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PRIVACY AND SECURITY TIGER TEAM

HEALTH INFORMATION TECHNOLOGY POLICY COMMITTEE

CONSUMER CHOICE TECHNOLOGY HEARING

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1 P R O C E E D I N G S

2 UNIDENTIFIED FEMALE: Everybody, we're ready

3 to begin, if you could please take your seats.

4 Welcome, everyone to the Privacy and Security Tiger

5 Team Hearing on Consumer Choice Consent Technology.

6 Just a reminder, this is operating under the

7 auspices of the Federal Advisory Committee Act, which

8 means there will be opportunity at the close of the

9 meeting for the public to make comments, and a

10 transcript and a video tape of the meeting will be

11 available on the ONC website within a few days.

12 So, just a reminder to committee members and

13 also presenters to please identify yourself when

14 speaking for attribution and also so people listening

15 on the phone and on the internet will know who's

16 speaking.

17 With that, I'd like the committee members at

18 the table up here to go around and briefly introduce

19 yourselves and say a little bit more than usual,

20 because I think the audience is a little different. So

21 if you'd just give one minute background on your

22 summary and then, perhaps, your particular interest in

1 the subject of consent technology. And I'll begin on
2 my right with Wes Rishel.
3 UNIDENTIFIED FEMALE: Judy, I think we also
4 wanted people to talk about whether they have any
5 biases or conflicts.
6 UNIDENTIFIED FEMALE: Oh, sure. And any
7 particular bias on the subject, if you could just
8 mention that for the record, please. Wes.
9 MR. RISHEL: I'm Wes Rishel. As a
10 technologist, I should know how to push a button. I
11 work for Gartner. I've been active in health care
12 interoperability since we've been trying to get the
13 beads the same size on the abacus. I have been very
14 active in the development of standards for information
15 exchange among separately chartered health care
16 organizations. I think that's probably enough.
17 MS. FLINK: Good morning. Ellen Flink. I
18 work for the New York State Department of Health, The
19 Office of Health IT Transformation. I'm filling in for
20 Rachel Block this morning, Deputy Commissioner of OHIT.
21 And I have been involved in all of the HISPC (Health
22 Information Security and Privacy Collaboration) funding

1 and have a particular interest in privacy and security
2 and consent policies. I have done a lot of work in New
3 York in that area as well as on consumer engagement and
4 education activities.
5 MR. McCALLIE: Good morning. My name is David
6 McCallie. I'm a long time employee at Cerner
7 Corporation, an HIT vendor in Kansas City. I'm also a
8 member of the HIT Standards Committee, and am on the
9 Privacy and Security workgroup of the Standards
10 Committee in addition to the Tiger Team. I have a long
11 standing interest in privacy issues, consent management
12 and various technology approaches to facilitate them.
13 MS. PRITTS: I'm Joy Pritts. I'm Chief
14 Privacy Officer, OMCHHS. Prior to my current gig, I
15 worked at Georgetown Health Policy Institute where I
16 did some work on this particular issue as to the
17 ability to implement consumer choice in electronic
18 health information exchange.
19 MS. McGRAW: I'm Deven McGraw. I'm the
20 Director of the Health Privacy Project at the Center
21 for Democracy and Technology, otherwise known as CDT.
22 It's a nonprofit 501(c)(3) organization primarily

1 located here in Washington, but we also have a small
2 office in San Francisco.
3 We do public education and advocacy around
4 health privacy issues both with respect to the
5 traditional health care system's handling of health
6 information as well as health information on the
7 internet as consumers and patients more actively share
8 it. We've written papers on the issue of the
9 appropriate role of consent which are available on our
10 website. Oh, and I also co-chair the Tiger Team.
11 MS. BAKER: Okay. I'm Dixie Baker and I work
12 for Science Applications International Corporation.
13 SAIC is a very large systems integration firm that does
14 both security work and health and life sciences work
15 primarily for the federal government.
16 I chair the Privacy and Security Working Group
17 of the Health Information Technology Standards
18 Committee, which is the other committee. I've been
19 working in security since everybody who worked in
20 security knew each other and nobody else knew it was a
21 problem. So I've been working in security technology
22 for quite a long time.

1 MS. HARRELL: I'm Gayle Harrell, former state
2 representative from Florida. While in the state
3 legislature, I served as chairman of various health
4 care committees and was very involved in health
5 information technology and moving Florida forward in
6 that arena dealing specifically with electronic health
7 records, e-prescribing, that sort of thing.
8 And privacy and security has always been a
9 great concern to me. I sit on the Health Information
10 Technology Policy Committee. I'm on the HIE committee
11 as well as the Privacy and Security Committee and the
12 Tiger Team.
13 So this is a subject near and dear to me. And
14 what makes it so is really my involvement engagement
15 with the public and with constituents in my district.
16 That is the number one concern of people when they
17 think about electronic health records.
18 Health information is so important to them and
19 their privacy and the security of that information is
20 the number one thing that they are concerned about as
21 we move into the 21st century.
22 I also have been a practice manager and

1 healthcare administrator and the administrator of a
2 large practice that were early adopters in health IT.
3 And I can tell you when you talk directly to patients;
4 they want to know what's happening to their
5 information. They want to know who's controlling it and
6 if that is divulged to anyone who is responsible.
7 They are very concerned about this and this
8 public hearing is one of the most important things I
9 think our committee is doing. And thank you all for
10 being here today.
11 MR. RANA: Good morning. I'm Sumit Rana
12 and I am filling in for Judy Faulkner. I am with Epic
13 Systems Corporation. We make software for healthcare
14 and my personal background; I have a formal background
15 in computer science, so I'm a programmer. And I have
16 been responsible for various applications at Epic.
17 I'm currently responsible for our ambulatory
18 medical record and in the past I have also been
19 responsible for our inpatient medical record. And
20 before, I also have background in our My Chart software
21 which allows patients access to the medical record
22 security. Thanks.

1 MR. HOUSTON: Good morning. I'm John Houston.
2 I'm with the University of Pittsburgh Medical Center
3 where I am Vice President of Privacy and Security as
4 well as an attorney there. I am also on the National
5 Committee of Vital and Health Statistics where I am a
6 co-chair of the Privacy, Confidentiality and Security
7 Subcommittee, and I am a member of the Tiger Team as
8 well. I'm very interested in these hearings today.
9 I think in larger measure because representing
10 a very large provider, clearly we have to understand
11 how we can translate people's desires and preferences
12 and all this testimony into something that works
13 operationally in a very, very large, integrated,
14 delivery environment.
15 UNIDENTIFIED FEMALE: Thank you. And let
16 me ask, are there any committee members on the
17 telephone, please?
18 (No audible reply.)
19 UNIDENTIFIED FEMALE: Okay. With that,
20 I'll turn it over to Deven McGraw.
21 MS. McGRAW: Thanks very much and I'm
22 actually going to defer my opening remarks to Joy

1 Pritts, the Chief Privacy Officer of the Office of the
2 National Coordinator for Health IT.
3 MS. PRITTS: Thank you, Deven. First of
4 all, I'd like to welcome everybody here today to what I
5 think will prove to be a very exciting meeting. I
6 wanted to set a little bit of the groundwork for why
7 we're here today and then talk a little bit about the
8 rules of the road for this particular meeting.
9 One of the challenges that has been
10 repeatedly raised during our process of considering how
11 we're going to be protect health information as we move
12 forward with computerized medical records and
13 information is how we are going to be able to handle
14 what many people would characterize as "sensitive" and
15 I put that in quotation marks health information.
16 This can include information that's related to
17 things such as HIV test results, mental health related
18 information, genetic information. These are some of
19 the categories that people often think of as falling
20 into this category primarily because people are often
21 stigmatized because they have these types of health
22 conditions.

1 The issue arises because as you all know the
2 HIPAA Privacy Rule allows for the exchange of health
3 information between providers, in particular, for
4 treatment, payment and healthcare operations without
5 the patient's express written permission or what's
6 often referred to as consent. The Privacy Rule does
7 not preempt or override more stringent state or federal
8 laws so that means that some of the laws that are put
9 in place that actually require individual permission to
10 exchange this type of information remain in place.
11 So the net effect is that under existing law
12 while general clinical information may be shared
13 without patient consent, providers and others must
14 obtain the individual's express consent to share
15 certain types of health information.
16 To address some of these challenges in high
17 tech, Congress specifically instructed the HIT Policy
18 Committee to make recommendations with respect to
19 segmenting and protecting from disclosure specific and
20 sensitive health information. This is often referred
21 to as data segmentation, that is, the ability to send
22 some information, but not all of it; or send

1 information to some people, but not to everybody.
2 This hearing is part of that consideration.
3 It's just one of the factors that this committee will
4 be looking at and will be making recommendations on.
5 We understand that people have varying opinions as to
6 the underlying policy here.
7 NCVHS of which John Houston is a member has
8 had numerous hearings on the policy involved with this
9 in the past. The most recent was, I think, a week or
10 two ago, John? And we will be receiving a white paper
11 from GW who we have a representative of here today,
12 George Washington University for those who aren't
13 local, discussing some of the policy implementations of
14 data segmentation in the near future.
15 However, the focus of our hearing today is on
16 technology for implementing the individual choice in
17 this changing environment and the challenges it's
18 designed to address, its capability and the limits of
19 it to address those challenges.
20 We have a number of presenters here today and
21 they will talk about the challenges that they face in
22 providing healthcare and managing sensitive health

1 information. And then, they are going to demonstrate
2 for us the technology that they use that facilitates
3 consumer choice in addressing these challenges.
4 This is not an endorsement of any particular
5 product or a means of protecting information. This is
6 a fact finding hearing. It's intended to give HIT
7 Policy Committee some real life examples of technology,
8 its capabilities, its scalability, its affordability
9 and the impact on workflow.
10 We have limited time to address these issues.
11 We've had a lot of policy discussion. So we're going
12 to request that members of this Tiger Team and the
13 Reactor Panel limit their discussion to technology
14 today.
15 And we're really going to try to retain that
16 focus, because we know once we get into the policy
17 discussion, that could take up the rest of the day and
18 we end up at the end of the hearing without the
19 information that we really are seeking to obtain.
20 So in the spirit of the World Cup, we have up
21 here, and I hope you take this with all of our good
22 intentions, yellow cards for when people are out of

1 bounds. Okay. And it says, it's technology. And this
2 will be if we start veering into the out of bounds
3 territory of getting into a deep policy discussion, we
4 will raise these cards as a gentle reminder to please
5 focus on the technology and to keep your questions and
6 your comments focused on that so that at the end of the
7 day we have the kinds of facts that this policy
8 committee is going to need to make a thorough set of
9 recommendations to ONC in the fairly near future.
10 And so I will now turn it back over to Deven.
11 MS. McGRAW: And we were joined by one other
12 member of the Tiger Team. Carol, we all introduced
13 ourselves and gave slightly more background than just
14 name, rank and serial number. And also asked to review
15 just what is your interest in this topic and also if
16 you have any conflicts or biases to reveal, now would
17 be the time to do so.
18 MS. DIAMOND: I'm Carol Diamond with the
19 Markle Foundation. I have no conflicts to reveal. At
20 Markle, we've been working on both the technology and
21 policy issues associated with health information
22 sharing for many, many years. We've published many

1 public documents on a common framework both for health
2 information exchange and also for personal health
3 services. So this is territory I feel like I've
4 traveled. Thank you.
5 MS. McGRAW: Terrific. Thanks very much. And
6 now we're getting to the meat of this hearing. I want
7 to thank everyone as Gail did as well and I know all of
8 us feel deeply appreciative of your taking the time out
9 of your very busy schedules to be here and help us in
10 this important technology fact finding mission we have.
11 I think a really interesting set up for the
12 way we're going to conduct this hearing today. We're
13 going to start this morning with allowing three of the
14 companies who work have a consumer choice technology
15 product or service that they're going to demonstrate
16 for us today and each of them have 30 minutes to talk
17 to us.
18 They are accompanied by not just the official
19 representative, but somebody who actually uses the
20 technology. I'll allow you to decide how you want to
21 divide up your 30 minutes and not withstanding that
22 we're running a little late, you'll get your full 30

1 minutes. We'll beg, borrow and steal some time from
2 lunch if we need to. It's important that each of you
3 have bothered to come here today have their full amount
4 of time.
5 We'll then follow that with a little bit of a
6 break, if we're not too far off the mark time wise.
7 And then we're going to move the time for our Reactor
8 Panel. Each of you have 12 minutes as you've been
9 told. Unfortunately, that's, I think, going to be a
10 very small amount of time. But we're going to have to
11 keep you to it pretty religiously in order to maintain
12 some hope of actually ending this on time as well as
13 leaving some time after the end of each set of
14 presentations in both the morning and the afternoon for
15 some public comment. So, unfortunately, we're going to
16 have to be a little strict on that in order to be fair
17 and to get out of this as much as we can.
18 I'm going to stop talking now and I'm -- yes,
19 Joy?
20 MS. PRITTS: Just as a technical matter, there
21 is a timer. I will push the start button. You will be
22 getting a yellow light when your time is almost up and

1 then the red flashing light will come on when your time
2 is ended. We would appreciate it, if when you start
3 seeing the yellow light, you will start wrapping up and
4 if you could finish by the red flashing light, you get
5 bonus points. Thank you.
6 MS. McGRAW: All right. Terrific. Thanks,
7 Joy. Why don't we start with the first company on the
8 Agenda, InterSystems HealthShare. And I'll ask you to
9 introduce yourselves personally and go from here. Go
10 ahead.
11 CONSUMER CHOICE TECHNOLOGY IN USE TODAY
12 1. InterSystems HealthShare
13 MR. LaROCCA: Thank you. I'm Michael LaRocca.
14 I'm with InterSystems Corporation. I'm responsible for
15 the direction of our HealthShare platform. HealthShare
16 is the way that we address HIE and exchange between
17 facilities of a community.
18 MR. KWAN: Good morning, everyone. My name is
19 Tim Kwan. I'm with Manatt Health Solutions and I'm the
20 technical advisor to the Brooklyn Health Information
21 exchange where we've implemented HealthShare as both
22 our health information exchange platform as well as our

1 consent management service.
2 MR. LaROCCA: So we have a half hour. What we
3 thought we could cover in that time is some combination
4 of some slides that set the stage and then, ultimately,
5 the demonstration, which we all want to get to.
6 We'll quickly introduce the organizations we
7 represent and then we'll start to really get into the
8 meat of the presentation. What are our goals and
9 challenges overall? And we'll talk about how BHIX is
10 using the technology, how they implement their
11 policies, and how they interact with patients to make
12 it as easy as they can for their participation. Then
13 we'll get into the technology. We'll talk about
14 architecturally what we do in our consent framework and
15 then, the demonstration.
16 MR. KWAN: Great. So BHIX was really formed
17 in the fall of 2005 just to set the setting for a
18 moment. It's a consortium of hospitals, nursing homes,
19 home health providers, as well as insurers who are
20 really set up to establish a regional infrastructure
21 for clinical data exchange.
22 And, as we are a recipient of the Heal New

1 York which is based on the healthcare efficiency and
2 affordability laws in both 2006 and 2008, I think
3 relevant to this group's discussion, one of our primary
4 use cases is based on the connecting of New Yorkers and
5 clinicians. That really establishes, I think, the
6 framework in which we'll have this discussion, because
7 it gives us a use-case-driven approach to what we are
8 trying to implement.
9 As an introduction, there's three kind of
10 primary goals that the use case sets out that are
11 relevant to this group, which is providing patient
12 access to the current medication information by New
13 Yorkers, establishing patient consent, the privacy and
14 then, the permissions infrastructure that actually must
15 comply with the New York security and privacy
16 collaborative findings and recommendations.
17 Again, as a backdrop, we'll be discussing
18 those briefly so we all have a common understanding of
19 the requirements.
20 Then, most importantly, is the final element
21 which is enabling the consumers to actually establish
22 those permissions and access rights for viewing their

1 data. I realize that that's not necessarily the entire
2 goal of consumer choice, but from an implementer's
3 perspective, we needed a place to get started and I
4 think that that these three points were our initial
5 framework.
6 MR. LaROCCA: Okay. Just briefly on
7 InterSystems, we are a technology and solutions
8 provider. We've been around since 1978. We have just
9 over a thousand employees. We're really experts with
10 our focus is in data management and data integration.
11 As you can imagine, this is a topic that's
12 really close to us and something we think we're good
13 at. Of all of the industries we work in, healthcare is
14 by far the most significant to us. More than 80
15 percent of our revenue comes from healthcare and we
16 have domain expertise in this domain.
17 MR. KWAN: So just a few words and oracles and
18 challenges. There's a lot we could say here. I just
19 put a few thoughts of what we think are the key ones
20 that really stand out today.
21 For goals, I think the one goal and the most
22 important goal is to improve patient care, but not at

1 the cost of compromising that patient's privacy and
2 rights. And so we're always trying to find the correct
3 balance between making things available and having the
4 latest and greatest in technology, but at the same
5 time, keeping an eye to the patient and making sure
6 that they're protected.
7 MR. LAROCCA: We recognize and believe that
8 the patients need control over their records and should
9 decide who should see that data, how that should be
10 shared, and who could us it. We also believe that
11 patients aren't just worrying about their own data, but
12 also their dependents. I know I have a few kids.
13 They're young. I don't believe that they'll fill out
14 consent forms anytime soon, so I know that I need to
15 worry about my kids as patients as well.
16 From a technology point of view, we need to
17 offer a wide range of protection and so projects really
18 vary. Some are very simple opt-in opt-out models.
19 Some need more advanced filtering; things like
20 filtering HIV results, filtering out a deep range of
21 results, things like that. And from a technology point
22 of view, we need to be able to support all of these

1 models and offer an incremental adoption path for
2 people. And, it has to be as easy as possible.
3 Some of these challenges are on the policy
4 side; some are on the technology side. I think the
5 biggest challenge that we've run into and see in the
6 field is who owns the data. This is a big debate.
7 Does the institution own the data or does the patient
8 own the data? From our point of view as a technology
9 provider, we have to be sensitive to both positions.
10 We have to be careful that the technology be applied in
11 a way that makes both camps happy. And as policy
12 starts to settle out, that the systems could grow
13 organically.
14 As much as we want to enable and empower the
15 patients, we recognize that we've got millions and
16 millions of patients in our own country. And they'll
17 vary in skills and understanding in terms of what
18 they'll understand about the issues.
19 I think we recognize as a challenge
20 determining how you have the appropriate outreach
21 program to educate people so they are making informed
22 decisions and so that when they show up to the their

1 doctor, they don't need to bring their lawyer with
2 them. They should be able to understand the forms. It
3 should be clear and they should be able to feel
4 confident that they're making a good decision.
5 Referrals and consultations are really
6 interesting for us technically. There are use cases
7 that everyone agrees we need and are very important,
8 but it raises some really interesting consent issues.
9 For example, if I as a patient go visit Tim and might
10 give him access to see my record, but he needs to
11 consult with a peer.
12 As you mentioned earlier, does that mean that
13 Tim could send my record out to the consulting
14 physician or should I have some control over how that
15 happens? And where it gets even more complicated, I
16 think, technically, is if the consulting physician who
17 receives my information saves it in any permanent
18 sense. Then, do I as a patient need to worry that that
19 consulting physician could then share that data later?
20 And how should I as a patient control that?
21 And the last goal that I put on here, I think,
22 technically is the biggest challenge we have. It's

1 about dealing with medical vocabularies and translating
2 semantically between systems. If we all agree that we
3 need a finer level of granularity and detail filtering
4 so that if I want to take a particular medication out
5 of my patient record or a particular lab result, in
6 order for that to work technically and the most
7 foolproof way, we have to know that either the data
8 source systems or the HIE integration framework is
9 putting things in a gold standard so that we could then
10 apply the appropriate filters and take things out.
11 So that's of interest to the goals and
12 challenges that we have. Let's take a closer look at
13 how this is in practice at BHIX.
14 MR. KWAN: The approach that we tried to take
15 in putting this presentation was really to put it into
16 a kind of a story board, if you will, relating from a
17 consumer's point of view how they interact with the
18 RIOs. BHIX is a regional health information
19 organization, so it does provide a particular view in
20 the sense of we're not talking directly of the provider
21 organization taking any actions. We're really talking
22 about a centralized type of point logically, from RIOs

1 perspective, in aggregating information across provider
2 organizations.
3 So from that perspective, the goal as we
4 mentioned earlier was to take what New York State had
5 published in terms of their policies and figure out in
6 practice how we actually engage the consumer. How do
7 we actually gather the information to begin with? Can
8 we do it in enough of a scale that it would be useful
9 to clinicians and balance those types of interactions?
10 This is a whole white paper that was published
11 and could probably could take up a lot of this time.
12 Instead, what I tried to do is boil it down to the
13 points that I think the consumers are most interested
14 in.
15 In general, from an implementation
16 perspective, each provider organization in New York
17 State is responsible for obtaining and affirmative
18 consent for access. That's important to distinguish
19 them from these disclosure-based policies. And it was
20 set in statewide collaborative process that was
21 established in New York State, which I know that many
22 of you are deeply familiar with.

1 There are, of course, tradeoffs in that
2 approach including that from an implementation
3 perspective we really did need to train and work with
4 each provider organization to do the things that Mike
5 had talked about; inform the patient, really explain it
6 to them, explain it, and then, of course, capture the
7 actual values. We'll get into some views of what that
8 actually looks like in practice.
9 The second policy element that I think was
10 really important, at least from our RIO framework and
11 how talk to patients about it, is that affirmative
12 consent as a starting point really covers the exchange
13 of all information and that includes sensitive data.
14 And that's, again, a really important educational
15 point, because it means that those HIV results and if
16 there's mental health ones, your affirmative consent
17 was intended to cover all of that.
18 And then, the responsibility really we
19 embraced as RIO is to maintain what those declarations
20 were of consent policy. But then also how do we
21 actually enforce it? How do we make sure that when the
22 patient comes and interacts with us that they can both

1 see them, publish them and then also, when users are
2 coming in that we're actually as the RIO as a consent
3 service actually enforcing what was stated? And then,
4 finally, in the event that this kind of workflow does
5 not exist, make sure in the emergent situations allow
6 for a break the glass. And, again, this is the
7 baseline. This is what the New York State
8 collaborative process came up with and backing us as
9 RIOs and implementers of really, I think, a good
10 framework for us to start from. And then let the
11 actual in practice data points tell us how well that's
12 working.
13 So from that perspective, let me go into, from
14 a consumer perspective, what we needed to do is a few
15 things. As inputs into matching the consents, we did
16 need to begin with capturing consumer identities across
17 organizations.
18 I think, again, that's a fairly common concept
19 that RIO is playing where we match all these different
20 patient identifies and now we need to match those
21 patient identities with a specific consumer identity so
22 that when they declare their consent, we know who it's

1 for and that each organization that is trying to access
2 that information also in linked in.
3 The other concept that I want to make sure
4 that we bring forth is the authentication of the
5 providers. And so, again, as part of the function of a
6 RIO and enforcing these consent policies, we did need
7 to tie essentially both the provider as a user and a
8 consent as a user together. And so that's a kind of
9 leave it there in terms of the actual technology that
10 we're using.
11 And I think one important point to mention is
12 underlying all this, especially for security, is the
13 importance of maintaining an audit trail of all of
14 these interactions whether it's the user touching --
15 that the provider as a user touching the clinical
16 information of the patient or the patient actually
17 tracking and submitting their consent policy as we need
18 it to make sure we have a full record trail so that
19 people can see what has happened with their
20 information.
21 With that, we're going to jump into just a
22 quick use. These are just the headers of these

1 documents and I've included the URL for the actual
2 forms that BHIX uses. But what I wanted to start with
3 is when we looked at this, we needed a place to start
4 and I think, thankfully, in New York there were models
5 where there already were ways in which people were
6 getting good success in getting and obtaining patient
7 consent, which is a frequent challenge that I think
8 opt-in organizations feel and when they go with a opt-
9 in model.
10 In New York, in particular, the approach was
11 to reuse an underlying clinical process by which
12 provider organizations really already interact with
13 their consumers and these are all probably pretty
14 standard forms that you've seen implemented in other
15 RIOs as well. And what you're seeing here is both the
16 patient consenting to a particular organization and
17 then, their ability to withdraw.
18 Now, what this in turn actually becomes is the
19 storage of this into an actual registration system. So
20 on the next slide; we have actually the information
21 sheet that is given to the patient. And, again, we
22 talked about the importance of information coming along

1 with it. So in addition to the published materials,
2 each of the registrars are also in charge of talking
3 with the patient and explaining it them and, then,
4 finally, entering it into the information exchange.
5 And on the next screen -- and I apologize for
6 the resolution -- but this is just a very standard
7 patient registration screen and each of them will look
8 different for our provider organizations. Under the
9 Step 2, if you were to click on that, you'd basically
10 see the three values. Again, this is the starting
11 point of this, which is the baseline established and
12 just enough to get information flowing and starting to
13 flow between organizations.
14 Again, I think the key point here is from an
15 implementation perspective. What this allowed us to
16 do, these flows, is really collect the consumer's
17 information views or their consumer policies through
18 the existing process, which allowed us to actually
19 scale. And through this approach, as has been
20 experienced, I think, by many provider organizations
21 and RIOs in New York State, we get upwards of 90
22 percent yeses when the patient is asked. From that,

1 you can imagine the throughput of the patients' results
2 in a fairly good framework for access.
3 This is about as technical as it will get.
4 But I think from the point of actually submitting
5 information, it's important to highlight two core
6 concepts because this is the basis by which the end and
7 connect framework established and we adhered and
8 subscribed to in New York.
9 What we actually implemented was a
10 standardizing the actual input of consent in to the
11 exacting framework. And that sets up two actors which
12 I'll talk about briefly here.
13 One is what they call a policy enforcement
14 point. So if you think about whether you're an HER or
15 whether you're a portal or some application that is
16 trying to get access to clinical information, that's
17 considered a policy enforcement point. What happens is
18 essentially that enforcement point sends a request to
19 the RIO that says, May I access this patient's
20 information?
21 The RIO then acts as a policy decision point.
22 Taking all the consent polices that we just talked

1 about allows for it to be submitted to us in a
2 standardized manner aggregating those, tying it to the
3 patient across the provider organizations and then
4 evaluating the intersection between a provider request
5 and what the consumer has declared for each request
6 that comes in. And that's the current state of the
7 balance that we allow for from a security access
8 standpoint.
9 In general, at this level I would say the
10 implementation has been successful. We currently
11 utilize when the clinician users are trying to access
12 information through our portal or through the EMR. All
13 of those requests are routed first to HealthShare as
14 the evaluation point and they get a response whether
15 it's permitted or denied. And based on that response
16 then, the information is either shared or not.
17 I think the important point about this slide
18 is it allows for two things. One is by validating the
19 use of the ending connect exact (inaudible) policies.
20 That basically gives us a way to capture a scalable way
21 -- or capture different levels of granularity in
22 consent policy declarations, even if the technology

1 isn't able to parse and use all of them right now as
2 rules.
3 We started by mapping the existing New York
4 State rules into this framework and now as we
5 experiment and look to extend additional consumer based
6 control, I think our assessment is that this model will
7 be just fine. Naturally, on the back end we made need
8 to update additional processing rules and logic in
9 order to make sure that the consumer's views are
10 controlled. But as a standard and as a starting point,
11 it's worked just fine.
12 MR. LaROCCA: Let's go and jump into the demo,
13 recognizing the time.
14 MR. KWAN: Let's get into the technology and
15 the demo as quick as we can. This is an image that you
16 would have seen in the written testimony and I won't be
17 able to go into tons of detail speaking about it, but
18 let me at least give an overview and plant a few seeds,
19 because it sets the stage for the demo.
20 Within HealthShare there are two core
21 components that make up our consent framework. The
22 first in the consent registry, so you could just think

1 of this as where the policies are physically stored.
2 The second component is what we think of as
3 the consent service. So the service does a lot of
4 things that Tim was describing that says for this
5 particular request for patient data, let me retrieve
6 the patient's policy and let me see what is permissible
7 and then make a decision as we should disclose.
8 Within our framework, we recognize three
9 entities. The first entity is the community
10 themselves. You could think of these as the system-
11 wide policy that establishes the ground rules for the
12 whole community. Then, every data provider, what we
13 thing of as facilities, can also create a policy. So a
14 facility could say, I will share this information or
15 not.
16 And the patient, of course, can define
17 policies. What are engine does is we take these three
18 policies and at run time we marry them together and
19 merge them into a single policy that then ultimately
20 governs what could be shared or not shared.
21 Every policy has two phases to it and these
22 phases line up with what the two most basic

1 interactions within and HIE, searching for patients and
2 fetching their content. Each of these phases give the
3 policy creator a chance to opt-in or opt-out data.
4 That data could be wholesale where we could
5 say things like, I just want out of the system, I want
6 nothing shared. Or it could be something like, I want
7 free text notes suppressed because those could be
8 compromised and they're tricky to deal with. It could
9 be all lab results or it could be something very
10 detailed that could say, for example, this specific
11 medication code, I don't want to be in there; or this
12 particular result code.
13 What we thought we could do as a demonstration
14 that could illustrate these concepts is that we have an
15 HIV positive patient who wants to declare a policy as
16 follows: The primary care physician should be able to
17 see everything. In the demo, you'll see we use a user
18 called S. Farrell. Any other clinician -- in the demo
19 we have J. Torre for any Yankee fans out there -- any
20 other clinician can see data as long as it's not HIV
21 related. Technically it means that the diagnosis for
22 HIV is suppressed, any information related to an HIV

1 clinic is suppressed, lab results and medications that
2 are tagged as being HIV related are suppressed.
3 Now, our system will allow patients to decide
4 if they want to enable break the glass or not. In the
5 demonstration we'll leave it enabled so you could see
6 what that looks like. With that, let me start and log
7 in.
8 I am logging in from the point of view of the
9 primary care physician so you can see what unrestricted
10 access looks like. On thing I'd like to clarify is in
11 the demonstration we use our own screens, the
12 InterSystems HealthShare screens. But remember the
13 enforcement and the governance of these policies is
14 done in the framework as a service. If it were someone
15 else's portal that were connecting to us, the same
16 functionality would exist.
17 This is the screen that, basically, does
18 patient searches. We have one patient in here, Eva
19 Dominguez, and we've got several records. The first
20 record represents what is available from the primary
21 care office. The second record represents what's
22 available from the HIV clinic. And the third record

1 represents what's available from the hospital. So you
2 can see apart from the variance in demographics, each
3 facility that's reporting data is also declaring what
4 data they have available. Are there medications
5 available here? Are there lab results available?
6 If we click on the patient, we're presented
7 with a summary screen that just gives an overview of
8 what is there. You can see there are a couple of
9 medications, the second of which is HIV related, so
10 that's one of the things we will eventually filter out.
11 We can see that there are lab results. And HIV test
12 was performed and it's in red, that red corresponds to
13 an alert here that says there are abnormal results for
14 the test. And, in the conditions, we can also see that
15 a formal diagnosis was made by the hospital listing
16 that this patient was HIV positive. That's what
17 unrestricted access looks like.
18 Now let's declare a policy to filter some of
19 this out. We're going to come into what we think of as
20 our consent registry. Let's start simple. Let's take
21 out any of the data related to the HIV clinic. We're
22 not just talking about data within their record, but

1 even the presence of data in that record. That is also
2 compromising information. In our system, we'll
3 configure what we think of as MPI consent or patient
4 search consent.
5 So, we'll add a policy to say that we want the
6 HIV clinic -- some scroll bar issues -- now, remember
7 what we said in our demo was that we wanted the primary
8 care physician to be able to see everything, but other
9 people to fall into a different category where they
10 could only see some of the access. We're going to
11 enable this particular clinician to see it. Everyone
12 else will not be able to see it. This is a framework
13 that is really interesting because in our system we can
14 allow patients to either name an individual provider
15 that can see data or they could name a group of
16 providers, for example the cardiology department at a
17 particular hospital or they can enable an entire
18 hospital. There's a lot of flexibility in how they
19 configure this.
20 Let's save that and I'm going to log out and
21 now I'm going to log in as the other clinician and
22 let's see what this user sees.

1 You can see, we immediately present a note
2 that says some records have been filtered out. We're
3 careful not to say what's been filtered out because
4 that's compromising, but we at least let them know that
5 something is missing. If was expand the list of
6 matches, notice that the HIV Clinic is no longer
7 presents. So as far as this user is concerned, there
8 is not data, there is not encounter at the HIV clinic.
9 If we actually fetch the patient record,
10 hopefully you will notice that medication, the
11 zidovudine is no longer present. It's not there.
12 However, the lab result, the lab order and the fact
13 that the correspondent lab result for HIV is there
14 because that was reported by a different facility.
15 This was reported by the hospital. The condition that
16 actually declared -- gave the person the diagnosis of
17 HIV positive is also there.
18 Let's deal with that. In our environment, we
19 think of that as the second phase filtering. This is
20 the clinical information or the content retrieval
21 filter. We'll build that and add a new policy, and we
22 want this policy to say for all facilities.

