been a really – pretty big change as we've put forth the testing criteria for the 2014 edition.

Carol Bean – Office of the National Coordinator

I'm trying to find the data right now, Judy. I do know that, for example, where we had originally had – in the 2011 edition, we had two test tools, and we have nine test tools, so for automated testing in the 2014 edition. So that's a huge leap. And I can't find the actual numbers right now, and I don't –

[Crosstalk]

Carol Bean – Office of the National Coordinator

– increase the number of tests that do require data, because the balance is, you know, on the convenience and the amount of time that it takes for testing, but also the rigorous testing. And as Wes noted, you know, guarding against, you know, somebody, you know, being able to yield to the temptation of taking, you know, perhaps an easy path, where they might have pre-canned some of their stuff.

Judy Murphy – Aurora Health Care

Yes.

Carol Bean – Office of the National Coordinator

So we – I don't remember the numbers.

Judy Murphy – Aurora Health Care

No, and if you can find them, maybe we can cycle back later, but –

[Crosstalk]

Christopher Ross – Mayo Clinic

Actually, just move – yeah. Exactly. If we can move on to another question, perhaps. I'm sorry. Didn't mean to cut you off, Judy.

Judy Murphy – Aurora Health Care

No, that's all I was going to say. It was significantly different and better, and so that was just another data point I thought might be helpful.

Christopher Ross – Mayo Clinic

Yeah. Yeah. Well, we'll – Carol, if you just want to speak up at some point if you find that data, that'd be great. I think – I had a note here that I think our chairman, Jon Perlin, may have had a question, and I think Anne Castro was trying to ask a question or make a comment earlier.

Jonathan Perlin – Hospital Corporation of America

Nope, I'm good, Chris. Let's go to Anne, and –

Anne Castro – BlueCross BlueShield of South Carolina

No, I didn't raise my hand. Thank you.

Christopher Ross – Mayo Clinic

Oh, I just thought I heard you.

Eric Rose – Intelligent Medical Objects

Hi. This is Eric Rose. I had a quick question. I think that –

Christopher Ross – Mayo Clinic

Hi, Eric.

Eric Rose – Intelligent Medical Objects

Hello. The – this very interesting development, I think is very, very wise to introduce it as an option initially, to see how things go. Seven years ago, when the certification commission for Health IT got going, we used scenario-based testing, and one of the things – one of the unintended consequences that we found is that it was very hard to develop scenarios that didn't have implicit requirements that unintentionally went beyond the stated, written certification requirements.

And it's a tricky business, because, you know, you can't necessarily anticipate exactly how easy product is going to fulfill each of the – you know, the written certification criteria. And so one thing I'm wondering if you're considering is simply asking the EHR vendors who go through this whether the – whether this scenario in their – in their view, you know, carried any implication for any – anything over and above what was in the – you know, the final certification rule, and to use that to inform future scenario development.

Christopher Ross – Mayo Clinic

Eric, I think that's a really great point. The intent here obviously is that the unit test is the gold standard and is what is required for certification. The scenarios are expected to simplify and streamline that, and not, you know, add any additional requirement. Perhaps that's something where we have posted this for comment, Scott and Carol, maybe it would make sense for us to call out that kind of request for suggestion from the vendor community.

Elizabeth Johnson – Tenet Healthcare Corporation

Another –

Christopher Ross – Mayo Clinic

Yeah, Liz?

Elizabeth Johnson – Tenet Healthcare Corporation

Cris, this is Liz. Yeah. Another thing that we're – that Cris and the implementation group and myself have been talking about is getting some volunteers, and I know John Halamka has often volunteered, to use some of this scenario-based testing to test that very hypothesis. I think it's a great point, and that's one of our next steps, is now that – once we get this approved and recommended by the Standards Committee, is to take that next step. So thank you for your input.

Christopher Ross – Mayo Clinic

Do we have –

Wes Rishel – Gartner, Inc.

This is Wes.

Christopher Ross – Mayo Clinic

Hey, Wes.

Wes Rishel – Gartner, Inc.

A, this may be – given how these procedures are bound in regulation, this may be not even something that's possible, but it strikes me that when I use the services of a lot of merchants now, I get the opportunity to not honestly comment on how it went afterwards. And generally, the services that do that are the ones that have the best support in their service organizations.

So perhaps we have a way of creating a separate stream of suggestions from the entities under test. They're obviously not going to want to risk a misunderstanding with their testing body, but if we have a way to capture outside input, some of it may be hard to interpret, but in general, the tenor of it, the frequency of it, the specifics of the well-written comments and so forth, may be very helpful to us as we begin to plan for 2016 – or 20 – whenever the next cycle is.

Christopher Ross – Mayo Clinic

An excellent suggestion. So are you suggesting that the testing labs themselves ought to do that, or are you suggesting – and/or are you suggesting that ONC, for example, ought to provide a means for feedback?

Wes Rishel – Gartner, Inc.

I'm suggesting that ONC ought to provide a means for feedback that includes some structured information, like what test was going on, if there's a specific test involved, what are the requirements ____ perhaps includes, but not for publication, the entity submitting it, identifies the test body that did the test, but is used, you know, in aggregate to work out the specifications that go to the test bodies and improve them, rather than to go neener, neener, neener to any one of them.

[Laughter]

Christopher Ross – Mayo Clinic

Well, we'll be sure to recommend a neener, neener, neener box –

Elizabeth Johnson – Tenet Healthcare Corporation

Yeah. I was going to say –

Christopher Ross – Mayo Clinic

– on the feedback form.

[Crosstalk]

Elizabeth Johnson – Tenet Healthcare Corporation

We'll see that in a minute.

[Laughter]

Elizabeth Johnson – Tenet Healthcare Corporation

I think Carol has the numbers for us.

Christopher Ross – Mayo Clinic

Excellent. Carol, do you want to go ahead with it? I'm sorry. I haven't been monitoring email while we're talking, if you were raising your hand. Carol?

Lisa Gallagher – HIMSS

I have an email from her.

Christopher Ross – Mayo Clinic

I did, too. I think Carol said she has the numbers on the differences between test methods.

MacKenzie Robertson – Office of the National Coordinator

Carol, are you on mute?

Christopher Ross – Mayo Clinic

We'll come back to her. So Carol, just speak up at an appropriate point. Are there other questions or comments?

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center

So Cris and Liz, let me throw one out there. How do you anticipate – one of the concerns that's been raised by some, particularly with the modular certification, is that a module may test through a scenario, and another module may test through a scenario, yet the interaction between the two modules may not be seamless. Can you expand on the sort of next step thinking about increasing the coherence of the technologies toward even more robust interoperability?

Christopher Ross – Mayo Clinic

Liz, let me take a shot at this, and –

Elizabeth Johnson – Tenet Healthcare Corporation

Sure.

Christopher Ross – Mayo Clinic

– please – and Scott, please improve. For this one, it would be helpful if we went back to slide 6 if at all possible. Can we tee back? Thank you. So John, I think the idea on this very, you know, simplistic diagram was intended to, you know, display the fact that at least that these processes are trying to be cognizant of this. So the only scenario that we've put out so far had to do with intake, which is probably not the most robust scenario to get at what you were just describing. And I don't think we've had conversations around a systematic process for assuring it. It's been a piece that we have been aware of as we've been talking about how do you link these tests together.

Frankly, I think, and others can comment, a lot of our heavy lifting here was to just get the concepts straight, and from here now we'll work on executing it across a bunch of different scenarios, and I think we'll stress test the concept a little bit. But just getting the nomenclature right and getting the ideas about how we're going to link unit tests together in a scenario was actually more challenging than maybe we had thought when we started the process.

Elizabeth Johnson – Tenet Healthcare Corporation

Yeah. I think – this is Liz. I think that is exactly right. John, I think what you're bringing up is the next step, but as Cris has quite clearly said, we – you know, we ran into much more difficult than we originally anticipated, even trying to explain to those who might be using the testing methodologies what it meant. So I think the implementation group needs to take on as a – the next step, to look at those more complex scenarios. And I think the timing is also dependent upon some of our vendors using the scenario-based testing, and giving us the kind of feedback, so before we make it more complex, we ensure that what we've put out there is viable and usable.

Jonathan Perlin – Hospital Corporation of America

Great. And let me just applaud the work in sorting out the fundamental concept, and indeed, I can't imagine that this would proceed well without some sort of iterative capacity in terms of refining. But I think all of us who are in the implementation – who are living the reality of implementation are struggling with the result of – or the need for assurance of that degree of interoperability.

Elizabeth Johnson – Tenet Healthcare Corporation

Yeah. I think you're exactly right.

Jonathan Perlin – Hospital Corporation of America

Let me – let me just applaud the work that's been done. It's really quite remarkable when one thinks of the first iterations of testing and the degree of progress that this demonstrates. It's really extraordinary. And to the entire workgroup, you and Cris and Scott from ONC, thank you for your leadership. But are we at a point we're ready to be comfortable in a consensus for forwarding this as a recommendation to ONC? So ... call the question and ask if there are any concerns about moving forward on that.

Carol Bean – Office of the National Coordinator

Carol's back on, if you would like me very quickly to –

Christopher Ross – Mayo Clinic

Please do, Carol. Yeah. That'll be helpful.

Carol Bean – Office of the National Coordinator

I am so sorry. I dropped.

Christopher Ross – Mayo Clinic

No worries.

Carol Bean – Office of the National Coordinator

Just in the speed – in the interest of speed, in 2011, we had two test tools; 2014, we have nine. So quite an increase there, 400 – over 400 percent. And the part that Judy was talking about was that as – before, only 14 of the test procedures had test data supplied in the testing environment, rather than having vendors bring their own data or use – you know, inspection tests, do their own data. And we've doubled that. So the bulk of the criteria actually have test data for testing, and so some of that, I think the – you know, really increases the rigor, but also makes testing more rigorous, take longer, and, you know, perhaps be a little more painful.

Christopher Ross – Mayo Clinic

Excellent.

Jonathan Perlin – Hospital Corporation of America

Okay. With those terrific statistics, we'll ask the question again. Does anybody have any concerns about moving this forward in transmittal to ONC?

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center

No concerns.

Jonathan Perlin – Hospital Corporation of America

Okay. Well, again, many thanks to all for tremendous work. This is really the beginning of a discussion, not the end of it. I frankly look forward to both the use and the support of these testing scenarios in practice. And I think particularly apropos of the new membership, the committee can see that no work is ever truly completed, but in fact, there's ... trajectory for continuing work, and appreciate the continuing commitment of the workgroup, the committee members, and the support of the new members.