1 We want to suppress any information related to
2 HIV. And I'll come back to that, because this itself
3 is a complex type; it's made of rules. What does HIV
4 information mean? In what we've preconfigured and I'll
5 show is that means that there's a rule for diagnosis
6 codes. There's a rule for medications. There's a rule
7 for lab results. If any of those rules match, then
8 we'll suppress the data. And that's the basic concept
9 behind it.
10 We'll make this a block accept, so everyone
11 except for our primary could see it. Just give that a
12 sanity check. Yes. That looks good.
13 Let's come through and let's research. We
14 again get our notes saying something's been filtered
15 out. But you'll now notice as the medications are
16 gone, just like they were before, because those were
17 attached to the HIV clinic. What we've also done is
18 shown that the lab order, as well as the results, have
19 been suppressed and the diagnosis condition has been
20 suppressed.
21 And it's not just suppressed from our user
22 interface. It's suppressed from any report that's

1 generated from the system. So if I come and look at
2 our summary report, this happens to be one in HTML
3 format, we support a few. But you'll notice that it
4 doesn't show up in this report. If this were to get
5 printed, it's not there. This report is not as easy on
6 the eyes and it won't tell you too many details. But
7 if someone requests that a CCD document which is very
8 popular these days for exchange, we'd also suppress it.
9 Very quickly, and this may all we have left
10 time for, I wanted to show you what the clinical
11 information types look like. I think you'll find this
12 interesting.
13 I declared a group or an information type
14 called HIV information and it had the rules, diagnosis
15 and medication test and test result. Those rules are
16 defined here. For every one of these we can say, this
17 coding scheme and this match value will fire and should
18 be suppressed.
19 I think with that, we'll end.
20 MS. MCGRAW: I'm glad to see the blinker
21 systems does work. Thank you very much. It's the
22 first time we've used this for one of our meetings. It

1 does have a very strange sound. But that was very
2 helpful. Thank you very much.
3 MR. KWAN: You're welcome.
4 MS. McGRAW: You'll have an opportunity in
5 their response to questions to fill in more I'm sure.
6 Then, before we continue we'd like to
7 introduce Christine Bechtel who managed to join us
8 during that presentation. Christine, could you just
9 very briefly give a little introduction of yourself and
10 any biases or conflicts of interest you might have on
11 this issue?
12 MS. BECHTEL: Sure. I'm Christine Bechtel
13 with the National Partnership for Women and Families.
14 We're a nonprofit consumer advocacy group based here in
15 DC and I have no conflicts that I know of.
16 MS. MCGRAW: Okay. Terrific. Let's move to
17 the next company, CMBHS.
18 2. CMBHS
19 MS. McCARTY: Good morning. I'm Connie
20 McCarty. I'm the Director of Admissions at Nexus
21 Recovery Center. Nexus is a nonprofit substance abuse
22 treatment center in Dallas, Texas and we specialize in

1 female services.
2 MR. MITRA: Good morning. I'm Debabrata
3 Mitra. I'm the architect for CMBHS project and I work
4 for the Department of State Health Services in Austin,
5 Texas.
6 MS. McGRAW: Mr. Mitra, I'm going to ask you
7 pull your microphone a little bit closer to your mouth
8 so we make sure we can hear you.
9 MR. MITRA: This is our agenda. We're going
10 to just go through a couple of details. We do not have
11 a lot of PowerPoint to show. We're going to jump into
12 the product demo which we promised to show here.
13 Again, we are not a vendor. We are the state agency,
14 Department of State Health Services. So what we build
15 is an open source product and it's in use for ten years
16 now. So we've brought in our provider from Texas so
17 she can talk about the advantage of using it, what's
18 the benefits and how it is working out there in the
19 field.
20 I'm going to just talk about what we did
21 definition of CMBHS as to what it really does and how
22 we build it and do a demo.

1 What is CMBHS? It is an electronic health
2 record. It stands for Clinical Management for
3 Behavioral Health Services. It is especially designed
4 for substance abuse and mental health patient related
5 records. But that doesn't matter; it can work for
6 primary care also. That was our focus as we built
7 that. The same agencies have just gone into
8 production.
9 We have another product called BHIPS, which we
10 build over ten years back for substance abuse only and
11 now we move to actually complete behavior health and
12 we're also trying to integrate the hospital system with
13 it.
14 We have, right now, 250 treatment locations.
15 These are not individual providers in Texas. There are
16 about 2100 clinics and locations under these 250
17 providers, who are using CMBHS. In each of these
18 clinics, you're going one to five professionals doing
19 their work. So you can see the volume. We have about
20 550,000 consumers, the patients in our system. We have
21 6,000 active clinicians using the system today.
22 This is a centralized database statewide, so

1 when they are trying to do their activities in one
2 location with the consent cards so often out of place
3 so that we can do all the continued of care.
4 Let hand it to Connie so she can talk about
5 before we implemented the IT product, how she used to
6 do her work and then we'll go back to it.
7 MS. McCARTY: I've been at Nexus for 11 years
8 and prior to CMBHS and BHIP system, we were using paper
9 consents. Frequently, what would happen, the consents
10 were lost or misplaced by the receiving provider on the
11 fax, mailed to the wrong address, the wrong zip code.
12 Medical records staff would be on vacation and so just
13 causing some unnecessary delays in treatment.
14 With the electronic consent, we have immediate
15 access to the records. We admit about 200 clients a
16 month. I've not had any objections from clients with
17 the electronic consent. The clients are eager for us
18 to receive their information, because they understand
19 the faster we have the records, the faster they are
20 able to obtain their treatment.
21 MR. MITRA: We'll switch to the demo quickly.
22 This is our product and I'm going to describe the login

1 and show you the actual activities, how is done there.
2 MS. MCGRAW: Pull that mike a little bit
3 closer to you.
4 MS. McCARTY: With the electronic consent, the
5 patients don't have to wait or spend time in the office
6 or on the phone waiting on the medical records person
7 to copy the information, waiting on the information to
8 get sent to us, we just have immediate access.
9 MR. MITRA: This is our product. I hope you
10 can hear me now. Okay. So what we do is right now, we
11 have a provider called Blue Bonnet Treatment Center.
12 As I said, we have about 250 providers and 2100
13 locations with that. So in our examples, Blue Bonnet
14 Treatment Center was the client actually presented.
15 And so they have done all the activities and I'm going
16 to be find my example client here. The provider can
17 always search whether the client exists in the
18 statewide system. Or if they don't find the client, we
19 have many options here for trying to find the client
20 and we do not expose any of the information related to
21 service. So this is just any individual in our system.
22 And they try to find out and I'm going to just

1 look for somebody with just, I know the first character
2 "J" and I'm going to search that line as Blue Bonnet
3 provider.
4 So I'm going to find the client and since I am
5 the owner of these records created in that location, so
6 I can obviously see all the records. I don't need any
7 consent from the patient. All I need is a consent to
8 treat the patient. And once I have all my activities,
9 then the patient is moved to another so our clinicians
10 at this location find out that this client has a mental
11 health problem also.
12 So when they're trying to do an assessment --
13 and the behavioral health assessments are very
14 extensive and it takes like one hour to three hours to
15 do an assessment. So it's very expensive. From the
16 State point of view, since we are implementing this
17 system where cost saving is one of the major things for
18 us, so we don't want people to do the same assessment
19 again and again statewide as the client moves from one
20 place to another place.
21 And as Connie was saying, before this product
22 was deployed and if they are using either vendor

1 products which are not connected -- different vendor
2 products as I realize they are doing facts and Excel
3 spreadsheet, but I wonder that have done before. And
4 there was not much option for them to save this
5 information in real time.
6 And right now, with this system, as the
7 provider finds out whoever the clinician working on the
8 patient, then they find out not only the substance
9 abuse problem, this is a substance abuse location I'm
10 working on, then I do see a mental health problem
11 there, then I can refer that client to a mental health
12 facility, even the client might need an hospitalized
13 and then I can send to mental health hospital. And all
14 the work I have done on that patient using the state
15 money or federal money that as the client shows up at
16 another location, a completely different provider in
17 that state, they do not have to do those work again.
18 They can see what the patient consent and we going to
19 ask the patient that what are the information we can
20 release to where you are going with the referral.
21 And patient signs that's. We fill it in, in
22 the electronic screen, and then we basically print the

1 document, the consent form and then we ask the client
2 to sign that. And the client will read the document
3 like we go to a doctor's office and we did the HIPAA
4 privacy stuff and then we sign it that we give our
5 provider permission to share our information to another
6 specialist. So similar kind of thing. We have a
7 supporting document signed by the client that we are
8 releasing this specific information. And we give them
9 specific date period that whatever activities I have
10 done at this location you can see many different
11 activities done at this location.
12 For example, we have done a screening to find
13 out what's the basic problem with this client. We have
14 done a treatment by assessment, you know, a detailed
15 assessment and then we have done some treatment plan,
16 how we're going to fix the problem and the issues.
17 And so that (inaudible) plan and assessment
18 can be shared with other providers. So if it is within
19 our domain, for example, behavioral health providers,
20 then they do want to see the detailed assessment done
21 by the other providers. But if it is primary care
22 physician, they might not be interested looking at the

1 entire assessment, three hours of data capturing. They
2 may be interested only in the diagnosis piece of the
3 assessment.
4 Depending what the other providers want to see
5 and what client wants to release really drives all
6 those. So any (inaudible) information service is
7 provided and medication order added, all this stuff,
8 all those can be shared with the patient's permission.
9 So I'm going to go to the consent screen. And
10 this is the way our consent screen looks like. So we
11 have the disclosure information, who's actually
12 disclosing. Disclosure is basically the provider, not
13 the client here. And they're facilitating the
14 disclosing -- disclosure. So they have the information
15 over there on the top. And then, we have the
16 disclosure where the provider will sending the target
17 provider who is receiving the information from us.
18 Again, we don't individual practitioner level
19 consent. We can do that definitely, but this is at the
20 location at the treatment center level. So we give
21 access to a specific treatment center. Then, if there
22 are multiple clinicians working over there, all of them

1 get the access. But they do have the -- what do you
2 call -- the qualifications and the credentials to work
3 on those specific client.
4 And then, we have an expiration date. We give
5 very specific date that you can always say that all the
6 records client consent. I want to give all the
7 records, no specific dates. Our client also have an
8 option saying September 1 to October 30th for all the
9 work done at this location I want to release. And
10 these are the specific information I want to release.
11 The purpose of the release, a person can also select
12 saying continue to have care is the purpose of the
13 release.
14 This is a consent already done, but if I go to
15 a brand new consent, you can really see the options for
16 them to select. And here they can select the provider
17 they are trying to send the consent to. And if I put
18 in an expiration date and if I say, no, I'm just going
19 to just do specific dates, then it's going to ask me
20 the begin date and end date I have to enter. I can
21 select specific segmentation. As you know, you all are
22 talking about how to segment that consent information.

1 So we have done it like nine or ten years now.
2 Within assessment, we have ten different
3 sections within assessment. Like the general section,
4 we have a psychiatric section, we have substance abuse
5 section, we have mental health sections,
6 education/employment section, all those are part of the
7 assessment. So you can give access to the client -- I
8 mean give access to only a specific clinician's reading
9 or something to the other provider and block all other
10 sections of the assessment. That's the way we have
11 implemented the segmentation.
12 And we also have a nice -- what do you call --
13 workflow within our systems and these are pretty
14 standard within the viral health industry that the
15 activities we have defined. And so we try to control
16 the segments pretty much map to the clinical activities
17 done with now -- or business workflow. So we know
18 (inaudible) is one activity, screening is one activity
19 and discharge plan, lab results, the medication order,
20 many things like that, service authorization.
21 And so that is the detail of the consent form.
22 And then, we have different reasons why the patient is

1 really giving access to the other provider, whether
2 it's a payment related thing, it is a referral, or is
3 it continue to have care which is a most important
4 thing for us. As you can see from the State
5 perspective, we have this 250 or 300 facilities or
6 clinics providing services in State of Texas and we
7 don't want them to duplicate the work as I said before.
8 That's one thing from the cost perspective. And from
9 the clinical perspective, we want to make sure that the
10 physicians; they have the information they need from
11 the other providers.
12 And one perfect example will be if there is a
13 mental health patient and the physician ask what kind
14 of medications you are taking currently, but you cannot
15 rely on that information where the patient is giving
16 you what medications they have, at the time, they might
17 not even remember the name of the medications.
18 And so, if you get the assessment and the
19 medication order from the other providers, so it is
20 very useful and State pays for this medication.
21 Obviously, we want to make sure what they are getting
22 are there and there is some accountability for it.

1 So from continue of care as well as from the
2 cost perspective, it is very important for us. This is
3 system is basically of no use for us if it is all
4 states locally and we cannot send it out.
5 And, Connie, you probably want to add
6 something to it.
7 MS. McCARTY: This consent is usually good for
8 a year, like Mitra said with the expiration is there on
9 the consent form. The consent, though, can be revoked
10 at any time by the patient without giving us any type
11 of explanation when the patient says she wants the
12 consent to be revoked, we revoke the consent
13 immediately. And then, at that point, the receiving
14 provider does not have any further access to the
15 records.
16 And like Mitra said, the patient is able to
17 determine to choose what information is to be released
18 for whatever particular days the information is to be
19 released and certainly to the provider.
20 MR. MITRA: And there are a couple of other
21 things, in the State of Texas, we also have about 75
22 drug courts today. And these drug courts, you can

1 pretty much cannot look at any of the patients' record
2 real time without a consent. So we have thousands of
3 treatment providers and we have 75 drug courts. But if
4 these clients are referred by the drug court, and the
5 judges -- they -- obviously nobody is entering any data
6 at the drug court level. All the treatment services
7 are happening at that (inaudible) provider level. But
8 for the (inaudible), it is very important to see a
9 client who is making any progress or not, there are
10 data for the client to a different provider. And as
11 many providers, probably, there's a coordination of
12 care going on depending on what judge decide to send
13 the client or patient to different places. May need
14 one provider or multiple provider in State of Texas.
15 And so the way it works that the treatment
16 provider is going to give using the same consent form
17 all the work they do and, again, with the patient's
18 consent, that what information judges can see to the
19 drug court. So all the 75 drug courts can very nicely
20 do the coordination of care just sitting in their
21 office and looking at that, so no fax, no phone call,
22 no paperwork there. Everything is all electronic

1 statewide.
2 And there is another program from (inaudible)
3 from the federal agency called Access to Recovery
4 Program. This all depends on, again, coordination of
5 care. We have many players play a role in that process
6 that as a patient come in, this federal program where
7 we, if remember that, like $2500 you basically give all
8 to the patient. And the patients have an option to go
9 anywhere in the state and spend that $2500 for their
10 treatment.
11 And so, they go to an assessment provider
12 first and the assessment provider going to and they
13 don't do the treatment at all, they just do the
14 assessment. And they're going to identify all the
15 problems and they will identify what other services,
16 number of units they need for services. And when they
17 do that, they will have statewide for each of the
18 service, they will know that who provide the service in
19 State of Texas for that specific service. And then
20 maybe five or maybe ten of them. And then, patients
21 see sitting in front of them that they will ask the
22 patient, tell me which provider you want to go to for

1 this specific service.
2 And so, when they do the assessment, they go
3 and select the specific provider for a specific service
4 and once it is done, the we also ask the patient to do
5 a consent, because all the assessment and financial
6 ability information and the screening done by the
7 assessment provider, that information needs to go
8 immediately to the other treatment provider. Otherwise
9 they'll be a huge delay when the patient actually done
10 the assessment maybe in Houston and now the treatment
11 based they chose is to go Austin, maybe. And so the
12 Austin provider by the time patient shows up in the
13 Austin provider, the data is already there. And so
14 they see the children provider will see the assessment,
15 will see the voucher for $2500. And all the service
16 providers are actually competing for that $2500.
17 So without a coordination of care, without a
18 consent in place, there's no way you can even implement
19 that. If it all manual process, how will you know who
20 is spending the money? That $2500 is a first come
21 serve basis. This is something we have been building
22 for more than ten years now. All these new programs

1 coming from the federal agency as well as some Texas
2 generated programs are working out very nicely for us.
3 We didn't have to build anything new.
4 With the centralized database, where
5 everything is connected, allows faster data processing.
6 But once you get to the data exchange fees -- many of
7 our providers are very big and they have their local
8 vendor's products. We're trying to integrate with them
9 and when you do that, that is an extra challenge than
10 doing just a website and consent form.
11 Right now, we are working to integrate
12 consents with these vendor products so that we can
13 exchange data with them. The consents are in our
14 database when the patients have entered through our
15 provider. It's not a big deal from the IT point of
16 view to do this integration. We know how to post that
17 data to the vendors, depending on what level access
18 they already have. But we're still working on the
19 legal piece of it pertaining to the data exchange and
20 then storing everything in one database.
21 MS. McCARTY: With the immediate access to
22 records, our clinical and medical staff is able to look

1 at prior treatment, which means that we don't have to
2 repeat expenses and unnecessary treatments or tests
3 that have already been tried or conducted.
4 We are also able to start our treatment
5 sooner. The treatment team is able to develop the
6 diagnosis and start the treatment plan sooner. We've
7 seen that the immediate consent has been very helpful
8 in the hand off transition between providers, which
9 assist in the continuity of care.
10 We've also seen an improvement in the
11 effectiveness of communication between the team members
12 who are located at different locations.
13 The immediate access to patient records have
14 been extremely helpful for patients with altered mental
15 statuses and also with those who are cognitively
16 challenged and who are not able to verbalize their
17 issues. Also, we've seen that this has been really
18 helpful with patients with medical and mental health
19 complications who are not able to remember the
20 medications that they're on or who are on medications
21 that sound a lot like other medications. It's been
22 really helpful in preventing errors. For example in

1 those situations where the client comes in and tells
2 you she's on one medication, when actually, she is not.
3 MR. MITRA: That's pretty much it. So from
4 our point of view, we built this and as a State agency
5 we want to make sure our providers are happy if
6 something works for them. When we built our first
7 product with the consent, ten or twelve years back.
8 There were some major concerns from our providers and
9 our state agency as to how all these things were going
10 to work out. Slowly we chose our providers through our
11 provider association actually in order to make sure
12 that we are not biased and we've gotten users who are
13 very happy with our product. We asked our vendor
14 association, the provider association, to go ahead
15 choose whoever you want to come to this meeting so that
16 you give us an opinion about your experience, whether
17 it's bad or good.
18 Honestly, there are a lot good things and some
19 bad things, but in terms of consent, I asked Connie
20 this morning how many patients really deny this
21 consent. There's no point in building consent if in
22 100 percent or 90 percent of the cases the patient says

1 I'm not going to give you the record. Then all the
2 data would stay local. Having a connected system with
3 consent doesn't help if the patients do not give the
4 consent to share the data.
5 Providers tell me that over 90 percent of the
6 cases and in some places 100 percent, patients are
7 giving consent and not denying the information. The
8 patients think that there is a benefit to them for
9 sharing the data. That's a key point for us. We're
10 happy hear that as you are, probably, that the patients
11 are not denying that information. Of course, if the
12 patient denies, then in our system, there isn't much we
13 can do.
14 We can duplicate records in our system. It
15 only happens in 5 percent, maybe 10 percent, where
16 duplicate data entries are happening in our system. We
17 are losing money on that. But 90 percent improvement
18 is a big improvement from the state point of view and
19 we do believe that we are very effective in sharing
20 data and contributive care from the cost as well as the
21 clinical perspective.
22 That's pretty much it from our point of view.

1 MS. McGRAW: Okay. Terrific. Thank you very
2 much. You've given us some time back and we'll be sure
3 to use it wisely. I very much appreciate it, thank
4 you.
5 Now, let's move to e-MDs Solution Series
6 Chart.
7 3. E-MDs Solution Series Chart
8 DR. STEARNS: Thank you very much. I'm Dr.
9 Michael Stearns with e-MDs.
10 DR. MILLICAN: I'm Dr. Troy Millican. I'm a
11 family physician in Columbus, Texas.
12 DR. STEARNS: We'll start out with some brief
13 introductory remarks and then we're going to right to
14 the demonstration. And then, as time allows, we'll
15 discuss some of the challenges from a developer's
16 perspective.
17 Thank you very much for inviting us here
18 today. We're honored to be here. As I mentioned, I'm
19 Dr. Michael Stearns. I'm a physician by training. I'm
20 currently president and CEO of e-MDs. We're an
21 electronic health management software and services
22 provider. I also serve as a president of Texas e-

1 Health Alliance and it's nice to see Texas is very well
2 represented here today.
3 The Alliance is a nonprofit policy and
4 advocacy body that is among other activities examining
5 consumer consent policies at the state level, which is
6 very important right now.
7 With me today, is Dr. Millican, who graciously
8 agreed to accompany us today. And he's actually to
9 provide the demo and give perspective from the provider
10 standpoint on how these tools are used. This, I should
11 mention as well, this is going to be focused on the EHR
12 level, not the HIE level to show how the physician can
13 be an advocate for the patient in privacy matters.
14 We appreciate being given the opportunity to
15 share approaches to managing sensitive patient
16 information. As we'll demonstrate, we have tools of
17 EHR that allow providers with specified privileges to
18 segment information that they deem as sensitive or
19 confidential. This information is either hidden
20 completely or blocked from being viewed in both the
21 internal and exported versions of a given document.
22 Consumers, that is, patients and their

1 designated representatives are given the ability to
2 export their accounting of care record from the patient
3 board or with or without the information that's
4 specified as confidential. The MEs agrees with
5 conclusion made in the consumer consent options for
6 electronic health information exchange, policy
7 considerations and analysis document created for the
8 ONC by Melissa Goldstein, JD, and Allison Rein, M.S.
9 We feel a great deal of research is needed to
10 return best practices to allow for appropriate consumer
11 controls of protected health information. In our
12 opinion, the policies that evolve around these
13 challenging areas will need to take into consideration
14 the impact and workflow, the level of consumer demand,
15 patient safety issues, administrative requirements,
16 local polices and requirements, and significant
17 educational techno-challenges surround the successful
18 implementation of consumer consent mechanisms.
19 We anticipate to the level of consumer
20 interest in having control over health information will
21 become much greater as the HIEs take on a greater role
22 in healthcare. For this reason, we are motivated to

1 contribute to efforts to move these policies forward
2 and to whether it protects each consumer's right to
3 confidentiality without compromising patient safety or
4 the appropriate use of healthcare data for research,
5 efficacy of current therapies, biosurveillance in
6 public health.
7 Dr. Millican and I will provide the
8 demonstration showing the tools we use during patient
9 care and in the written testimony, there are some
10 screen shots walking through this for people that
11 aren't attending the meeting today.
12 I'll turn it over to Dr. Millican.
13 DR. MILLICAN: All right. Thank you. I think
14 that there's been some really valid points brought up,
15 up until now, and I think that Mr. Mitra's discussion
16 of the fact that really in practice, not many people,
17 if anybody, really doesn't want their information
18 shared with their other health care providers. And
19 delving more into the topics that were brought up
20 earlier, not many patients even with sensitive
21 information are really wanting their disease processes
22 blocked from other doctors that are taking care of

1 them.
2 But I want to show you some things that are
3 ways that within this software as one example that we
4 use on a daily basis to block some of those things. If
5 you look at the screen, this is just an example of the
6 way that the office visit shows up as you're actually
7 seeing the patient. This is a gentleman with HIV
8 disease and tension headaches and he comes in for those
9 two things. This is medications over here on the left
10 hand side. This is problem list up here at the top on
11 the left.
12 One of the things that you can do as the
13 physician at the time that you're taking care of the
14 patient and you realize that this is a disease this
15 gentleman may not want to be shared with other
16 providers or it's confidential or somewhat
17 confidential, then you can block it with just this lock
18 thing up here. And that shows the locked content as a
19 big giant black box, which really looks pretty nasty on
20 the screen. And if you notice, if we were to go over
21 and look at the visit note and the way it looks, this
22 is the way it would print out. You would actually have

1 these big black boxes around the things that are
2 confidential.
3 The way that it's actually gotten in there are
4 through the template process. And those templates are
5 made confidential on those particular disease
6 processes. It's a confidential template and you tell
7 the record to hide those confidential templates by
8 clicking the little lock button.
9 As we show you another example, this is a
10 gentleman with anxiety disorder and panic attacks and a
11 history of drug abuse. He may be a fine upstanding
12 citizen at this point in time, but he's used heroin and
13 cocaine in the past, doesn't necessarily want that
14 information known out and about in the hospital or
15 whatever. So those things are also able to be made
16 confidential.
17 Really as a doctor, everything is
18 confidential. Everything that my patient tells me is
19 treated the same way as drug abuse or HIV or any other
20 condition. And we don't share anything without the
21 patient's consent. I understand the concern with the
22 information technology and the fact that it's so much

1 easier to access it.
2 So to give you an example that's really closer
3 to home and something that happens on a more frequent
4 basis in my office-- as a fairly big multi-specialty
5 practice most of our employees are also our patients.
6 It's so much easier to just go into the computer and
7 pull up anybody's chart that you want to rather than
8 walking to a records file room and pulling the chart
9 off the shelf. You're not going to go do that because
10 there are eyes that are going to see you. But you can
11 look at the computer from anywhere.
12 The way that you can actually block the chart
13 from specific people and say that this gentleman was
14 clinic employee, well, he wouldn't want his colleagues
15 to know that he has HIV. And so, you can actually
16 block the chart from particular users.
17 All of these on the right side are excluded.
18 These on the left side are allowed to use it. The way
19 I use that in particular practice is when I'm seeing a
20 patient that's also a clinic employee, I'll allow
21 basically all of the doctors access to the chart and a
22 few of the nurses that are nurses for the doctor that

1 the person is going to see on a regular basis and
2 excluded all the other ones, even, perhaps, the medical
3 record staff.
4 Sometimes that can be problematic, because
5 then if the patient needs a referral to somewhere, they
6 have to come in and ask you to please unlock it. And
7 another thing I did once where the default was to allow
8 the user and I excluded, actually thinking I was
9 choosing to allow people and actually excluded the
10 people that I wanted to allow. The only people that
11 could look at the chart were the people that didn't
12 need to. We had to fix that.
13 There's definitely human error always as a big
14 possibility. You live and learn.
15 That's a much more common use of chart
16 security from my practice standpoint. Like Dr. Stearns
17 said, most of the health information that we're using
18 in this particular software is all within the clinic.
19 It's not out there in health information exchange as
20 yet. There's got to be a way to reconcile how to work
21 the data to show that these things are confidential.
22 Another thing I'll show you is the way that

1 this can show up on a problem list. You can actually
2 print the problem list with the confidential
3 information showing up as confidential basically like
4 this black box, or you can print the problem list as if
5 that confidential information never existed. You can
6 print the whole health summary or the hidden health
7 summary -- actually the whole health summary and it
8 asks you while you're printing it. The regular health
9 summary actually shows that there are confidential
10 items out there, confidential medications, and it's got
11 some things actually still blocked out, whereas if we
12 printed the hidden health summary, if the patient were
13 going to take this over to the hospital for some
14 testing or whatever, then it doesn't raise big red
15 flags because it just acts as if that doesn't exist.
16 As a practicing physician, that's a little
17 concerning from a safety standpoint, because you've got
18 this person onto antiretroviral HIV medications that
19 have all kinds of side effects with everything else and
20 they're as if they didn't exist. Then you're back to
21 relying on the patient to remember what medicine
22 they're on and to tell their next provider, oh yeah,

1 I'm also on this medicine and this medicine and this is
2 the dose, which not every patient can remember.
3 And then as we can export the data through the
4 CCR and eventually the -- what's the new one going be?
5 -- CCDs, which is the way to send the data to the
6 health information exchanges. Once those things are
7 more fully utilized, you can export the full CCR or the
8 confidential CCR. It's actually a tricky name, you
9 think the full CCR is everything, but the full CCR is
10 -- the confidential CCR is everything.
11 DR. STEARNS: And that's how we looked to the
12 HIA and very soon the CCD as well. They're the same
13 mechanism. So the provider will the choice as to
14 whether or not it will go with or without the sensitive
15 information.
16 Now, from the patient portal, they have that
17 choice. The patients have the choice which version to
18 pull and to send. And the patient's do not have a
19 direct choice in the EHR as to what is segmented. They
20 could do it in the PHR, of course, but they do have the
21 ability to ask providers to segment certain information
22 if they want to.

1 DR. MILLICAN: I think I've shown you
2 basically, the way that I use this in a clinical
3 setting and I'm sure that there will be more questions
4 later on.
5 DR. STEARNS: What I'm going to do is in the
6 time remaining and hopefully we'll finish early is back
7 on track. I'm just going to touch on some of the
8 issues that we're facing right now related to privacy
9 as the EHR development organization.
10 Of course, we have to deal with requirements
11 that are evolving right now which everyone's seen a
12 little bit, of course. And they're at the federal
13 level, which we have to take on first. And then, the
14 state requirements, so the states have a variety of
15 requirements for privacy management which we have to
16 address. And also, these are evolving and they're
17 likely going to change once the federal policies are in
18 place. There's some major challenges for developers.
19 Provider education issues. We do not see a
20 large uptake of this tool. Some docs when they hear
21 about it think it's pretty nice. They just don't use
22 it. It's not really in demand right now. So most docs

1 are not exporting data. They're not required to and
2 everything is kept internally. They do report claims
3 data, of course. But they're not really asking for
4 this.
5 A few people, many years ago, did ask for this
6 functionality that for certain situations is very
7 valuable. But I think a lot of systems have not really
8 added (inaudible) as high priority as it would be if
9 the patients, consumers and providers really wanted it
10 badly. Of course, it becomes part of a certification
11 that we'll push as well.
12 Consumer education issues. One of our
13 concerns is that we reach out to consumers and give
14 them and give them a choice, they're going to become
15 alerted to the fact that, wow, I realize that was going
16 on, how much of my information is out there already.
17 So we're going to face some very significant consumer
18 education challenges. Also, at what level -- what
19 consumer issues are going to arise when we give them
20 all this complex data management if we allow them to do
21 segmentation? Is there going to be a provider role in
22 helping and assisting the patients or are many patients

1 going to turn this over to the providers and just say,
2 you take care of it for me, please, I trust you?
3 Workflow considerations have been touched on.
4 If we're going to grant segmentation, is that going to
5 be in the waiting room? Where is going to occur? Is
6 it going to occur before the patient comes into the
7 portal, etcetera? Is that going to impede flow in the
8 clinic, sharing the information, etcetera? I think
9 that's been looked at a few places, but I personally
10 think that it needs more research.
11 And then patient consent implications are
12 probably the greatest concern right now and there's two
13 side to that which we'll touch on. And then there's,
14 of course, technical limitations on how we're going to
15 do all this.
16 I touched on requirements already. There are
17 some are EHR specific, some are health and base
18 exchange specific, some are PHR specific, etcetera,
19 etcetera. So there's a lot of moving targets out there
20 for development organizations.
21 Then the evolving state requirements as I
22 touched on before and there's also local governance

1 issues. There are certain HIEs in communities which
2 are going to require certain features and functionality
3 based on their local governance policies. So that's
4 another challenge for the industry.
5 And then provider education, the providers are
6 generally not very much in tune with privacy related
7 issues. They're familiar with paper records, but not
8 that familiar with digitized patient data, how easily
9 it's shared, data ownership issues. Very often the
10 docs are really not aware if the information they're
11 gathering is being used by someone else for another
12 reason. They're not aware of federal and local
13 policies and requirements. There is a very low uptake
14 of docs awareness of new guidelines that have been
15 enacted. And then, they're not really aware of the
16 army of people that see even claims data right now once
17 it's released.
18 So that's part of what we have to do, is
19 educate them, because now we want to start introducing
20 -- we've got claims data right now, which is -- I think
21 actually has 15,000 concepts. SNOMED, once that gets
22 going, is 400,000 concepts so we have incredible

1 granularity of data that we're going to have to address
2 and it's going to create more challenges.
3 And the other thing is when people have a bug
4 in their software, they'll of course do the screen
5 capture tool. Unfortunately that screen capture tool
6 and they'll send an email through an unprotected,
7 unsecure vehicle. And in that screen shot, it'll have
8 patient sensitive information. We've had people see
9 and recognize people they know. This is a big problem
10 too in the vendor organization because they've often
11 gotten to deal with local people or otherwise you could
12 come across people you're aware of. So we have to have
13 policies in place at the vendor level within the
14 company how to deal with that. And we ask and a we put
15 a message everywhere, please do not sent screen shots.
16 The first person who sees it has to know the policy is
17 don't send that around to the developers and say what's
18 wrong. Here's the error message. Let's go ahead and
19 remove that -- type it up. Those are some of the
20 challenges you run into at the vendor level.
21 Then source of accurate information. There's
22 a lot of information on the internet right now. Some

1 of it is actually accurate regarding patient policy and
2 issues like that. There's a lot of information which
3 is of great concern to patients. Again, a lot of
4 people very upset and they hear something and they
5 don't interpret it quite correctly. So the use of the
6 grant (inaudible) materials we touched on already. And
7 then healthcare utilization concerns once patients, as
8 I mentioned earlier, become aware where their data is
9 going, they're like holy cow, what am I doing? I'm not
10 telling you anything, doctor. And then the other thing
11 is, really how do you convince patients who really may
12 not have the kind of background to understand the value
13 of what we're doing with HIT?
14 To everyone in this room, most likely, they're
15 very familiar with the value of HIT, but the patients
16 are not there yet. We have too really raised that with
17 consumers to sell them on this concept and therefore,
18 they might be willing to contribute their information.
19 Workflow considerations, of course, the full
20 impact of consumer enabled segmentation data workflow
21 needs to be determined. Ideally we could have this
22 perfect system where patients would make their complete

1 determinations and it would never impact patient care.
2 It would never impact workflow. But unfortunately,
3 although theoretically, I think it's worth evaluating,
4 I think we really have to look at it many different
5 ways before we're ready to go forward.
6 What percentage of patients will use
7 segmentation tools given the option? A lot of patients
8 have expressed interest in this, but when they're
9 actually presented with the ability to use these tools,
10 will they use them?
11 Is this going to be predominant in a certain
12 demographic? Is a 35 year old computer programmer who
13 works for an EHR company going to have the same level
14 of interest in segmentation as someone who's retired
15 and really has, in their opinion, nothing to hide? We
16 do have to look at that as well.
17 Then, how will providers react to this process
18 that's introduced in their clinic, especially if it's
19 mandated? Patients have a fundamental right to
20 privacy. I'm sure we'll agree to that. A physician
21 should do no harm. Sharing patient information in the
22 wrong setting might compromise patient employment and

1 then may compromise patients in social venues. There's
2 many examples of that have been cited by other people
3 in room who are far more familiar with this topic than
4 I am.
5 MS. MCGRAW: Dr. Stearns, you're getting
6 carelessly close to getting yellow carded. Try to
7 stick to the technology if you wouldn't mind.
8 DR. STEARNS: Okay. All right. Providers
9 central viewpoint, it is policy and technology. I'm
10 sorry, they cross over a little bit. It's difficult to
11 determine when and where the cutoff should be. So we
12 can provide tools to do this. But to give you an
13 example, many years ago, I was seeing a patient who was
14 HSV2, general herpes positive and I opened her chart
15 and I'm a neurologist. I'm seeing her for headaches.
16 And she burst into tears because she realized the first
17 thing I could see in chart this herpes status and it
18 was very embarrassing to her. I didn't really need to
19 know that in that setting. However, if she came in
20 with a seizure or something like that and they were
21 related to herpes virus, I would need to know. So
22 there's all kinds of challenges there on the policy and

1 technology side as to when the information is needed.
2 It's very difficult to predict ahead of time when that
3 data should be blocked from certain view by certain
4 providers.
5 And then also we have to convince the
6 providers what the data is need for. And I thought
7 this was an interesting quote, "In order of us to be
8 able to get the information the patients, they have to
9 trust us." So they have to be sure the information is
10 confidential and this is a quote from Henry Maudsley,
11 which talks about semantic disorders, semantization
12 disorders. But if the patients feel compromised from
13 sharing their medical history, they could suffer
14 injury.
15 Safety considerations. If the consumer
16 controls were removed, the patient is, as I mentioned,
17 less likely to report a mental health history,
18 etcetera, which has already been covered. I'll skip
19 over that.
20 Patients of impact are likely of seeking
21 medical care. Then if consumer controls are fully
22 enabled, patients determine what information will be

1 shared. We've covered this already, but just to touch
2 on it again. We have to come up with a lot of very
3 precise rules and it's really such a huge challenge.
4 There are two opposing stances. One is the consumer
5 having the right to control everything and then will
6 that impact patient safety down the road? Okay. Just
7 in time.
8 Anonymousation, can it really be achieved?
9 And I probably should spend more time on this slide
10 based on the yellow card. But at any rate, that's
11 covered in much more detail by other people who are far
12 more familiar with it than I am. There are some major
13 challenges through anonymousation. There is a sense in
14 the provider community that as long as it's anonymized
15 then we're fine with it.
16 However, there are some real significant
17 issues surrounding anonymousation where I think some
18 people have basically given up on it as never being
19 truly achievable. And that's going to be a bit of a
20 hard sell, I think, to providers and to patients, that
21 we can't truly block their information. There may be
22 people that have a different opinion on that.

1 And then to touch just touch briefly on this.
2 Those are the challenges so large systems may have
3 difficulty processing disclosure reports. We've run
4 into challenges from some medical centers when they run
5 a report to see who was touching these patients
6 records, it actually shuts their system down for
7 several minutes, which for hospital-wide can be a major
8 challenge. And that's to do with the development of
9 technology but it is dealing with legacy systems can be
10 a challenge.
11 Prioritization for vendors. This, as I
12 mentioned, these are not tools that our docs are asking
13 for. Their patients aren't asking for it either. So I
14 assume this would become a much greater priority, but
15 we do have a lot of things on our plate right now to
16 address on the development standpoint. We have a
17 certain amount of development bandwidth so we do need
18 some prioritization guidance on this for how it's going
19 to impact and whatever is determined by the policy
20 bodies and the regulatory bodies, we have to look at
21 the impact on the providers as well.
22 That's all I have. We'll have some time for

1 questions later, but I promised to finish early and I
2 did. Thank you very much.
3 MS. McGRAW: Thanks to this panel. It's
4 terrific. Thanks to each of you actually. Back on
5 schedule. And so we're going to per our agenda take a
6 break. But we are going to start promptly with our
7 reactor panel at ten. So please don't go far. And we
8 definitely the three companies and their users and
9 representatives back for people to answer those
10 questions and then the Tiger team questions will follow
11 from there. Thank you.
12 (Recess.)
13 MS. McGRAW: We'd like to ask people to please
14 come back into the room and get seated, especially the
15 people who are on the respondent panel, the discussant
16 panel.
17 Thank you all for promptly taking your seats.
18 That's actually quite good.
19 I want to briefly introduce our reactor panel
20 in the order of the agenda. Before I do that, we are
21 joined by another member of the Tiger Team, Latonia
22 (ph) Sweeney. So go ahead and give us a brief

1 introduction of who you are with slightly more detail
2 than we do in our usual meetings including your
3 interest in the topic and if you have any conflicts to
4 report since this is kind of a new audience. Some of
5 these folks are not our usual audience members.
6 MS. SWEENEY: My name is Latonia Sweeney. I'm
7 a professor of computer science technology and policy
8 currently related to three schools, Carnegie Mellon,
9 Harvard and MIT. I've done a tremendous amount of work
10 in privacy technology and in data privacy and in
11 particular finding these sweet spots where a lot of
12 times the clashes between new technology and
13 established privacy concepts clash and technology and
14 so forth can make the difference.
15 Perhaps many of you in this community probably
16 know me on the other side that and that is exposing
17 vulnerabilities and so forth through re-identification
18 experiments and things like that.
19 In terms of conflict of interest, I don't
20 think I have any conflict of interest, but I certainly
21 do have patents in companies in privacy technology
22 space, none of which I think is appropriate to this

1 community.

2 MS. MCGRAW: Thanks very much, Latonia. We

3 have a very distinguished reactor panel to ask the

4 first set of questions and again, each of you is

5 limited to 12 minutes. There are detailed biographies

6 for each of them in the handouts for this meeting. But

7 I want to briefly who each of them is and then allow

8 them to begin.

9 The first panelist to makes remarks is Dr.

10 Deborah Peel, who is a practicing psychiatrist and

11 she's the founder of Patient Privacy Rights.

12 Melissa Goldstein is an associate research

13 professor at the Georgetown Washington University

14 Medical Center.

15 Ioana Singureanu is the co-founder and CEO of

16 Eversolve, LLC, which is a healthcare interoperability

17 consulting practice.

18 Dr. David Kibbe, it's unclear which one of

19 these I should pick. You have so many on here. But he

20 certainly has served for many years as a senior advisor

21 to the American Academy of Family Physicians.

22 And Jim Walker, who serves as the chair of the

1 Medical Informatic Subcommittee of the American College
2 of Physicians, is with the Geisinger Health System.
3 So, Dr. Peel, why don't you start?
4 CONSUMER CHOICE TECHNOLOGY IN USE PANEL DISCUSSION
5 DR. PEEL: Thank you. How's that? First of
6 all I want to even though he's not here yet, I want to
7 thank Dr. Blumenthal and I want to thank Joy and her
8 terrific staff for working so hard to make this happen.
9 This is an historic first look for consumers
10 and patients at what health technology actually looks
11 like and how it works, what the state of health
12 technology is today and what is could be tomorrow.
13 This is particularly critical that patients and
14 consumers in all of the states get to see what really
15 can be done now, because all of the states are getting
16 money now. And people need to be able to know that
17 there's great solutions that enable the data to go all
18 the right places, enable us to protect it from being
19 used against us and to share it for all the ways that
20 they want to.
21 So this is really historic and exciting.
22 It'll be a massive resource for the states and I hope

1 everyone talks to the patient and consumer groups back
2 in there home states and tells them about this resource
3 where people can begin to actually learn about these
4 systems.
5 In terms of my biography, Patient Privacy
6 Rights has 10,000 members. The Coalition which is
7 bipartisan for patient privacy has 10 million members.
8 We represent the views of the majority of the American
9 Public who want control over their information in
10 electronic systems.
11 So in terms of talking about conflicts, I just
12 want to say as you listen to people that talk today, I
13 hope the audience and I hope everyone here tries to
14 think about their point of view and where they're
15 coming from, because it's often not clear. So I want
16 to talk about the fact that our point of view and what
17 we represent is crystal clear. We are working to
18 restore your control over the most sensitive
19 information that exists about you on earth and we want
20 to see technology be used to strengthen and improve
21 controls, not eliminate them.
22 And so, you can look on our website. You can

1 look on the websites of all the people and all the
2 companies that are here and you can see what they stand
3 for and what they do. Conflict is not just about who
4 pays you, who you sold your company to, who you're
5 working for, but it's also about your principles.
6 We have so little time. So I'm going to do
7 Joy Pritts and I'm going to say I've got questions for
8 all of you, so I hope you'll try to be brief, because I
9 want to ask all my questions. And we'll see how we do.
10 I'm probably not as good as you Deven, or you Joy at
11 managing things, but I'm going to try.
12 So first I want to start with InterSystems and
13 I want to point out the amazing positives about what
14 InterSystems says that it can help and do for Health
15 Information Exchange. That people can be able to
16 choose whether they release their data to a hospital,
17 to a hospital department, to a doctor. They can choose
18 to decide whether they want to share allergies,
19 diagnoses, medications and so forth. And so that's
20 really amazing and wonderful to hear.
21 So I have several questions about
22 InterSystems. Mike, what percentage of healthcare

1 systems use your cache database today in the U.S.,
2 would you estimate?
3 MR. LAROCCA: That's a good question. I mean
4 the underlying cache database is used throughout
5 healthcare. We would argue it's the lead in the
6 database in healthcare technology.
7 DR. PEEL: Okay. Range?
8 MR. LaROCCA: I don't know. I'd have to say
9 it's probably two-thirds of the systems in some way
10 shape or form have cache.
11 DR. PEEL: Okay. So that means two-thirds of
12 the systems in the U.S. could provide the kind of
13 consent and controls over who sees the information and
14 what information like you just described in your
15 presentation. Is that correct?
16 MR. LaROCCA: Yeah. I mean from my point of
17 view.
18 DR. PEEL: Using that database, the database
19 would enable that to happen?
20 MR. LaROCCA: Yeah. In a sense, our group,
21 HealthShare group, if you will, is in a way a cache
22 customer just like any of our other partners. And what

1 we've been able to implement in HealthShare if you like
2 what you saw there, then our belief is any of our
3 partners could.
4 DR. PEEL: Okay. Who are your top five,
5 quick?
6 MR. LaROCCA: Top five categories?
7 DR. PEEL: VA? That have this database system
8 that enables it.
9 MR. LaROCCA: Yes.
10 DR. PEEL: Who else?
11 MR. LaROCCA: The VA, the DoD, the Epic
12 Systems is a big partner, QuadraMed.
13 DR. PEEL: Great. Okay. Now, in Sweden, you
14 have implemented all of these segmentation
15 possibilities. Why haven't you implemented them in the
16 U.S.? Are there any implementations in the U.S. that
17 allow this capacity to be built into health information
18 exchange or the use of EHRs? And if they're not, why
19 not?
20 MR. LaROCCA: Well, across all of our
21 projects, I think, in general they all share a belief
22 that patients do and should have control over their

1 data at the finest level. In my experience, they tend
2 to walk before they run. They'll often have an opt-in
3 and opt-out model initially and incrementally add finer
4 features and detail.
5 DR. PEEL: Okay. But Sweden didn't. They
6 started with the whole thing. Okay. I'm going to have
7 to race because I want some other people some
8 questions.
9 Okay. All the Texans, welcome. I think it's
10 an interesting coincidence that so many people are
11 working on privacy enhancing things in Texas. First of
12 all, I want to complement on the unique feather of your
13 system, which is when data is disclosed to anyone, it
14 can be used for one purpose and one purpose only and
15 there is no onward transfer. That is unique. That is
16 very important and that is why patient privacy rights
17 in our coalition has recommended the functionalities in
18 your consent module to be used as a national standard.
19 So, why did you build it this way? Was it
20 based on a law?
21 MR. MITRA: The reason we built it, as I said,
22 since we had state and our scope from Day 1 we have 250

1 different providers to work with. And the first thing
2 we looked for is how are we going to do continued care?
3 People cannot see other data without a consent. If we
4 have the centralized database, we have all the data but
5 what good is that if the providers cannot use that for
6 continued care.
7 The other piece is since we are using public
8 money, we have to make sure we get the best out of the
9 dollars we spend. So we don't want the same assessment
10 to be done as I said a typical assessment takes one to
11 three hours to do it and within 30 days if the client
12 goes to another provider, there is no reason to do
13 another assessment. From the state point of view, the
14 cost is part of continuity of care. That's the reason
15 we built that.
16 DR. PEEL: Thank you. I understand that your
17 system takes care of 550,000 people, but isn't it true
18 that this open source electronic health record and
19 consent system is being used for over four million
20 patients in eight or nine states, because many states
21 use and contributed to the EHR and consent system?
22 MR. MITRA: And SAMSA actually, when we built

1 BEHIX, they looked at the consent. They used a target
2 system from Maryland and they used similar kinds of
3 concepts to screen for 17 other installation states and
4 counties. Nevada is another state using BHIPS as it
5 is. So they're using consent for all their providers
6 for the viral health. And a couple of other states are
7 also planning to use CMBHS.
8 DR. PEEL: Thank you. It is widespread. I've
9 got a couple questions for e-MDs, but first I want to
10 compliment you on what seems to be rather unique among
11 EHR vendors, which is that long before any of this
12 became a topic, you all decided to provide a way to
13 segment sensitive information. And so I compliment you
14 on that.
15 My question for you all is as you told us,
16 your system doesn't enable the patient to express those
17 preferences about what gets segmented or what gets kept
18 private. Do you have a process then or do the doctors
19 -- maybe Dr. Millican can have a process where they
20 routinely talk to patients about the fact that there is
21 a way to keep certain kinds of information private from
22 other doctors. Do you sort of go through that

1 routinely as a matter of care or I just wondered how
2 the patients can find that this could happen that their
3 information could be protected since they can't do that
4 yet electronically?
5 DR. MILLICAN: I think that that's really
6 going to be doctor specific. It's going to depend on
7 the individual practice as to whether they take the
8 time to mark something confidential. Because as Dr.
9 Stearns pointed out, since this data right now is not
10 going anywhere other than within the office, there's
11 not a critical need to be marking these things.
12 DR. PEEL: Okay. Thank you. I have got two
13 questions that I want to ask each of you very quickly.
14 So we'll go down the line.
15 The two questions are, the stimulus bill
16 requires that if patients pay out of pocket for
17 treatment, they have a right to prevent any of their
18 protected health information from flowing to insurers
19 or others for claims, payment, or for healthcare
20 operations. And what I want to know from each of you
21 is does your technology permit that, which is now a
22 matter of law. And the second thing is also a

1 requirement of the stimulus bill which is protected
2 health information cannot be sold without consent. So
3 does your system have a way to get patient consent
4 before data is sold? Do you have a way to enable that
5 in your system and so, Mike, maybe you can answer, and
6 then Mr. Mitra you could answer and then Dr. Stearns.
7 MR. LaROCCA: For your first question, yes,
8 the patient has control over who that data is disclosed
9 to. And as you saw, that could be a sweeping statement
10 that says I don't want the outside of this hospital or
11 it could be to this particular target, wherever that
12 may be. But the patient is in control of the.
13 For the second question, if the patient has
14 control over what can be sold for secondary use of the
15 data, the patient can control what is available in
16 different reports. So for example if they want to make
17 certain information suppressed in all cases they can do
18 that --
19 DR. PEEL: No. This is a little bit
20 different. Patient consent has to be obtained before
21 data can be sold -- before protected health information
22 can be sold. That's a new right that our coalition

1 worked hard to get into the stimulus bill. So is that
2 enabled in your system, a way to get patient consent
3 before data is sold?
4 MR. LaROCCA: I'm not sure.
5 DR. PEEL: I'm sorry. We're running out of
6 time, I'm going to cut you off. Mr. Mitra?
7 MR. MITRA: Right now, one example will be
8 have an insurance company called --
9 DR. PEEL: You have to work faster or Mike
10 won't get to say anything.
11 MR. MITRA: Yeah. That option is one of the
12 insurance company we're dealing with today and they are
13 the one of parents for our providers and they cannot
14 see any of the records without patient consent even
15 though they are parents.
16 DR. PEEL: That's a different question. Can
17 Dr. Stearns answer? Okay. You got the questions,
18 right?
19 DR. STEARNS: We don't actually control the
20 data from our company so we don't have any data we
21 could possibly sell. So it's all done at the provider
22 level.

1 DR. PEEL: So a physician could sell the data?
2 DR. STEARNS: The physician can sell the data
3 if they so choose, but really won't have to address the
4 policies and regulations.
5 DR. PEEL: Okay. Does your system though,
6 provide the ability, if a patient pays privately for
7 care, to block the information from flowing to insurers
8 and others for claims or for healthcare operations
9 purposes?
10 DR. STEARNS: Yes. It would be some work on
11 the provider interaction but there are tools that would
12 allow that.
13 DR. PEEL: Okay. Well, it's a law now.
14 DR. STEARNS: Hm?
15 DR. PEEL: It's a matter of law now.
16 DR. STEARNS: No. I mean it's available for
17 them to do that right now so the capability is there.
18 The shot gun just went off.
19 DR. PEEL: Okay. We'll be shot now. Thank
20 you.
21 MS. McGRAW: Terrific. Very admirable job
22 under the time constraints. Melissa Goldstein.

1 MS. GOLDSTEIN: Hi. I'm Melissa Goldstein.
2 As Deven mentioned, I'm an associate research professor
3 at George Washington University in the Department of
4 Health Policy within the Medical Center. I'm not sure
5 if it's a conflict of interest, but I do need to
6 mention that GW does have a contract with the Office of
7 the National Coordinator to write white papers on these
8 particular issues.
9 We've written on consumer choice models and
10 health information exchange and we're currently
11 actually focusing on data segmentation issues. I've
12 spoken with most of you on the phone and I'm going to
13 try to limit my questions now, to the conversations
14 we've had today. But I apologize if my brain can't
15 segment data that well.
16 Just a little bit about what we're doing.
17 What we've heard so far from most of you is that the
18 barriers to segmentation are moving forward with
19 perhaps exchanging interoperable segmented data have
20 little to do with the technology and more to do with,
21 perhaps, outside influences that strongly affect the
22 use and access of technologies.

1 I'm not speaking about policies here, so if I
2 get yellow carded, I hope that I can still participate
3 in the next game. And I'm not speaking about the
4 desirability or appropriateness of choosing to
5 sequester data and offer varied consent options. What
6 I mean is that current culture and approaches of
7 institutions, providers and patients may actually be
8 the most difficult part about developing these
9 technologies because you're obviously trying to do
10 something that your customers want. Right? And that
11 will grow with what you customers need.
12 To me, there are two big questions that are
13 very different here. The first is does the technology
14 make this feasible? And the second is does the
15 technology facilitate adoption of it. For example, is
16 there an intuitive understandable PHR interface for
17 patients possibly? Can people use it? Can patients
18 use it? And is the technology easy for physicians to
19 use? I see both of these as very important.
20 My questions for you, and perhaps this is
21 unfair, but I'm going to do it anyway. Sorry. The
22 first one, I want to ask of all of you actually. Many

1 of you mention feedback from users and feedback from
2 patients.
3 And as an academic, I'm very interested in
4 data. So I'm wondering if you have particular and
5 numbers on what your users think. Now this can be
6 providers, institutions, the people that are actually
7 using the EHRs that you've developed, or the patients.
8 Are they happy? Do they think that it establishes a
9 level of trust that they want.
10 A number of you have also mentioned that very
11 few patients actually decide to use this information,
12 to block it from view. Do you have any numbers? And
13 should the fact that patients aren't using it yet make
14 a different in what you're developing. Because as we
15 know, as information is exchanged more broadly, more
16 patients may be interested in it.
17 So, if you could start at this end of the
18 table.
19 MR. KWAN: Sure. I think there were a couple
20 questions in there. So let me see if I can break it
21 down. I think from an implementation perspective,
22 you've hit on the three core elements that every system

1 needs to have in the sense of being user friendly. And
2 that's the user interface level, or the workflows or
3 the way things are being communicated clear to the
4 target user.
5 You also, I think, mentioned the data model.
6 Is the technology feasible? And I think a lot of
7 times, people think of that in terms of do the
8 structures like the ones that are in InterSystems, do
9 they have enough granular control so that even if
10 someone was to express their preference or their
11 consent policy, in this case, is it being stored
12 correctly?
13 And then finally the final segment in there is
14 the logic. Is the business logic in place that can
15 evaluate at that fine grained control?
16 And I think on the technical feasibility
17 question, I think, from an information exchange
18 perspective as a service, there is work that needs to
19 be done on two ends. One is as an information
20 oftentimes, we're not the source of the information.
21 We take it from other sources. And so I would say at
22 this point, in the middle, we are able to catch it and

1 receive it. However, I do find an astounding lack of
2 inability of the sources. So when we think about
3 meaningful use in the EHR that there does seem to be a
4 real lack of the sources systems to be able to emit
5 data in that manner.
6 And so, in New York in particular, we're
7 working with several EHR vendors to do exactly that,
8 work with them to establish the standard. Can they
9 generate the consent policies at that level of
10 granularity even at the core screen New York State
11 level as a start and then with the idea that we can
12 iterate and layer those in?
13 The second in terms of how do we measure these
14 things and does the measurement or the existing use of
15 it matter. In my opinion, I think of it as a
16 resounding yes. And just in the frame of networks, I
17 think in order for a network to be successful and grow,
18 there does have to be a standard and it does need to be
19 a common pattern that everyone agrees to. Otherwise,
20 you wind up with multiple networks and fragmentation.
21 While it's perfectly fine to experiment
22 prototype and work with it, I think, in order for this

1 to actually reach the use of it, until it hits that
2 common approach. I think of it quite practically that
3 every EHR can go to a particular place and have a very
4 clear recipe. A recipe to say, okay, if I need to
5 capture a consent and emit it to anywhere, regional or
6 statewide, that that is a clear standard both at the
7 package level and the transport level, which I know
8 other groups are working on.
9 MS. GOLDSTEIN: Do you hear feedback from your
10 users and the patients about using it?
11 MR. KWAN: The feedback from the people who
12 have adopted the consent capture right now is again,
13 like I said, very what I think of as implementation
14 focused. So we tag onto and existing patient
15 registration process. From that perspective, it does
16 seem to working. They're gathering the consents.
17 Their patients seem to be engaging.
18 But, I'll be honest, we're just now
19 implementing a PHR based view of this as one of the
20 pilots with our target population is 3000. One of the
21 questions we want to get out of that is this answer,
22 but we're not at that point yet where we have the data.

1 MS. GOLDSTEIN: Thank you. You guys next.
2 Ms. McCarty, is that correct? I'm having trouble
3 reading it again. You mentioned some patient feedback
4 and some user feedback. I'd like to know more about
5 that, if you have numbers, if you guys are studying it
6 in particular, if you're perhaps going to publish any
7 papers on it?
8 MS. MCCARTY: We don't have any data, but the
9 feedback that I have received and the feedback that I
10 have is that the system is very easy to use. We're not
11 IT people, we are clinicians. And when we need the
12 information, we need the information. So we view the
13 information as if it's just a paper file, so it's easy
14 to use.
15 MS. GOLDSTEIN: Thank you.
16 MR. MITRA: From an IT point of view, we built
17 this product and we already saying to all of our
18 providers, what do you think of the build process. And
19 when we designed our consent form, we got feedback from
20 them as to whether it was going to work or not.
21 Again, this has been used for more than ten
22 years, so we know it is working out in the field. We

1 continuously monitor it for complaints or concerns
2 through our legal process.
3 You asked about the PHR, that's in our mind.
4 We haven't built a PHR, but, as you know, it's a web-
5 based centralized database for getting patients to
6 connect to our website and log on with a user ID and
7 password that will let them see that access. They can
8 go to the consent form and give the consent to another
9 provider.
10 Right now the treatment providers are actually
11 facilitating for them as not all of our users -- non-ID
12 people still do not agree that all of our users are
13 sophisticated enough to log into a website and try to
14 manage their health records. That belief and trust is
15 not there yet. We are still relying on our providers
16 to facilitate that with their patients.
17 From the technical point of view, if you have
18 a person who knows how to use an internet browser, they
19 can log in from their home and use the same consent
20 form to decide which providers will access to what data
21 and for what period of time.
22 MS. GOLDSTEIN: In your testimony, I think

1 mentioned that you have 6000 providers using the
2 system. Is that correct?
3 MR. MITRA: Yes. There are staff providers,
4 yes.
5 MS. GOLDSTEIN: Have you done any surveys of
6 the group to see use, success, happiness with the
7 product, actual implementation of it?
8 MR. MITRA: We have done it for BHIX, which is
9 our first product for many years. For CMBHS, we
10 haven't done it, but we do have some feedback loupe
11 where the providers using the system and letting us
12 know if there is any issue with it, but not exact
13 count. I do not have the number right now, since we
14 are the State, it is very difficult to give you a
15 number. We have to go back through the formal process
16 to get that count. If you need it, we can get you one.
17 MS. GOLDSTEIN: Thank you. Dr. Stearns?
18 DR. STEARNS: In the course and preparation
19 for this meeting, we reached that. We've had the tools
20 there for a number of years and we wanted to find out
21 how many people were using them. This is the
22 providers.

1 We were surprised to learn how few people were
2 using them. Some people said that's nice, I might use
3 that one day. I think the low demand right now is
4 because there's no real requirement to export data.
5 It's not really a need right now, but it is a nice
6 utility to have in certain situations, which is why we
7 developed it. But it's not a common daily workflow
8 issue. Even though it's available to all of our 7000
9 or so providers, I'd say probably a very small
10 percentage are using it right now.
11 MS. GOLDSTEIN: And I believe you said that
12 very few patients, in general, are interested in this.
13 DR. STEARNS: Well, on the provider's
14 standpoint. We haven't surveyed the patients. Maybe
15 Dr. Millican has some comments about the patients.
16 DR. MILLICAN: I think that most patients are
17 not really going to be that sophisticated as it was put
18 to know what data they want sent where and they really
19 leave it up to their doctor.
20 If I'm a general surgeon, then they expect me
21 to know what information that that specialist is going
22 to need to be able to take care of them. And so we

1 have them sign a consent form, but, generally speaking,
2 I would say 80 percent of my patients or more than
3 that, 95 to 99 percent of my patients sign the form not
4 really caring what it says. They don't have their law
5 degree and they're not reading the fine print to what
6 they're signing or what they're sending. This is
7 anecdotal; we don't have data.
8 We're a clinical practice and so we're doing
9 good to stay afloat with keeping up on our charts, much
10 less generating about other things.
11 But I would say that it's going to be the
12 extreme minority of patients that have really any
13 concern about this in my practice population. One in a
14 thousand maybe that even cares. On the other hand, to
15 talk about some of the misinformation that's out there,
16 just to give you an example, my mom called me a few
17 weeks ago -- a month or so ago -- oh, sorry.
18 MS. McCARTY: If we could stick to the
19 ecology, it would be helpful. Thank you.
20 DR. MILLICAN: Okay. Basically, there's all
21 kinds of misinformation out there about the technology
22 and the fact that there's bureaucracy that's going to

1 be collecting your data and sending it to some big
2 government database that's going to know everything
3 about you.
4 MS. GOLDSTEIN: Which might be a patient
5 education, right? Do you agree?
6 DR. MILLICAN: Absolutely.
7 (Bell rings.)
8 MS. McGRAW: Thanks. I think I'm going to be
9 hearing that thing in my sleep, yet another thing to
10 panic you. Thank you very much, Melissa. Ioana
11 Singurereanu.
12 MS. SINGUREANU: Hello can you hear me?
13 MS. McGRAW: You might want to pull the
14 microphone a little bit closer to you.
15 MS. SINGUREANU: Okay. It the type of
16 microphone, I apologize. My name is Ioana Singureanu
17 and my only bias, I'd say, is that I come from a
18 perspective where I think a lot of what we want to do
19 with consumer choices is doable by the technology. I
20 think the trick is to find out exactly how that is done
21 and what is the optimal solution.
22 I think the standards are there. One of my

1 areas of concentration is to develop standards to
2 describe the consent directives in a consistent way and
3 identify all the different traits, including for
4 instance the payment choices that are applied to the
5 data that would allow you to construct rules to exclude
6 information if it was paid for out of pocket.
7 In a nutshell, that's my bias. I'd like to
8 start with three questions that I would like to ask of
9 all the participants.
10 The first one has to do with the data quality.
11 And I see two different schools of thought here. In
12 one instance EMD is putting a provider in charge of
13 segmentation by giving them a way of controlling
14 confidentiality and indicating sensitivity.
15 I see, on the other hand, CMBHS and
16 InterSystems customers are providing an automated
17 segmentation modality where rules are based on the way
18 that data encoded and structured and computers can
19 understand those rules to determine which information
20 should shared and which information should not be
21 shared.
22 With those two caveats, I'd like to hear from

1 you if you see any barriers, because I'm an integrator
2 interoperability person. Do you see right now any
3 problems with the quality of the data people are
4 putting in the systems that may prevent it from being
5 automatically processable and segmented by computer
6 systems? We can start with the people who have chosen
7 not to go that way. Maybe, why?
8 DR. STEARNS: Actually yes, in that a lot of
9 the data is garbage in, garbage out, if you're free
10 texting things into the electronic health record,
11 there's no way for the computer to know what that's
12 saying. I mean it doesn't know that you're talking
13 about HIV or STDs or mental health issues or what ever.
14 So it's going to have to be incumbent upon the
15 person that's entering that data to the market some
16 way, if it's just a free text field, which a lot of
17 people are still using, because all of the other ways
18 to capture data have some limitations. There's a way to
19 tag data ahead of time and we actually do it through
20 templates right now. Automatically it should be always
21 flagged as a privacy issue.
22 And we can also go one step further and tag

1 that through attribution as a privacy sensitive piece
2 of information when we're sending it to be uploaded to
3 the HIE. Since we're not an HIE vendor, it's fairly
4 different between the two. We do have the ability
5 right though in the EHR to provide segmentation to a
6 level, but it would need to have the next step to have
7 that marked somehow, identified somehow so when it
8 flows outside the clinic and goes into the HIE, it's
9 identifiable.
10 MR. MITRA: We came up with those segments in
11 our system to make sure -- just capturing the consent
12 form from the technology point of view is not a big
13 issue. In implementation, how to expose the data and
14 what to hide in the consent the form, that's the
15 important and critical piece, a complex ID piece. For
16 that, up front, we had to structure the consent form
17 with different segments and activities that we know are
18 going to be useful for our business domain.
19 Obviously, we consulted with the providers and
20 all the clinicians we work with. So it's not an IT
21 reason what components and what segments are really
22 needed for selling. So we worked with our physicians

1 and clinicians as well as the provider clinicians to
2 find out what segments we really need. Then the ID
3 piece comes and then we designed our form and then we
4 implemented that. It makes sense for us to have that
5 segment already in the form so whether we expose or
6 hide the data, we can use that logic in a structured
7 way.
8 MR. LaROCCA: I think you ask a very good
9 question. Typically, what we find is that data quality
10 really varies by the site. At a high level, there are
11 two things that we deal with when we integrate data.
12 There's dealing with the structure and there's dealing
13 with the semantic vocabulary within the structure.
14 Our implementers, basically, will go through a
15 two-step process to bring the source online. First
16 it'll say if they are an HL7 data source. Did they use
17 CCD? Did they use some other technology or some other
18 standard? How can we bring that to what we think of as
19 our canonical format internally so that our internal
20 engine knows how to process the data in a consistent
21 way.
22 Then, the other issue is the semantic

1 vocabulary, which I think is the harder of the two to
2 deal with, wherein that someone codes in Oink and
3 someone else uses SNOMED, it becomes a real challenge.
4 And as part of bringing the data server online, we have
5 to be able to get to a gold standard so that we can
6 then apply the consent filters.
7 MS. SINGUREANU: But can I ask now whether you
8 canonical representation of the information within your
9 system supports local terms, standard based terms or
10 both? And I acknowledge the issues that Mr. LaRocca is
11 indicating. I just wanted to get a quick idea. So
12 maybe we can start with you, Mr. LaRocca.
13 MR. LaROCCA: Sure. Our internal standard
14 does support both. And in fact, we remember both the
15 old and the new codes, if you will, so that when we
16 ultimately project what you would think of as a CCD
17 summary, we're capable of saying the original code that
18 we received was this, but after the translation, it's
19 now that.
20 MS. SINGUREANU: Okay. So you support both
21 local and translated standard codes?
22 MR. LaROCCA: Yes.