With that, let us close this topic, and John, why don't I turn back to you to introduce our discussion of unique device identifiers?

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center

Absolutely. As I said in my words of introduction, a unique device identifier is truly foundational for patient-generated data or for the robust ingestion of data in just about any clinical setting. So I think it's important that we hear from the FDA as to what constitutes a device, what's the scope of the UDI initiative, and what's the timing of the UDI initiative. So Terrie, please take us through the material.

M

John, did we get – did we get a presentation for this one?

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center

We did.

M

Okay.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center

And the presentation is on the website, but it's also labeled UDI and HIT 3/27/13.

M

Okay. Thanks.

Terrie Reed – U.S. Food and Drug Administration

Hello. This is Terrie Reed from FDA. I am the associate director of informatics. Jay Crowley and I are responsible for the successful implementation of UDI. So I thank you to the Health IT Standards Committee for allowing me the opportunity to share my expertise on unique device identification. At FDA, as you know, FDA has been working to bring this into existence for many years.

I've broken my talk into three major sections. First, I'll provide a regulatory overview of UDI and the global unique device identification database, which I will from now on refer to GUDID. I'll start by noting that this presentation on UDI and GUDID is our current thinking and our attempt to be as transparent as possible. Given that we are in the middle stages, we have a proposed rule, but not a final UDI rule at this time.

So I say this to emphasize I am going to give you timelines and all the data attributes that I think are important for this discussion, but those may change as we continue to address the 3,000 pages of comments that we received on the proposed rule, and when that published final rule comes out. However, we are committed to the timelines, from our perspective.

The second part of my talk is based upon ideas that we've collected from those who are – have more insight into how UDIs would be used in the healthcare ecosystem. Just as all of you are mentioning all the collaboration going on in your space, we have turned to members of public and private groups that offer up many of the ideas that are in this presentation, suggested possibilities for ways to facilitate adoption of UDI into the electronic health record certification criteria, and ultimately meaningful use.

So while I am a student of your world, and I have worked in hospital IT in the past, I am certainly not an expert. So I offer these suggestions in a spirit of collaboration, and in that vein, my final section of slides will focus on trying to answer your questions about UDI and offering some questions for you. So I'm interested in knowing your perspective on what I present about UDI and how we can work together to ensure that the UDI benefits can be achieved by adoption of healthcare stakeholders and how we work together to make that happen.

So the next slide, let's start with the regulatory definition of medical devices. And I will not make you read this slide or have a quiz on it. I only show it in – to illustrate that fact that it is a very long, encompassing definition. There is an ISO definition, ISO 13485, that is very similar. And it shows that devices are not just one group of objects, but a range of equipment, implants, in vitro reagents, etcetera.

So more specifically, that range includes, if you go to the next slide, point of care devices, just by courtesy of an IEEE documentation, where they were showing wireless devices, interoperability, not only in institutions but inter-institutional. And it's been used in ISO standards in the past. So these devices are represented here, but if you go to the next slide, there are also a range of other, more simple devices. And the common thing they have is that they do not have unique device identifiers. So we have syringes, catheters, surgical instruments, implants as some examples of those.

I show you the table because this is a table we use often. It's actually not the complete table. This has several pages showing a half milliliter insulin syringe, 28 gauge needle, and its various representations now. This has about ten different item numbers, and it's all the same device. So we want to of course have one unique device identifier for that product and all of these devices.

So if you go to the next slide, because of the impact of devices on healthcare and because of this lack of a UDI, Congress in 2007 in FDAAA felt that it was important enough to have UDI enacted in legislation, and gave FDA the authority to establish a UDI that adequately identifies the device through distribution and use. And it is this paragraph that a few people in FDA have been working on and working with stakeholders to make happen.

In FDASIA 2012, we had some timelines added to ensure that UDI is implemented in a timely manner. So those items in black and red are from the original FDAAA. The items in blue and italics were added in FDASIA 2012, and those set a timeline that six months from the proposed regulation, we would have a final rule. So that's what we're working towards. And also that all implantable life-saving and life-sustaining devices would be in our GUDID no later than two years after the regulations were finalized. Next slide.

For a better understanding of this UDI system that we're implementing, I thought I'd go over four steps that we have put in place. The first – and I'll go through the details of these in the next slides. The first is to develop the standardized system to create that UDI, which we see as a foundational element to unambiguously identify a specific device at its unit of use, place that UDI in a human readable and/or auto ID on a device, its label, or both, create and maintain the global unique device identification database, and then the part that we need help with is ... created to implement it into the healthcare ecosystem. Next slide.

So the UDI will be created under ISO 15459, and it has a concept of an issuing agency, and I've listed three here. Things to note. Again, we don't have a final rule, and we haven't officially accredited any particular issuing agencies, but these meet the criteria of ISO 15459. Those entities would be assigning the UDI. It would not be done by FDA.

Under the FDA proposed rule, the UDI would be required to appear on the label of the device, and it would be composed of two parts: the device identifier, which is a unique numeric or alphanumeric code specific to a version or model, and that device identifier or DI, as we call it, meets the requirements to uniquely identify that device through distribution and use.

The production identifier defines the production information for a device. That will be on the label of the device. Those are lot or batch numbers, serial number, expiration date, and manufacturing date. While those will be on the label, they will not be stored in the GUDID, and I'll talk about that in a little bit. I also have in the backup slides more information about those issuing agencies. Next slide.

So UDI would be physically on the label of the device in most cases. It would come in this human readable and encoded in a form of automatic identification. We have not specified the technology to be used, and have remained technology neutral. We also have a provision for direct part marking for implantable devices, and we have a definition for what that is as well. The most important piece is that it's in the body for greater than 30 days as well. The direct part marking would also apply to devices intended to be used more than once and standalone software. Next slide.

So we have UDI on the label of the device, and we need a repository to store that information and make it easy to submit for manufacturers and easy to access for everyone along the supply chain, and for patients and families. So the GUDID is that repository. Jay Crowley and I are the business owners for the development of that database, and we lead a team of people working to meet that June 2013 deadline for making the GUDID available.

A thing to note is that the GUDID is a catalogue, using that DI as the primary key to identify a device down to the model version of a device. The identifiers, primary, secondary, and packaging, are all used to link history and packaging configurations of the same device. I noted in comments that we received from the Health IT Standards Committee that you were asking about linking identifiers, and so I wanted to make a note of that.

The DI is used to look up associated device data attributes, which I'll go over in a minute. And the DI and those attributes will be accessible via internet search, database download, and/or web services. And I say and/or in that you could do any or all of the above. Those will all be available.

The submitted attributes will meet regulatory requirements, and one of the important features is that in all of our instructions, we want the manufacture to ensure consistency between the information on the label of the device, even in terms of the data attributes, and what they submit to the GUDID. Next slide.

So this provides a select list of the GUDID data attributes. So I said the DI was the lookup to these attributes. You could enter a DI and pull back manufacturer, make/model, brand/trade name, the size, contact information for the labeler or manufacturer, sterility information, natural rubber information, 510k numbers, the pre-market FDA numbers, FDA product code, marketing status, whether it's a single use device, and I point out GMDN and SNOMED, because that was also in one of your comments. We do make that link.

As an example of what GMDN, which standards for global medical device nomenclature, I pulled up some – which I did manage to get on the slide, but I have things like a bi-ventricular pacemaker. That would be a GMDN term. Or a dual-chamber pacemaker. Internal orthopedic fixation system. So those kinds of things would be in GMDN and would have, we are hoping, similar SNOMED terms. So GMDN allows grouping and aggregation of devices that is not possible at the UDI level. So if we're thinking about an analogy to the drug world, the UDI would be analogous to NDC, and the GMDN would be analogous to RxNorm.

Next slide, please. So a summary of what I've said so far about the GUDID. This is a very high level overview of how this would all work. A manufacturer, in yellow in the top left, would create a label. This is a fictitious label that we have on our website. That label would contain the UDI, which is in the lower right corner. It's in human readable, which you cannot see, but it would be human readable, and it would be in a bar code format, and on the label of the device.

In addition to having that go out to distribution on their product, if you go down the tree, the DI plus the structured data attributes would be submitted to FDA via these three ways in blue. We offer – they can come through third party. We have a web-based tool for entry. And we have a bulk HL7 SPL batched submission that we're building. Those three forms of submission would come into the GUDID. We have business rules. Actually, my informatics side of the house, we have a master data management program that we are linking to this GUDID to ensure the data quality, because we see, of course, the GUDID is the source of truth for device information. And so we are making every attempt to ensure that data quality.

And as I said before, the GUDID will have three ways to access, through web service, download. It will also be available to other FDA systems, which I'll talk about in a minute. Next slide.

So this is the timeline as we see it today. It's based upon the current proposed rule. And the FDASIA timelines that I pointed out earlier. So if we go down the – there's the GUDID implementation activities, and most of those are actually based on that UDI regulation. So if we assume that the final rule comes out in June of 2013, the GUDID is scheduled to be available for submission in June of 2013. The implementation by class of device, class 3 devices are the highest risk – that would also include implants and life-supporting/life-sustaining devices. So if all goes well, in June 2014, those class 3 devices would be in the GUDID.

In two years, in June 2015, would be the deadline for class 2 implants and life-supporting/sustaining devices. Three years from that final rule, June 2016, would be the deadline for the rest of those devices. And then five years would be a deadline for any other class 1 devices in the GUDID.

There was a mention in the Health IT comments asking about NDC and NHRIC. Those will be in the GUDID, but our intention is to phase those out, but include them in GUDID as a linking tool until they're phased out. I also point out that the direct part marking requirements are effective two years, because of the FDASIA timeline requirements that we have. Next slide.

I've already mentioned some of these, but I think it's good to reemphasize. The GUDID is a device catalogue. It's not a patient registry. It does not contain patient or device-specific production information, such as lot or serial numbers. It's not for track and trace or other similar purposes. It contains only the static identification information.

However, it does provide a link to other product information. So the way we see it is the GUDID, as this source of truth, it is not a – so it would be the source of truth not only externally, for the healthcare ecosystem, but our own internal FDA databases. So we have internal efforts for linking to our FDA recall system, our FDA adverse event databases, and any system where device information is now being collected in text, and should be replaced with UDI and structured data.

So the benefits of all this will accrue only if it's adopted by all stakeholders, not only regulatory stakeholders, but those that are concerned in the healthcare environment, EHRs, claims, inventory systems. So with that in mind, we go to the next slide. And I've provided the regulatory overview. Now I'm going to move more towards your area of expertise and what have I learned through collaboration with many, many people. I start with a proposal that I'll flash out in the upcoming slides.

So the proposal is for UDI to be the code used in health IT systems to link a patient with specific devices used as part of his or her care. We would link the UDI of medical implants first, as a start, and the UDI of other devices would follow. The notion would be that you would scan the UDI at the point of care, store the UDI and sufficient UDI data attributes, which would be determined by expert groups other than myself, to maximize the benefit to patient, care providers, and other stakeholders. The certification and meaningful use criteria would be facilitate the ability to search, exchange, alert, and provide patient access to patient device information. Next slide.

So the question has come up several times in discussions with external stakeholders, why start with implants? The rationale for focusing on implants first are that they are high risk devices with serious consequences if something goes wrong. They are prevalent – in the backup slides, I have some HCUP data just taking a select group of implants. There's over a million discharges, and you can see that at the end of the slide set.

The other important thing is that in the GUDID, because of the FDASIA requirements, all implants will be submitted into the GUDID two years after the final rule. Another aspect is for coordination of care. That device, unless you have ... like this that you're carrying around, the device and its ID are not visible to the human eye. It is, unlike some other devices, persistent to the patient. So it could involve calendar years when this patient has an implant, and that is unlike devices that are just tied to patient visit. While they're very important devices, like ventilators, implants have a persistency that's not in those other devices.

Another aspect is that the device data for implants is often already captured to support patient charging. So if you go to the next slide, as an illustration of this – I apologize. This is a scanned piece of paper. It's actually my operative case records, so there are no HIPAA problems. It shows – and the x-ray is mine, but it was not on this record. So that's a whole other issue. But what this shows and what I found interesting is that it shows the manufacturer of the device. It actually shows the screws that are in that plate. It talks about a catalogue number. The table in the bottom shows various other devices that were parts of kit. There's a cautery pencil there, surgical suction unit, and so all of those things are in this operative case record on a piece of paper. But they are not accessible to me or care providers, and I couldn't pull up my patient record somewhere and pull this out.

So in that regard, we have turned, as I said, to folks like the Pew Charitable Trusts, Mercy Health Systems, who have been working with us on integrating UDI into electronic health records, and we've pulled together some possibilities for certification criteria. So we went through how would this UDI be received and parsed in an EHR. How would it be searched and accessed? And I'll go through each of those.

So some possibilities for receipt and parsing would be that the EHR would accept the electronic UDI data either via scanned barcode or other emergent technologies. So we didn't want to limit to barcode technology. That the EHR would capture multiple UDIs per patient visit and per procedure. You can see that there were multiple UDIs in that operative case record. That the EHR would parse out the device identifier and production identifiers from the UDI and store in the patient case. And that the EHR would use the device identifier to capture other GUDID attributes, from the GUDID either using web services or some other method. Next slide.

Once captured, the EHR could store the UDI at the level of unit of use, recognize and source secondary device identifiers if need be. The EHR could use the UDI as the code to identify and exchange device information between other systems and modules within the EHR. Next slide. And provide access to that information so that the patient and device information are together. So making the DIs, PIs, and select attributes accessible to the EHR for reporting purposes, such as adverse event reporting, registry population, recall. Allow the user to look up the UDI information and retrieve the patient cases associated with that UDI. Allow the user to look up patient and retrieve associated device information.

So right now, I show a slide where the EHR is on one side and the inventory control system showing that implanted medical device is on the other side. As you can see, it's populated that record, but there is no true interaction there. If you go to the next slide – okay, I just talked about that one. I apologize. The next slide.

So we used the medication criteria as models for devices, and that currently includes scanning at the point of care, having access between the pharmacy information system and the EHR, having the drugs the patient takes associated with the patient in all EHR modules and at discharge, having clinical decision support around medication. Very interesting that your test scenarios have medication lists, medication problems. I would love to see device lists and device problems in your testing scenario someday. Next slide.

If that link is made, the following clinical care benefits could be achieved, and I want to attribute this set of benefits – we are working with the Brookings Institute. There's a Brookings expert panel that ... met last week. Jim Walker, who's on this group, pulled these benefits together after that meeting, and I thought they were very appropriate to today's discussion, so I put them on this slide.

So some of those benefits would be to support care coordination in the hospital and in subsequent visits by a patient to care providers, inform future patient care, improve recall effectiveness, improve the ability to conduct active surveillance, make devices available by summary views of patient – through patient lists, summary documents, link devices to diagnosis and other elements of patient care, enable device maintenance. There's an example. A vascular access port is put in the hospital and the patient takes it home, could get infections. If certain alerts were sent to the patient on how to properly maintain that device.

Provide rapid access to accurate standard device information when needed. Enable the building of meaningful quality and performance measures and clinical decision support tools. We have information we're going to be collecting about natural over latex, about MRI safety, that could be in the future put towards clinical decision support tools. Excuse me. Next slide.

Not to leave out FDA's perception of the public health benefits. We will use that information to improve our decisions related to adverse event reporting, better understand risk profiles of particular devices, mine population-based data sets to better understand the risks and benefits of device used within certain patient populations and indications, and better and more quickly address concerns raised in our pre-market submissions.

So to summarize, FDA and the manufacturer are just the start of the adoption process of UDI. We are nurturing that UDI coming into being. Manufacturers will be required to label the device and meet regulatory timeframes and submit UDI and the attributes to the GUDID. FDA will provide access to the GUDID. It will work with all data standards and healthcare groups to educate, as I'm trying to do today, and align with other EHR standards and activities. Next slide.

As I said, we already have many, many contributors to this process. I'm sorry. I'm behind by a slide. We have many contributors to this process. We're working with Brookings to build a roadmap for adoption of including expert panels. We have UDI pilots going on, including one with Mercy Health Systems to integrate UDI into EHRs and actually see how it works. We've had ongoing collaboration with the Office of the National Coordinator, speaking here today. Many, many other people, too many to list, who we've tried to engage for ideas and discussion to improve the likelihood of adoption of UDI into EHRs. Next slide.

So now I turn to you. I have many questions. I will do this however you like. I can entertain your questions and then move on to these.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center

Thanks very much, Terrie. And I think probably in the interest of time what we should do is go through a couple of questions from the Standards Committee members, and then maybe one of our workgroups can work with you on getting you some of these questions answered. So let me start off with two questions. You said something very interesting, and I just want to make sure I got it right. I think of RxNorm as the generic description of a chemical substance, and the NDC as, oh, it's in the purple package in the 100 tablet form, and there are many, many indices per RxNorm code. I think what you said is that GMDN is sort of equivalent to the RxNorm, and the GUDID is equivalent to the NDC.

Terrie Reed – U.S. Food and Drug Administration

Well, the UDI is equivalent to the NDC, so it's –

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center

Yeah.

Terrie Reed – U.S. Food and Drug Administration

– it's a pretty – right. Yes. That's what I said.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center

Good. Yeah. I just wanted to make sure we got that analogy, because I think that's a powerful analogy to explain to folks the difference between these two standards or two approaches. In the comments the Standards Committee offered back to you, we wanted to make sure that Fitbits and iPhone appliances that add new hardware to say a consumer device would also be included in the scope of your work, and any comments on consumer-grade devices?

Terrie Reed – U.S. Food and Drug Administration

The scope of our work is medical devices. So if it meets that big definition, and there are other groups who decide what is a medical device, then it would be included in UDI.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center

And of course the reason we ask is that as more patient-generated data comes to us, it's certainly going to be very helpful to understand the nature of the device the consumer is employing and the relevance of the data, the accuracy of the data, the units of measure of the data, all this other stuff.

Terrie Reed – U.S. Food and Drug Administration

Right.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center

Well we have two hands raised, Andy Wiesenthal and Floyd. So Andy, please.

Andrew Wiesenthal – Deloitte Consulting, LLP

Just a comment and information for the committee. For the last several years, I have been a member of the management board of the ISDS, as some of you know, and that controls NCT, and I will continue in that capacity for another six months before stepping down. But in any event, I wanted to ensure everyone that GMDN and SNOMED CT are fully harmonized. There's an agreement between the two entities. So I think there was a statement made earlier in the presentation that there was hope that they would be true. It's a reality. It no longer needs to be hoped for.

Terrie Reed – U.S. Food and Drug Administration

Okay. Thank you.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center

Good. Well, thank you for that. Now Floyd?

Floyd Eisenberg – Independent Consultant

Thank you. Terrie, this is terrific. I'm glad to see you are presenting this. This is very good work, and well-needed. One comment to the committee is I think what I'm hearing about UDI is while I may know the device itself and I may be able to go to the GMDN to know the class of device, the type, I really might need to carry that as metadata, along with the information about that device as its brought into different summary that's sent for – summary sent for interoperability. And we might want to think about other metadata that would be required for provenance to be able to evaluate use of the device along the patient's course of care.

The other question I want – the question that I wanted to ask Terrie, when you talk – and I apologize. I'm only on the phone and my memory is short. You called it the GUD Rx or whatever you called it?

Terrie Reed – U.S. Food and Drug Administration

GUDID.

Floyd Eisenberg – Independent Consultant

GUDID. Thank you.

[Crosstalk]

Floyd Eisenberg – Independent Consultant

Will that also have a link to the RxNorm, if in fact there are components like latex in the device?

Terrie Reed – U.S. Food and Drug Administration

There are no plans for that today. I actually had – I had not thought about that, so if you put that forward –

Floyd Eisenberg – Independent Consultant

Or especially devices that might have – say antibiotic-impregnated devices.

[Crosstalk]

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center

Floyd, the drug-eluting stent.

Floyd Eisenberg – Independent Consultant

Yes.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center

So you would have both the fact that it is a stent and the fact that it contains some RxNorm coded medication within the stent.

Terrie Reed – U.S. Food and Drug Administration

That's an interesting idea. We do have a provision for – a drug-eluting stent is actually a combination product, drug and device, so we do indicate those right now in our initial phase of GUDID. You bring up an interesting point.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center

I love the pronunciation, by the way, Terrie. GUDID. How could it be bad?

Terrie Reed – U.S. Food and Drug Administration

That's right. It wasn't our idea, but we took it.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center

So other questions?

James Ferguson – Kaiser Permanente, Institute for Health Policy

Hi. This is Jamie. I'll put my card up.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center

Please, Jamie, go ahead.

James Ferguson – Kaiser Permanente, Institute for Health Policy

Hi, Terrie.

Terrie Reed – U.S. Food and Drug Administration

Hi.