1 MS. SINGUREANU: Mr. Mitra.
2 MR. MITRA: For the data exchange, we plan to
3 use all the standard codes and slowly we will adjust
4 our system as to standards and build for the SNOMED
5 codes and low-end codes and for viral health,
6 particularly for our domain, they are a very specific
7 thing. And we would then adjust our system to those
8 codes.
9 But right now, when we are doing data
10 exchanges, we plan to use the standard codes.
11 DR. STEARNS: We're not exporting specific
12 attributes especially in the codes right now, but it
13 does raise some interesting issues related the
14 challenge that we have with things like negation. And
15 certainly, right now with modifiers traveling through
16 HIEs to standard data does create another level of
17 complexity. And it will require the same level of
18 study, I think, in order for it to be effective to make
19 sure the quality and the representation of privacy
20 information is accurate.
21 MS. SINGUREANU: I have a question I'll start
22 with this end of the table just to keep things

1 interesting. You indicated that your consent would be
2 basically marking of specific information as
3 confidential, which means either it is included or is
4 not included. Is it possible in your system -- and I
5 want to think just more generically about extensibility
6 of your current consent structure. Is it possible to,
7 for instance specify that for a specific receiving
8 provider you will allow medication, for instance, to be
9 exchanged under certain circumstances and is that
10 extensible in your system? Can you add new criteria
11 such as --
12 DR. MILLICAN: In our clinic, for example, and
13 I think that this is the correct answer that this
14 software allows such flexibility that it's really up to
15 the individual clinic or provider as to how they're
16 managing the patient consent. We have just a standard
17 patient consent form where they mark what they want
18 sent of what they don't want sent. And then it's up
19 the medical records technician to go in there and send
20 that information. And click, click, click and she has
21 what they're going to send.
22 MS. SINGUREANU: So you're able to extend what

1 information may be shared and to whom it may be shared?
2 DR. MILLICAN: Yes. You can print one single
3 document or you can print the whole chart or anywhere
4 in between.
5 MS. SINGUREANU: So is it possible to extend
6 the information or artifacts that your consent form
7 specifies? So right now you have a set of predefined
8 documents, that's an extensible set and can you add
9 other criteria such a payment out of pocket versus
10 public, private.
11 MR. MITRA: Yes. You can, absolutely. It's
12 all (inaudible) driven so from the IT point of view, so
13 we can additional components to that consent list.
14 MR. LaROCCA: Our system is very extensible.
15 I think commit these projects believing that no two of
16 them are exactly the same and they will always have
17 their own requirements that they need implemented. And
18 so our approach has been to implement a framework that
19 could be extended.
20 People could add their own information types,
21 add their own filters. From a clinician or patient's
22 point of view it's pretty easy to use and extensible.

1 But even from the developer's point of view or
2 implementation person's point of view, for whatever
3 reason they need to, all of our business logic is
4 extensible. They are classes and so it uses object
5 orientation. They could subclass our code and refine
6 it in some way or they could even replace our module
7 wholesale and implement their own.
8 MS. SINGUREANU: And can you also answer then,
9 the following question, how are the consumer choices
10 translated into rules that computers can understand and
11 perhaps automatically execute?
12 MR. LaROCCA: That's also a good question.
13 Our rules whether they're defined interactively through
14 a user interface or we've got a Jackamo policy, we turn
15 that and also put it into our internal standard for how
16 a consent policy should be represented. So when the
17 data comes in, the data's been normalized to our
18 canonical format and codes and then the rules that have
19 come in that represent the consent policy or compare it
20 against the data structure.
21 One of the things that we that's important to
22 us is unconsented data never leaves and Edge system.

1 It's a guiding principle that we have that identifiable
2 unconsented data should not be central. The rules are
3 processed on edge servers and then exported.
4 MS. SINGUREANU: Mr. Mitra.
5 MR. MITRA: Going into real technical detail
6 to answer that question.
7 MS. PRITTS: I'll give an extra minute for
8 this but I think that there are people in the audience
9 who don't know what you mean by "the edge" reference.
10 MR. LaROCCA: Okay. Thank you. I'll clarify
11 that. In one of our deployments, we have what we think
12 of edge gateways or edge servers that live physically
13 in the hospital networks, in the data provider
14 networks. So what's central at the community is what
15 you might think of as the record locator service, the
16 service bus. But the actual physical data storage are
17 owned and managed at the data provider level.
18 So when a consent policy is actually
19 evaluated, it's evaluated locally on the edge server.
20 So as that data provider is responding to queries, any
21 sensitive data is filtered out before it leaves the
22 network.

1 MR. MITRA: Our point of view was the way we
2 designed the CMBHS, all we care about is whether the
3 data, the consent form, is filled into the web
4 application or through the data exchange process. It
5 doesn't matter what format it's coming in on. All we
6 care about is if a provider discloses, disclosing and
7 the dates and kind of activities you are trying to
8 release. There is a place for the signature. And then
9 we can talk to the other system and we verify their
10 MPI, which providers requested the information and then
11 we know from the patient what information we can
12 release to that MPI provider. That's the way we
13 release information.
14 DR. STEARNS: We're almost out of time. The
15 capacity to give patients the tools do their own
16 segmentation is something that we're actively looking
17 into at this time.
18 MS. McGRAW: Thank you, very much.
19 MS. PRITTS: I'll give you the extra minute if
20 you feel like you need to -- since I interrupted, if
21 you need additional time to answer that question. I
22 won't set the beeper off.

1 DR. STEARNS: Well, thank you. This is all
2 future thinking. But the idea of giving right now as
3 you saw the EHR, the physician makes the choices and
4 they have to understand navigating the software and
5 understand the meaning of the concepts, etcetera. So
6 it's a big a challenge to give similar tools to
7 patients. But that's what one of the goals would be,
8 to give them access to the information in a correct way
9 that they can understand and they can make informed
10 choices. Thank you.
11 MS. McGRAW: Thank you very much. Dr. Kibbe,
12 you're up.
13 DR. KIBBE: Good morning. It's a pleasure to
14 be here and I want to thank the committee members for
15 asking me to come today and for the presenters who are
16 doing an excellent job. You've given us a great deal
17 to think about.
18 I'm here today representing the American
19 Academy of Family Physicians, which is the organization
20 that represents approximately 100,000 family doctors,
21 medical students and residents in this country. And if
22 I have a bias, and most people in the room probably

1 already know this, it is that I have been interested
2 most of my career as a practicing physician and as an
3 interpreter of information technology in the small to
4 medium sized medical practices, the staffs in those
5 practices and the patients who are served by those
6 practices. And, of course, we all know that the great
7 majority of physicians and patients are in small and
8 medium sized medical practices, not in very large
9 enterprises, which has always set up a difficult IT
10 dilemma which is that most of the money and most of the
11 IT is in the large enterprises and not in the medical
12 practices, although that is about to change.
13 So what I'd like to do here very briefly is to
14 set up a problem and then see if we can solve it. And
15 I think the panelists here are capable of doing that.
16 This conversation reminds me of the lyrics of a song,
17 "I'll do anything you ask me too." Because software
18 can do anything we ask it to do. The question is at
19 what cost and what practicality and what ease of use?
20 So I'm going to suggest that there's a problem
21 here for small and medium sized medical practices and
22 vendors who serve that market in terms of doing this

1 practically and at a reasonable cost. And I'm going to
2 make two or three assumptions and then start my
3 questions.
4 I'm going to assume, because I think it's
5 true, that most patients at some point in the future
6 will want to control access to their health information
7 and make choices about consent.
8 I'm also going to assume that meaningful use
9 and the criteria they are about to a part of the
10 regulatory program for the adoption of electronic
11 health records and the incentives there are very much
12 putting even the smallest medical practices in the same
13 position health information exchanges are in with
14 respect to displaying patients and their data and
15 ultimately having to allow patients to make those kinds
16 of decisions.
17 And then the third assumption I'm going to
18 make is that what we've seen this morning with respect
19 to the software from InterSystems and that program that
20 you have shown us are really state of the art, that
21 they get to a granularity with respect to the decisions
22 that patients can make about where their information is

1 seen and where it's not seen, and it's very cool. And
2 I like it. I think everybody in the room appreciates
3 the value there.
4 What I want to start out though is with a
5 question to ask Dr. Stearns and Dr. Millican. What
6 would it cost a medical practice today to have a vendor
7 who could build that system into the EMR or the portal
8 associated with the EMR? What kind of estimate would
9 you make around how expensive and costly that might be?
10 DR. STEARNS: That's a great question. It's
11 definitely, I think, the trend where we're heading
12 right now. I think with the use EHRs designed for
13 physicians, if we can covert that over to a tool that's
14 designed for patients using similar paradigms, using
15 cognitive engineering and other constructs, we could
16 actually come up with something that would be useful
17 for patients.
18 I think there will be some challenges though
19 that's going to require a fair amount of R&D. But I
20 think it's very doable and the patients will then
21 identify like they're in their own PHR, their portal,
22 they identify patient information they have access to

1 other educational materials and then they make a
2 decision. I don't think the cost would be exorbitant.
3 It would require some effort, but I would be supportive
4 of that direction.
5 MR. KIBBLE: Is it reasonable in your opinion
6 for every electronic health record company to build
7 into its application the software necessary to do what
8 we say from InterSystems and HealthShare?
9 DR. STEARNS: Yes. I think it's going to be
10 something where we really have no choice. I totally
11 agree with you and we've mentioned earlier that when
12 people start sending data out and patients become much
13 more aware of where the data is going, they're going to
14 really push for this. So it's going to become policy
15 and then requirement, so it's just a trend that's
16 developing.
17 MR. KIBBE: Well, Michael, you and I have
18 known each other for a long time and you're being very
19 diplomatic, sir. But I think the answer is that in the
20 short term it would probably be prohibitively expensive
21 for the small - medium size medical practices to be
22 able to afford the kind of patient consent controls

1 we've seen built into every electronic health record.
2 So you helped out, but I'm posing the problem.
3 What I'd like to do in the last five minutes
4 or so is ask the other two presenters, what can we do
5 to scale and to make extensible the kind of services
6 that you've shown us can be implemented in fairly large
7 enterprises? In other words, is it possible for
8 consent services, for consent management services to
9 become a web service that could be used in a modular
10 fashion, let's say, 50 different electronic health
11 record products and services, which, of course would --
12 could significantly lower the cost to everyone of the
13 practices that was using that service. Is this a
14 reasonable question and if so, what could be done to
15 make that happen in next five years? Because we really
16 have a five-year framework, I think, for this under
17 meaningful use. And start with you, Tim. Go ahead.
18 MR. KWAN: I think to answer that question; I
19 think your point earlier that software can do anything
20 because it's soft is a valid one. But rather than
21 discuss that, I'd like to just talk about the prototype
22 that we're working with in BHIX with a couple EHR

1 vendors. And the reason that we used a couple is we
2 didn't want to be proprietary to one in particular.
3 I think the short is we'll find out. But let
4 me describe the experiment and how we're segmenting in
5 that project because I do think that it's a useful
6 example. And certainly, as an experiment, we can see
7 whether or not it will work.
8 So recognizing that in general the use by
9 clinicians of the portals that are available through
10 health information exchanges have tended to be quite
11 low. We're getting lots of great data and people can
12 access them. We're not finding tremendous adoption.
13 In fact, one of the most common functional requirements
14 we is please get this into the EHRs because that's
15 where our workflows are and that's what we're used to
16 using.
17 What we're doing with these EHRs is having
18 them capture the actual patient consents and then
19 declare them centrally to the HIE in the form of these
20 policy statements. What they've agreed to do is move
21 the actual evaluation point. So we go back to this
22 concept of separating these functions, breaking it out

1 of a monolithic business logic flow, for example, or
2 something that's tied directly to a portal and breaking
3 it out as a web service. In both of these cases, the
4 client nature is the EHR and then the server side of it
5 is the actual health information exchange where store
6 the policy declarations as a set of rules. And then,
7 as Mike mentioned, we then evaluate it and send it back
8 to the EHR, are you permitted or are you denied?
9 So the combination of clinical data coming in
10 as one stream separating out consent as a separate
11 input stream and then separating out the evaluation
12 allow for that scaling and that extensibility.
13 But the challenge, and I'll bring this out as
14 a final point, is getting the consents as they're
15 updated by multiple systems to the originating source
16 system is another one of those challenges. And
17 naturally, we iterate through these, but you can
18 imagine from a conflict standpoint, you have EHRs now
19 sending patient consent policies.
20 Now, if we implement another PHR in there
21 where the patient can look across organizations and
22 state consent policies, in the center, we can handle

1 and hold them and reconcile them both. But it becomes
2 important that both the PHR and the EHR are also able
3 to accept them back so that as things get updated,
4 they're able to reflect that. That's a very foreign
5 notion oftentimes, I think. Who is acting as the
6 source of truth? But by separating it out, that
7 problem becomes much more manageable because as long as
8 somebody agrees on one end point, then they can use
9 that.
10 MR. KIBBE: Ms. McCarty and Mr. Mitra, could
11 you answer that question from your perspective?
12 MR. MITRA: Yes.
13 MR. KIBBE: Is what you've done available to
14 other people as a service?
15 MR. MITRA: Right. All of our CMBHS
16 activities, including consent, is all web services
17 based. But it is not exchanging or used by any other
18 vendor products. That is what we were trying to
19 promote from day 1 and as you can see, we built an open
20 source product. Nothing against the vendor, but it is
21 an open source product and we believe in that. From
22 our point of view we have the standards which many

1 people are working their standards and directional med
2 codes and low end codes and all those.
3 So there can be a website which is centrally
4 hosted by somebody. Most of the IT cost is not
5 building a product, it is about maintenance. The ten
6 or twenty years of maintenance is where you spend 80
7 percent of money on an IT product.
8 So if you build a consent and every vendor in
9 the nation is building in a consent product, and
10 normally the front cost, if you multiply, then you have
11 the maintenance cost. But if you have to spend the
12 money the build the product up front with all the
13 vendors, everybody involved in that process, once you
14 have a nice consent form, as you said, as a web
15 service; and then every vendor product or the state
16 product, it doesn't matter. We make a call to that and
17 try to find whether I have the rights to share the
18 information or not.
19 And the patients, whether they are viral
20 health or they are primary care, they log into that
21 centralized websites and manage their electronic health
22 consent. And all other products just look for whether

1 there is a consent or not.
2 Again, that's my concept of where you can save
3 money. The initial person was from the physician's
4 point of view, how much it's going to cost the
5 practice. We do not charge any of our physician or the
6 practice. It is zero cost for them. We take care of
7 all the building (inaudible) as the maintenance from
8 the state point of view.
9 So using the same concept, before we
10 implemented our product, there were maybe 20 or 30
11 different products out there used by many people. And
12 the issue was they are not consistent. And then too,
13 are the maintenance spots that the state has to pay for
14 every year for maintaining and changing every time we
15 need something new, we have to pay for it.
16 Now, we centralized that cost so we are making
17 one change in one place and 250 providers are using it.
18 So that's a great saving for us. But when you are
19 trying to do it any kind of consent web services, yes,
20 you have to build a very powerful infrastructure to
21 host it as software as a service so that nationwide
22 people can use it.

1 We have to make sure that we have the
2 reliability and all this so that all these systems are
3 talking to it, that we have the inner power to manage
4 it.
5 But maintenance costs are the main thing that
6 will kill it if you spend all the money up front to
7 build it and then just hosting monthly. Thanks.
8 MR. KIBBE: Thank you, all.
9 MS. MCGRAW: Dr. Walker.
10 DR. WALKER: I'm Jim Walker. I'm a physician
11 and the Chief Health Information Officer of Geisinger
12 Health System, which means that I'm responsible for
13 trying to make an integrated inpatient outpatient EHR
14 and a network to PHR that serves about 149,000 patients
15 and a regional health information exchange that has
16 about three million patients in the database and
17 400,000 patients consented, and a keystone beacon
18 community where we're trying to take all of the above
19 and run it out and provide it to an entire community of
20 providers and consumers and patients.
21 So my experience is there are a couple of
22 things that are really critical if you're going to try

1 to do that. There's a theory which is based no the
2 best evidence that there is that technology adoption is
3 a function of usability and usefulness. I'm going to
4 assume that usefulness is a policy question and talk
5 about usability. And the second issue that compels me
6 is the issue of health IT safety. It's clear that any
7 time you bring two systems as complex as health IT and
8 healthcare together, there is a potential for hazards
9 and worse. In every industry except healthcare, hazard
10 control is a core component of safety engineering. And
11 so those are the two things I want to ask you about,
12 are usability and safety.
13 I want to do this like I would treat a vendor,
14 so we're on a reference call and I'm going to ask you
15 real pointed, bulleted questions and I want to have you
16 give real pointed, bulleted answers so that we can get
17 through some of them. I might even gong you, heaven
18 knows.
19 So the first just quickly, did you base your
20 solutions design on a written needs assessment?
21 Yes/no.
22 MR. LaROCCA: Yes. Very often through RFPs.

1 That's one very good written way of communication.
2 DR. WALKER: Great. Okay. Thank you.
3 MR. MITRA: Yes.
4 DR. WALKER: Okay.
5 DR. STEARNS: Yes.
6 DR. WALKER: Super. Starting at this end, by
7 any chance, did you use cognitive work analysis or
8 anything similar?
9 DR. STEARNS: That is the process we're
10 undergoing right now that's been going on for about
11 three years.
12 DR. WALKER: Okay. Great. Thank you. Mike?
13 MR. LaROCCA: Speaking from a user
14 perspective, I think the short answer is yes in the
15 form of use cases engaged with clinicians in terms of
16 what they would actually see and be able to do.
17 DR. WALKER: Super. Thank you. Next set of
18 questions. I want to know to what extent your approach
19 used user centered design as a core design principle.
20 MR. KWAN (?): Yes. Especially in the early
21 days, whenever we released we have a focus group, a
22 field test users that really helped shape what you saw

1 today.

2 DR. WALKER: Super thanks.

3 MR. MITRA: We have done a similar kind of

4 thing. We spent two years with seven or eight

5 clinicians in a room for two years sitting down and

6 designing the CHMBHS and the consent included in that

7 form where our providers are also included in that.

8 DR. WALKER: Were the clinicians all docs?

9 MR. MITRA: Not all of them. There were

10 mental health professionals and substance abuse and

11 CDCs.

12 DR. WALKER: Thank you.

13 MR. MITRA: And some docs.

14 DR. STEARNS: We have a few veteran clinicians

15 and we actually hired a third party cognitionary (sic)

16 firm to go in and do more formal metrics analysis.

17 DR. WALKER: Great. So you all do have some

18 data about usability. Okay. Good. What members of

19 the health care team did you identify as potential

20 users of your system? And by that, I mean everybody,

21 patients, caregivers, doctors, nurses, pharmacists,

22 case managers, the whole team.

1 MR. LaROCCA: Our initial focus from a user's
2 point of view was the clinician. And interestingly
3 enough, what we often found talking to clinicians was
4 that they sometimes delegated the lookups of patient
5 data to proxies -- to their administrative staff. So
6 from the doctor's point of view they would say, well,
7 I'm going to see this patient later today, could you
8 make sure I have their summary in place so that when I
9 see them I have that information readily available.
10 DR. WALKER: Great. Thank you.
11 MR. MITRA: We have the clinicians, since it's
12 electronic, we have mostly clinicians. We also use the
13 administrative people, business managers, and they're
14 making sure that the money is coming in and they are
15 effectively spending the money. So we have all the
16 rules.
17 DR. WALKER: Great. Thank you.
18 DR. STEARNS: We're similar. We started with
19 the clinicians and also office managers now and more
20 recently, reached out to the patients.
21 DR. WALKER: Okay. Thanks. There's a science
22 and methodology of risk communication and obviously

1 there are significant risks for the patient as well as
2 benefits in this process. And as some of you noted,
3 there are questions about what consumers can and can't
4 do. Obviously, there's research that shows that when a
5 system like this is well designed, low literacy
6 consumers are actually benefitted more than high
7 literacy consumers.
8 But my question to you is what kind of risk
9 communication science methodologies have you used or
10 thought about using particularly as you explain this to
11 clinicians, but particularly patients?
12 MR. LaROCCA: I think with data sharing at a
13 high level, there are two risks that stood out to us, I
14 think from the patients point of view at least.
15 Referrings and consultations I think raise a lot of
16 issues. And in terms of from the patient's point of
17 view should this referred to clinician or the
18 consultant clinician be able to see everything that my
19 primary doctor can see? And that's been one very
20 interesting thing.
21 I think free text notes or progress notes have
22 also been a very problematic area, because it's very

1 difficult to concretely and in a foolproof way tag free
2 text with the right clinical codes so that you could
3 filter it out or not.
4 And so what we basically do is we do our best
5 at it and we audit everything, so that someone always
6 after the fact could see exactly who their data was
7 disclosed to and why.
8 DR. WALKER: Great. Thank you.
9 MS. McCARTY: What was the question?
10 DR. WALKER: The question is what kind of risk
11 communication science and methodologies you used to the
12 extent that you've tried to involve patients in setting
13 their own information sharing and what have you used
14 with clinicians so that they understand better what the
15 risks are?
16 MS. McCARTY: Sure. Our clinicians explain to
17 the patients very clearly what information will be used
18 so the patient has the choice on what information is
19 released and also the purpose of that release. So we
20 make sure that the clinician and the patient understand
21 that this is the information that will be released and
22 this is the reason why it be released and only for

1 those reasons.
2 DR. WALKER: Great. Thanks.
3 DR. MILLICAN: In e-MDs it's really the same
4 way. It's based on the individual practice and
5 individual clinicians to recommend to the patient what
6 is to be released and then the patient to give consent
7 for that.
8 DR. WALKER: Great. Thank you. So then for
9 the developers, what are your hazards control
10 methodologies both as you control hazards that could be
11 introduced by your systems designers and then hazards
12 that could be introduced by users?
13 MR. LaROCCA: I think one of the best ways
14 that we have to deal with hazard conditions is through
15 auditing. Transactions that pass through our
16 infrastructure are always highly audited, especially
17 certain key things like when someone does a break the
18 glass or emergency access, the user has to attest to
19 certain things before they're allowed to that sort of
20 transaction. And all of the attestation is logged and
21 any access of the data is logged.
22 We also do things like log changes to consent

1 policy definitions themselves. So a patient may say,
2 well I never allowed this user to see my data. And we
3 could go back and look at the trail that the history of
4 that user's of that patient's consent policy and see
5 the history of changes that occurred and when.
6 DR. WALKER: Great. Thank you.
7 MR. MITRA: We dealt with since all our
8 providers are all contracted, independent private
9 providers, and so they have their own policy, internal
10 policy, for the privacy and security and eval. So we
11 just build the IT product. We train them how to use it
12 and make sure we don't have any holes in that. But,
13 ultimately, it's still the provider's responsibility
14 whether they use an IT system or they use a paper
15 system.
16 The IT system does not mean that you can just
17 click on a button and give your data to some patients
18 and some other provider by mistake. They still have to
19 follow the same process and report the HIPAA privacy
20 officer in case there is any break in their process.
21 So they follow the same thing we pretty much created
22 the IT system to (inaudible) and help them out and we

1 do our training as much as we can.
2 DR. WALKER: Thanks.
3 DR. MILLICAN: Since we're not actually
4 sending the data segmentation, we're not quite at that
5 level yet. But within our system, of course, we
6 actively do quality control and data testing, standard
7 methodologies. And then we prioritize things that may
8 be a patient safety hazard issue, get the highest
9 priority and we do have methods in place to alert our
10 providers if we see something that could be a danger to
11 care.
12 DR. WALKER: Thank you. Melissa a little, but
13 I want to push just a little more. On measure of
14 success, everybody has ideas in their head about what
15 would constitute success and failure. I think Melissa
16 talked about usability, have you measured care process
17 efficiency, how long it takes to do this? What kinds
18 of changes it makes in the normal care process? Any
19 attempt to measure consumer satisfaction with their
20 choices one or so years after they make the choice,
21 when they've had a chance to live potentially with the
22 consequences? Any measurement of sensitivity and

1 specificity? How good are clinicians or patients or
2 whomever at blocking what they meant to block and not
3 blocking what they didn't mean to block?
4 MR. KWAN: Again, speaking from I think a user
5 perspective on this, my sense is we're at the very
6 beginning and we're still defining what to measure,
7 which is frequently the important part. And to be
8 honest, I think it's just getting to the technology
9 piece of it, I would say in general, we don't have the
10 hooks built into the technology itself to measure
11 usability. We're kind of taking a more cognitive
12 approach first and saying what ought we to be
13 measuring. And some of that depends on the patterns of
14 actual usage and which consumers actually engage where
15 and how.
16 And so I think just to be frank, we're not at
17 that point yet. But we want to establish the measure
18 and then not all things computing problems, but we do
19 think embedding specific usability measures is
20 certainly one of them. So tracking user clicks,
21 tracking how long they spend on each section is
22 important.

1 DR. WALKER: Thank you. Let me just say
2 quickly, I'm incredibly impressed with your work and
3 have some understanding of what it is to be out in
4 front and just building it.
5 TIGER TEAM DISCUSSION
6 MS. McGRAW: Terrific. Thanks very much to
7 the reactor panel for getting us started. We now have
8 a period of time questions from Tiger Team members and
9 I've noticed we're running a little overtime, so we
10 will need, I know, the full 45 minutes that we were
11 allotted so we may break a little bit late for lunch
12 because we also want to make sure we have sufficient
13 time for public comment.
14 We will not -- if I sort of count us and
15 divide up the time, each of us have the same 12 minutes
16 that our reactor panel did. So I will ask you to be
17 judicious in your questions so that we can get through
18 as many of us as is possible.
19 I want to start by asking the companies with
20 us, one, if you are willing to allow us to ask you
21 further questions afterward that you can respond.
22 Hopefully you will nod your heads and say yes. We

1 won't get through all of this, I fear.
2 Secondly, I know one thing that we definitely
3 want to see is screen shots of your consent screens.
4 So we'll remind you of this, but that's just giving you
5 a heads up on that.
6 So I am going to allow the Team members to
7 begin and I think these tent cards balance up pretty
8 well. So I'm going to ask you to put up your tent card
9 if you've got a question and I knew Dixie would. So
10 we're going to start with Dixie Baker to my right.
11 MS. BAKER: I'm going to put card down so you
12 can see me. Okay. I don't care all that much about
13 your consent screen. My biggest concern is that the
14 tools and discussion today seem to be focused on the
15 consent screen and the user interface and there's not
16 much in how the screens that are used to set up the
17 rules. And there hasn't been much discussion about how
18 the rules are enforced in the system and how the rules
19 are translated into access control rules and how those
20 rules, in turn, are enforced in the system. I got some
21 indication from InterSystems and maybe you use metadata
22 tagging and the others, it looked like the block was

1 blocked out fields in a relational database. But I'd
2 really like to know more about (1) how you translated
3 the consent rules into access control rules and (2) how
4 those access control rules are then enforced in the
5 system. And related to that, I'd also like to know
6 whether there are particular data types or data records
7 or data object that you encrypt by default. For
8 example, psychotherapy notes, under these especially
9 sensitive types of information and to whether there are
10 any of those that you by default protect.
11 MR. LaROCCA: There were a couple of questions
12 in there. I think from the most important thing to
13 recognize about what we do is we are accepting data in
14 lots of different formats. The only good way
15 technically to apply consent filters is to make sure
16 that we've normalized those into a common format so
17 then our consent engine can take the consent rules that
18 you've described an actually apply them with accuracy.
19 We take things like HS7 version 2 messages or
20 CCD messages, whatever they may be, and we put them in
21 our canonical format. Now, separately from that, in
22 our consent registry, we have the actual rules defined.

1 And those rules were collected from patients or
2 collected from the other stakeholders. Whenever
3 someone requests data, with every request, the first
4 thing that happens is the consent rules are fetched
5 from the registry, if you will.
6 And then, as part of the actual content
7 retrieval request, we package that policy and send it
8 along to what I called the edge system earlier. And
9 so the edge system as part of the input request
10 actually has the policy that is going to allow or deny
11 certain data.
12 When we actually take information out of the
13 edge systems and we put it in our format, before we
14 actually respond over the wire, we apply the policy
15 that was embedded in the request and then filter out
16 the sensitive data.
17 MS. BAKER: And send the policies along with
18 it?
19 MR. LaROCCA: Yes.
20 MR. MITRA: The way we have implemented that
21 is we know if, for example, a patient got a hundred
22 clinical activities and when you as a clinician log

1 into the system and search for the patient and go to
2 the client workspace, the first thing we do from the IT
3 programming point of view, whether you are the
4 (inaudible)of that specific location who owns those
5 records or not. If it is, then regardless of the date,
6 we bring them in. And then we scan through all the
7 records and we know the document dates and if any
8 consent exists from the patient and whichever location
9 you logged in and are trying to use the system, thus,
10 we know which provider you are.
11 The consent has a begin date and end date and
12 the consent must be active. If all of those 100
13 documents that I am scanning through, if I see the
14 document date for all of those that are between the
15 begin and end date of the consent date, and the consent
16 is active, and I'm the disclosee (sic) in this
17 scenario, then I will bring that record. I will check
18 two conditions, whether I own the record as a clinician
19 or I have access to that record. Then I will display
20 that record in the client workspace.
21 MS. BAKER: It's based on the physicians
22 identity?