James Ferguson – Kaiser Permanente, Institute for Health Policy

Just a couple of things, a couple of brief comments. One is I think one of our comments from the Standards Committee out of the clinical operations workgroup addressed the thing that John mentioned earlier, which was our request that there should not be any exceptions for the over the counter devices, which I think was something in the proposed rule.

And then the other thing, I saw in your list the comment about timely maintenance, and I think the issue that we heard about there was that in comparison with FDA drug databases, there's not always timely maintenance when things are withdrawn from market, and so getting that timely marketing status update was something that we thought would be a good thing to make sure of.

Terrie Reed – U.S. Food and Drug Administration

I just – I wanted to be clear. We actually had a three-hour meeting about marketing status as a concept, which I know you'll all appreciate. And so when you talk about marketing status, it sounds like you're talking about recalls. Is that what you're talking about, withdraw from the market?

James Ferguson – Kaiser Permanente, Institute for Health Policy

Withdraw from the market. Exactly.

Terrie Reed – U.S. Food and Drug Administration

Because our marketing status in that case was more about when the device is being pulled. So it's kind of recalls, but it could just be that the device was taken off the market. I just want to be clear that we were talking about the same thing.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center

Other questions?

Wes Rishel – Gartner, Inc.

Yeah. This is Wes.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center

Please, Wes, go ahead.

Wes Rishel – Gartner, Inc.

Terrie, on slide 7 you talked about issuing agencies, GS1, HIBCC, and ICCBBA. So I'm trying to – and if you have presented it, I'm sorry. I may have forgotten. But the process by which a device gets registered and comes to market, what are the steps? Who sets – sends what to who when? Is it possible for a device to actually be shipped before it has a number?

Terrie Reed – U.S. Food and Drug Administration

No.

Wes Rishel – Gartner, Inc.

Is it possible that the same class of device, down to the last detail, just two different items off the assembly line, could have different coding for the type because they happen to have been issued by different issuing agencies? You know, I'm thinking of various challenges around working with NDC data involved in the unique identifiers not always – not always allowing comparison of two items.

Terrie Reed – U.S. Food and Drug Administration

Well, if I understand your question, and there were a couple of questions in there, so the first, about you must register and list the device, and we will be checking that that device has been registered and listed with FDA, before entry into GUDID. And you must be in GUDID before you go to market.

Wes Rishel – Gartner, Inc.

Okay.

Terrie Reed – U.S. Food and Drug Administration

So you have to be for that. As for the issuing agency, the reason for citing ISO 15459 is that that outlines a process to maintain this global uniqueness of the ID through these issuing agencies. But the global uniqueness should be assured. And if it comes into the GUDID, we have business rules that would prevent two of the same IDs coming in.

Wes Rishel – Gartner, Inc.

At the GUDID level?

Terrie Reed – U.S. Food and Drug Administration

Right.

Wes Rishel – Gartner, Inc.

So this leads to – I think one of my questions is still standing about whether the identical device can end up with entirely different nomenclature because of different issuing IDs – issuing agencies.

Terrie Reed – U.S. Food and Drug Administration

Well, that's part of what – if I understand, there's a primary device identifier, but there are secondary device identifiers, and they're all in the same record, and they're linked. So for example, if GS1 was the primary device identifier issuing agency, that company would also have – if they used HIBCC as well, they would have to put in the alternate into that record. So the same device could have those IDs, but they would be unified in that UDI record, that GUDID.

Wes Rishel – Gartner, Inc.

Okay. And my last question is when those codes are issued from the issuing agency, who owns them? Is it the issuing agency, or are they in the public domain?

Terrie Reed – U.S. Food and Drug Administration

That's I'm going to have to defer and get back to you on.

Wes Rishel – Gartner, Inc.

Okay. Thank you.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center

So Arien, last question, and then we'll turn it back to Jon Perlin and move on to our folks, long-term care.

Arien Malec – RelayHealth Clinical Solutions

Thank you. So I just want to follow up on the point – on the Fitbits and the OTCs. What I think I heard was that the determination that a device ID is required is tied up with a determination as to whether there's a registration process for the device? Is that right?

Terrie Reed – U.S. Food and Drug Administration

That is – you must register and list before you go into GUDID.

Arien Malec – RelayHealth Clinical Solutions

Okay.

Terrie Reed – U.S. Food and Drug Administration

If they're talking about the over the counter question, I didn't answer that directly. There were many, many comments that came back from the proposed rule about that particular exception, and I can say that we have looked at those comments. You know, the final determination will be in the final rule.

Arien Malec – RelayHealth Clinical Solutions

Okay. And so understanding that, I think it would be worthwhile for FDA to consider voluntary use of GUDID for devices – or I won't use the term devices – for objects that may not be classified as medical devices, but where there may be – or may not be classified as registered – as medical devices that require registration, but where there may be value in using an ID for provenance purposes.

John Halamka – Harvard Medical School/Beth Israel Deaconess Medical Center

Very good. Thank you. So Jon Perlin, let us turn it back to you. Thanks so much, Terrie. Very informative presentation. And Jamie, I think it's probably you and I who end up working with the clinical operations workgroup and enumerating a few answers to that last slide that Terrie provided.

Jonathan Perlin – Hospital Corporation of America

Well, thank you, John. That is a good way for us to provide back to Terrie more substantive detail on the answers. And Terrie, thank you very much for a comprehensive and thoughtful presentation for all of us. This is such a hot topic. And Arien, appreciate your question, because indeed, that ecosystem doesn't have the sharp margins in the practical world as it does administratively. And that's something we'll need to contend with in the ever-broadening ecosystem. So terrific discussion. Appreciate that.

And this – we are moving to an area that I know has been one that one of our committee members has really challenged us to address, and I am thrilled that we're at the point where we can have a conversation about the progress we've made, but also the areas in which further work is needed. And with that, let me turn to Evelyn Gallego from ONC, Larry Garber, and Bill Russell, to introduce or present on the topic of the long-term care coordination update.

Evelyn Gallego – Office of the National Coordinator

Great. Thank you. This is Evelyn Gallego. I am the LCC or longitudinal coordination of care workgroup initiative coordinator for S&I, and my intent is mainly to introduce two of our LCC workgroup leads, Dr. Larry Garber from Reliant Medical Group, and Dr. Bill Russell from Seasons Hospice and Palliative Care. Dr. Bill Russell will start the presentation, followed by Dr. Larry Garber. So I'm just handing it over now to Dr. Russell. Please go ahead with the objectives of this session.

Bill Russell – Seasons Hospice and Palliative Care

Thank you, Evelyn, and thanks especially to Dr. Perlin and Halamka for the kind acknowledgement of the importance of this work, and of course, a special shout out to John Derr, a pioneering champion of technology adoption.

Jonathan Perlin – Hospital Corporation of America

I'm sorry to interrupt. If you're on a speakerphone, could I encourage you to use the handset, because it's very muddled.

Bill Russell – Seasons Hospice and Palliative Care

Sure, sure.

Jonathan Perlin – Hospital Corporation of America

Oh, much better. Thank you.

Bill Russell – Seasons Hospice and Palliative Care

Hopefully that's better.

Jonathan Perlin – Hospital Corporation of America

Much, much better.

Bill Russell – Seasons Hospice and Palliative Care

It's better? Okay. Great. Okay. So let's go to the next slide and talk about our objectives for today. We intend to discuss how current and proposed standards for transitions of care and the exchange of care plans do not meet the policy expectation for stages two or three of meaningful use for eligible providers and hospitals, to talk more about the extensive national effort behind evolving standards for transitions of care and care plans, and the expected level of maturity of those standards during this year. And to recognize the efforts that support the adoptability of those evolving standards, and to support the inclusion of these evolving standards in Meaningful Use Stage 3 for transitions of care and care plans, including a home health plan of care. Next slide, please.

We're going to discuss the limitations of the current and proposed standards to support meaningful use for transitions of care and care plans. Next slide.

Stage 2 Meaningful Use extends the summaries of care to include very important data elements to support care planning and to promote the initiation of effective care delivery by receivers of patients. These elements include the care plan section, which includes goals and instructions, and team members. In addition, cognitive and functional status are important elements to inform care plans. However, this data set, as it is currently specified for exchange, will not support a complete care plan, and it will not permit the uninterrupted delivery of care as patients change settings.

In this presentation, we will describe a more refined view of these concepts and related standards which we believe will be available for implementation prior to Stage 3 in support of care planning and – in support of care planning and coordination, including transactions where the receiver of care is a community-based provider. Next slide.

The Policy Committee recently requested input on transitions of care and care plans. The comments received endorsed those objectives. However, concerns were raised, including the lack of adoption of existing standards, the need for more precise definitions for the partners in the exchange, the emerging distinctions between care plans and plans of care, concerns about the level of effort required to create and consume the documents if the input and output data are not available for reuse due to immature technologies and the extent of the use of unstructured data to complete the documents.

In addition, comments correctly identified that while the medical summary is quite mature, the care plan relies on somewhat more expansive comments, which are still in the process of standardization. And finally, the CDA itself will need to involve somewhat to support the creation and exchange of robust care plan documents. Next slide.

So let's talk about Stage 3 and the process by which the standards will be ready to support the exchange of key elements of the care plan for transitions in care and shared care. Efforts are underway to standardize the terminologies for care plan, to evaluate the CDA standard to meet the functional requirements for an interoperable care plan as defined by the S&I LCC workgroup, and the evaluation of candidate standards for key concepts required to create the care plan, including a plan to identify gaps and a strategy to fill those gaps. Next slide, please.

This stuff is important. The average Medicare beneficiary sees seven providers in 14 different organizations every year. Within organizations, information must flow to an interdisciplinary team. The LCC workgroup has created a number of artifacts to define the elements of the care plan and to evaluate the standards to support its creation in CDA format and its exchange. Gaps are already clear. The care plan and its component parts are ambiguously defined in the current rules for meaningful use.

In addition, standards do not support the exchange of a care plan capable of guiding care in the receiving facility. In other words, assessments have to be recreated prior to the creation of a care plan, and so there is a significant interruption in care delivery during that time. The concepts of goals, instructions, and team members are not inclusive of the concepts used as input data elements for care plans. Those input data elements are primarily health concerns, which is a superset of problems, interventions, a superset of instructions, orders, and other related concepts, and goals which need to be defined at various levels in the care plan.

Nutrition assessment and diet instructions are key elements, and they are missing. Roles need to be precisely defined and standardized to allow the care plan information to be appropriately parsed and to allow the discipline-specific communication from sender to receiver, or from receiver to sender. In addition, plans of care and care plans will be published from multiple sources, and the reconciliation and versioning process, as well as governance of the care plan, need to be precisely defined. And lastly, and perhaps most critical from an implementation perspective, is the need for the current standard to support the complex many-to-many relationships between the core elements of the care plan. Next slide, please.

So let's discuss the information flows which follow patients in the post-acute care settings. Next slide. This complex slide depicts over 200 potential transitions for a patient moving from an acute care hospital to a final destination. The boxes represent different sites of care, hospital, inpatient rehab, skilled nursing facility, home health aide, patient's home, and even death. The lines connect between the sites of care. There are over 190 different trajectories through this system of care, and they are often associated with multiple handoffs of care and exchange of information. The complexity of the flow increases with higher comorbidities and increased complexity of care, and it is simple to see how an ineffective exchange of information can result in a treatment failure. It should also be evidence that care delivery needs to be seamless, and that care initiation in the receiver setting should not be interrupted during the period of time when a new care plan is being created de novo. Next slide, please. You can see they go everywhere. Next slide.

So we know that meaningful use has an enormous impact on post-acute care, even though it is the ineligible provider community. We think the standards to align care across settings are necessary and will be ready in time for Stage 3. Forty percent of Medicare patients are discharged to traditional settings, SNF, home health, inpatient rehab. These patients are the sickest population and account for about 80 percent of Medicare costs. Hospitals must be responsible and given the tools to convey the information needed by the recipient of a patient to initiate care promptly.

With that, I'm going to turn it over to Dr. Larry Garber, and we will both be available for questions at the conclusion of his presentation. Thank you.

Larry Garber – Reliant Medical Group

Thank you, Bill. Next slide. Can you hear me okay?

MacKenzie Robertson – Office of the National Coordinator

Yes, we can. Thanks.

Larry Garber – Reliant Medical Group

Yes, you can. And so I want to reinforce that last piece that Bill talked about, is that when – you know, we know that meaningful use focuses on eligible professionals, hospitals, and their patients. And it's important that when an eligible professional or a hospital is sending a patient to another facility or organization, that it's their responsibility to not just send what they think they can send, but really to focus on what are the needs of the recipient, and that the recipients are across the entire healthcare system, whether it's LTPAC or other eligible professionals or hospitals.

So we received one of the ONC HIE Challenge grants up in Massachusetts, and we have a project called IMPACT, Improving Massachusetts Post-Acute Care Transfers. And we decided to study what are the needs of the receivers, not just in the long-term post-acute care community, but across the entire spectrum of care?

And so under the guidance of Dr. Terry O'Malley from Partners, we conducted this survey well over – almost two years ago, and we studied 46 different organizations, and we – they're all different types of organizations. These were physician practices, specialists, primary care, hospitals, emergency departments, skilled nursing facilities, home health agencies, etcetera. And we also surveyed patients. And we surveyed users of different roles within those organizations. You know, physicians, therapists, social workers, care managers, nurses, secretaries. We – so we had – it was a very broad survey.

And we asked them, you know, for specific transitions of care, you know, from the physician's office to the emergency room, from the hospital to the skilled nursing facility or home health. For each of those transitions, for each of those users, what are your data needs? And we asked them if a particular data element was required, optional, or really not required at all. And we received over 1,000 survey responses back to give us an idea of what are the data needs for different transitions. Next slide, please.

Then we took that input and we, you know, took – created a data set and ran that by other organizations throughout Massachusetts as well as throughout the nation. So, you know, we've taken this on the road quite extensively. You know, we've spent a lot of time in the S&I, S&I framework, reviewing the data elements. We've also evaluated transfer forms that existed in Rhode Island and in Ohio, New York, New Jersey, and really tried to make sure that we have a comprehensive representation of the needs of receivers across the healthcare system. Next slide, please.

So what did we find? Next click. So first of all, the CCD document as part of the consolidated CDA has approximately 175 data elements. Next click. When we looked at the data elements that were needed for transitions of care, we found an additional 150 data elements that were required by some receiver across the healthcare system. Next click. And then when you add the rest of the elements that are necessary for the care plan for true longitudinal coordination of care, we found an additional 100 and – almost 160 data elements. Next click.

Now a lot of these data elements can be conveyed through a CDA template. Now there is a template that could be used, but sometimes it's really not constrained enough. So for instance, if a patient has congestive heart failure, it is important to convey what the ejection fraction is, and there is a place in the CDA template to convey ejection fraction, but there's no guidance that under this particular disease state, you really need to be sending this data element. Or if someone's on the blood thinner Coumadin, that you really need to be sending one or more INR test results.

So some of the – some of the issues of missing data elements were really that they're not clearly defined under given circumstances in the consolidated CDA. Next click. However, 30 percent of the data elements that were – you know, were not at all mappable to templates in the consolidated CDA. Next slide.

We've been working with the ONC S&I framework based on work that has been done through other groups, the ... which is transitions of care workgroup. We've been coordinating with the electronic signature medical documentation workgroup. We've also been work – coordinating with HL7, patient care workgroup, IHE's patient care coordination technical committee, and also John Derr's AHIMA LTPAC HIT collaborative. And we've all been working together, trying to move in the same direction with the same models in mind for how to do transitions of care and care planning. Next slide, please.

So let me give you more information about how these have been evolving. Next slide, please. So within the longitudinal coordination of care workgroup, we have generated several artifacts. We've come up with – come up with use cases for transitions of care, and we're almost done with the use case for care planning. And I should let you know that our workgroup has over 200 committed and interested members, so this is a – an active, broadly interested workgroup. And in addition to that, we've got – we've generated some work specific to care planning. We have a white paper that talks about it. We have a glossary that explains the terms.

And then we've also been – spent a lot of time focusing on the impact of the data set that we talked about, and the expanded data set to include the care plan. Next slide, please.

And what we've realized, that as far as transitions go, we really – you really can come up with – even though there are, you know, a couple hundred different types of transitions, you can really lump them all into five data sets. And so the first two data sets are the data sets that you could need if you're sending someone for let's say outpatient testing, so you're sending them to the hospital to get a PET scan or a colonoscopy. You need to send enough information so that the procedure can be done safely, and if there's a problem, that they know how to deal with an emergency. So, you know, it's meds. It's allergies. It's the fact that the patient has emphysema and they're on two liters of oxygen, or whatever. That's the information that needs to be conveyed.

And then the returning data set is, okay, we did this procedure. Here's what we did, and here's what we found. So those are the first two data sets. The third and fourth data sets are when you're sending someone for a consultation. You're requesting a consultation. You're going to give more information, you know, because you need to let them know what workup have you already done, so that they don't have to repeat that. And then there's the summary document that comes back from the consultation. And the emerge – sending patients to the emergency department and having them sent back is really another labor of consultation with just a sicker patient.

And then the fifth, the largest data set, is the full transfer of care data set, and that's really where you're taking someone from one care setting and one care team and sending them to an entirely new care setting and care team. You know, that would be the patient is discharged from the hospital and they're handed over to the skilled nursing facility, or they're given to the home health agency to take over the care. Next slide, please.

So there's – you can – go ahead and click. You can see that – another click. You can see that these are subsets. Each of these is a subset – is a superset of the smaller transfer data sets. Next click. And one more click. So – and then one more click. So in the IMPACT project in Massachusetts, we've been focusing on the full data set. While we've identified the subsets, you know, that are necessary, our major focus has been on the full transfer of care data set. And we wanted to pilot this, to find out if this is truly usable. Next click, please.

So what we did last spring is we piloted this on paper. We have a pilot community in Central Massachusetts with 16 organizations. We have two large integrated delivery networks. We have two large group practices, two home health agencies, eight skilled nursing facilities that also do long-term care, an inpatient rehab facility, and an LTACH. And we got them all together and worked out a process to test these data elements on paper, because we didn't have the electronic process in place yet, and we did this through several hundred patient transfers. Next slide, please.

And what we found, because one of the questions that was asked – mentioned on the meaningful use Stage 3 comments was is it doable. I mean, can you possibly fill in all of these data elements? And what we found is that the sending organization 93 percent of the time could send what the receivers needed. They have all the data elements that were necessary. So this is a paper process, so we hope that electronically we can even improve this even higher than the 93 percent. Next slide, please.

So in June of this year we're going to be actually testing the electronic transfer among these 16 organizations across the healthcare system, doing it electronically. We anticipate there'll be well over 1,000 transfers per month. We're going to be studying this in terms of the usability as well as the impact on utilization and quality of care. Next slide, please.

Now as part of this IMPACT project, we hired Lantana. Many of you know Bob Dolin and ... as the mother and father of the CCD, and so they -- through their work, they created the implementation guide for us to represent this full -- this large ... transfer of care data set. So we now have a 300 page implementation guide, so it's only about half the size of the consolidated CDA, but it reuses, you know, almost all of the components of the consolidated CDA, plus some additional templates that were needed for this transfer of care document. They've given us a sample XML file for this document type. We've got a schematron that's been developed. And so this is -- which is a validation tool. So they've done some excellent work, and that's what we're going to be piloting this June. Next slide, please.

This is just showing you some of the artifacts that we created for care planning ... glossary as well as the use cases. Next slide, please. And we've officially signed a contract with Lantana. With the help of both public and private funding, we've secured over half a million dollars of public and private funding to hire the work in the S&I framework, to work with Lantana to create implementation guides for the three largest transfer data sets, as well as the care plan data set, as well as specifically the home health plan of care data set. Just for information, that's the CMS 485 that -- for those of you physicians out there, those are the ones we sign. We're trying to make that an electronic process, where the nursing facility sends to our EHR the document, we sign it using the esMD standard that's being developed for electronic signatures of CDAs. We send that -- we send that back, or we negotiate that between the two of them.

So these five data sets are now being contracted to be developed by -- under the S&I framework for Lantana to be validated in HL7 through the structured documents workgroup in the August/September timeframe, and as I said, it'll -- the home health plan of care will include the digital signature standard as well. Next slide, please.

Now there's been a lot of involvement by vendors across the continuum of care, so not just LTPAC vendors, but also eligible professional and hospital vendors of EHRs have been involved in helping define the standards through the LCC workgroup, as well as they've been exploring incorporating these standards into their products. We have several that are intended to pilot this. They'll be -- they want to have this piloted by September, so they'll be using the pre-ballot version, recognizing that after balloting, there will be some reconciliation, and that we probably won't have a final public version of the standards until November or possibly December of this year, but we do have commitment to do pilots.