1 MR. MITRA: It is by the location, the
2 provider's location, since from our perspective the
3 treatment locations, if there are five clinicians with
4 all clinical roles, they all see the same records.
5 MS. BAKER: Okay.
6 DR. STEARNS: There are tools to identify
7 which provider it is and then it's a security saying
8 who can actually visualize what type of data and what
9 settings are there. Providers specifically we do what
10 we do to support encryption, I'd have to defer to
11 people more technically familiar with our specific
12 details on how data is stored and how it's encrypted
13 and shared. We do allow for encrypted email
14 correspondence and also communications with external
15 sources.
16 MS. BAKER: But you don't encrypt data at
17 rest?
18 DR. STEARNS: I'd have to defer. I don't
19 believe it is at rest. But it's stored within a silo
20 database so it's protected. If it's shared, it is
21 obviously encrypted to any access to it. I'd have to
22 defer that question. I can do that as part of the

1 follow up, actually.
2 MS. MCGRAW: Just to make sure we get at least
3 one question in from the folks who want, I will go as
4 requested around. Carol, do you have one? Okay.
5 MS. SWEENEY: First of all, I really
6 appreciate you guys being here and the questions, both
7 the responses and the questions, they were really
8 excellent. I'm reminded many years ago during the
9 middle of the HIPAA debates, the base became known as
10 the privacy rule. Milton wrote a commentary in the New
11 England Journal of Medicine about how Mayo Clinic did
12 everything through consent and that they got 100
13 percent consents. Of course, his real commentary
14 question was that why should things be any different.
15 And, of course, back then, Mayo Clinic's file system
16 was their information system and the idea of IT coming
17 onboard and the issues that that raised was something
18 he didn't really foresee.
19 I think this panel, this whole day, is very
20 timely because we're right at another crux like that as
21 we move towards the in hand and widespread EMR
22 adoption. We're definitely going to see another

1 acceleration.
2 But one of the things that happened and so
3 I'll ask my questions really quickly now. One of the
4 things that happened was HIPAA, the privacy rule took a
5 position that it's kind of paternalistic. It talks in
6 terms of rights and responsibilities. And so it
7 doesn't really actually have a real role for consent.
8 And so one question that I have is -- you were
9 asked this question both by Jim Walker and some people
10 who were trying to get to measures. I mean to what
11 extent -- does any consent you've ever given or seen in
12 your system actually been adhered to? How does it
13 address the fact that HIPAA doesn't really -- the
14 sharing is irregardless of business associate agreement
15 or any of the other sharing that's prescribed? It is
16 irregardless of the consent.
17 MR. KWAN: Right. I'm not sure I hear the
18 technical question in that. If I can comment just
19 really briefly. I think the sense is that there does
20 need to be modifications to a framework to make it
21 clear to organizations who are implementing it. It's
22 just one of those rules that I think it's been brought

1 up before.
2 Technology enabled many things, but the more
3 clear and specific you can be, the more helpful. In
4 the meantime, I think, from a technical sense, we
5 really are experimenting and hopefully those
6 experiments can feed back up into the policy frameworks
7 to guide the decisions, what works, what doesn't work,
8 what got adopted, what was usable and what wasn't.
9 MR. MITRA: A lot of our providers are HIPAA
10 covered entities, as I said before, it's their
11 responsibility to make sure they are following the
12 process and the privacy concerns. We build the IT
13 product. We give it to them. And we follow up on that
14 anytime we see any issues with the HIPAA. We try to
15 address those through training. Providers pretty much
16 are using the system on their own. We are involved in
17 the process. We just build the product and we are
18 prepared, like an insurance company.
19 DR. MILLICAN: I think your right on in that
20 HIPAA allows us as providers to share information much
21 more freely than any of us are really comfortable with
22 sharing. All the stuff with consultants that have been

1 brought up, HIPAA doesn't prohibit me if I'm sending a
2 patient to a specialist then I'm automatically given
3 the right under HIPAA or the ability to share that
4 information.
5 However, I think, it's either stayed (ph) or
6 it's just good practice management or it's good
7 professional responsibility to not do that. And I
8 would say that nobody -- this is a very broad
9 generalization you can't really make. But nobody does
10 that. Nobody just sends information willy nilly to
11 various places.
12 Now as for the operations and insurance
13 companies and all of that, that's all -- maybe Dr.
14 Stearns could talk more to that because I try to stay
15 out of that sort of stuff.
16 MS. SWEENEY: Well, I also was glad to hear
17 your responses, because it reminds all of us that why
18 it is you may not be able to talk about the experience
19 level or some of the integration issues, because in
20 some sense, the policy -- you're in a catch-22, I
21 understand with HIPAA being one way, this is a
22 technology in a different area. And I think the first

1 response was really excellent about how these are
2 really just experiments themselves or proof of
3 concepts.
4 But along the proof of concept now, as your
5 harder technical question is actually the inference
6 problem. And so the inference problem goes hand in
7 hand with segmentation. A classic example of that is,
8 if I don't want to release -- if a persons says I have
9 HIV, I don't want that information out. I want to
10 protect against it. It's at that level that they're
11 answering the question. There are many other pieces of
12 data that might be in the system, just who the doctor
13 is that they saw, the prescription itself, the series
14 of tests that were used as a part of the diagnosis as a
15 blueprint for a positive HIV sending and so forth. And
16 the person is stuck in the roles that you give them of
17 what they can choose to consent with. And so there's a
18 clear mismatch. Because probably the person just says,
19 I just don't want to be harmed. But they're left with
20 how you say it and if you give me a box and no HIV
21 status, what do you then do about the segmentation
22 problems, which isn't a matter of just prescribing

1 rules, because it will differ from one setting to
2 another and one issue to another. Or is that beyond
3 the experiment? Anyway, I'll let you answer.
4 MR. KWAN: If I could, I'll start with that.
5 I think you raise a very good issue. I mean the
6 inference issue is an important one. A doctor seeing
7 someone's medication list will probably figure out what
8 their problems are and there's all kinds of examples of
9 that throughout the clinical record.
10 What we've tried to do is to use rules to
11 essentially package up certain related data from what
12 the patient just knows as HIV information or STD
13 information or mental health information and from their
14 point of view, they're checking the box and yes, I'll
15 do this or no, I won't. But internally, the technology
16 is actually quite sophisticated. We look for codes.
17 We look for code systems and we compare that against
18 the data that's been captured and then make a decision.
19 Is this HIV related information based on those rules?
20 If it is, we're going to take it out.
21 MS. SWEENEY: So you're saying you hardwire it
22 in, but a lot of times hardwiring doesn't -- I mean

1 have you done a specificity -- I mean normally in
2 computer science, we consider this an intractable
3 problem. I'd be interested in how you could get around
4 it with a hard set of rules.
5 MR. LaROCCA: We, in our system, don't
6 hardwire rules. What we have is a framework for the
7 rules and then typically what happens at one of site
8 like BHIX, for example, or other projects, they'll have
9 some combination of clinical staff and implementation
10 staff that will make the decisions on what rules they
11 want to build in. So as a provider of technology, we
12 give them the framework. But then an implementation
13 person along with someone with clinical expertise will
14 actually define the rules for that site.
15 MR. KWAN: I think just to add a quick
16 implementation perspective the discussion that you're
17 having here in terms of the heuristics and inference
18 are frankly, far more advanced than where we are even
19 from a proof of concept perspective.
20 So even though -- and I do want to highlight
21 this distinction which is the underlying framework is
22 there and has very significant capacity. But the

1 actual policy framework and even what we're testing, I
2 would say is much more rudimentary. So I think the
3 devil is always in the details, which is what you're
4 getting to here. Heuristics and base level of rules
5 can work at a core strain level, but as we getter finer
6 and finer levels of control, (a) we haven't even
7 started planning for those requirements and (b) I think
8 that's where the ability of the system to learn and
9 keep up with those patterns becomes as you point out,
10 intractable.
11 MR. MITRA: In out system the rules are right
12 now part of the system. We are trying to extract them
13 out and use some kind of business rule, soft manager
14 software to manage those rules, so that the business
15 users can manage their own rule. But right now, it is
16 the way the product is built, it is hardwired in the
17 system, the business rules are.
18 DR. STEARNS: I think it's a very important
19 safety issue. There are lot of labs that are drawn
20 taking care of same issue, the patients who would be
21 valuable in other settings. It's very difficult to
22 determine what should be segmented and what not,

1 because you can't predict where the patients going to
2 be and what information is necessary. I think that is
3 an area is going to require a great deal of study and
4 research.
5 We do have a similar paradigm in current
6 medicine. I've seen a lot of HIV positive patients who
7 denied being HIV positive. I only found out later. I
8 mean it's a patients right to deny -- to not share
9 information with you in the paper setting in previous
10 years. So it's not like it's unheard of. As
11 clinicians we have to be always a little on guard that
12 we can't trust everything the patient has to share.
13 But if you're relying on information, if you
14 become overly reliant on information you got say
15 through an HIE, it could become a problem. I think
16 that is a provider education issue.
17 MS. SWEENEY: Thanks.
18 MS. McGRAW: Thanks. Latonya. Gayle?
19 MS. HARRELL: Thank you very much. And I want
20 to say thank you to each and every one of your for the
21 incredible information. I am nontechnology person,
22 more of the policy side, so if I stray a little please

1 don't give me the yellow card. I have to ask a few
2 questions that perhaps stray slightly into it.
3 First of all, having run a very large
4 practice, I know in Florida we have certain things that
5 you have to ask, and I'm not sure where you're asking
6 those questions. If you're at the HIE level when you
7 deal with consent, are you depending on the provider to
8 determine what those consents are? Certainly when
9 you're dealing with the electronic health record, you
10 are. But on the data that is to be shared, whether
11 it's STD data, mental health data, abortion data,
12 whatever, who's responsible for asking the questions
13 and the patient really having control?
14 MR. KWAN: At least in our implementation and
15 this is what I tried to suggest earlier, which is even
16 though the system has the ability to have that level of
17 fine grain control, we are at this point, in terms of
18 what's current, implementing at the level of when the
19 patient specifies consent, it's consent to access for
20 all information including the sensitive data. So we
21 have not implemented consent at the finer grained level
22 within Brooklyn. So I think that the response to that

1 we would probably look from an implementation
2 standpoint to continue training and moving that down to
3 the provider level because it's a very effective
4 implementation approach. And the technology,
5 certainly, can handle it. But again, we're looking for
6 policy guidance as well.
7 MS. HARRELL: So the provider then gives you
8 the parameters under which the patient will consent to
9 their information being shared. Is that done through
10 the electronic health record? And if the record is not
11 specific enough -- or do you find that most records,
12 most products out there are specific enough to work
13 into your system and give that level of control at that
14 upper level, that RIO level?
15 MR. KWAN: No. Most products in their current
16 production deployments do not have that already built
17 in. Speaking with the various vendors, what they're
18 asking for is a very, very clear standard by which they
19 could submit that information. And secondarily, I
20 think that it's also the sense of even if they were to
21 capture it, when there are updates to that information,
22 how do they then get access to that to the extent that

1 the patient may also be using something like a personal
2 health record to capture their policies. How does that
3 get back to the actual sources?
4 MS. HARRELL: Do you see a role for
5 certification as we move forward in State 2, for
6 certification of vendor products. As I talked about
7 before, to be part of that, should that be a question
8 that the certification committee looks at to build into
9 EHRs that are going to meet the standards in order to
10 get the reimbursements for?
11 MR. KWAN: I'll have to say, being a
12 technologist, that sounds very much like a policy
13 question. But my sense is --
14 MS. HARRELL: Duck. Duck. But my question
15 is, is it an important enough element in order to make
16 the system work and to really empower the patient to
17 have control of their data, that, that is
18 technologically something that would be required to do?
19 MR. KWAN: I'll respond in this way, which is
20 that, again, in implementation, in the proof of
21 concepts, it's actually the EHR vendors that are asking
22 for that standard. I think that when you try and solve

1 this particular problem, all the systems that are
2 working together want to use a very common protocol in
3 order to exchange the information. Having said that, I
4 think once it reaches that steady state, it certainly
5 seems to be a reasonable candidate for certification.
6 MS. HARRELL: One more question. Concerning
7 liability issues, and I'm very attuned to liability
8 issues. Okay. I won't go down that road then. That
9 perhaps is more policy. Okay. I'll pass on this right
10 now. I may find another technology question.
11 MS. McGRAW: Okay. Thanks, Gayle. Sumit?
12 MR. RANA: Thanks, folks. This was very
13 helpful. I am, I guess, the resident programmer on
14 this side today. So I have a couple technical
15 questions. It'll be very bad if get yellow carded
16 here.
17 I'm not a physician myself, but in my role, I
18 think I actually work with a lot of physicians,
19 hundreds and hundreds of physicians. And this topic
20 has come up quite often. They have worries on both of
21 sides of either not disclosing enough and, therefore,
22 having a patient safety-type issue; or not being sure

1 that they can actually hide the parts that patient is
2 asking for. So one specific technical question getting
3 to that relating to the hiding aspect is the progress
4 notes. And I want to just confirm with you. I think
5 you mentioned that technically you are not filtering
6 things out of that, but you are essentially, after the
7 fact, auditing that their progress note was shared,
8 because you can't technically filter out the free text
9 aspects. Could you clarify or talk more about that?
10 MR. LaROCCA: Yes. Let me clarify that. I
11 think there are actually two issues. One is the easy
12 one and one is the hard one. The easy one is just to
13 say a wholesale policy will not share progress notes.
14 Right? And that's something absolutely we support.
15 The hard thing is to say, this progress note
16 has some concepts associated with it and to parse that
17 free text in an intelligent way where then we could tag
18 the text with certain clinical codes and those clinical
19 codes then become the basis of the consent filter.
20 That's a tricky problem. It's something we're looking
21 at. We're prototyping some things, but it's not yet
22 something that we've solved.

1 MR. MITRA: Our answer is similar. The
2 progress notes can completely taken out using the
3 consent. But in a narrative form in a text box, if you
4 type in some HIV information, the IT system won't know
5 that. It is the providers responsibility to make sure
6 they don't type sensitive information if they're
7 trained right and that can be disclosed if there is a
8 consent and we're disclosing progress notes, but there
9 is no HIV data supposed to go. But if you, as a
10 provider, put in the comment box HIV sensitive
11 information, that will go out. And that's probably
12 happening today in any IT system. There's no way for
13 us to stop that.
14 DR. STEARNS: Yes. We don't have the fine
15 lines to do either, but our system has demonstrated --
16 will allow you to tag certain data manually by the
17 physician or he can have things set up ahead of time
18 with templates so that essentially the information is
19 automatically blocked if that filter is set.
20 The document is printed, but it is printed
21 with a big black box around the data. We did it on
22 purpose. We didn't remove the data completely, because

1 we weren't certain about patient safety issues at this
2 stage in our development process.
3 MR. RAMA: Okay. And I have one other quick
4 question. From a technical implementation standpoint
5 you mentioned that you need the code to do the
6 filtering, but then you need the actual content rules
7 that specify -- the data in the tables, if you will,
8 that specify what constitutes an HIV. Do you have any
9 thoughts on does that scale as you go from a simplistic
10 single example like HIV to maybe ten or fifty or a
11 hundred?
12 MR. LaROCCA: I think it a complicated
13 problem. Certainly in demos, everything looks easy.
14 But I think the reality is if systems are contributing
15 data in different code systems, then those rules start
16 to become a lot more complex. Maybe there's ten
17 different ways to represent a medication concept and
18 you have to make sure you capture all of them if you
19 don't have faith in your translation service under the
20 covers. That becomes pretty tricky.
21 We also run into translation issues just from
22 going from a generic code like potassium to something

1 specific like potassium that was collected in blood
2 sample. So sometimes going from generic to specific
3 has some challenges in the translation. It's not
4 foolproof. It is tricky to do.
5 What we've tried to do at least in terms of
6 the usability aspect and scalability part of your
7 question, we think of rules as things that match some
8 criteria and those rules can become part of one or more
9 consent groups, if you will, or information types.
10 Maybe you have AZT recognized as a rule and you know
11 how to filter for that or trap for that and recognize
12 it. And maybe that appears in HIV information type and
13 it also appears in another information type. Over
14 time, the theory and the idea is that implementation
15 partners will build a library of these rules and
16 information types that then can be consented to or
17 denied.
18 MR. MITRA: Right now, our system built on
19 this legal piece. The consent is mostly driven by our
20 legal veteran Texas state attorneys. They decided what
21 should be in the consent form, exactly what text word
22 by word. And IT doesn't control that. So if there is

1 an HIV location, we automatically, dynamically, bring
2 up some additional questions for the provider to ask
3 the patient and fill in that information. Again, it is
4 what we have done. It is not just Texas specifically,
5 but that's whatever our attorneys told us.
6 When you try to do a national standard, in all
7 the standards we're talking, hopefully we discern if
8 you engage in process there will be more adoption when
9 you have a standard in place so you can look at all the
10 vendor products or state products, whatever is out
11 there, and for that specific sensitive information,
12 then come up with the standards that need to be
13 captured at a minimum level. And then you go through a
14 certification process so that nationwide, people will
15 at least follow those rules and best practices.
16 DR. STEARNS: If I understand the question
17 correctly, it's a huge content issue where everyone's
18 kind of freaking about it. I see ten and then we're
19 going to add a bunch of other concepts, relationships,
20 mappings, etcetera into the process. The scalability
21 issue on the content side is going to be enormous.
22 We're truly protecting personal information.

1 MR. RAMA: Thanks.
2 MS. MCGRAW: Christine?
3 MS. BECHTEL: All my questions are policy
4 questions. So I will refrain.
5 MS. McGRAW: You have to. Hold them in
6 reserve. We'll have plenty of other opportunities
7 outside of this hearing. John?
8 MR. HOUSTON: Sort of a follow to both Latanya
9 and Sumit's questions, concern about the idea that
10 certain, not just potassium might have some dual
11 meaning, but a great example is something like
12 methadone could be used in the treatment of heroin
13 addiction, but at the same time it could be used for
14 pain management. You don't want to -- I guess the
15 logic needs to be there in order to ensure that you
16 don't overly block information that might have some
17 dual purpose. That's the first thing.
18 And I think the second thing, I'm interested
19 in your thoughts on from a technology perspective is
20 that even when you have an encounter like a psyc
21 encounter, which might have very sensitive information
22 that's a part of it. There are test results. There's

1 medication that have, again, other types of generic use
2 as well as significance outside of psyc or otherwise.
3 Again, is this part of the logic model you're
4 trying to build into what you're doing?
5 MR. LaROCCA: If I could, let me address the
6 first question. The methadone example you bring up, I
7 think, is a really good one. What we do today is we
8 would filter out methadone in all cases, which you're
9 raising a good point. What we've been thinking about
10 and starting to sort of prototype just internally in
11 our own group is how the combination of rules would
12 then an information type become what makes the
13 decision.
14 Maybe the presence of methadone, but with this
15 other criteria also present becomes what makes the
16 filtered decision.
17 MR. HOUSTON: So almost diagnosis specific?
18 MR. LaROCCA: Yes. It could be. You could
19 think of it as right now the implementation says if any
20 rule fires, it's suppressed. But maybe the rules
21 should evolve to say, if this rule and this rule fire,
22 then suppress them both. And I think it's that sort of

1 end that sort of Boolean logic that we're starting to
2 think about.
3 I'm sorry. I actually forgot your second
4 question.
5 MR. HOUSTON: It's simply related to the
6 nonsensitive portion of a sensitive encounter. By
7 example, if there's a psyc encounter which involved
8 some type of prescribing of drugs that again may have
9 significance outside that psyc encounter, how do you
10 make sure that that drug information -- a great example
11 is made available that could have drug to drug
12 interactions if that drug information isn't made
13 available.
14 Is there any attempt to try to differentiate
15 that as opposed to information about the notes from the
16 psychiatrist or the psychotherapy notes, things like
17 that?
18 MR. LaROCCA: Well there is actually. When
19 input data is brought into HealthShare, it's either
20 aligned with a specific encounter or it could be sort
21 of elevated, if you will, to the patient level to say
22 what are my current mediations or what are my current

1 problems. There are filters that could be applied to
2 either. So then your example, what we would suggest
3 the implementation teams do is keep the mediation with
4 the psyc encounter, but you probably want to filter out
5 the whole psyc encounter and anything related to it.
6 But make sure as part of the data input pipeline, if
7 you will, that you've also made a copy of that
8 medication and put it on their current med list. And
9 then the current med list would export and be available
10 for people.
11 MR. MITRA: Right now, since all of our
12 providers are pretty much substance abuse provider.
13 Hiding the methadone information probably wouldn't be
14 that useful for us. As soon as we go out of our domain
15 to maybe extending data with primary care, which we are
16 planning to do in the future, obviously, those things
17 will be implemented. Right now, we don't get to the
18 medication level or the substance level to hide
19 information.
20 DR. MILLICAN: Well, as a practicing
21 physician, I really find it quite conceptually
22 difficult to understand why anybody that is taking care

1 of that patient wouldn't need to know every medicine
2 that that patient is on. As for how to do it, there
3 are some complex things and this isn't necessarily
4 safety, but it's the same concepts, where the database
5 they are using might be overly broad, like you pointed
6 out. I can think of an example where it gives me
7 medication cautions with certain medicines
8 contraindications. For example, medication for
9 migraine headaches is contraindicated in a patient with
10 basilar migraines. And this is related the diagnosis
11 code of migraine headaches. Therefore, every single
12 patient that has a migraine headache is going to have a
13 big red x that they shouldn't be taking this migraine
14 medicine. That just doesn't make sense. So from the
15 database standpoint, it's going to get hugely
16 complicated. I'm sure it's possible, but as for
17 whether you're going to spend billions of dollars on
18 making a very complicated process that's really in the
19 big scheme of things never going to be used or in a
20 very minimal, infinitesimally small proportion of
21 patients that are going to need to use that.
22 MR. HOUSTON: And one other question.

1 MS. McGRAW: No. I'm sorry, John. I really
2 am sorry. We have another half of the panel to get to
3 in about fifteen minutes. So I'm afraid we're going to
4 have to submit that one to the next one. Thanks.
5 MR. RISHEL: Talk about complexity, tracking
6 the down numbers is going to be ◆
7 I'm going to try something just a little bit
8 different. I'm going to state some conclusions I heard
9 and then ask you to respond to them.
10 Fundamentally, what I heard was statement
11 about the ability to control the retrieval of
12 information, to deny retrieval based on various rules
13 and policies and consumer choices. I didn't hear
14 anything about any technology to support what happens
15 with that information once it is retrieved. In other
16 words, if it goes somewhere else, does the consent --
17 is there technology to avoid a policy issue? Is there
18 technology that supports the consent going with the
19 data as opposed to going with being monitored where the
20 data is stored?
21 Secondly, I want to express particular
22 appreciation to the panelists who risked a yellow card

1 to try to make the point that the notion of engines and
2 coded data and all of that stuff is easy to program
3 much more difficult to implement and often parsimonious
4 use of the technology is the best. So I would be
5 interested, not now, but if we could ask them to
6 provide information on specifically what rules they've
7 implemented, what indicators in production as opposed
8 to in demo. I think that would help us determine where
9 we are in terms of the ability to support complexity.
10 And finally, I don't think I heard anything
11 about rule based consent. I thought I heard about
12 consent based on individual practitioners. I thought I
13 heard about consent based on locations, but not on the
14 kind of facility that was at the location. I don't
15 think I heard anybody say that as a consumer I could
16 say I want my psyc data to go to psyc institutions, but
17 not to by rule other kinds of institutions or certainly
18 by individuals. I'd just like to confirm whether I
19 understood that properly.
20 So those are my questions. I'd like you to
21 react in terms of did I hear it right.
22 MR. LaROCCA: I'd give a shot at first. I

1 think I remember at least two of your questions. I'm
2 working backwards. Actually, let me start with the
3 first one if I could.
4 The issue you've raised, I think, is a very
5 good one. If a patient is allowed information to be
6 disclosed, what guarantees are there that that
7 information has been disclosed are then, protected from
8 them on and what technology is in place to enforce
9 that? I think it's a really difficult issue, because,
10 at least form point of view if our infrastructure is
11 installed in a community and someone outside of the
12 community, maybe through an NSA that does a request and
13 fetches data that the patient consented to at the time.
14 And now, if that data is permanently stored in any
15 sense in the requesting community and then the patient
16 decides to change their consent policy later on and say
17 I don't want that disclosed, how does that chain occur?
18 And it's a tricky problem.
19 At least what we can do -- there are two ways
20 that we can do technically. Whenever someone requests
21 data of us, assuming that's coming through web services
22 and what you might think of as the SAMOL (ph) header,

1 we could embed the patients policy at the time so that
2 they can remember at lease, this the patients policy
3 and what their wishes are and to honor those and
4 respect those going forward.
5 The bigger issue is what happens when the
6 patient changes their consent policy. How is that
7 broadcast out to people that previously requested data.
8 It's a complicated issue.
9 MR. RISHEL: Could we go back to the first
10 part of that answer for a second?
11 MR. LaROCCA: Yes. Sure.
12 MR. RISHEL: So let's say we have a standard,
13 the technologists have done all their work to allow you
14 to express a consent rule and send it with the data.
15 To what extent are you relying on the receiving system
16 using the same exact way of encoding the data, if role
17 base is involved, the same way of determining what
18 their roles are an what would you -- you would really
19 have to require this incoming store of information of
20 every electronic medical record that ever supported a
21 physician making a decision, because they want to have
22 the information they used to make the decision. Do you

1 see a lot of EMR products that have that capability?
2 MR. LaROCCA: No. I think you raised a very
3 good point. It's tricky, because what we would think
4 of -- and it almost addresses your third question a bit
5 too wrapped up in here -- but from our point of view we
6 recognize roles and we recognize consent groups. They
7 are not the same for us. So what we think of as
8 authorization has to do with I'm a doctor or I'm a
9 nurse or I'm a clerk. What is my role and what tools
10 do I have access to?
11 Consent groups are more about who are my
12 affiliations? I'm affiliated with this practice or
13 with this hospital and with this department. And
14 through those affiliations, assuming that I have access
15 to the tool, what can I actually see from the personal
16 health record. They are different things.
17 So if it's our infrastructure on both sides of
18 the fence, then that becomes a lot easier to manage.
19 If it's a different infrastructure that may have a
20 different interpretation of what security roles are and
21 consent groups are, then there really are not
22 guarantees today to make sure that it's being used

1 appropriately.
2 MR. RISHEL: All interoperability problems are
3 solved if everybody uses the same product. Is that
4 right? So just one last question and then if I have
5 any time left, I'll ask the other people the same
6 question.
7 All right. Okay. So you have been describing
8 HealthShare today, which is an InterSystems product.
9 You were then asked how many people use Cache, which is
10 another InterSystems product in the United States and
11 you gave a large number, which I'm not going to argue
12 with. Cache is a general purpose system that you can
13 do anything with. Is that right?
14 MR. LaROCCA: Yes. It's a database platform
15 and an application service.
16 MR. RISHEL: And HealthShare is the product
17 that implements this consent mechanism that you showed.
18 Is that right?
19 MR. LaROCCA: That's correct.
20 MR. RISHEL: And how widely is HealthShare
21 being used in the United States? I'm not trying to
22 embarrass you, but I just need to clear that in our

1 evaluation of the availability of technology, that we
2 understand the difference between the consent
3 technology and your platform.
4 MR. LaROCCA: Yes. And I think that's a good
5 point. As I mentioned, our platform, the HealthShare
6 platform is itself a solution written in underline
7 Cache and Ensemble technologies also from InterSystems.
8 Cache and Ensemble are industry agnostic
9 platforms that you could use to address financial
10 service issues or healthcare issues or other
11 industries. What we've done with HealthShare is used
12 those core technologies and built reusable services for
13 healthcare integration. There's nothing inherent, so
14 to say, in Cache that addresses these issues, but
15 there's quite a lot of functionality in Cache that we
16 leverage as a HealthShare implementation.
17 MR. RISHEL: I'm not trying to ask you to
18 demean your own product, but fundamentally, the number
19 of people that have HealthShare in the country, can we
20 agree that it's considerably smaller than the number of
21 people that have Cache?
22 MR. LaROCCA: Much smaller.

1 MR. RISHEL: Okay. Thank you.
2 MR. LaROCCA: We have four customers in the
3 U.S.
4 MR. RISHEL: Okay. Thanks.
5 MR. LaROCCA: And we have one internationally.
6 MR. RISHEL: Thank you.
7 MR. LaROCCA: You're welcome.
8 MS. McGRAW: Okay, David.
9 MR. MCCALLIE: I knew that if I let Wes go
10 first, he'd ask all my good questions. So I actually
11 want to repose Wes's questions in a different way go
12 over the same ground. Really, the question is about
13 interoperability of consent policies. In the current
14 structure of the in end, a patient could end up with
15 data distributed out over many different systems around
16 the country. If you've moved a lot or lived in a
17 number of places, you could have data in four or five
18 different systems. So if you have a serious intent of
19 managing those consents in real time you need a way to
20 distribute policy across all those systems. They
21 policies and the enforcement of those policies has to
22 be as interoperable as the billing codes and SNOMED

1 codes etcetera that we've been focusing on with Stage 1
2 of meaningful use.
3 So my question is really what is the state of
4 the art and how prepared are we to manage the
5 interoperability of these consent policies? And I'm
6 directing it to the InterSystems Group, because I think
7 guys have used Exactmo (ph) which is certainly one of
8 the standards that a lot of people are interested in
9 using this. Is that an adequate standard? Are the
10 taxonomies necessary to express the rules adequate? Is
11 the rule expression itself adequately well understood
12 so that we could, in fact, distribute these policies?
13 MR. KWAN: I think I'd like to address that
14 just from an implementation perspective first of all.
15 In the New York process when we evaluated the federal
16 standards that were put forth and we were basically
17 asking the exact same question. The problem that we
18 tried to solve, first of all, is can we express New
19 York State consent policies in Exactmo?
20 And rather than trying to solve it for all
21 permutations, we really focused on our regional
22 exchange and managing to those policies. To be frank,

1 we have to spend a considerable amount of time in our
2 statewide process, first even coming up with it.
3 And then, what we found is most vendors when
4 they look at things like are pretty much, can somebody
5 please take a first stab at this. Because I don't
6 think there's enough implementation specificity at this
7 point. To be honest, it seems like it works, but,
8 again, New York State consent is very course grained.
9 It essentially ends at that level of a patient opt in
10 or gives consent to or access to a particular
11 organization.
12 And what we're finding is the underlying
13 Exactmo standard is fairly good, but there absolutely
14 are implementation decisions that we are having to make
15 in New York. And I think because we're in this proof
16 of concept prototyping where people are being flexible
17 and saying, sure, we'll go with it.
18 But whether or not that can scale
19 sufficiently, I think, is a real good question. And
20 recognizing that different states are implementing
21 different consent models, the ability of those consents
22 to truly be interoperable across then, I think is a

1 question we haven't evaluated. But, again, I think
2 that's the idea of states working at a specific policy
3 level so we can at least get information flowing in a
4 smaller area, first of all.
5 MR. MCCALLIE: Great. That's all I have.
6 MS. McGRAW: Allen, my apologies. No problem.
7 MS. FLINK: So this is probably a more
8 granular question, but being from New York and being
9 familiar with what's gone on, on both the policy and
10 technology level. In terms of your prototype, can a
11 patient make different consent choices at an encounter
12 level? So I've consented to allow my access to my
13 information, but then I have a sensitive health visit
14 and I want to change my consent preferences. And I
15 want to block all of the information at that encounter
16 level, which includes testing, labs, medications. My
17 understanding is that some of the routing of this
18 ancillary data comes in differently, and so therefore,
19 how would that be handled and could it be applied?
20 Could these consent choices then be applied to all of
21 the provider organizations where I receive healthcare?
22 MR. KWAN: I think the question is, really,

1 what's the implementation scope and use case. I
2 actually think Wes's suggestion of looking at it in
3 terms of what is the current state and what's actually
4 being deployed is analogous to that. I think the
5 answer right now is no, we're not deviating from the
6 higher level consent approach of all in type of
7 consent.
8 However, where I'd like to point out in terms
9 of experimenting that I think this is one way to look
10 at a similar problem is because we're engaging consumer
11 entered information through a personal health record,
12 we're looking to see if we can segment that data, first
13 of all, but with the use case that a consumer is
14 entering information and may want to provide two levels
15 of more granular control. One is at the provider level
16 and then the second is can we filter out specific data
17 types? And rather than interfering with the existing
18 provider exchange of information or what you might
19 think of as clinician generated date, we're starting
20 with patient entered information as a source of
21 differentiation first. It was a different way to cut a
22 similar problem.

1 MR. LaROCCA: If I could, I would just add
2 something, because I think I may have heard a question
3 a little bit differently. And I just wanted to make
4 sure at least I respond to what I think I heard.
5 Filtering out an encounter is actually easy. I think
6 the hard thing technically is what happens when you
7 have a group of encounters that are sort of logically
8 connected in some kind of case. How do you filter that
9 out?
10 You may be able to say, well, I filtered out
11 my psyc encounter, but I was separately, maybe I went
12 to the hospital to ER and then I was later admitted to
13 a different department and these different clinical
14 systems that manage those departmental areas of the
15 hospital and they don't necessarily use a unified
16 encounter number. So it starts to become challenging
17 to say, well, technically, how do you filter those
18 things out? Because from the patient's point of view,
19 they might think of them as one encounter even though
20 technically, they're implemented as several encounters.
21 There's not really in the data exchange that
22 we've seen, a case number that's supplied across

1 systems, across EMR vendors. So it's hard. What we've
2 tried to do -- some people have experimented with the
3 patient account number to see if that was way to
4 simulate this case and we could filter on that. Or we
5 could just filter out a date range, and often, that's
6 the safest thing from the patient's point of view to
7 actually do. To say, just to be safe from January 1 to
8 January 31, I just want everything suppressed.
9 But it is challenging technically.
10 DR. MILLICAN: From the provider standpoint, I
11 had a case recently where the patient asked me the same
12 sort of thing. I don't want this in my record. And
13 the reason given was that it might be somehow
14 subpoenaed for a divorce issue. And so the only way
15 really for me to avoid getting it disclosed was to not
16 put it in there at all. So basically, this was a
17 nonsense encounter in the computer, because to do
18 otherwise would have -- there was no way really for me
19 to assure that that information would be protected.
20 MS. MCGRAW: Okay. I think we need to move
21 into the public comment period now before we close for
22 lunch. Before I let Judy do that, I want to let folks

1 from the public know that we're going to be holding you
2 to the same standards that we held our Tiger Team and
3 all of our panelists today. Ask a question, make a
4 comment about the technology, or I'm afraid we're going
5 to have to yellow card you.
6 PUBLIC TESTIMONY
7 MS. PRITTS: Right. This is the public comment
8 for this part of the meeting. If there's anybody in
9 the room who would like to make a public comment, if
10 you would please come up to the microphone. I believe
11 they are on the aisles. Please state your name, the
12 organization and keep your comments to two minutes.
13 And operator, can you tell those on the
14 telephone and on the web how they might dial in to make
15 a comment, please. Go ahead.
16 OPERATOR: (Operator instructions.)
17 MS. PRITTS: We have one over here, if you
18 could please state your name?
19 MS. RICHARDS: Sure. My name is Wendy
20 Richards. I'm the president of HIT Secure, which is a
21 division of Sky Catcher Communications, an IT security
22 company. These are great fascinating applications that

1 we're hearing about today.
2 What concerns me is the lack of discussion of
3 IT security in relation to the storage and transmission
4 of this data. And if I could just give a quick ten
5 thousand foot view. We're a sole source of this
6 technology and it's new, emerging technology. It's a
7 portable systems device that can provide opportunities
8 for everybody from individuals and families wanting to
9 have their own portable personal health record, to the
10 small and medium sized, even rural physicians offices
11 to the larges HIE.
12 It's very scalable. It's hardware encrypted
13 versus software encrypted up to three factor
14 authentication including biometrics and authentication
15 certificates. We're all fixed --
16 MS. PRITTS: Can I interrupt you for a minute
17 and ask you to address your comments to consent
18 technology as opposed to security technology generally
19 then?
20 MS. RICHARDS: Essentially, our technology
21 allows for the individual to have enterprise
22 management, if you will, over their own personal health

1 records as individuals or through their healthcare
2 providers for the healthcare providers to have that
3 same enterprise level ability to partition out
4 information. For instance is you're seeing your
5 dentist and you use your personal record, you don't wan
6 them seeing your family physician information. Or if
7 you're a storage for a family, you want them to see
8 yours, but not your children's, that kind of thing.
9 So it's technology that allows for that access
10 and allows for the secure transmission, whether it's
11 voice data or video, secure streaming video, if you're
12 have for instance a remote for a rural application to a
13 doctor.
14 I just wanted to make sure that the security
15 factor was taken into consideration. Thank you.
16 MS. PRITTS: Thank you, Ms. Richards. Do we
17 have anybody on the telephone?
18 OPERATOR: You have no questions on the phone
19 line.
20 MS. PRITTS: All right. Let me take the
21 gentleman over there.
22 MR. HACKETT: How you doing? My name is Leroy

1 Hackett, I'm with McFarlane Associates. I've been
2 involved with a number of EHR implementations on a
3 community bases and regional and also I've been
4 involved with a number of HIE efforts. We've had a lot
5 of talk here about segmentation data, encryption, and
6 various products, technologies. But I think what we
7 need to look at is giving back the patient control of
8 this privacy.
9 And I think from that standpoint, some of the
10 focus needs to be geared more towards the patient
11 portals and PHRs. That it's much easier to allow a
12 patient on a one-on-one basis to get permission through
13 his PHR, one doctor, two doctors, to come one visit to
14 see his record or what the poor party wants to see.
15 I think whether then -- of course, we have to
16 pursue this effort, but I think we need to focus
17 somewhat on a personal health record avenue in
18 addressing this, because that allows the patient
19 himself, which is most important, to decide at any one
20 point in time, what doctor can look at his records, for
21 how long, how many times and what section.
22 I think this is much more an issue to address

1 than trying to allow the technology companies, allow
2 the other groups to dictate with the patient what
3 should be seen in his record. Thank you.
4 MS. PRITTS: Thank you, Mr. Hackett. Anybody
5 on the telephone?
6 OPERATOR: Yes. We have got one party on the
7 telephone line.
8 MS. PRITTS: All right. Let's take the phone
9 caller.
10 OPERATOR: Joe Cahn (ph), Modern Healthcare,
11 your line is open.
12 MR. CAHN: This is a follow up on a question,
13 an issue raised by Wes regarding tagging of metadata --
14 MS. PRITTS: Can the caller please identify
15 himself?
16 MR. CAHN: This is Joseph Cahn with Modern
17 Healthcare.
18 MS. PRITTS: Keep in mind, Joe, that this is a
19 comment period, so we won't be able to address any
20 particular questions. But if you've got a comment go
21 right ahead.
22 MR. CAHN: Okay. My comment, is I guess I

1 want to know more about what this metadata tagging, if
2 somebody could follow up with that, that'd be
3 wonderful.
4 MS. PRITTS: Thank you, Mr. Cahn. I believe
5 we have another commenter in the room?
6 MR. TOWNES: Hi. My name is Mike Townes (ph).
7 I'm with Bio Armor, LLC. We're more commonly known as
8 ZOID (ph). To address a lot of the issues when it
9 comes to the patient's ability to authenticate himself
10 and therefore approve access to the records, we're kind
11 of under the radar. Probably nobody knows about us,
12 but we have a product that allows individuals to
13 globally authenticate themselves through their mobile
14 phone, computer, or mobile device. This process is
15 very short and sweet. It's about 100 percent accurate
16 anyplace in the world. And you can do this in about
17 two to three seconds.
18 This technology lends itself to open up the
19 door for patients to approve who accesses your medical
20 records and it's very, very simple. I would ask you if
21 you wanted to find out more about our company, you
22 could go to zoid.Com and I'd be glad to talk with

1 anybody who'd like to talk with us.
2 MS. PRITTS: Thank you very much. Anyone else
3 on the telephone?
4 OPERATOR: No other responses from the
5 telephone.
6 MS. PRITTS: All right. Nobody in the room.
7 Deven, back to you.
8 MS. MCGRAW: Okay. Thank you very much Judy.
9 We're going to conclude the morning session. I want to
10 thank all of the panelists and the companies who showed
11 us your technology today. You are welcome to stay for
12 the rest of the day, of course, if you'd like. And our
13 reactor panel doesn't have that choice. We need you to
14 come back.
15 Second of all, I just want to thank the staff
16 from the office of the national coordinator for all of
17 the work that they did to pull this together. We
18 wouldn't be here today if it were not for the work of
19 Scott Weinstein and Betsy Ranslow (ph), and, of course
20 Joy Pritts, but she tells me that I need to thank Betsy
21 and Scott even more, so kudos to both of you and really
22 for pulling together this terrific day for us.

1 We do have Dr. Blumenthal on schedule to come
2 and speak to us at one. I think that's going to happen
3 at one. If he's a little bit tardy due to his
4 schedule, we'll start without him and then move to him
5 immediately when he gets here. But that just means the
6 rest of us can't be any later than one.
7 So with that, thank you all for a terrific
8 morning and we'll see you shortly.
9 (Luncheon recess)
10 MS. McGRAW: We are reconnecting after lunch.
11 We are going to start our afternoon session with some
12 remarks from Dr. David Blumenthal, who is the national
13 coordinator for health IT.
14 REMARKS BY DAVID BLUMENTHAL, M.D.
15 NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY
16 DR. BLUMENTHAL: Thank you, Deven. Thanks to
17 everyone here, the members of the policy committee, the
18 standards committee, the Tiger Team on privacy and
19 security. We are enormously indebted to you for your
20 dedication to this project and many other projects
21 you've helped us with.
22 I also want to thank our contributors today.

1 I see a range of them in front of me right now. I'm
2 sorry to have missed the morning's proceedings but I
3 have heard that they were extremely informative, a
4 great education for the members of the group and for
5 our staff. Joy Pritts, our chief privacy officer, did
6 yeoman's service in putting this activity together and
7 deserves a great deal of credit for it. And I also
8 want to thank the consumer and provider and other
9 organizations, Coalition for Patient Privacy, Dr. Peele
10 (ph), and others for their -- for stimulating this
11 work, the work that you all are helping us to do in
12 thinking about privacy and security.
13 We understand, as I'm sure you've heard
14 already, that we can't be successful unless the public
15 supports the work that we're doing to try to modernize
16 our health information system. And I think for many of
17 the public that means absolutely that it means
18 protecting their view of what privacy and security
19 constitutes.
20 We also know that we are dealing with a
21 rapidly advancing technology both in this particular
22 are of privacy and security and the electronic health

1 record and health information technology sectors
2 generally. That, of course, creates a very, very
3 important challenge for us. It means that we have to
4 engineer a continuing dialog between what we'd ideally
5 like to see as a matter of policy and what we're
6 capable of doing as a matter of practice. And
7 technology and its functionality and its capabilities
8 are very important parts of that practical reality.
9 For those of who come out of a clinical world,
10 we're used to thinking about technologies in terms of
11 their efficacy, which is how well they work in a
12 laboratory or experimental situation and their
13 effectiveness, which is how well they work when
14 deployed widely.
15 And so another challenge that we have is to
16 try and anticipate for any technology or any policy
17 what it looks like in an ideal or test situation and
18 what it actually can do when it's broadly implemented
19 and used by hundreds of thousand or millions of well-
20 intended, often skilled, but nevertheless, varied,
21 heterogeneous and sometimes fallible human beings out
22 there in the real world. So that's another thing we

1 are hoping to learn about as we go forward with this
2 dialogue between the policy and technology.
3 Though the dialogue continues, I understand
4 that you all have focused today on technology, which is
5 where we wanted to be. We have and will continue to
6 have an ongoing vigorous discussion about policy issues
7 related to privacy and security. In the Policy
8 Committee meeting we had last week, we had a very
9 informative discussion that, unfortunately, Deven could
10 not be present for because she was in imprisoned in the
11 San Francisco airport.
12 MS. McGRAW: Not in prison.
13 DR. BLUMENTHAL: That's right. But that
14 discussion will go on. It will go on in front of the
15 group here. It'll go one in front of our security
16 committee and our privacy committee and in other
17 forums.
18 I just want to thank all the folks who have
19 donated their time. We've had thousands and thousands
20 of hours of almost uniquely qualified, volunteer time
21 form a whole host of folks in both the private and the
22 public sectors and literally, almost everything we've

1 done in the last year at the Office of the National
2 Coordinator at the Center for Medicare and Medicaid
3 Services to try to advance the high tech agenda would
4 have been impossible without the kind of forum that
5 we're having here today.
6 So, once again, our gratitude and I look
7 forward to hearing more as the session goes on. I also
8 wanted to say how impressed I am with this set up,
9 including the technology. But having watched a lot of
10 Wimbledon over the weekend, I kind of feel like we're
11 set of court here, but hopefully not for eleven and a
12 half hours.
13 I know you've had a lot of sports analogies
14 and maybe tennis is a little out of bounds in the
15 parapet.
16 All right. So thank you very much. Deven, do
17 you want to take over and move us forward?
18 MS. McGRAW: Okay. We're going to proceed
19 along a similar path as we did in the morning with two
20 presentations on the technology, then a short break.
21 And then two more presentations on the technology and
22 then our reactor panel will go in the opposite order of

1 where we went the first time around, just so you're
2 ready, Jim, you'll be up first. We'll go exactly in
3 that order and then the Tiger Team will have a chance
4 to ask questions. And I'm going to go this side first
5 with my circle so that we can try to fit everybody in.
6 With that, we'll hear first form the Tolven Institute
7 and you can introduce yourself personally, please.
8 CUTTING-EDGE CONSUMER CHOICE TECHNOLOGY
9 1. THE TOLVEN INSTITUTE
10 DR. JONES: I'm the Chief Medical Officer for
11 Tolven. And for those of you in the audience who
12 actually don't recognize me, and that includes a lot of
13 old friends. There's a reason for because I reached
14 into the pocket of this suit this morning and I
15 realized I hadn't worn this suit since TEPR in 2007.
16 So this confirms everybody's worst suspicions about
17 open source companies who are located in Northern
18 California. Yeah. That's a double whammy.
19 What I'm going to do first is go through just
20 a few slides to describe the themes that have led to
21 this particular project and this particular
22 implementation of the Tolven software.

1 So as always, I tend to start with the NCVHS,
2 because the documents that they have published over the
3 last decade have not been so many, but the one's
4 they've published have been gems. So if we take as our
5 mantra some of the things that are in this document
6 remembering that Tolven was organized precisely in the
7 month that this published, the idea of exchanging
8 information across these three areas of health; patient
9 care, population health (including clinical research),
10 and personal health is something we took to heart. So
11 what we decided to do was to develop an open source
12 platform that supported all of these areas with a
13 single code line. And that the applications that we
14 developed as example applications were really different
15 personalities of the same platform.
16 Being a small company, we relied very heavily
17 on the notion of engaging partners which done on a
18 worldwide basis to further customize the platform and
19 also to develop plug ins most of which were open
20 source, but some which can be proprietary that fit into
21 this overall architecture.
22 Really the full potential of PHR systems in

1 our judgment is truly dependent upon their ability to
2 exchange with other systems. In addition to that, of
3 course, consumer control over who accesses that
4 information is absolutely critical.
5 Embedded in this -- and I hadn't realized it
6 until I looked at this again and again and again -- is
7 a problem. Who accesses the consumer's information
8 within the PHR? Because what we decided to do was to
9 say that is like granting somebody access to look into
10 my checking account. Well, we don't do that.
11 So we decided that peeking into other people's
12 accounts is not a good idea. So that the notion of
13 Tolven is to develop these series of accounts which
14 actually represent the accumulations of copies,
15 authenticated copies of information sent from source
16 systems, from other systems developed by the patient,
17 developed by the doctor, copies that can be sent from
18 one account to the other, but no one ever looks in
19 anyone else's account.
20 Now, this dovetailed very nicely with a
21 dilemma that has occurred in the Netherlands and I have
22 just put up some words from the Dutch law about how the

1 Netherlands restricts patient privacy. You can't, as a
2 physician, send information to another physician
3 without patient consent. It cannot be done. Moreover,
4 and this is support to not only the Dutch Constitution,
5 but the EU and everything. And they're very, very
6 religious about this.
7 Patients have the right to access their own
8 records. So the patient, in a sense, may be the only
9 person who can accumulate the totality of their medical
10 information, but they can certainly grant access to
11 physicians to do the same thing. Okay.
12 Now, what the Dutch have done to get this
13 going was to develop a system. And you'll have the
14 slides, so I don't read the details to you. It's
15 basically a very, very complex patient locator service
16 very familiar to those of us that have been around for
17 awhile.
18 So, if you will, the system's on the right
19 side, the little blue boxes are the areas where
20 information is created. It's in the provider's source
21 systems. And then there's this thing called the
22 National Switching Point. And, believe me, I did not

1 do the translation for the Dutch. Somebody else very
2 kindly did it for me and wrote this article.
3 And then the folks on the left are clinical
4 provider groups that want to access this information
5 and they go through the switching point and they can
6 get to it. As I said, this sounds very familiar.
7 Well. Well. Well. It turns out that another
8 decent organization called the ISO had published a
9 paper nearly seven years ago that said there are
10 basically two models. They used many, many more words.
11 I've distilled it down without distorting the meaning,
12 trust me, commonly proposed for the sharable electronic
13 health record.
14 A federated model and that's the one I just
15 showed you. And a consolidated model which is the
16 great bugaboo. Oh, it's going to be a national
17 database and they're going to have all this data. Oy,
18 yoi, yoi. Terrible. Terrible.
19 Now, the problem is, of course the federated
20 is a little rickety. It's only as good as the weakest
21 link and it has many performance difficulties not least
22 of which is security, because there are all these

1 different systems that have to reestablish security and
2 on and on and on. The consolidated system has support
3 access control, better security, and it's likely to
4 have a better price to performance ratio for those of
5 you who are running your budgets.
6 All right. So this is a terrible tension.
7 That tension has been reflected in the documents that
8 have been put out by RijnmondNet. It's reflected in
9 other decent documents that I'm aware of.
10 So a year ago, they approached Tolven because
11 they had discovered us on the open source stuff. These
12 people are into SourceForge and so then came to us to
13 establish a partnership for developing a system that
14 would resolve these tensions and the system had to
15 comply with Dutch law. The system also had to be able
16 to scale up to include the health information of 3.5
17 million citizens living in the region around Rotterdam,
18 at least that.
19 And they were aware that we'd published a
20 benchmark study with Sun regarding the scalability of
21 our solution, about two years ago.
22 Okay. So let me just run through, briefly,

1 the design. In the initial step of this
2 implementation, clinical information is pushed as CDA
3 formatted documents. Their choice, not mine. That's
4 okay. Tolven will take in any electronic format. The
5 four of us, who have been around for a very long time,
6 decided that if we were going to make mistakes, we were
7 going to make new ones. And an old mistake was
8 restricting the format.
9 So we said, okay, any electronic format can
10 come in and we'll store it, but we'll also use JBoss
11 rules engines to process these electronic documents, to
12 extract information which we in Stage 8, insofar as is
13 humanly possible, in the HL7 reference information
14 model. So it's duplicate storage of data. As my CTO
15 says, the space is cheap, just do it.
16 Okay. So there's double storage and you could
17 actually run your rules and everything on the stuff
18 that's stored in rows and columns. It's hard doing
19 rules on a CDA document.
20 Then there's an aggregation area that is
21 within the firewalls of the enterprise. This is still
22 okay with Dutch law. So the aggregation area

1 accumulates all these CDA documents organized by
2 patient. No one can view this information yet. No
3 one, not the doctor, not the patient.
4 Personal health records are set up outside the
5 enterprise in what I'm going to call a health record
6 bank concept boundary. And the health record bank
7 concept is something that Bill Yasnoff has an
8 organization called the Health Record Banking Alliance
9 that is very big on this and I am too.
10 Personal health records are set up at the
11 patient's request. The patient says, I want a personal
12 health record. The technical platform, including the
13 information model and vocabulary standards is identical
14 to that of the aggregation area. In addition, EHR for
15 clinicians who participate in the system are created
16 within this environment. The boundaries between
17 accounts are strictly enforced. No information can be
18 copied from one account to another without the explicit
19 action of the record account holder. The patient can
20 initiate a request to have copies of his or her
21 clinical information forwarded to his or her PHR
22 account. This request may be in the form of

1 subscription so that information will be automatically
2 copied unless the patient cancels the subscription or
3 it can be one at a time, we don't care.
4 So now we've got copies, the real stuff is
5 copied into the patient PHR. Clinician now publish
6 their availability. I'm a doctor. I am willing to
7 have you send me copies of your information so that we
8 can conduct business between us, patient care setting.
9 They publish their availability to receive copies of
10 patient information. The patients find these
11 clinicians in an online directory, a very simple online
12 directory. Those of us who make airline and hotel
13 reservations know what it's all about.
14 Then they select what portions of that
15 clinical information should be copied to the chosen
16 clinician EHR account. Let me say that again. The
17 patients select what they want to have copied.
18 Now if Dr. R wished to have patient HV's
19 clinical information sent to Dr. S, that request is
20 carried out by patient HV through his PHR account.
21 Rules operate to prevent copies of his information
22 being sent directly from Dr. R to Dr. S within this

1 environment. It can't happen. It has to go through
2 the patient.
3 Patients can send copies in a variety of
4 electronic formats including CCR and CCD profile of
5 CDR2 outside the boundaries of the health record bank.
6 They can print it. They can do anything they want.
7 However, further electronic copying or sharing of
8 information can no longer be governed by the rules of
9 the HRB and must now be governed by the rules of the
10 receiving system, which is why you do need an overall
11 governance set up.
12 So let me just show you a little bit about
13 what the underlying technology looks like, because I
14 can't show you the Netherlands project even though it's
15 being actively used. I am not a member of those
16 accounts. I'm just not. That's not the way Tolven
17 operates.
18 So we have a demo system that is widely
19 available on the internet. It requires me to be
20 absolutely certain that I'm typing it correctly,
21 remember my password. You can use biometrics, whatever
22 you want. We can work with any system. See? What did

1 I tell you? This always happens. I'm the world's
2 worst typist and, of course, with an audience of this
3 distinguished character, you can just imagine. Okay.
4 Let's see if that does it. That seems to have done it.
5 All right. Now, here's a whole bunch of
6 accounts that I'd created, which is of course, very few
7 users would have more than one account. Clinicians
8 could very well. For example, for a big clinical
9 trials project we're running for the NCI, it runs
10 across 18 academic medical centers, each researcher may
11 have a clinical account for identifiable patient data,
12 but then certain researchers will be able to access the
13 pool of de-identified which is used to aggregate
14 information and forward it to the NCI for clinical
15 trials. I'm not going to go into that except to point
16 out that's just the way it is.
17 Let us look at one of these crazy clinics and
18 I create them for all sorts of reasons. Again, I want
19 to say that the PHR, Personal Health Record, and the
20 Clinician Health Record are the same technology,
21 virtually the same functionality with some differences,
22 of course, that are configured by the enterprise. One

1 can actually start out with any one of the
2 personalities, if you will, of this Tolven platform.
3 Some of our partners started out with a PHR.
4 Some of them started out with CHR. Some of them
5 started out with both at the same time. And some, as
6 I've said, started out with CHR in a clinical research
7 portal. That's fine.
8 So here's a list of patients who belongs to
9 this doctor, Ann Lawrence, who is one of my mentors at
10 the University of Chicago, so I do this in honor of
11 her. And if I'm looking for a patient, it's easily
12 searched. I can search last name, first name and if I
13 find this lady who is a 77 year old, what this is
14 representing here -- and I'm going to show you a little
15 bit of functionality, because, as I said, it pertains
16 to the PHR as well -- is the ability to intake
17 information. So we have for our own peace of mind, we
18 created a data generator that generates volumes and
19 volumes of CCRs. We had to do this to do stress
20 testing.
21 So the data generator can generate CCRs that
22 are quasi-meaningful. Let's face it; we didn't put a

1 whole lot of time into it except to say we needed
2 volume. We wanted volume of things to look at. For
3 instance, this is actually a composition of results
4 that came out of a CCR document. That's been
5 processed. The rules have operated as I said they
6 should and extracted the stuff into tables and rows so
7 that, among other things, you can do fun stuff like
8 graph things if you want. Why you'd want to graph this
9 against those things, I don't care. But any numerical
10 value in this system can be graphed on the fly.
11 So that's a nice functionality. And, again,
12 this shows what I believe is an effective use of open
13 source components, because there's these open source
14 widgets out there that we've been able to bring into
15 the system. Graphing happened to be one of them.
16 There are others. There's a calendar widget. There's
17 a timeline widget and we are able to bring all those
18 in.
19 If, in fact, you want to create a new allergy,
20 for instance, for this patient -- mind you, this is all
21 very clunky because all we're trying to demonstrate to
22 our partners how it is that you go about doing this.

1 They streamline these things that we call wizards very
2 effectively. Let's say suddenly we've discovered that
3 Betty developed a rash to adhesive bandages. And by
4 the way, that dropdown list that I showed you. That's
5 from SNOMED. So those are all SNOMED encoded. If you
6 have another list, give it to us. We're vocabulary
7 independent. We happen to have loaded SNOMED because
8 it's free. But there is other stuff that you can load
9 to meet your needs.
10 So the onset of symptoms or you've got a
11 little calendar that says you can adjust it or you make
12 adjustments within the body of the things itself and
13 you add additional details, yes, no, maybe, well sure,
14 why not. And again, it turns out that SNOMED has a
15 nice set of coded allergic reactions which is really
16 lovely. So if I find rash, that's fine. SNOMED has a
17 bunch of stuff that says severity.
18 What we're doing, you see, is we're creating
19 an aggregate of things. We can match that to an
20 encounter if we want. We can marry it to an encounter,
21 but we're not going to do that this time. Here it is.
22 And what we do as we march along with this is we create

1 what we call a TRIM, a Templated Reference Information
2 Model. It's an XML document that complies with the
3 Health Level 7 Reference Information Model and is then
4 instantiated inside Tolven and, of course, it's
5 available to send out to other systems.
6 Now, nobody in their right mind would in the
7 middle of their office practice say, Oh, I'd like to
8 see the XML of this. That's why it's part of the demo.
9 And you submit and it should, within a very short
10 period of time, join the patient's roster of allergies.
11 Okay. There it is. So it came in.
12 These three things had come unloaded from the
13 CCR. This one comes from a direct input. So, of
14 course, if the CCR didn't have a source behind it, you
15 wouldn't be able to publish the source. So all of
16 these displays are entirely reasonable.
17 The same is true -- and I'm not going to go
18 through all this, but the same is true for things like
19 active medications which our RX Norm is behind that.
20 Our problem list is the Kaiser VHA problem list, but
21 you can put in anything you want, including all of
22 SNOMED. Our procedure list is the 46,000 things in

1 SNOMED that are procedures. And we use another tool to
2 bind vocabulary to the RIM. We use a semantic wiki
3 that we've developed so that we can actually bind great
4 hunks of SNOMED to the RIM based on what the stuff is.
5 Observations, we can enter a list of stuff.
6 As you can see, time is going to run out on me if I'm
7 not careful here. By the way, if you say to yourself,
8 specimen, what in the world to I want specimen for?
9 Let's put that over there. So all of the portables are
10 switchable aroundable (sic). All of these things here
11 are easily moved so that if I want to say, I'd like to
12 have procedures moved up here. All right. Fine.
13 So this is end user stuff, by the way. This
14 is end user. This is not you have a degree in HML
15 blah, blah, blah. Because, believe me, that won't
16 work.
17 If we do that, then we can save it and it'll
18 change around as we want it to. That kind of
19 rearrangement of columns and portals and tabs is hugely
20 important. However, I need to go over to the PHR.
21 Again, you're going to have to take a little bit of act
22 of faith that the same functionality exists there.

1 I want to do a couple of things. One thing I
2 want to show is that you can actually identify who it
3 is that you want to exchange information with. In this
4 case, I've got the Ann Lawrence account, but what I
5 wanted to do with another one? Well, this is dropdown
6 of the all the different CHR accounts that have been
7 created not just by me, but my colleagues and Tolven
8 and other people. I can actually exchange information
9 with those accounts and actually create that person in
10 their CHR. I'm not going to do that so anything I do
11 is cancellable.
12 By the way, one cool thing of Tolven, if
13 you're in the middle of doing something and you get
14 called away and you come back, you don't lose anything.
15 It appears on your activity list as unfinished
16 business.
17 To save time, what I had done, is I had set up
18 a connection between Wallace Jones and the Ann Lawrence
19 account. Let's just enter a really simple thing like
20 an allergy. By the way, we also have drug allergies.
21 That's unfortunately in a plug in that's just being
22 finished. We're developing a whole e-prescribing round

1 trip with a Sure Scripts Gateway that I'm going to see
2 the final version of it Thursday. But that's not
3 today, is it?
4 If I create an allergy to dust, I submit it
5 and say okay, I've got a dust allergy that's going to
6 put part of my allergies. Now, this is the fun part.
7 I built this thing called Share. You see the one Share
8 that said I'm joining Dr. Lawrence's practice. That's
9 sent over, Wallace Jones and his address and stuff like
10 that. There's a new one and so you always have the
11 destination to be confirmed. I've only got one
12 destination that I've selected here.
13 Then, type of information to share, again,
14 this is just a tiny menu, that's I'm going to send over
15 all allergies, all personal events. You can make the
16 menu as large as the entire contents of the medical
17 record. The engineers know how to do this. It's just
18 that the sponsoring enterprise for these things may
19 say, we think that our users will want to just send
20 over categories, subsets, rather than I just want my
21 serum sodium from that day, not my serum sodium for the
22 next day. That's very attractive for things like

1 weight; it may not be so attractive overall. It may be
2 harder to do.
3 So we're going to send allergies over. Why
4 are you sending this information? Well, keeping
5 informed. Informed, isn't that great? And I can't
6 stand to see it. And here it says, this is what's gone
7 over. By the way, that was another XML document. I
8 could have opened up that TRIM again, but I think
9 you're getting used to it.
10 If I close out Wallace and switch accounts and
11 relog in, of course, because you don't anybody to take
12 advantage of the fact that you've walked away from the
13 computer. And you could have timeouts with anything
14 you want.
15 This is another important thing. You can send
16 the stuff, but the receiving account doesn't have to
17 accept it. That's the same as a PHR. Not only do you
18 have control over what you send, you have control over
19 what you take in. Everything I'm talking about goes
20 two ways.
21 All right. I'm getting patient data from
22 another account. It's from the Wallace Jones family.

1 So I'm Wallace Wellford Jones, one of my medical school
2 classmates, of course, add this data to my patient and
3 here's the information that's in there, address, blah,
4 blah, blah. Part of the allergy to dust? Yes. Yes, I
5 accept this data and comment that you can actually
6 arrange a secure message to go back to the patient that
7 says we got it, thank you so much. Resubmit it. It
8 disappears from the activity list. The activity list
9 is like a begin box. It can be notification of stuff
10 that's coming from another system. It can be things
11 like this that are coming from another account. So, if
12 I go to patients again and find the Jones' and there's
13 just Wallace here. I open it up and there's my
14 allergy.
15 The two-way back and forth just keeps going on
16 and on and on. And if you resend all the allergies,
17 the system has to be smart enough, the rules engine has
18 to be smart enough to say instantiate one of these,
19 unless it's truly a new instance, in which case, then
20 you configure the display to say I've got this thing
21 that has multiple instances on the drill down, because
22 that's the way in which sort of comply with the RIM.

1 We think, by the way, that the RIM is terribly
2 important because not only does it tell you things like
3 the binding of the vocabulary, but gives you the time
4 of the instance. It gives you the source of the
5 instance. Who said it da, da, da, da, da, which allows
6 you to do a number of interesting drill downs and
7 allows for a lot of things that we can leverage for
8 meaningful use analysis.
9 It's an example of, again, this whole business
10 of this -- well, here, let's look at the problem list.
11 Of this binding of vocabulary, I want to just again say
12 that this is hugely important for us because that's a
13 big list. It's a very, very large list. And so if I
14 wanted to say well let's talk a little about something
15 that just happened to me three years ago, traumatic
16 rupture of the quadriceps tendon and here it is.
17 By the way, this says now that I've
18 established the relationship it has this thing that I'm
19 instantiating -- let's short cut, but I want to send
20 that to the Wallace Jones family when I'm done -- onset
21 of symptoms and I said it occurred three years ago,
22 about January of 2009. I could add additional details

1 and I can instantiate this diagnosis, related to
2 encounter if I want to. All these linkages, the idea
3 of relating things to diagnosis, things to problems are
4 stuff that we know how to do. It'll be part of our
5 next fold in, the one that includes the e-prescribing
6 so it occurs there.
7 I think you're getting the idea of how you
8 accumulate information in both CHR and the PHR. As I
9 say, Tolven weird. We get request all the time that
10 says I want to start a PHR on Tolven. We're not a
11 service delivery organization in that sense. We
12 provide the technology, but we don't have a PHR that
13 you can use. We have a PHR that is used by an
14 enterprise and maybe that's all they want to do. But
15 since everything is web enabled and the software as a
16 service all part of this, it's just wildly reasonable
17 in terms of finances compared to other things.
18 I see I'm down to two minutes. I'm going to
19 back to the PowerPoints. Three more slides and you
20 will be thrilled to know that I will be done on time.
21 So we've done a demonstration. As I said,
22 copies that leave the health record bank environment

1 can be distributed easily without consent of the
2 patient. Get over it. In other words, it's like
3 losing money or dropping blank checks. The only
4 protection is this one that's both familiar and often
5 violated. You've seen it all the time. You don't even
6 look to the end of the thread to see it, right? You've
7 already copied and it's too late.
8 It's best to not send electronic copies to
9 organizations that don't have the same grasp of patient
10 privacy and confidentiality. Moreover, even inside the
11 health record bank and this applies to every system
12 that you'll see that goes on the computer screen.
13 You can print out reports in the application
14 or disable printing, be my guest. See what your users
15 think about that. Where's that piece of paper I'm
16 going to take on rounds. It's possible to disable
17 printing but squawks will rival a truck running into a
18 crowd of geese.
19 You can take screenshots. You can print and
20 transmit screenshots. It can't be audited or
21 prevented. It applies to all systems. You can take
22 photographs, bring out the camera. The same laxity

1 applies to photographs of the computer. And there's
2 gossip. One of the tragedies when I left the
3 University of Chicago was three of the nurses in the
4 area that I supervised for years and years and years
5 about a year and a half after I left, got fired. Why?
6 They were overheard in the elevator gossiping about
7 somebody's pregnancy report. Gossiping. It had
8 nothing to do with electronic this, that or the other
9 thing. They just saw it.
10 In essence, the policies you're all struggling
11 with require technology to be implemented. But the
12 policies need to be broadly understood as to what kind
13 of mischief can be done even outside the electronic
14 environment. So that's enough of me being on the
15 podium and I look forward to questions you have.
16 Thirty seconds to go. Thank you.
17 MS. McGRAW: Thank you very much. Private
18 Access, go ahead.
19 2. PRIVATE ACCESS
20 MR. SHELTON: Good afternoon, Deven, Dr.
21 Blumenthal and members of the privacy and security
22 Tiger Team. Thank you very much for inviting me to

1 present. I'm Robert Shelton. I'm the CEO and founder
2 of a company called Private Access.
3 I have a written testimony that I had
4 submitted that I would ask be entered into the record.
5 It was something that worked on extensively before
6 submitting. We thought about each of those statements
7 they made in those remarks. And I'd like them to be in
8 the record, but I'd rather not read the statement.
9 With that what I would like to do is to
10 provide a few overview statements in terms of a little
11 bit about Private Access, a little bit about the
12 architecture, and the object is of the architecture
13 that we have been building for the last five years.
14 And then provide a demo for you at the first
15 instantiation of the use of that architecture in a
16 specific context with a patient population and
17 researchers. And then, finally, if I have time to come
18 back with a few closing remarks.
19 First, I'm going to start with, basically, a
20 little bit on Private Access. We look at ourselves as
21 a technology company that is providing a service do you
22 consider to be about 2 inches wide and about 5 miles

1 deep. And that is the service of providing the privacy
2 architecture for the work that a lot of other people
3 are doing in terms of building pipes and building data
4 repositories and building data analytics. We are not
5 in the to your repository business. We are not in the
6 data transmission business. We have selected this
7 little narrow niche around privacy, and we call that
8 enabling the use of the Internet to safely and securely
9 share confidential health information.
10 Our purpose is to make it fast and easy for
11 parties with the proper authority to locate use this
12 information for a variety of purposes. The strategy by
13 which we are implementing this is by building and
14 operating what they would call a Private Access Bureau.
15 It's a little bit different model from what you've
16 heard discussed before, but I think you'll be familiar
17 with it by the time we get down to zero on the clock.
18 But from our perspective it is a means to be
19 efficient, easy-to-use and cost effective way to okay,
20 to protect, and to share sensitive or confidential
21 health information based on law, institutional policy,
22 and personal privacy preferences.

1 The core technology inside of the Bureau is
2 what we call privacy layer. Privacy layer has three
3 objectives. The objectives are first to protect the
4 information, to protect the confidentiality of the
5 information. And we look at that as serving the
6 patient.
7 The second is to make it possible for data
8 seekers to locate data that they are entitled to
9 access. I would underline entitled to access. And the
10 third is at full build out to enable any holder of
11 confidential data to know quickly at a nominal plot,
12 whether the applicable laws, institutional policy and
13 the patient's privacy permissions permit that the older
14 to share the requested information.
15 If the data holder establishes a charge for
16 the use of the data, we have built into the system in
17 the privacy layer the ability to transact that charge
18 at the time that the privacy permissions are verified
19 and to distribute the proceeds received from the data
20 seeker to the appropriate parties.
21 We also have, as built into the core
22 architecture, an independent audit trail so that the

1 transactions are accounted for. This is three reasons.
2 First, to fulfill the data holder's accounting for
3 disclosures or obligations under law. Second, to
4 protect all of the participants permissible interest.
5 And finally, to help assure trust in the system. That
6 last one I would consider to be the most important.
7 So how does this work? And high-level
8 architecture, we think of the system we're dealing
9 with, that we are all dealing with, as dealing with the
10 constituencies of data seekers and data holders.
11 Data seekers is simple. They are seeking
12 data. They are seeking access to data that is held by
13 a data holder. Sometimes a data seeker doesn't know
14 who is holding data, so what do they do? They issue a
15 request saying I'm looking for this sort of data and
16 the data holder may wish to you that in permission.
17 The challenge that we are all dealing with is
18 that the data holder has obligations of protecting
19 privacy. And so, the data holder is interested in
20 protecting privacy. And so the data holder is
21 interested in knowing. Quickly, efficiently, and
22 inexpensively do I have the right to share that data

1 with the data seeker?
2 And that involves several questions? Is it
3 permissible under federal law? Is it permissible under
4 state law? Is it permissible according to my
5 institution's policies? Are there any special
6 considerations I should be concerned about? What would
7 my patient think? There is a reputational issue.
8 There are legal and reputational risks that are being
9 entailed, and there needs to be a place to get those
10 answers quickly and efficiently. And, I would add,
11 inexpensively.
12 So, what we do is we push those questions in
13 architecture up to a service bureau. So we're taking
14 those questions and wishing them up to a service
15 bureau. And then, that service bureau is what we would
16 call the privacy layer technology, which is an
17 automated transaction-based service to respond within
18 seconds to give the answer according to the law or the
19 institutional policies and the record subjects wishes
20 and to include in that any current charges for access
21 to the data for the intended purpose. We would call
22 that simply a red light and a green light, and, in most

1 cases today, an amber light.
2 It was included in the architecture of the
3 contemplation that we need to be able to reach out
4 efficiently and inexpensively to the patient to obtain
5 their consent or their decline to make the sharing.
6 I'm going to show you how this operates in a moment in
7 a demo. In this little illustration, you see the box
8 up by the patient that has a green box to consent, a
9 red box to decline to consent and a yeah box for I want
10 more information or I need to wait.
11 So from a patient perspective, it needs to be
12 that simple from their determination, should I permit
13 this data holder or not from sharing the information?
14 That information comes back and is included in the
15 privacy layer answer to the data holder and on the
16 basis that answer.
17 The data holder is able to share that data or
18 any means. Again, we are not looking at the
19 transmission of the data. The data could be shared by
20 a Federal Express envelope that contains the x-rays
21 that have been requested if they are in a paper form.
22 The data could be shared by digital means if the

1 digital means exist.
2 What we are interested in picking up, and this
3 is where electronic records are very useful, is the
4 audit trail of that transaction, because they can be
5 looking for that audit trail to come across. And what
6 we're doing is we're taking that audit report and
7 pushing that up to the patient's account so that they
8 can see the accounting of disclosures of who has access
9 to their information provided that they were adhering
10 to their audit policies. So the patient is receiving
11 the audit reports so they can view the audit trail in
12 the their account.
13 On top of this, we have built this
14 architecture to accommodate empowering what we will
15 call privacy assured applications. I said at the
16 outset, we are not trying to be everything. We're
17 trying to do something very good that's very narrow.
18 But there are a lot of other people who need to do what
19 they are doing and do that very correctly as well.
20 Hopefully we can reduce their burden in that regard.
21 We had one application that is called Recruit
22 Source and that's what I want to demo for you today.