There are also several of the skilled nursing facilities that have representation across the country that are interested in using these standards, incorporating them into their products. So we have -- there's a great input and interest in the vendor community and participation. Next slide, please.

This is just to show the timeline I mentioned, which really is that the ballot -- the -- at the end of July, we have to have our ballot ready. Balloting will go in August and September, and then for reconciliation, and we expect by November, December, to have the HL7 standard published. Next slide, please. Next slide, please.

So we know that it's important to us and to you and to the community that these are adoptable. In other words, it's great to have a standard, but they need to be actually usable and implementable. And so we feel that the fact that we're building this off of the consolidated CDA, that it's really an extension of the consolidated CDA, that we gain a lot of the benefits that are inherent in CDA documents. You know, there will be -- we ... be developing implementation guides. We have -- there are sample documents. There's a schematron that we used that will be publicly available for validating these. We will be creating a companion guide next year to help with the implementation process.

Also, the fact that these are displayable with the standard CDA style sheet, so it doesn't require a new style sheet to be able to view any of these. And that helps -- and also, the nature of CDA is such that you don't have to -- it has to be human readable, but doesn't necessarily have to be electronically incorporatable into your electronic health record. So if an organization that is using the new standard is sending it to an organization that isn't using the new standard yet, it still can be displayed through a standard style sheet. They just may not be able to take advantage of all the elements, but it won't fail the validation.

So this is important for Wes Rishel's notion of bilateral asynchronous cutover, where this can be forward and backward compatible, and we think that that will help with the adoption of this as it moves throughout the healthcare system and industry. We're also developing – Lantana has developed for us a tool we call SEE, Surrogate EHR Environment, which allows you to view, edit, and generate new documents with these standards. It's a web-based tool. It's a – it will be open source and made available this summer. Next slide, please.

So in closing, we feel that the current standards for transition of care and care plans do not really meet the policy expectations of Meaningful Use Stage 2 and Stage 3, and that hospitals and eligible professionals are responsible when they send a document through transitions of care to send what is needed by the receivers. Many of those are in the long-term post-acute care community, but they are all across the healthcare system. And that we've done a lot of work with national participation to define the needs of receivers across the healthcare system, both for transitions of care and care planning. We're creating standards that will be published through HL7 by the end of this year as an extension of the consolidated CDA, and in fact, they will be incorporated into the consolidated CDA the next time that goes to ballot. It may be this fall, but it may be early next year.

And we look forward to the Standards Committee supporting this work and including these standards in the meaningful Stage 3 for care transitions and care planning. Thank you.

Jonathan Perlin – Hospital Corporation of America

Thanks, the three of you, for really a very thoughtful and provocative presentation. There's a lot to work with, certainly more than we'll be able to discuss in today's conversation. David McCallie has raised his card, but before I go there, we've referenced John Derr a number of times. Let me just turn to John Derr and ask if you have any capstone comments that you'd like to offer.

John Derr – Golden Living, LLC

Yes. I – first of all, thank you very much, Bill and Larry. I just want the committee to know, and this presentation shows how much work that this sector is doing on our own, and with the support of Dr. Mostashari and the Standards and Policy Committee. We've really been working very hard to be involved in the meaningful use three, and I hope that the committees will allow us to do that, because the market – the LTPAC sector is really waiting for us to give them more guidance, and they are rallying around being able to adhere to these standards and that – so they can have interconnectivity and transitions of care for the betterment of our – of our patients.

And I just wanted also to add that next month, the key HIE Transform software will be available from Geisinger that takes out the meaningful – takes out from the MDS and the oasis, so we can have some transitions of care capability along with Project DIRECT. So there's a lot of work being done in our sector, and we really appreciate this time on the Standards Committee to give you an update, and appreciate what the LCC group has done in the S&I framework, which as I've said before to Doug and the rest of you, is very important to us, because it's one of the places, plus the LTPAC HIT Collaborative, where everything is aggregated.

And I'll take this moment to sell the summit, the ninth Summit for the LTPAC HIT Collaborative. It's going to be held in June 18th in Baltimore. And thank you very much, Jonathan, for the opportunity.

Jonathan Perlin – Hospital Corporation of America

Well, thank you for that, and thank you for your support and leadership. David McCallie, your card is up. Why don't you go ahead?

David McCallie, Jr. – Cerner Corporation

Yeah. Thanks. It's David McCallie with Cerner. First, I'd also like to acknowledge all the hard work behind this report, and congratulate you on getting so much expertise organized on the question, an important question. But I was struck by a couple of things that I hadn't thought about very clearly before, and one of which is maybe confusion between templates that are – would start to become disease specific versus a template that could handle multiple diseases, and some independent way of specifying the kinds of data that is relevant to a particular disease.

And I wish – I'd like for you to clarify that. So when you mentioned, you know, sending an ejection fraction or an INR, you know, clearly those make sense in certain diseases, but don't make sense in other diseases. And I'm wondering how you would accommodate – how you would design a template that would reflect disease specificity like that, as opposed to specifying a template that says you can send lab results in this part of the template, and if the disease is congestive heart failure, you should send an injection fraction if you have it available, and if the patient is on Coumadin, you should send an INR if you have it available.

[Crosstalk]

Larry Garber – Reliant Medical Group

It's exactly – I'll –

[Crosstalk]

Larry Garber – Reliant Medical Group

Yeah. This is Larry. It's exactly that latter situation. So it's reuse of the exact same templates with additional rule constraints, and that's something that Lantana has been working on.

David McCallie, Jr. – Cerner Corporation

And how is that – where are those rule constraints expressed? What's the – you know, what would an EHR vendor need to do to consume those rule constraints? Are these constraints inside CDA?

Larry Garber – Reliant Medical Group

Those are within the – within the temp – within the definitions that are in the implementation guide. So I – you know, I probably can't go into more technical detail in that other than – without bringing Lantana in, but this is something that Bob Dolin has been working on and would be part of. It basically would be in the implementation guide. As you said, it's reusing existing templates, and it's part of the implementation guide. It's additional rules, you know, looking for these SNOMED codes, for instance, then suggesting that you – you know, you provide results with these line codes.

David McCallie, Jr. – Cerner Corporation

Okay. Thanks. Well, I'll look forward to more details in some other setting. Thank you.

Jonathan Perlin – Hospital Corporation of America

Thanks, David. And I'd like to suggest that we take this very provocative and thoughtful presentation as a start, not a completion. There's one other card that's up, and that's Dixie, and let's take this as a brief –

[Crosstalk]

Stanley Huff – Intermountain Healthcare

This is Stan, too. I'm not where I can put my hand up, but I'd like to comment as well, if I could get in the queue.

Jonathan Perlin – Hospital Corporation of America

Absolutely. So we'll take two, and let's keep their fairly brief, because I want to make sure we get to the ONC series of presentations, and clearly, this provocative discussion is one we're going to be coming back to. So Dixie first, then Stan, and then we're going to go to Judy Murphy to start with the ONC. So Dixie, please go ahead.

Dixie Baker – Martin, Blanck, and Associates

Thank you. The transfer of care, the number of data elements that were included in there was – is obviously very, very extensive. And I didn't hear you mention anything about considering the minimum necessary when you were identifying these data elements. And I just had a question about whether that was a consideration in your work.

Larry Garber – Reliant Medical Group

Yes, and to be done. So we've done some – you know, as part of the survey process, we did get feedback as to which are required for which transitions of care, and as I said, you know, Lantana has done an implementation guide for us right now, but it's what we consider very high level implementation guide. In other words, it's not something that today could be brought to HL7 ballot. And so some of the refinements that will be done over the next few months through the S&I framework will be doing exactly what you're suggesting, which is determining which are the shalls and the shoulds, you know, optionalities for the data elements. Also, there will be work on further defining the vocabulary constraints that are required for some of these new templates and elements.

Dixie Baker – Martin, Blanck, and Associates

Thank you. And very nice presentation. Thank you.

Larry Garber – Reliant Medical Group

Thank you.

Jonathan Perlin – Hospital Corporation of America

Okay. Stan, last word.

Stanley Huff – Intermountain Healthcare

Yeah. I echo others in saying this was a great presentation, and I'm convinced by the presentation of the need for these enhancements to the standards, and convinced that there are very bright people that have made a wonderful recommendation in terms of the data elements and other things.

I'm – I have some concerns. The primary concern is that we don't have real experience that – to say that if this were implemented as designed, that it would accomplish the goals. And I understand the paper – the paper experiment. At the same time, and I may be exposing some bias, there – I think even mentioned in the presentation was the fact that, you know, the standards that do exist around care plans have not been implemented that successfully in existing organizations. And so while I support the goals and intents of this, I – my bias would be that we support, fund projects to implement and get experience with the implementation to ensure that what we're asking will actually have the impact that we hope on the quality of care.

I think there's substantial risk that if we – if we move forward with this as a phase three requirement, that we could be in the situation that even though it's implemented as designed, it doesn't have the impact that we hoped on the quality of care, and it certainly would come at some cost, in spite of all of the work that they've done to make it simple and consistent with CDA and with the implementation guides and other things. I just – I'm really concerned that we move forward and make this a requirement without having it been implemented electronically and know something about the outcomes of that implementation.

Bill Russell – Seasons Hospice and Palliative Care

This is Dr. Russell. Larry, let me just speak at this briefly. IMPACT is one of four Challenge grants for transitions of care funded at ONC in 2011. Some of the Challenge grantees have already implemented a sort of, quote/unquote, non-standards-based version of a transition of care document or UTF, coupled that with direct notification and some other document types, and are developing data, which indicate both usability and a significant reduction in hospital readmissions.

I think your concern is absolutely the right concern. It would be our hope that the Challenge grants as a whole would produce significant evidence of the value of these – exchange of these kind of data points in reducing admissions and improving outcomes. So I think the Challenge grants –

Stanley Huff – Intermountain Healthcare

My concerns were – my concerns were specifically around care plan, where I think the evidence is less strong.

Bill Russell – Seasons Hospice and Palliative Care

Those are fair comments. I think – go ahead.

Larry Garber – Reliant Medical Group

I just – I think you're also spot on. I think it's also not the first time that something's been implemented with limited evidence, and I know that it's a sensitive issue, particularly these days. But we think that this is really an extension of the CCD. We're moving the ball a little bit further down the field. I don't think, you know, come December we will have reached the end game. But I think we'll be moving the healthcare system in the right direction, and I think that there will be other iterations of this, you know, as we learn more and get more experience. Our work is not done, and – but I think we're moving in the right direction.

Jonathan Perlin – Hospital Corporation of America

Okay. Well, let me just take that as a segue, because indeed, this is an absolutely fabulous presentation, very provocative, and to the points that were just made, there's additional work that needs to be done. After this meeting, we'll work with MacKenzie and Doug and the ONC team, and look at the different touch points. Clearly, clinical operations ... have certain touch points. Additional work will be required and requested of the long term care group.

So let me – let's stop there and let's take this as a wonderful step and thread it into the continuing activities, which is a good segue to Judy Murphy and Doug Fridsma and the update from ONC. But before we go there, just want to acknowledge and thank Evelyn Gallego, Larry Garber, and Bill Russell, and in fact, all the members of the workgroup, as well as John Derr, again, for really inspiring us to continue pressing in this direction. Stan, I think you said it right. It was a beginning, more work to be done, and the rest of the committee will be very much engaged in those efforts.

So with that, Judy, if you are ready to go, let me turn to you and Doug. And just a footnote, that Doug, there may be a couple of addenda that you want to add in terms of our earlier discussion. Judy?

Judy Murphy – Office of the National Coordinator

Okay. Sure. And if I could have my slides up, that would be great, and I'll try to get us close to back on time. Okay. Next slide, please.

So the things that I'm going to run through are itemized out here. We'll talk about the FDASIA workgroup, the governance forum, the eHealth Equity Summit, PDMPs, advancing interoperability and health information exchange RFI, some – draw your attention to some hospital adoption briefs that have been posted on our website, along with a couple of other highlights of what's new on the website, particularly the interoperability basics training course.

So if we could go to the next slide, this is the detail on the FDASIA workgroup. And that's such a good word, FDASIA. I feel like I do need to make sure everybody knows what it stands for, Food and Drug Administration Safety and Innovation Act of July 9th, 2012. So the charge of this workgroup, which is getting started in the near term – in fact, if you go down to the last bullet, we suggest that the first meeting was going to be on April 9th, but it's looking now like probably not going to make that. It'll probably be a little bit later in April.

Again, the call had gone out for this. Paul Tang is going to serve as the chair. The workgroup members are being notified as we speak, so we are not prepared to announce the list of members at this point. And the announcement will come out late next week. But the charge of the group is really going to be to provide expert input on issues and concepts identified by the FDA, ONC, and FCC to inform the development of a report on an appropriate risk-based regulatory framework pertaining to health IT.

So we can go on to the next slide, and that particular one highlights the details on the HIE governance forum. Now this is a different way that ONC is going to be getting some input. This is a forum that's being convened by NeHC under a cooperative agreement with ONC. Their charge is going to be to address crosscutting governance issues among our various exchange approaches and identify key issues and common problems in the governance of health information exchange, and some – suggest some best ways to address them. So again, this will be looking at developing a landscape of all the current governance activities and identifying common approaches and problems for follow-up.

I'll pause here to remind everybody about the governance RFI that we put out and the fact that we all identified that this whole area wasn't real mature, and so what we're really trying to do is get a handle on how mature it is, and then move things along by identifying some best practices and disseminating or proliferating those best practices. So again, we're in the throes of identifying the participants on this forum. This will be a relatively large group, around 30 or 32. They will have their first meeting on April 12th, and we will be soliciting input from the Policy Committee and the Standards Committee working groups as appropriate, and presenting those findings to the – the findings of the forum to the full committees. There is additional information on a website, and that one's identified on these slides.

Okay. If we go to the next slide, this is a summit that we held at the White House back on February 21st. It was cosponsored by ONC, the HHS Office of Minority Health, and Zero Divide. The purpose of this summit was to focus on how we can achieve eHealth equity for underserved populations specifically, and quite a number of opportunities and key actions, as well as next steps, were identified. Those proceedings are going to be coming out in April. There will be an announcement similar – and I hope you're all familiar – some things come out in push announcements, but if they don't come out individually in a push announcement on our listserv, there's always the Friday recap of what's new on the website, and so that would be a way of keeping track if you wanted to know when things like this or some of the other announcements were made. So again, that'll become publicly available in April.

So if we go to the next slide, this is about the prescription drug monitoring program, and linking those prescription drug monitoring programs to some health IT pilots. This was the collaboration that was done, again, between a group of federal stakeholders, so ONC, SAMHSA, CDC, and ONDCP, and I'm using a bunch of acronyms, again. SAMHSA is the Substance Abuse and Mental Health Services. I think everybody knows the Center for Disease Control. And ONDCP is the Office of the National Drug Control Policy. They did – that collaboration ran six different pilots that integrated existing health IT technologies, like electronic health records and pharmacy systems, to connect to the state prescription drug monitoring programs for the purposes, of course, of providing that good information to the clinician at the point of care. We made that data available to physicians as part of their normal workflow.

The six pilot sites are identified there on the slide, and – as well as the type of partner that was involved in the pilot in that particular location. The evaluation reports of those six pilots actually has been already released on the HealthIT.gov website, and you can see the URL there. So it's HealthIT.gov/PDMP.

Okay. If we go to the next slide, this is the RFI that was announced during HIMSS, Advancing Interoperability in Health Information Exchange. It was a request for information co-produced, if you will, between CMS and ONC. We're seeking input on a series of potential policy and programmatic changes that would facilitate the acceleration of health information exchange. The deadline on this particular request for information is April 21st. There's more information listed on the URL that I provided there. And in addition to that, Farzad had a really good blog post about this, and so I wanted to highlight that as well, which gives some additional background information and his opinion really on why this is so important. That blog was released on the same day that the RFI was released.

Okay. If we go to the next slide, possible adoption data briefs. And again, for those of you that were at HIMSS, these were two data briefs that Farzad relied a bit when he generated his slides for his particular keynote presentation at HIMSS, and so I do draw your attention to them, because they're really good information. They are data briefs, ONC Data Briefs 9 and 10, and again the URLs are listed there. Basically, it is information that has been consolidated and data mined, if you will, out of the American Hospital Association report from 2012. Our ONC data geeks, if you will, have gone back and done some comparisons between previous AHA survey results and shown really a dramatic change in some of the information availability and EHR availability in the hospital setting.

So if we go to the next slide, I'm just giving you a small preview of some of the information that's found in that data brief. And you can see the wonderful curve, you know, up to the right in terms of hospital EHR use, and particularly notifying that certified EHRs have gone in the last two years from 72 percent to 85 percent of the hospitals using an EHR that is certified.

One – or a couple more real quick highlights. If you go to the next slide, it shows EHR adoption of eligible hospitals by state. And again, you can see the different types of penetration. The darker the blue, the higher the percentage of hospitals that have qualified for meaningful use in that space.

And if we go to the next slide, another interesting comparison in the data brief is to show what has happened to some of the meaningful use objectives over the years, and how many – what percent of hospitals were able to qualify for those objectives in 2008, as compared to 2012. And I'll particularly point out on this one that CPOE went from 27 percent in 2008 to 72 percent in 2012, so again, quite a bit change.

There are a – if you go to the next slide, there's a couple of other data briefs that I want to draw your attention to. We certainly have been doing some discussion about long-term post-acute care today, and there was a data brief published on March 15th related to health IT and long-term care and post-acute care, so I definitely want to draw your attention to that one.

And then there was a second data brief, building better consumer eHealth, a Summary of the Report of Consumer eHealth Unintended Consequences. That particular one was a contract that we had, and there's some good information in there related to the unintended consequences.

Okay. If we go on, I want to advertise the interoperability basics module that is now available on HealthIT.gov. This is a true training session related to understanding the interoperability that's going to be required at Stage 2. It takes between 60 and 70 minutes to run through, so it's got quite a good level of detail. The target audience on this is providers. So the real idea here is to give providers the right ammunition so when they're talking with their vendors, that they can understand some of the requirements that the vendors are going to need to help them provide.

So there is this basics module, and if you go to the next slide, we identify the upcoming – or excuse me, this is just the landing page that if you did click the link, this describes the detail. And here are the four additional interoperability modules that are coming out over the next couple of weeks. They will be out by the middle of April. So there will be another training module on each one of the interoperability criteria that again is going to do a nice, deep dive, target audience, providers, so that they can understand what's actually required in Stage 2, and particular emphasis so that they can talk with their vendor in an educated way. So we'll be doing TOC, the lab interoperability, the VDT, and then public health.

And last but not least, we always love to highlight the – Steve Posnack, who has done a health IT video also on Stage 2. His focus is around TOC and how you really do understand those criteria, and help you to determine how you calculate your numerators and your denominators. So again, just drawing your attention to all those great things.

And if we go to the next slide, that's just me stopping and saying, any questions on anything that I reviewed?

Jonathan Perlin – Hospital Corporation of America

Obviously, Judy, very clear. I suggest you continue on, or move to Doug.

Dixie Baker – Martin, Blanck, and Associates

I have a question. This is Dixie.

Jonathan Perlin – Hospital Corporation of America

Yes. Go ahead, Dixie.

Dixie Baker – Martin, Blanck, and Associates

One of the things that I heard mentioned, Judy, is that the – you know, Stage 2 requires the consumer portal and the ability to download and view, download, and transmit, etcetera. And it's been mentioned to me that some of the vendors are charging pretty high fees – well, very high fees – to add that capability to the EHR.

Judy Murphy – Office of the National Coordinator

Yeah.

Dixie Baker – Martin, Blanck, and Associates

Does the ONC have any input, any – you know, any way to really motivate these vendors to provide the meaningful use capabilities that are required without overcharging the providers?

Judy Murphy – Office of the National Coordinator

Boy, it would be nice if we did, Dixie, but we don't. However, the one thing that is at Stage 2, you might recall, is price transparency. So the idea is when a vendor does charge extra for any particular item, particularly those that would require – that are needed for Stage 2, they have to be transparent about that and be very clear that those are, you know, add-ons that are going to have additional fees.

Dixie Baker – Martin, Blanck, and Associates

Thank you.

Judy Murphy – Office of the National Coordinator

Yeah. Okay. Thank you, guys.

Wes Rishel – Gartner, Inc.

Judy, this is Wes. I just want to say overall, this – yours and the prior presentations represent a tremendous amount of in depth staff work that I for one really appreciate.

Judy Murphy – Office of the National Coordinator

You're most welcome. I think you can see what we're really trying to do is make it real for people, and make it easier. We've all learned a lot from Stage 1, and the idea is with Stage 2, let's, you know, stand on the shoulders of that work and make sure that it's a lot easier, so that everybody doesn't have to do this stuff individually, and we dovetail onto each other's work. So I appreciate the comment. Thanks, Wes.