1 It is an instantiation. It is a use case that around
2 recruitment for clinical trials, which was the market
3 segment that we selected to focus on. But it consumes
4 these data flows in the manner that I described and I
5 think will provide you with a good sense of what is
6 possible with this architecture.
7 I'm just going to overview what you are going
8 to see in Recruit Source. In addition to seeing
9 privacy Layer, which I'll show you how the patient
10 interacts with that. I'm also going to show you how a
11 researcher interacts with Recruit Source. The Recruit
12 Source is a researcher centric search site that employs
13 the search tools and uses the Privacy Assured Data
14 Index, so it is using these privacy preferences before
15 it makes a search response. And it will look something
16 like this, hopefully.
17 We are also able to pull back in search
18 results anonymous were fully identified search results,
19 again, based on privacy preferences, based on text
20 string or UMLS terminology inquiries. In the search
21 results page will look something like this. And
22 finally, I'll show you how the dynamic consent rules

1 are built into this from Privacy Layer in order to pick
2 up the patient's consent or lack of consent on a
3 dynamic basis to the information sharing that is
4 contemplated by the results to the search query.
5 So let me jump out of PowerPoint and now jump
6 over to the Internet. I hope my Internet connection
7 hasn't gone dead. If they have, then I'll refresh here
8 in a moment.
9 In addition to serving as the CEO of Private
10 Access, I served as chairman of the board of a
11 nonprofit. Actually, I resigned last Wednesday to
12 spend more time on this. So through last Wednesday, I
13 served as the chairman of the board for the last seven
14 years of the nonprofit disease advocacy group focused
15 on the condition that my son was prenatally diagnosed
16 with having. It's a chromosomal abnormality. We have
17 unusual privacy requirements within our community even
18 though we aren't in the legally protected group. I'll
19 talk about that another time so as not to run out of
20 time here.
21 We build on our website and list of clinical
22 trials that are being recruited and what Private Access

1 has done to this list is we have added these I'm
2 interested buttons. So here we have a trial on Judith
3 Ross at Thomas Jefferson University. If someone is
4 interested in participating in this trial, if the
5 patient is interested, they can click on I'm
6 interested. If I were to do that since I'm, hopefully,
7 on a live webpage here, I would actually be going to
8 our live system and I want to do, instead, to our demo
9 system. What they would be going to his website that
10 looks identical to this, but it is now on our demo
11 server as you can see in the URL up at the top.
12 Basically, they are receiving a few things
13 here. There are receiving Private Access's branding
14 for controlling his seizure health information. They
15 are also seeing the co-branding of the referring page,
16 because trust, we believe, originates with people and
17 relationships. It doesn't originate necessarily with
18 technology. It needs to be technology enabled, but the
19 relationships are vital. So we want to retain those
20 relationships throughout the flow of what we're doing.
21 In this case KS and A is the relationship that
22 was the referring relationship. This study was Dr.

1 Ross's. Actually, I picked an early androgen treatment
2 study. And I'm there, not because I am the president
3 of Private Access, but rather because I'm the chairman
4 whereas the chairman of the board of the organization.
5 So I am there because we are trying to provide the
6 continuity with the relationships that the patient has.
7 So I'm going to login and I already have an account,
8 rather than set up a new account. I'm going to login
9 as a user named Chris Briggs. And we use the same kind
10 of security and authentication protocols that are used
11 on online banking sites to protect the site from being
12 pfished or farmed to protect each of our users. So my
13 first name is Chris.
14 I try to keep the security questions easy for
15 my memory, but we used the site keys. You notice I
16 didn't allow the computer to remember me, because if I
17 did, it wouldn't bring back the site key next time.
18 Chris is now into the system and he can
19 establish another family member if he wants to bring
20 them into this or you can fill it out for himself.
21 We're going to say he selects this for himself. And
22 remember, Chris came in because he was interested in

1 Dr. Ross's androgen study. Before we get to what she's
2 interested in, we're first going to ask him to manage
3 his private information associated with who is getting
4 access to sharing.
5 So we're going to ask them a couple of
6 questions and were going to try to keep those simple,
7 by recognizing that this can be very difficult to deal
8 with granular privacy preferences, we've dealt with a
9 series of guides, or trusted intermediaries. In this
10 case we have three members; KS&A, two other than
11 myself, one is Myra Byrd who just took over as
12 chairman. So we'll follow her lead and see which she
13 suggests.
14 And what we're looking to do here is to help
15 Chris to know how other people who have similar
16 circumstances to his, respond to how they set their
17 privacy settings. We're not asking them to do it de
18 novo. We also don't want to compel him in any
19 direction. So each of our guides has lower privacy
20 concerns. So if someone has lower privacy concerns,
21 then you're going to be giving a testimonial associated
22 with how they would respond to someone who has lowered

1 privacy concerns.
2 And you can see in Myra's case, she is saying
3 for Dr. Ross, I'll let her see anything on a search and
4 I'll give her access to contact me. For all case KS&A
5 researchers, I'll give them the same. But if they're
6 outside the loop of KS&A as an aid researchers, then I
7 want them to notify me before they get access to my
8 personal information or my identifying information.
9 If she steps up to moderate privacy concerns,
10 her perspective is she would keep the other two the
11 same. She would eliminate sharing with anyone that's
12 not in the circle of trust of KS&A and in greater
13 privacy concerns, she would move it this way.
14 So let's say that Chris wishes to accept this
15 so he can customize it or accept. I'm going to accept
16 the preferences. I've involved lawyers and building
17 our disclosures so this is the restatements back of
18 what he is just permitted so he could accept those
19 privacy settings.
20 We now ask them to confirm his contact
21 information so this has been filled out. And if he
22 said, I don't have those headaches any longer, but I

1 now have a runny nose, we now have a detailed health
2 questionnaire that was developed by our researchers
3 because we're looking for things that the researchers
4 are interested in here. I'm going to go ahead and skip
5 the questionnaire. You've seen questionnaires before,
6 but just know it's there. And he has now done what it
7 takes to share his data.
8 Now, let's go over to the research side and
9 let's look at Recruit Source. I'm going to log in, but
10 instead of logging in as Judith Ross, that would be too
11 easy in some ways, I'm going to go again as Jay Guide
12 (ph). Jay is a friend of mine who is a researcher at
13 the NIH and who does work in this area of Klinefelter's
14 syndrome. Jay's favorite color is blue. And his last
15 name Guide. And I'm not going to remember him and not
16 remember the computer, so again, we get a site key.
17 So now Jay is logged into the system.
18 Remember in the case of this demo, he's looking for
19 people that meet certain criteria. So we could do a
20 text search by a keyword search or a string search if
21 we're looking for a DNA snip.
22 We could look for ages, all different sorts of

1 information if he has the right to receive that. If he
2 has the right to get that information by the privacy
3 preferences, he would receive it. If he didn't have
4 the right, it would be though it didn't exist in the
5 database. So he is only able to do the search of what
6 he has the right to see.
7 Let's say you're looking for a male. Let's
8 say he is looking for someone who A. as Klinefelter's
9 syndrome. For those of you who were doctors in the
10 room, I apologize. Klinefelter's syndrome is a
11 disorder that only affects males, so I'm a little
12 redundant there. But we see in our database, we have
13 117 search results.
14 So now if he wants to come in and narrow that
15 search, he does say let me search for people that are
16 within 50 miles of a zip code 76123. You can see I've
17 done this before. And refine the search. He's now
18 down to a single record. You see that the record is
19 pseudo-anonymized.
20 Every time a search is done, a different
21 identifier will come up for this patient. This is not
22 the same identifier, so we can't vector in on

1 identifiers. It's ID verified. We use ID verification
2 before we permit people to get into the system. And he
3 can bookmark this result. He can set up a search alert
4 so if someone in the future meets same search results,
5 he will get the new entry to the database. Or he can
6 click make contact if he wants to get in touch with
7 this person, for instance, to recruit them for, in his
8 case, let's say a specific trial. I know he has a
9 brain imaging study. So let's say he is looking for
10 someone for his brain imaging study. He can submit
11 that.
12 This is this terms of use of that data, which
13 will say he agrees to. And now tells them that the
14 search result has been submitted for consideration by
15 this person that he doesn't know who this person is as
16 of yet.
17 So we'll go back over here into privacy into
18 Private Access for Chris. And I just brought up the
19 homepage and you can see Chris Briggs logged in is
20 Chris has one privacy alert. Now he would be brought
21 here by an e-mail, a simple text e-mail, that said you
22 ever privacy alert that requires your attention.

1 But he would be brought here to see by
2 following, which is there is a research opportunity.
3 It could be a record sharing opportunity. It could be
4 a movement of my record from one specialist to another.
5 But in this case, he has a research opportunity for
6 Chris Briggs from Jay Giude.
7 And he can now open and view his research
8 opportunity. You can click on the links to read more
9 about the researcher. Remember, he originally gotten
10 into this because he said Judith Ross. So he may not
11 know who Jay Guide is. He can read more about the
12 research itself. He can view more details of the
13 specific trial. And, let's say, that he agrees to
14 consent to making available his information, it's
15 additional information, personally identifying
16 information to Dr. Guide.
17 Now the privacy alert disappears. He no
18 longer has any things to do there. But over on Dr.
19 Guide's side, if I refresh the screen, watch my
20 contacts. Did you see that my contacts just pumped up
21 with one more contact? And this contact shows here is
22 my request details on this contact if I forgot it right

1 to say, yes, I'm interested in that contact. The
2 consent has been granted. And I now, with permission,
3 and opening it up and seeing Chris Briggs personally
4 identifying information, which pursuant to the rights
5 that has granted me, I can download to my address book
6 were used in a manner that is granted the rights to use
7 it.
8 One of the questions that was in the Tiger
9 team's inquiries related to the audit requirements all
10 right, under law, is called the accounting of
11 disclosure requirements. We pay particular attention
12 to that, because in architecture we would believe that
13 should be a Bureau based service as an independent
14 party keeping those audit logs, in this case we can
15 look at this afternoon's log in from 10:55 a.m.
16 California time through Chris Briggs viewing of this
17 information at 11:04 California time with roughly 7
18 minutes to go in this demo.
19 And all of the actions in between is Chris set
20 up his directives, modified the directives, the dynamic
21 consent on the fly to give more rights than was
22 originally granted, and then ultimately seeing where

1 his data ended up and how it was implemented, how it
2 was used.
3 I would say that, for the moment at least,
4 would conclude what I intended to do a demo. Let me
5 move back to my slide presentation here for one more
6 moment.
7 Sorry for the period of silence as my
8 animations upload.
9 So what we saw was the use of the data seeker
10 hitting a database of data that was held by a data
11 holder. That data holder, not knowing, seeing some
12 data which they've been given permission to see by the
13 patient's wishes, but not seeing all of it, wanting to
14 know could they get more and then at that point had
15 reached up to the privacy layer, got the answer. It
16 said he needed to get consent from this person, whoever
17 they are. So he reached out and got that consent,
18 brought it back, employed it, and then gave him more
19 information according to this patient's wishes, and
20 then, ultimately, the audit trail being taken.
21 We call that creating an environment of trust,
22 which we established that the Markle Conference in

1 2006, where we heard trust, trust, trust being
2 discussed all over the conference as being what people
3 are looking for in order to build into the system
4 something that is trustworthy and to participate in the
5 system.
6 So what we see doing in our technology
7 development roadmap is developing three additional
8 applications, something we call Records Agent for
9 sharing records. Something called Records Valet for
10 redacting those records where a patient can redact the
11 information and determine specifically what can and
12 cannot be said. And then, finally we are building the
13 APIs in order to allow any applications that wish to
14 abide by our API set and our adaptor protocols to use
15 this technology, the basic architecture as opposed to
16 building it themselves.
17 The final comment, and I may get a yellow card
18 for this, but ultimately privacy can be viewed in two
19 ways. It can be either viewed as huge speed bump in
20 moving healthcare data to data liquidity. Or, it be
21 viewed as an achievable goal that will in fact enable
22 the promise HIE. In fact, I think both have truth.

1 The piece that I recommend you review, and if
2 you read my written testimony, you're going to see it's
3 very fundamental to my DNA through interactions with
4 patients through my own experience with the system
5 through my own familiarity with the industry that we're
6 all participants in is that trust is the essential
7 precondition upon which all of our real success
8 depends.
9 And so, hopefully, what Private Access is
10 doing is helping to build that trust and helping to
11 give technology capabilities to allow the most advanced
12 technologies to reach the consumer in a manner that is
13 useful and productive. Thank you.
14 MS. McGRAW: Thanks very much, Robert. We
15 have an early break in our RNR agenda, but since it's
16 on the agenda we're going to go ahead and take it.
17 We're running a little ahead, but I'm not going to give
18 you a longer break, because we need every bit of this
19 time. So I have ten after on my watch. So please, at
20 25 after, no more than 15 -- yes, Robert.
21 MR. SHELTON: I had three minutes left, so I
22 want to reclaim one piece that I didn't realize.

1 MS. McGRAW: Okay. Go ahead.
2 MR. SHELTON: And that was hearing the reactor
3 panel and the Tiger team's questions in the morning
4 sessions, I realize that a lot of your questions are a
5 lot more technically detailed than I'm going be able to
6 answer. And so I think I would get yellow cards,
7 because I would be telling the why as opposed to the
8 how. And I think a lot of your questions are around
9 how.
10 And so, I've asked for permission, and I want
11 to make sure that you all concur and know it's coming,
12 to get our CTO on the phone at the period where the
13 questions are being so that to the extent that you are
14 shooting over my head, which I assure, Jim, you and a
15 lot of other people are going to be doing that there's
16 someone on the phone that can answer you as opposed to
17 just waiving arms and talking like a CEO type.
18 MS. PRITT: I believe that's been arranged.
19 MR. SHELTON: Yes. Thank you.
20 MS. PRITT: So you're set.
21 MR. SHELTON: Thank you, Joy.
22 MS. McGRAW: You won't be yellow carded. Okay

1 you still only have until 25 after.
2 (Recess)
3 MS. McGRAW: Okay, folks. Come on in and take
4 your seats. Terrific. I'm going to start talking in
5 the hopes that people will quiet down and sit down,
6 including Joy. I just got yellow carded. That's
7 right. It has to happen to everybody at least once.
8 All right. Well, thank you all very much for
9 rejoining us. We're going to continue with some more
10 examples of cutting edge consumer choice technology and
11 the next up is DoD/VA VLER. The floor is yours.
12 3. DoD/VA VLER
13 MR. DUANNE DeCOUTEAU: Thank you, Madam Chair
14 and distinguished panel members. Thank you for
15 inviting the Department of Veterans Affairs, Veterans
16 Health Administration, Office of Health Information to
17 participate in these demonstrations and report to you
18 on our ongoing efforts in regard to consumer choice
19 technologies being developed for use within Healthcare
20 Information Exchanges.
21 The Department of Veterans Affairs is
22 committed to the vision that consumer choice can be

1 provided through open, mature, adaptable service based
2 architectures and standards.
3 Today's presentation is about implementing
4 advanced security and privacy in the Nationwide Health
5 Information Network, NHIN, from a security
6 practitioner's point of view. We demonstrate the core
7 technologies are themselves fundamentally practical and
8 that they make current and future security and privacy
9 needs within the healthcare community without the need
10 to replace existing electronic health record systems or
11 EHRs.
12 The VA currently participates in a number of
13 standard development organizations as co-chairs, which
14 include Health Level 7 (HL7), the Organization for the
15 Advancement of Structured Information Standards
16 (OASIS), The American Society for Testing and Materials
17 (ASTM), the American National Standards Institute
18 International Committee for Information Technology
19 Standards (ANSI INCITS), and the U.S. Technical
20 Advisory Group to the International Standards
21 Organization (ISO) and others. Healthcare standards
22 and information models provide basic building blocks

1 needed to respond to the security and privacy needs of
2 our nation's Veterans.
3 Our road to consumer choice technology has
4 been one of strong collaboration. In addition to our
5 federal partners, such as my distinguished colleague,
6 Captain Emery Fry, MD, from the Department of Navy,
7 Navel Health Research Center in San Diego, California,
8 who unfortunately wasn't able to attend today, as well
9 as Mike Davis, within the VA, who has been leading the
10 charge in this area for some time.
11 We have also enjoyed a working relationship
12 with the vendor community through our participation
13 within OASIS. Our OASIS partners include IBM, Sun
14 Oracle, Jericho Systems, JBoss/Redhat, Axiomatics,
15 Symlabs, Cisco and others, all of whom share credit for
16 the demonstration today.
17 We have lead and participated in a number of
18 multi-vendor OASIS and Health Information Technology
19 Standards Panels (HITSP) sponsored interoperability
20 demonstrations depicting real-world security and
21 privacy scenarios in healthcare. Those demonstrations
22 include:

1 RES 2010, San Francisco, California,
2 Protecting the Human Genome.
3 HIMSS, 2009, Chicago, Advanced Security and
4 Privacy in Healthcare.
5 Ditton Manor, 2008, London, England, Extension
6 to Healthcare Security and Privacy Services.
7 RSA, 2008, San Francisco, Healthcare Security
8 and Privacy as a Service.
9 Our demonstrations today are live and
10 illustrate two prototypic organizations involved in the
11 Healthcare Information Exchange. Both healthcare
12 organizations are hosted at the DoD Lab at Arizona
13 State University. One organization acts as the
14 requestor in the Healthcare Information Exchange.
15 We're actually looking at that screen right now. Its
16 policy decision point is provided to us by IBM. And
17 incidentally, today it is hosted in Australia.
18 The second acts as the responder of the
19 Healthcare Information Exchange. Its policy decision
20 point is provided to us by Jericho Systems and is
21 hosted in Dallas, Texas.
22 So the picture here is that we are separated

1 in service space. The exchange of healthcare
2 information between these prototypic organizations is
3 based on the OASIS standard for Cross Enterprise
4 Security and Privacy Authorization (ESPA) profile of
5 (inaudible) for healthcare. The responding
6 organization who enforces the consumer policy
7 preference is utilizing the OASIS ESPA profile of XACML
8 for healthcare.
9 We consider the OASIS reference implementation
10 of ESPA to be fast. IT is flexible in that it is
11 layered on top of existing healthcare infrastructure
12 and does not require wholesale replacement of exiting
13 systems. Adaptive, it can change as medical knowledge
14 changes. Scalable in that it is service based and
15 pluggable, able to scale horizontally. Transparent as
16 we extend its use through development supporting
17 ontologies that are standard based and peer review.
18 We have selected three use cases for the
19 demonstration today. These are not all inclusive, but
20 simply serve to demonstrate the available technology
21 and use of standards.
22 In our hypothetical Healthcare Information

1 Exchange, the default organizational policy allows
2 providers from the outside organization asserting the
3 role of medical doctor to gain full access to clinical
4 summaries and genomic information. Registered nurse,
5 however, are only allowed access if the stated purpose
6 of use is emergency treatment. All other users are
7 denied. And I can show that policy right now within
8 the servicing organization.
9 We'll see right here that if the purpose of
10 use is normal healthcare treatment that a medical
11 doctor is allowed access. In the case of a registered
12 nurse, it requires a purpose of use of emergency
13 treatment.
14 MS. PRITTS: Could you expand your screen a
15 little bit. It might make it a little easier to see,
16 please. Thank you so much.
17 MR. DeCOUTEAU: Okay. How's that? That's
18 perfect.
19 MS. PRITTS: I'm sorry.
20 UNIDENTIFIED: It's private.
21 MR. DeCOUTEAU: Yeah. You don't have rights.
22 MS. PRITTS: We stopped the clock.

1 MR. DeCOUTEAU: Well, we're probably going to
2 need an audio video guy to --
3 MS. PRITTS: All I wanted him to do was hit
4 the green.
5 (Conversation not related to these
6 presentations)
7 MR. DeCOUTEAU: Okay. I'll get back to the
8 screen. Our test patient, Sasha, has a long history of
9 depression for which he has not received medications.
10 Other than nonspecific abdominal pain, she is otherwise
11 healthy.
12 With the exception of her problem list, no
13 other section of her medical record contains data that
14 might disclose her mental health condition. Sasha,
15 therefore, meets with her privacy advocate or security
16 administrator and authorized the Primary Healthcare
17 Organization to share her record under the default
18 organizational policy.
19 However, she is still uncomfortable with full
20 disclosure of her mental health diagnosis even to
21 nurses. She therefore requests an additional
22 constraint preventing such disclosures to nurses under

1 any circumstance. Additionally, Sasha has recently had
2 her genome mapped. In doing so, she was identified as
3 being at risk for developing schizophrenia in the
4 future. This too makes her uncomfortable. She
5 requests a final constraint that prevents the
6 requesting physician from viewing genotype information
7 associated with schizophrenia even under normal
8 circumstances.
9 Given that, we're going to go ahead and build
10 her consent directive or her consumer choice. And what
11 you're looking at here is actually the reference
12 implementation. We've exposed the ESPA Service Based
13 Architecture in a GUI for this demonstration so that we
14 can make these changes and create this consumer choice.
15 Initially, I'm going to act a Sasha's privacy
16 advocate or security administrator and I'm going to go
17 in and create her consumer choice. First I need to
18 find here within the healthcare organization. And
19 initially we're going to opt her in using the default
20 organizational policies within Healthcare Domain B.
21 So we're going to opt in. And this is saying
22 that she wants to participate in the Healthcare

1 Information Exchange. The allowed organization, she's
2 going to allow that to default to whatever her primary
3 provider currently exchanges data with. We're not
4 going to change anything from the HL7 Confidentiality
5 Code set. This is basically a way of driving policy
6 behavior.
7 She does want to mask her problem list from
8 registered nurses. So I'm going to go up here and
9 select the structured role of registered nurse, if I
10 can find it, and create a constraint that will
11 basically deny access to her problem section of her
12 clinical summary.
13 She is also concerned about being identified
14 as at risk for developing schizophrenia. And if we
15 look at her genotype, her genome, we can see that we
16 validate with the patient that she is at risk. She
17 does have that snip. So she's able to create a
18 constraint to, again, mask that data from ever being
19 delivered. So there's the constraint.
20 Now let's demonstrate the consumer choice and
21 how it affects access to the requesting nurse. I'm
22 going to log in as Nurse Ellis. And Nurse Ellis is

1 going to bring the patient's record up from the
2 requesting organization in the Healthcare Information
3 Exchange. And two things we expect to see happen.
4 One, the nurse will initially be denied access based on
5 the organizational policy where it says that a nurse
6 can only access the clinical summary or do patient
7 discovery if the purpose of the use has been asserted
8 as emergency treatment.
9 So I'm going to go ahead and do that cross
10 domain document discovery. And then we can see that
11 the remote organization has denied access to Sasha's
12 record from the responding organization.
13 So the nurse is now going to declare or change
14 the purpose of use to emergency treatment. And during
15 the Healthcare Information Exchange, that purpose of
16 use is transferred from the requesting organization to
17 the responding. She is now granted access. So she can
18 see that there is a clinical summary available, labs,
19 and genomics.
20 I'm going to go ahead and request her clinical
21 summary and our expectations is that the problem within
22 the clinical summary has been redacted. And while that

1 clinical summary is being generated, let's go ahead and
2 take a look at the access control decision that
3 occurred during the Healthcare Information Exchange.
4 We can see that initially a deny was generated by the
5 policy engine that resides in Dallas, Texas, that being
6 Jericho Systems. We can see the secondary request for
7 document query produced a permit because the subsequent
8 purpose of use -- and I'm going to dive into the
9 technology here -- the change in the purpose of use
10 that was asserted in that exchange between the
11 organizations drove the permit in this case. We can
12 see it right here.
13 So if we go back and we look at what was
14 produced in the clinical summary, we can see that the
15 problem list has, in fact, been redacted. She is able
16 to see allergies and medications, but the problem list
17 has removed from access.
18 In the second use case, I'm logging in as Dr.
19 Bob and the expected behavior is that the physician
20 will gain access to the summary directly. Please note
21 in this case full access to the problem list has been
22 granted. Also, that Dr. Bob has access to genomic

1 data. If he searches known breast cancer alleles on
2 chromosome 6, he will discover that Sasha is, indeed,
3 at risk. However, if he searches for schizophrenia
4 alleles on chromosome 7, we will see that Sasha known
5 at risk genotype is not disclosed.
6 So I'll log in as Dr. Bob. And, again, I'll
7 bring up our test patient, Sasha. And we'll do the
8 cross-enterprise document discovery. And we see that
9 he has access. There was no organizational deny. That
10 he does have access to the clinical summary. I'm gong
11 to go ahead and request that now. And while that's
12 being generated, again, we'll go look at the access
13 control decision provided to us by Dallas.
14 So initially we see a permit was granted to
15 Dr. Bob and that the subsequent authorization decision
16 from the policy decision point in Dallas, Texas
17 produced a permit for the request of the medical
18 record. Also, one thing I should note, that the
19 redaction is an event of obligation.
20 So when my counterparts here discuss how do we
21 build a redaction service, it's an obligation basically
22 stated from the consumer's choices that says I don'

1 want you to share this, you need to remove it. And
2 there's a piece of code there someplace within the
3 architecture that actually does that for you.
4 So in the case of the nurse bringing up the
5 medical record, there would have been a obligation
6 generated to redact the problem list. Now we can see
7 it right here that within the XML obligation that the
8 patient is -- this isn't the exact one, is it?
9 Well, here's an example of an obligation where
10 medications were redacted.
11 So now if we go back to Dr. Bob we can see
12 that he problem list is available. It does identify
13 the nonspecific abdominal pain. He does have access
14 allergies, medications and so on.
15 Our next use case, we're going to look at how
16 the system can be dynamic in utilizing current and
17 future medical knowledge to drive policy decisions.
18 So in our use case, we talked about Sasha
19 being at risk for breast cancer or possibly being at
20 risk for breast cancer. So Dr. Bob is going to go
21 ahead and bring up for chromosome 6 and do a search on
22 breast cancer. And it does show, in fact, that she is

1 at risk.

2 If I do a subsequent search for schizophrenia,

3 which was the concern of the patient we see that no

4 information was found. And if we look at the policy

5 decision that occurred in that exchange, we look at the

6 obligation which says that the patient has chosen to

7 mask the genome based on a specific trait name. So

8 this tells the policy engine and the redaction service

9 and the enforcement point that it will need to redact

10 that information before delivering it to the requesting

11 organization.

12 So far I've demonstrated that a patient can

13 prevent disclosure of genotype data known at the time

14 her policy authored to be associated with any number of

15 sensitive conditions. But what about next year? What

16 about when new gene associations with schizophrenia are

17 discovered? Will Sasha have to create a new policy?

18 Fortunately, no.

19 The system dynamically searches for up-to-date

20 genotype associations at the time of the exchange. If

21 a new association has been discovered, the patient's

22 consumer choice policy will automatically adapt and

1 include the new research and the allele will be
2 redacted, if necessary.
3 In essence, the use of the reference
4 association service by the underlying security and
5 privacy framework allows the consumer choice to become
6 a living consent directive. That's an important point.
7 How do we enforce the patient's intent over time?
8 This provides a powerful bridge between
9 semantics and operational requirements that enables the
10 system to be both user friendly and ultimately
11 implementable. Our consumer choice is sustainable
12 without such dynamic adaptability.
13 So I'll go ahead and demonstrate, what does
14 that really mean? If I look at chromosome 7 and bring
15 up all of the alleles that are associated with that
16 patient, what we wanted is all of the alleles, not just
17 the at risk ones. I'll let that go ahead and refresh
18 here.
19 So what we've done is we've created Service
20 Based Architecture that allows us to insert clinically
21 relevant adaptive technologies. In this case, the
22 genome wide association study interface allows us to

1 update or provide new mappings to the human genome at
2 any given point in time.
3 Now, what I'm going to do here is I'm going to
4 actually add some new medical knowledge and show how
5 the patient's policy or the consumer choice is, in
6 fact, enforced at a later time. So I've added a new
7 risk allele for chromosome 7 for schizophrenia. There
8 it is. And if we look at the patient's current data,
9 the previous transfer data, we can see that that risk
10 allele is not mapped, nor was there any kind of
11 consumer choice decision made on that healthcare
12 object.
13 So I'm going to go ahead a re-request now for
14 schizophrenia and we should also see that again that
15 that information is redacted. We see that no results
16 are found. And, again, on the policy engine decision
17 that was made, we can see that the obligation again,
18 there was an enforcement based on the consumer's choice
19 to mask a specific portion of the human genome.
20 I've got six minutes. Thank you, again, for
21 the opportunity to participate in this important
22 hearing on consumer choice and technology options.

1 We believe that core consumer choice standards
2 are in place. New standards are under development to
3 meet gaps. Multiple vendors have demonstrated the
4 ability to implement consumer choice technology with
5 shipping products. Significant gains in consumer
6 choice can be made without change or replacement of
7 legacy electronic healthcare records systems.
8 Key policy decision point solutions exist and
9 are available at no cost. Electronic health record
10 systems need to be able to define and identify
11 sensitive data if security systems are to enforce
12 consumer choice regarding data sensitivity and other
13 aspects under the control of the electronic health
14 record. Thank you.
15 MS. McGRAW: Thank you very much. HIPAAT?
16 4. HIPAAT
17 MR. KELLY CALLAHAN: Good afternoon. This is
18 the seventh inning stretch.
19 MS. McGRAW: Hold on a second. Oh, we have to
20 reset the clock here. Hold on a sec.
21 MR. KELLY CALLAHAN: Well, wait a minute, I'll
22 start fast. Good afternoon, distinguished Tiger team

1 and discussion panel members. On behalf of Terry and
2 myself, thank you for the invitation to present our
3 technologies to this hearing. It is indeed an honor.
4 At this time, I would like to take a moment to
5 introduce you to Terry Callahan who is to my right. In
6 2002, Terry founded and incorporated HIPAAT in
7 recognition of a growing need for health information
8 privacy management and serves as its managing director
9 for the organization. Not surprisingly the company
10 name is an acronym based on HIPAA. For us it stands
11 for Health Information Protection and Associated
12 Technologies. Our mission is to empower patients and
13 enable providers with innovative health IT privacy and
14 security solutions that enhance patient safety.
15 Our specialty is consent management and
16 auditing. Terry began his career in medical
17 electronics in 1964 following a certification in
18 digital electronics. He held various sales and
19 management positions with diverse organization in the
20 medical imaging industry.
21 In 1979, he co-founded Omni Medical Devices, a
22 company which sold and serviced ultrasound equipment

1 throughout the 1980s. In the early 1990s, Terry
2 recognized that the healthcare industry needed a
3 software and hardware solution to satisfy the
4 requirements for the new digital imagine communications
5 in medicine DICOM standard. Product development
6 started in 1992.
7 And in 1994, he incorporated a company called
8 DICOMED (ph). Its first product, the DICOM image
9 manager was introduced in 1995 soon after industry
10 adoption of the DICOM standard. The product enabled
11 ultrasound and other analog images to be viewed
12 digitally over local or wide area network viewing
13 stations. For the end users organization, the product
14 design facilitated dramatic annual savings in film,
15 storage, documentation and retrieval costs and provided
16 an excellent return on investment.
17 As the originator of 7 U.S. approved patents,
18 it was Terry who provided the leadership and design
19 criteria which led to the development of various 3D
20 imaging products on a DICOM platform.
21 In 2000, Terry sold that company Sadera (ph),
22 an organization which later merged with MRG Film(ph).

1 Terry.

2 MR. TERRY CALLAHAN: Thanks, Kelly. It makes

3 me feel so old. So you have the opening screen, of

4 course. I'm not going to just give you an idea of the

5 agenda that I have in mind here.

6 So just a little about us, a little bit of

7 propaganda, consent management. Our products, we'll

8 have a demonstration and then a summary. You'll have

9 to bear with me as I'll need to be quick so as not be

10 subject to the dreaded buzzer.