Jonathan Perlin – Hospital Corporation of America

Thank you, Wes. Are there other comments? Or Doug, did you want to jump in with any additional comments or questions?

Doug Fridsma – Office of the National Coordinator

Sure. We've got just a few more minutes before we open up the – open up for comment and things like that, so I'll try to be very, very brief. In terms of – in terms of updates, much of – many of the updates that you've heard just today with the various committees that have been presenting represent a lot of the work that we've been doing within our office, and I just want to thank both the LCC community for being so robust and doing such high quality work, as well as the work from the FDA on the UDI and the product identifier as well.

I think we'll be working very closely I think with the LCC community within the S&I framework to figure out what the next steps are, and we'll look to this committee, the HIT Standards Committee, to help us clarify where the priorities should be and where the focus should be as we look towards the next stage of meaningful use.

When it comes to the unique device identifier and the product identifier, I think there's a number of things that we probably need to do within this committee, and to think more broadly about – I think it's important to recognize sort of two important factors. The first is – we went through them very, very quickly, but there are actually three standards that are recognized within the NPRM. There's GS1, there's HIBCC, and then there's also ICCSSA. All of – all three of those have a slightly different syntactical approach to how they represent the UDI, and there are some implementation issues with regard to how each one of those standards might work.

I think one of the things that we would welcome is input from this particular committee about whether we should have one standard, two standards, three standards, or more around the unique device identifiers. And so I think it will be important for us to understand which of the – which of the standards are sort of coming up, which are legacy, which ones are tightly linked to a particular area or domain, so that we can have thoughtful comments that we can refer then to the National Coordinator.

I think the other thing that we have to think about is there are two different pieces to this. GUDID gives you the unique device identifier, which is really, you know, the manufacturer, the kind of product, and the version, if you will, of that. So it really tells you the class of devices, whether it's a – you know, a hip transplant or a knee transplant, the manufacturer and the version, and the serial number on that. But it doesn't have what is referred to as the product ID, and the product ID uniquely identifies that particular product that comes off the assembly line.

And so I think one of the issues is while GUDID will tell you all about the kind of catalogue of things and devices that the FDA knows about with all of the additional information and metadata that you need, we have to figure out who should be responsible for the patient registry piece of that. Is that something that hospitals who implant the devices need to be maintaining? Is it something that a manufacturer needs to take care of? Is it something that a state HIE or a government agency needs to cover? Or is that something that's the responsibility of a patient with their personal healthcare record?

And so I would really welcome the HIT Standards Committee to think through both use cases for how we can improve patient safety using the unique device identifier and the product identifier, and make sure that we've got the right use cases and the right responsibilities in place.

So with that, I'll just give you a couple of other updates. Judy mentioned the PDMP pilot in the S&I framework, which is – which will be ending in March. We hope to take all of the work of that particular pilot, learn from it, and then determine what the next steps are for us to be able to support the prescription drug monitoring programs and link that into some of the standards that are currently used across government agencies.

The second thing I'd like to just mention is to – last week, there was an announcement made that the US/EU memorandum of understanding around health IT, we just recently published the initial roadmap for activities that are going to be ongoing. And I know that there's been some questions that have come up. We intend to have a call for participation in some of those activities forthcoming in the course of the next couple of weeks. We're working on both developing the infrastructure and coordinating with our European partners on that.

I think what's important, if I can just highlight, there's certainly going to need to be work on that – on the roadmap around workforce training. That was something that the current EU presidency in Ireland would like to provide as a focus going into the next term of their presidency. But in addition to that, the kinds of activities that we've got will be joint between ONC and NLM, and will essentially have three key components: trying to identify a subset of commonly used vocabularies that represent say the 80 percent of all kind – all diagnoses or drugs or laboratory tests that would be internationally recognized, and that could be then used both in the US and in the EU.

The second component of that is to identify an internationally recognized standard for supporting patient care summary or transitions of care, and there are some – World Health Organization, some standards that are used within the European community, as well as those that we've adopted here within the United States. And we believe since most of those are based around HL7 that we should be able to identify at least a subset or a parsimonious set that can be used internationally.

And the third is that we've agreed to move forward on patient and provider-mediated exchange. And it's important to recognize that within a country or across countries that have strong sort of contractual and treaty arrangements, provider to provider exchange can occur. But in many circumstances, it's more challenging to have that kind of exchange occur across country borders. And so there's a commitment to make sure that patients are engaged in healthcare information exchange, and that they have access to their information within a particular country that would then allow them to use a personal healthcare record or other device to be able to take that information and take it with them if they're traveling or if they're cross borders.

And so those were sort of the three standards-related components, plus a piece related to workforce training, that are part of the EU/US roadmap, and more information will be forthcoming about participation.

And finally, I'd like to just end with a thank you to all of the people out in the community, those that are participating in the HIT Standards Committee and many of the S&I framework activities. I was at HIMSS just a couple of weeks ago, and really humbled by the amount of enthusiasm and the amount of work that's been done, and those people who are doing pilots and demonstrations of all of the work in the standards and interoperability framework and standards to support not only Meaningful Use Stage 2, but future stages as well.

And so with that, I'll just end, and turn it back over to the chairs.

Jonathan Perlin – Hospital Corporation of America

Thank you very much, Doug.

Doug Fridsma – Office of the National Coordinator

Right on time, too, I might add.

Jonathan Perlin – Hospital Corporation of America

Remarkably so. Let me just amplify Wes's comment about the incredible staff work and leadership. One of the most important parts of the meeting is the opportunity for public comment, and I want to make sure that we move to that space. But if there are any brief clarifying questions for either Doug or Judy, let me just ask if there's anything on anyone's mind that you want to bring up at this moment. Okay. Well, you have been terrific. Both you, Judy and Doug, not only for the terrific work, but also the very timely and very clear presentation. Many thanks for all of that.

As I mentioned, one of the very most important parts of a federal advisory committee is the public nature of the committee. That includes not only the openness of these fora, be it in person or virtual, but the opportunity and encouragement for public comment. So with that, let us turn to MacKenzie Robertson to invite the public comment.

Public Comment

MacKenzie Robertson – Office of the National Coordinator

Thank you, John. Operator, can you please open the lines for public comment? And I'll just remind members of the public that I will be limiting your comments to three minutes. So if you run into the three minute time barrier, I will be interrupting you. Thank you.

Rebecca Armendariz – Altarum Institute

If you would like to make a public comment and you are listening via your computer speakers, please dial 1-877-705-6006 and press star 1, or if you're listening via your telephone, you may press star 1 at this time to be entered into the queue.

MacKenzie Robertson – Office of the National Coordinator

And while we're waiting for the queue to form, I'll also just remind everyone that it is a public comment session. The members of the committee are not required to provide any additional comments back. Thanks. Do we have any public comments?

Rebecca Altarum – Altarum Institute

We do have a comment from Ben Moskovitch.

MacKenzie Robertson – Office of the National Coordinator

Thank you, Ben. Go ahead.

Ben Moscovitch – Pew Charitable Trust

Good afternoon. My name is Ben Moskovitch, and I'm with the Medical Device Initiative of the Pew Charitable Trust, which seeks to enhance medical device safety and foster innovation that benefits patients. As you know, the FDA is developing a unique device identifier system for medical devices that will serve as the cornerstone for significant improvements in medical device safety and post-marketing surveillance. This UDI system will benefit patients, clinicians, and public health officials by providing for more rapid identification of medical devices associated with adverse events, assisting with prompt and efficient resolution of device recalls, delivering an easily accessible source of definitive device identification, and increasing healthcare savings through a more accurate accounting of the devices used.

However, to realize these important goals, healthcare providers and hospitals must incorporate UDI into clinical practice. To achieve that outcome, we encourage ONC and CMS to include and the HIT Policy Committee to recommend the capture of the UDI from implanted devices as a Stage 3 core meaningful use objective. That goal is only possible if electronic health records can properly store device identifiers. Therefore, we urge the HIT Standards Committee to recommend the necessary technical specifications for how UDIs will be incorporated in EHRs with the next standards and certification regulations update.

Enabling the capture of UDI will facilitate several meaningful use objectives, including SGRP 405 and SGRP 408, which support the reporting of information from EHRs to registries and the FDA. This new standard should identify a technical specification for UDI data, require that certified EHR technology be able to electronically import, manage, and export the UDI, and mandate that certified EHR technology handles the UDI and any associated data in a dedicated section of the EHR.

Given that Congress instructed the FDA to publish the UDI final rule this year, and CMS is expected to conduct Stage 3 Meaningful Use rulemaking next year, the timely revision of the EHR standards and finalization of the UDI rule are critical to a subsequent capture of UDIs for implanted devices as a core meaningful use objective. Prompt accomplishment of this goal will require recognition from outside experts, including this committee, of the importance of UDI adoption to improving patient outcomes. Thank you for considering our comments.

MacKenzie Robertson – Office of the National Coordinator

Thank you very much, Mr. Moskovitch. Are there any additional public comments?

Rebecca Armendariz – Altarum Institute

No further comment at this time.

MacKenzie Robertson – Office of the National Coordinator

Thank you very much. Jon, do you have any closing remarks?

Jonathan Perlin – Hospital Corporation of America

Let me just note that John Halamka has a board meeting, so he's just dropped off, and I thank John very much for his leadership, which is really quite remarkable. MacKenzie, let me thank you again. Many thanks to the Office of the National Coordinator. Let me just one quick go-round, if there's anything for the good of the order before we adjourn.

MacKenzie Robertson – Office of the National Coordinator

So this is MacKenzie. I'll just note that our next HIT Standards Committee meeting is scheduled for Wednesday, April 17th.

Jonathan Perlin – Hospital Corporation of America

I appreciate that. And further details forthcoming on that. Obviously, we've set an agenda that identifies a number of things that we need to get back to, including device and long-term care. And Judy, appreciate the very thorough update. It really does reflect a very robust agenda, and terrific work.

Thanks again. Words really are inadequate to thank the members who are departing from the committee. We appreciate your work, appreciate your collegueship and friendship and all that you've done, working with many of you through the workgroups, certainly in the informatics community. To the ongoing members, thank you for your commitment and dedication. I think, to the new members, you saw how robust the agenda is. We had a bit more that was informational, but really, it is testament to the expanding ecosystem, the platform of interoperability that is expanding and making incredible possibilities available.

To the new members, again, welcome, and thanks. Look forward to meeting you in person. And we stand adjourned. Thanks to everyone.