11 So a little about us, we are the provider of

12 consent management and auditing for personal protected

13 health information. We do enable organizations to

14 manage privacy, both proactively and reactively. And,

15 of course, proactively through access control and

16 reactively through auditing.

17 We have benchmarked best practices in multiple

18 jurisdictions. And I think it's very important

19 especially to this group here that we are committed to

20 standards, their advancement and adoption. And we are

21 a participant in the HHS initiatives, all very

22 important to your folks here.

1 These are just examples of some of the best
2 practices. As I said, I'll just skip through some of
3 these because you'll have this at the end of the
4 session anyway.
5 Some of the standards and profiles
6 initiatives. Of course the initiatives that
7 contributed to our design are all included here.
8 You'll all be very familiar with these, but it's
9 important that you know that we're involved also.
10 HHS initiatives, you're quite familiar with
11 these too. In particular, we wanted to point out that
12 the implementation in bullet 3 of NHIN 2 (ph). We were
13 the consent engine for IBM for NCHICA (ph) for the NHIN
14 2 Forum, just to give you an idea that we've been
15 around for awhile. These were the participants that
16 were the NHIN 2. And, of course, you'll see that we're
17 in the center here, luckily easy to point to.
18 This was a good example of the use of SOA.
19 SOA was very important for the NHIN 2 project and this
20 gives you the participants in that particular project.
21 So I think it's also important just to review
22 quickly, the benefits of SOA. Of course, it is

1 consistent. Dwayne mentioned some of the benefits
2 also, of course. But it does move the heavy lifting of
3 evaluating the user's authorization away from the EMRs.
4 I think that's something that was discussed earlier
5 this morning to web based services. We'll be giving
6 you lots more about that. Privacy management and, of
7 course modification to access control policies. When
8 they're made, they're made network wide in real time.
9 So that's also important to mention.
10 The evolution -- we really started with a
11 bundled solution in '07. We did a lot of clinical
12 testing, SOA in '08 as I mentioned, commercialized with
13 IBM. Version 3 was introduced last July, almost a year
14 ago now. And, of course, that was to show that we
15 accommodate and are well informed by the HITSP
16 constructs. We're participants also in those Tiger
17 Teams, TP 20, 30, 50 to 60 and most of you will be
18 quite familiar with these.
19 And our current and ongoing work as you see
20 here is to address ARRA high tech with tools to support
21 both the accounting of disclosures, breach alerting
22 reporting. And I think some of you will be interested

1 to know that we developed dual documents, CDR to PDF
2 and CDR documents in XTSB repository. So just trying
3 to bring out some of these standards for you.
4 We area standards based. We have standards
5 based interfaces available to support applications that
6 want to provide access control in a standards based
7 format. It is important that we mention too that we
8 accommodate not only the individuals but also the
9 organizational and jurisdictional policies.
10 Again, back to standards, we're IHE ATNA (ph)
11 compliant. Comprehensive reporting is provided and
12 JAVA based. Our market engagement which would be a
13 question was we have a provider. We've included
14 consent management with some major HIT vendor prime
15 bids, usually those who are most concerned about
16 meeting standards and following standards.
17 One, in particular is a 24 hospital diagnostic
18 imaging system. Two provincial electronic health
19 record systems and here in the U.S. we are included in
20 one of the Beacon Initiatives that's been proposed, so
21 we're pleased to tell you that also. Hopefully that
22 will go forward.

1 As to consent management, of course, you'll be
2 quite familiar with all of this, but I think it's just
3 important to point out it's from our perspective it's
4 who may collect, use or disclose their PHIs. We
5 accommodate all of these in any combination of use,
6 collection and disclosure.
7 What PHI may be accessed for what purposes and
8 under what circumstances? And again, as I mentioned
9 before, supporting the creation, management and
10 enforcement of all three of the individual
11 organizational jurisdictional polices. And, of course,
12 through access control mechanisms, which will support
13 what Dwayne has been saying too.
14 It's important, we think, and as you think,
15 that we empower the consumers with privacy choices
16 about their collection, use and disclosure. But at the
17 same time, providers have to have access. So we've
18 incorporated an emergency override or break the glass
19 in that we'll be showing that to you in few minutes
20 also.
21 So there's never a concern, depending, of
22 course, on what is permitted by law and by the

1 jurisdictional policies. Anyway, it's always
2 available. Our objective was just to provide a full
3 set of tools so they could be used in any jurisdiction.
4 That was our objective.
5 And this is what we'll show you. So we have
6 nothing to do with the policies as such. That's not
7 our business. It's to provide the tools.
8 So, again, I think I've really covered this
9 already and you known about all this. Perhaps bullet 2
10 is important just to point out that a policy is a
11 patient policy, individual, organizational or
12 jurisdictional, but a policy can include one or more
13 directives. So, one or more consent directives
14 underneath the policy.
15 We do extend the rule based access. And, of
16 course, the point here I think to show that rule based
17 access has proven to be inadequate for managing privacy
18 on many occasions. And also even when a user's role
19 would typically permit access, of course. So I think
20 that's the important point, that we kind of layer on
21 top of that.
22 These are examples, which I won't go into and

1 I think this just gives you a little more detail on
2 what Dwayne was talking about following OASIS. And
3 OASIS, of course, describes information points,
4 administration points, decision points and enforcement
5 points and you can see the detail of what we do under
6 that as does the VA.
7 I think this is a good time just to mention
8 where we fit. So we are the comprehensive consent
9 management and auditing solution as you might expect.
10 What we do is we are, in fact, a third party service as
11 we see ourselves. So we support any that you see on
12 the right.
13 So if I just kind of take you to the left.
14 First of all, we have an administrator that sets up the
15 tables. We have a patient or an individual, a
16 consumer, that want to record their consent directives.
17 They do that on their own or they do it with a privacy
18 officer or with somebody who is supporting them.
19 Our connection is typically with a patient
20 registry, a provider registry. On the far right, you
21 see somebody who is making a request, so this is the
22 clinician view on the right and the patient view on the

1 left, if we could keep that in mind as we go forward.
2 So the clinician then is making a request and
3 getting a response. And he's doing that typically
4 through an EHR or a portal. From our perspective, it
5 doesn't really matter because we're just getting a
6 request and providing a response. So that EHR, that
7 portal, then is sending that access request to us.
8 We're just given the specific information; the
9 provider, consumer, what information they want to have
10 access to. And we just give back a simple response of
11 allow, deny or allow with override. So really that's
12 all that's required for an EHR to really respond to us.
13 I just want to go through a couple quickly.
14 I'm going to run out of time here, I can see. So these
15 are the services that are included in the comprehensive
16 consent management solution. And these are the
17 products that would be provided by us. The privacy
18 suite, which I mentioned was commercialized in '08, my
19 consent minder which we'll show you in a moment, which
20 is really a web services, a template display of a
21 consent. And of course, auditing.
22 Over here on the right, you see down below the

1 Privacy Manager. This is really the enforcement point
2 that can be incorporated in any HIE and I'll be
3 demonstrating that to you.
4 The JAVA consent validation interface is
5 really what is available as a software tool kit for any
6 EHR if they want to communicate with us or any standard
7 space solution in XACML and XSPA (ph). This is a tool
8 kit that's available for the various EHRs. I know I'm
9 going to get a question of the small EHRs. I might as
10 well say right now as far as that tool kit is
11 concerned, we make that available at no charge to the
12 small EHRs.
13 Just quickly, our products are My Consent
14 Minder is the policy administration point. It is
15 consumer facing. As you'll see in a moment it provides
16 the consumer a template, a web template, which is quite
17 familiar to them in that it's in the same format as
18 they would expect a consent form. It's based on
19 standards.
20 Privacy e-Suite I spoke about. It's also
21 based on standards. Privacy Manager, which is, again,
22 an application that can be incorporated into the EHR.

1 Audit Repository is a stand alone and JAVA based.
2 The last bullets, I think are important.
3 Provides automatic breach alerts of break the glass
4 access which we'll speak about. And toolkits, one is a
5 JAVA as I mentioned a moment ago for an EHR. The last
6 one is the ATNA Audit Log Toolkit, which is a toolkit
7 that is available to anybody who is proprietary and
8 wants to be ATNA compliant.
9 So now to the demonstration, if I may. So I'd
10 like you too, if you would, I'm going to show you the
11 view, the clinical view. So for example, this is any
12 clinical view, again, keeping in mind this is just one
13 way to present this to you. And what I'm presenting
14 here is the one electronic health record vendor
15 application.
16 We have Michael Briggs down on the bottom who
17 is the actual user, the clinician you might say.
18 Michael has under rule based access is allowed to see
19 only this one application. Running in context, we have
20 our application. Just bear with me, I've got to go
21 open this up for you. Okay. Here it is. We tried to
22 make this big so you could see it all quite frankly.

1 So anyway, over here, this is our application
2 that's running in the tray. So what's happening here
3 is our application. This is the Privacy Manager that I
4 spoke about earlier. And what's happening then is the
5 privacy manager is running in context with the EHR. So
6 you might say so what integration is required to work
7 with the particular EHR? If you use the standard,
8 which is HL 7 SICO(ph), we are running in context with
9 this application meaning that when I as Michael Briggs
10 go to choose in the context manager running up here a
11 different patient, that patient's name, my name and the
12 PHI that I'm trying to access goes to the Context
13 Manager. That Context Manager then goes to all
14 applications and asks if you're allowed to have access.
15 We'll make the decision based on privacy yes or no.
16 And we'll provide the information back and we'll show
17 you how all this happens.
18 And I should mention before I got on. It's
19 often asked if, in fact, the Privacy Manager has to be
20 running in context and it does not. But this is how
21 it's easiest to show it to you here.
22 So we have Michael Briggs looking at patient

1 James Warner. And now I'm going to choose Ellen
2 Johnson. There are no restrictions to access for Ellen
3 Johnson, so the context will change right away. We put
4 in a couple of consent directive so we could show you
5 how it looks. And then we'll create on at the end of
6 this demonstration.
7 So Jamie Jordon has said, I will allow Michael
8 Briggs to have access but on emergency override and, if
9 so, you have to put in a reason. So we have the
10 Privacy Manager provides a message here. This patients
11 chart has been sealed. You have to put in a reason to
12 have access. This reason also goes in the Audit
13 Repository and you click okay. Once you click okay,
14 then it switches over to Jamie Jordon and you see the
15 PHI of Jamie Jordon.
16 If in fact Michael Briggs had chosen cancel,
17 the context would not change. He never would have had
18 access. It would have been record as an unsuccessful
19 audit -- sorry -- unsuccessful access.
20 So that's an override. An override is
21 available and I'll show you some more about that in a
22 moment. Michael Duvall as an individual has said for

1 whatever reason, perhaps they're colleagues, that
2 Michael Briggs can have access to my PHI. He can
3 access to everything but my image of my CT. So in this
4 particular case we know the place or ordered number.
5 So getting back to some other questions. Can
6 we use place order numbers and other such granular
7 control items? Yes. We can.
8 So here's Michael Duvall. So it switches over
9 to Michael. In this particular case, Michael Briggs
10 say could I have access. I'm just going to cancel this
11 particular case. But I showed that from a granularity
12 standpoint, we just recorded the place order number.
13 We knew that from this application so all we're doing
14 is matching up what we received as a request with what
15 we recorded as a consent directive, as a policy.
16 Let me show you now that we have Evelyn Woods.
17 Evelyn Woods, you'll see the changes the context that
18 Evelyn Woods went out, did the consent check, comes
19 back. This takes about 50 milliseconds to do all this
20 by the way.
21 So now I'm going switch over and now we're
22 looking at the clinical side. We're now going to go to

1 the consumer side, the patient side as you recall on
2 the far left of our opening diagram. And we're going
3 to choose -- Okay. First of all, I'm going to have to
4 scroll here, because I want to make it big so you could
5 read it. So what we're showing here is my Consent
6 Minder. So this is the patient view, for example, or
7 the consumer's view. This could be accessed through a
8 PHR online, anywhere where you want to go online, a
9 portal would be another example. And what we've done
10 is we just created in this particular case five
11 examples of five policies that in this particular
12 jurisdiction, the patient could have access to.
13 So we've got one here. Allowed disclosure,
14 restrict disclosure. Allow use. Restrict use.
15 Patient masking policy. I'm going to show you this
16 because it just gives you a sense of the granularity of
17 what we're doing in the background here.
18 So what is happening here is this top portion here
19 is static. This just describes as the patient would
20 see in any consent policy what the consent is of the
21 jurisdiction.
22 So this is just standards of what they'd see

1 during admitting in the hospital or if they were
2 wherever they were going, the doctor's office.
3 This is, in the background, what we're going to do at
4 the end of all this, we're going to create two
5 documents again. One is a pdf and the other one is
6 going to be an XACML expression of this particular
7 policy.
8 So the patient can actually change the XACML
9 portion themselves depending on what they choose and
10 what they're allowed to choose. And, again, this is
11 just one example because this is going to vary
12 according to then requirements of the jurisdiction.
13 So the jurisdiction might say, we're going to
14 allow a patient to restrict disclosure of clinical
15 information, immunization record, lab tests, medication
16 history and are we going to allow them to override or
17 not? There's a selection there.
18 And you'll see here, restrict disclosure of
19 clinical information. You can turn it off. You can
20 turn it on. So, again, this XACML portion is all
21 selectable by the individual patient.
22 Going down to the bottom here, we have the

1 patient can sign it or the patient's representative.
2 And I'm going to leave this now, because I don't have
3 all the detail of this going over to the policy engine.
4 But I do want to show you how we create one at least
5 for use. Here, we're going to restrict use of
6 healthcare information. So I'm going to restrict
7 disclosure. Here is this -- this is just a very basic
8 call. The City says restrict disclosure of all PHI
9 from -- you could choose the dates from today or
10 another day until revoked or another date.
11 So this is a very, very simple ability to
12 restrict disclosure. It says, but will not be
13 disclosed except in emergency situations. Emergency to
14 us means you allow override. So in this particular
15 case, restrict disclosure of all PHI from today until
16 revoked. But I'm going to allow override is basically
17 what it says.
18 So I'm going to continue and save and as soon
19 as I save this, what's happened here is I have created
20 that pdf. It's gone into XTSB repository as CDR
21 document or two. And at the same time that XACML
22 expression has gone to the Consent Management Service.

1 The Consent Management Service has in turn created the
2 rules and the rules are sitting there now for
3 validation.
4 Let's go back from here and we'll go back to
5 our application. These are a number of virtual
6 machines as you would expect that are running on my
7 desktop here now. We're going to go back here. We're
8 show our Ellen Johnson no restrictions and here's
9 Evelyn Woods. So that's a whole chain of events that's
10 happened within 40 milliseconds, basically.
11 And we'll choose a reason, Mental Health Act.
12 Click okay. It switches over. So from a clinical
13 perspective, it really didn't affect the workflow at
14 all. And if you look at it from the clinical view and
15 you look at it from the patient's view, we did
16 everything in between. So all they did was they looked
17 at the typical consent form they're used to looking at.
18 The clinical view was not different, basically, than
19 what it usually is to the clinician.
20 Let me leave that now and I just want to
21 finish off. I'm going to run out of time here, so I do
22 want to give you a couple more slides just to show you

1 some of the other things that we can do. I won't have
2 time to demonstrate it, but I'll show you here.
3 If you were the privacy officer and you
4 wanted to see the details, the content, of that
5 particular consent policy that the patient just signed
6 off on and all the XACML information, you can go to the
7 -- this is successful by the privacy officer typically.
8 So they would see here we have a patient. I don't know
9 if you could read this, but we have a patient here,
10 Evelyn Woods. This is the policy. The policy is to
11 restrict disclosure of healthcare information.
12 And the next slide we'll show you that you
13 click on that particular restrict disclosure and this
14 shows the content of all of that XACML information in
15 a very user friendly way. So you have Evelyn Woods,
16 the patient ID, restrict disclosure of healthcare
17 information, the purpose of use that was selected was
18 "all." It was the standard static -- that's a PHI
19 directive. It's regarding disclosure. "Do not
20 disclose listed PHI." So the directive title is "allow
21 the patient to restrict disclosure."
22 Who does it apply to? So the question might

1 be who can you make this applicable to. So in this
2 particular case, we made a provider's organization or
3 facilities, departments, rules, jurisdictions. You
4 could have up to 15 different selectable entities
5 depending on the jurisdiction and to what extent they
6 want to have consent policies.
7 Who's allowed to override? So, always chosen.
8 And who's authorized to view the consent directive or
9 the consent policy itself? So that's also provided
10 for.
11 The starting date, you can it was today.
12 There's the 26th. Isn't today the 26th? No. I did
13 this the other day. That's right. Okay.
14 MR. KELLY CALLAHAN: Screen shot.
15 MR. TERRY CALLAHAN: Screen shot. I just want
16 to show as it happens, the policy decision happens to
17 be a very, very effective place for filtering out
18 information for disclosures. In other words, if we
19 follow the IFR and then say what is required -- what is
20 recommended at the moment, it is -- and I had made a
21 couple notes here so I'd have this right. So the time,
22 the date, the subject, the requestor and the reason are

1 the attributes that are required.
2 These are all available today in IHE ADNA
3 repository. The only thing is the reason we put it in
4 as an optional field. So that's what we do and we do
5 this and this is the kind of report that we're
6 providing. So this one and we can also do it manually
7 and automatically so you can have a very comprehensive
8 report.
9 So here you see on the left, the date and
10 time, the info disclosed was a diagnostic imaging
11 report by Dr. Bob disclosed to the reason, the method
12 and the decision. So I wanted to point that up to you.
13 What happened with the override, because
14 that's a potential breach, then we record it as a
15 potential breach so it's recorded in the repository as
16 a security incident. Being a security incident, we
17 recognize that as a potential breach and we immediately
18 send out an email to the privacy officer saying that
19 there is a potential breach here. And the reason that
20 we had selected in the dropdown is the reason it goes
21 in this report. So in this particular case, this
22 message number, this is what the privacy officer would

1 see. Message ID 281 created on the date, who the user
2 was and what the message was. In this particular case
3 it was to eliminate or reduce the significant risk of
4 bodily harm. So that information is provided to him or
5 her and if they want detail behind that, they can go in
6 and they get a report, an IT report specifically on a
7 breach alert so that they could see what it was, was it
8 a successful override, who it was, all of the
9 information to eliminate or reduce a significant risk
10 of bodily harm, all that information is provided to the
11 privacy officer.
12 In summary, we want to mention that -- I'm
13 doing pretty good here -- enabling providers,
14 organizations and jurisdictions to both proactively and
15 reactively manage privacy. The design does support
16 high tech provisions for accounting of disclosures and
17 breach alerts.
18 It was and I'm reading this because I think
19 it's important to say everything, "architected to allow
20 for a distributed consent management model where a
21 multistate interaction is desired." So as an example,
22 the Consent Management Service that records the

1 policies can be centralized and the access controlled.
2 The validation service can be otherwise -- all
3 distributed. Because it is that way, it could work in
4 any configuration like that.
5 We benchmarked against best practices. We
6 mentioned we are committed to standards and we do
7 participate in HHS and three minutes left. Thank you.
8 MS. McGRAW: Excellent. Thank you all very
9 much for giving us some great information and all
10 staying within the time. Greatly appreciated.
11 Okay. So now we move to our reactor panel.
12 And as I said, we're going to go in the reverse order.
13 So, Dr. Walker, you're up first. Same amount of time
14 as last time.
15 CUTTING EDGE CONSUMER CHOICE TECHNOLOGY PANEL
16 DISCUSSION
17 DR. WALKER: Thank you, Deven. So I'm still
18 obsessing about usability and health IT safety. What
19 was each of your approach to use the center design?
20 What kind of methodology? What numbers of users? What
21 kinds of users provided input into not just the
22 screens, but the design of the tools themselves?

1 MR. TERRY CALLAHAN: Do you want me to go
2 first?
3 DR. WALKER: Go ahead.
4 MR. TERRY CALLAHAN: Yes. So we mentioned
5 that in 2007, of course, this was after a few years of
6 development, we talked to anybody who would listen to
7 us. We went to CIOs. We went to privacy
8 commissioners. We went to hospitals. Anybody --
9 privacy officers. We did a lot of that.
10 And then that ended up in a bundled solution
11 and that bundled solution, we took that to a university
12 hospital and the program was actually done by the
13 privacy officer. The privacy officer, himself,
14 selected all the individuals he thought would be
15 important from his perspective that should be looking
16 at this and should be involved and should know about
17 it.
18 One of things we thought, who's going to
19 reject this and what extent? And we were quite
20 surprised when we found out that a lot of these
21 individuals actually quite liked it. Just to add some
22 detail to your question, because there always seemed to

1 be concern because am I going to get in trouble because
2 I shouldn't be doing this? Like, am I allowed to this?
3 Can I do it? Should I be doing it? And so it really
4 answered a lot of questions there too.
5 DR. WALKER: Great. Thank you.
6 MR. DECOUTEAU: We didn't have a model.
7 Actually our focus of what we demonstrated today is the
8 underlying standards based technology. So the user
9 facing tool set is just there to show that we're able
10 to create consumer choice preferences at a very
11 granular level.
12 The implementation of what ultimately will be
13 used inside the VA or DoD is going to be driven by
14 their business requirements, not what I'm showing
15 today. So basically, we've built the underlying
16 technology and now we can layer on top of the GUI
17 presentation layer.
18 DR. WALKER: Thanks.
19 MR. SHELTON: We almost have the opposite
20 answer. We started with a model and the model was that
21 it had to be consumer facing and that our interest was
22 what would the consumer respond to? We took a couple

1 of basic fundamentals. We said, (1) the consumer will
2 not pay for this. (2) The consumer will not work hard
3 for this. It needs to be simple. It needs to be
4 intuitive and if it isn't both of those or all of those
5 things that it will not get used.
6 So we started there. Your question was around
7 who do we interact with? We interacted with consumers
8 first, what I used to call taxicab surveys. We then
9 hired a company that did consumer interfaces for
10 gaming, for consumer based gaming that did the work for
11 Universal Studios, Hollywood, to do our Graphical User
12 Interface design.
13 And we married that with also hiring the
14 person who had been Chief Privacy Officer for the ONC
15 and head of the HITSP panel, Lee Jones, program manager
16 for HITSP and head of the statewide implementation
17 architecture for the State of New York. So when the
18 people doing the user interface design could look in
19 the face of the use case of how that interface design
20 was going to be used and see everything in that use
21 case consumed by their interface, then were done. And
22 when Lee could look at them and say, I see in your

1 interface how it will accomplish everything that I need
2 to serve this market, then we were done.
3 DR. WALKER: Great. Thank you.
4 DR. JONES: We went into this with the
5 stunning realization that we did not have perfect
6 wisdom. And that the worst thing we could do was to
7 develop the whole thing up too the user interface and
8 call it a day and congratulate ourselves.
9 I'd had the privilege of sitting in user group
10 meetings for major software companies where the users
11 argued about such things as the order of the columns
12 and everything else began to get a little flavor of
13 that when I talked about the flexibility of what have.
14 So we faced technical users by having a
15 swappable component stack. So, for example, even
16 though our quote/unquote "out of the box deployment" is
17 built on durable open source components, there will be
18 people who have a love affair with a proprietary
19 relational database who I can't mention, but whose name
20 begins with O. So if they want to do that, that's fine
21 by us. If they have an all you can eat license for O,
22 press a button and it'll run on O rather than POSCRS

1 (ph) or My SQL or whatever have you. The interesting
2 thing --
3 DR. WALKER: Great. Thank you.
4 DR. JONES: -- is the same is true with end
5 user and that we meet with the user groups either with
6 wire frames or with engineers on site to say, okay, how
7 can we do this better for complicated documentation
8 input, you need deep domain specific users. So we have
9 twofold ways of approaching this.
10 DR. WALKER: Thank you. The next question is
11 hazard control methodology for designers and users.
12 What I mean by hazards came out of one the examples.
13 If that patient with potential to develop
14 schizophrenia, starts to have subtle symptoms and their
15 caregiver can't figure out what's going on, partly
16 because they don't have that information, then the
17 patient's at risk of slow diagnosis and treatment.
18 And how do you manage those hazards? How do
19 you assess those respectively? And then what kinds of
20 methodologies have you used to communicate them
21 particularly to patients and consumers but also to
22 clinicians?

1 MR. TERRY CALLAHAN: Certainly you try to
2 incorporate them. Okay. So your prime example would
3 be the override provision or break the glass? I think
4 once that's available, I think it really provides
5 everything that every wants. In other words, the
6 patient wants privacy but the clinician wants access.
7 So I think that in particular provides a very good way
8 of making sure that that information is available
9 regardless.
10 DR. WALKER: Thanks.
11 MR. DECOUTEAU: I totally agree with that.
12 The purpose of use should drive that decision within
13 the clinical environment.
14 DR. WALKER: Okay.
15 MR. SHELTON: And I guess I would answer more
16 -- agreeing with everything that's been said, I would
17 add to it a layer of education with the consumer. That
18 the consumer needs to understand what's going on,
19 because no consumer wants to get bad treatment. What a
20 consumer wants is the same things as the provider
21 wants. But the consumer, at the same time wants to
22 know that their data is being protected privately.

1 So they're right, but the education component,
2 which is why we brought in the guides and the pieces
3 that you saw in the demonstration is from my
4 perspective critical to getting consumer buy in and
5 trust.
6 DR. WALKER: Thank you.
7 DR. JONES: Yes. Again, it's unwise to be
8 perfectly wise on this. So that our own approach is to
9 say to the sponsoring enterprise, what are the policies
10 that you want to implement? If you want to implement a
11 policy that notifies clinicians that there is
12 incomplete data, it is very simple to use the JBoss
13 rules engines that says when the patient selects
14 information and does not select the entire record,
15 there will be a note that goes to a clinician that says
16 this is incomplete information. That's number one.
17 Number 2, you can sequester information in an
18 anonymized database for instance of drugs that says,
19 okay, we'll run the rules over this stuff and we'll
20 notify you that there's a problem without telling you
21 what the problem and you must go to the patient to get
22 permission to see this.

1 So there's all sorts of things you can do, but
2 we utterly depend upon the sponsoring and implementing
3 enterprise to inform us of the policy and then we will
4 technically empower it.
5 DR. WALKER: Okay. Thank you. What standards
6 are needed to facilitate extension of your solution?
7 MR. TERRY CALLAHAN: Certainly, I think that
8 the standards that out there now are adequate to get
9 going. We have accepted all the standards that are
10 available currently and people on the panel here, of
11 course, would know about the CBCC document which is
12 coming up very shortly.
13 In any case, we've already incorporated the
14 CER2 and doing everything that is described in that
15 document including the XACML, which then we'll go to
16 HIMS (ph) or HL7 etcetera. So quite frankly, we don't
17 know of any standards that are necessary over an above
18 what we do now. We could stand corrected, of course.
19 But that's our current assessment.
20 DR. WALKER: Thank you.
21 MR. DeCOUTEAU: I think the standards that we
22 need are, in fact, in place. I think wholesale

1 adaption of those standards is needed within the
2 electronic health record industry. That's pretty much
3 it. We are working towards, in our group, ontologies
4 to make our standards that we're building within OASIS.
5 It's more usable to the end user. And we're working on
6 things that describe care teams, organization and
7 treatment ontologies and things of that nature. So
8 these things are ongoing. We understand there's gaps,
9 but right now for us to get going, probably the core
10 standards are in place.
11 DR. WALKER: Okay. Thanks.
12 MR. SHELTON: I think the core standards are
13 in place as well, but I'm going to use my lifeline and
14 call out for Monte's input on this one to give a more
15 personalized answer.
16 Monte, are you in the room?
17 MONTE GIBBS: (By telephone) In diversity, in
18 the standards that exist out there, I do agree with my
19 colleagues as well that we have the basis of what is
20 there to get us started. But would most likely help
21 propel this or produce new innovation and better
22 adoption is to look for industry initiated convergence

1 around those standards.
2 Obviously, we approach from the perspective of
3 form agnosticism. We look to be able to enable
4 granularity at both the document and the field level
5 basis. I think so long as that specificity exists,
6 we'll continue to be successful, but we do need to
7 begin to see better, closer, cleaner, and more
8 compressed adoption of a few of the standards, rather
9 than the production of new standards.
10 DR. WALKER: Okay.
11 DR. JONES: I think I would agree. It's
12 extending important standards. I think that HL7 needs
13 to have additional work done, but they're currently
14 beavering away at that and that's fine. They need to
15 pay attention to the fact that these things have to be
16 implemented. They can't exist as abstract entities to
17 be argued in nearly airless rooms. So I think that's
18 terribly important. I think SNOMED CT always needs to
19 be extended, but we need to participate in that very
20 actively. And finally, I think that the marriage
21 between C Disk and HL7 or the interrelationship between
22 C Disk and HL7 is absolutely critical and they've got

1 to continue to play nice in the sandbox to forward
2 clinical research activities.
3 DR. WALKER: Thank you.
4 MS. McGRAW: That couldn't have been better
5 timing. Thank you. Okay. Dr. Kibbe. You're up.
6 DR. KIBBE: Okay. First, I want to thank all
7 of you for leading us through your software, its
8 development, and the ideas behind it. As a software
9 developer myself, I can understand how difficult a
10 journey it has been for all of you to get to the point
11 where you are now. And in my comments, I don't want to
12 diminish at all what you've accomplished because I
13 think it's very significant.
14 But at the same time, I'm really struck by the
15 complexity of the job that your software is trying to
16 get done. And I think part of that may be that you're
17 all starting from the policy needs that aren't real
18 clear that are sort of being developed as we -- or as
19 you've gone along. Of particular organizations, it's
20 maybe just the world has been for the past while.
21 The same thing, you've got business
22 requirements that you're to meet. And I'm also struck

1 by the fact that the access model here assumes that the
2 data are in a provider organization and generally
3 speaking in a large provider organization so that the
4 patient is -- I mean this is not entirely true. You're
5 shaking your head. I understand, Robert. But my point
6 is is that I think the world is actually in the
7 opposite direction very, very fast.
8 And that is we are having more and more
9 sources of information in electronic format. Not just
10 large provider organizations, but laboratories and the
11 pharmacies and the little electronic health record
12 systems in small medical practices and personal health
13 record stores and so forth. And so to this begs trying
14 to think through how to make it simpler. And that's
15 what I want to ask you. I want to throw this out,
16 because I think I like this idea of attaching the data
17 with the patient or the person and then attaching the
18 consent management or at least some of it to the data
19 some way.
20 One of the reasons why we develop the
21 continuities of care record standard was this idea of
22 being able to empower the patient to have his or her

1 own relevant data set and structured data that could be
2 used by the person, by the individual, as well as be
3 used by the providers and services. So I'd like to ask
4 each one of you a question. What would it take in your
5 mind to create a way of attaching at least some of the
6 consent management to the data itself?
7 For example, do we need an new data object in
8 the continuity of care record entitled consents, in
9 which we could encode the patients preferences with
10 respect the release of their information in a global
11 sense or specific components or even related to
12 specific actors like particular providers and it could
13 be changed? And I know that that's difficult because
14 you'd have to encrypt or shield from view the rest of
15 the file in order to be able to then unwrap it at the
16 time that you looked at that information and said, oh,
17 here's what I can see.
18 But my question to you is, is there some sort
19 of breakthrough disruptive innovation that would make
20 your job as software developers and people who are
21 trying to do a good job at this really much, much
22 easier?

1 MR. TERRY CALLANHAN: Thank you. There's a
2 few things there. First of all, I think that
3 centralizing some of this is quite important. From our
4 standpoint, again, what we produce is a set of tools,
5 as I mentioned at the onset. And that set of tools can
6 be used anyway you want.
7 So if we look what's going to be attached,
8 that could change according to the policy of the
9 jurisdiction in that some jurisdictions don't want a
10 consent seat at al.
11 So we really have three pieces that we can
12 work with depending on the jurisdiction. So we have
13 the consent document itself, typically in our case in a
14 pdf. We have the machine readable information also
15 that's available. And we also have, of course, the
16 ability to accept the request and provide a response.
17 So any of these three, depending on the jurisdiction,
18 can be used. Any combination of these three could be
19 used.
20 So that information is available and it is
21 available in a XTSB repository such that with an XTSB
22 you can subscribe, you can publish, you can inform.

1 That's all included. So a lot of these things are
2 available. It just has to be decided in the
3 jurisdiction as to how they want to do it. And then,
4 of course, we'd have to do the implementation
5 accordingly.
6 And I think a question you had this morning
7 which was very sound was the looking after the small
8 EHRs, the small hospital environments. And I think a
9 request and response handles that requirement very
10 nicely. And the cost of it, of course, is almost
11 nothing. It can be just software as a service or
12 whatever.
13 Or, for example, because in our case it's SOA,
14 if it's maybe a little larger EHR perhaps they would
15 have the access control themselves. That component and
16 we'd just provide the machine readable. Any
17 combination of that could work. Did I answer your
18 question?
19 DR. KIBBE: Yeah. That was good.
20 MR. TERRY CALLAHAN: One addition.
21 DR. KIBBE: Sorry. Just as a quick follow on.
22 If you test to closely to the PHI, the notion of

1 confidentiality and publish it at the same time, that
2 can change over time. So what could be confidential to
3 you today, may not later on the road and vice versa.
4 So if you marry it too closely to the PHI itself, you
5 might have to regenerate the PHI if you want to change
6 the confidentiality.
7 MR. TERRY CALLAHAN: Yes. My assumption would
8 be that the PHI is going to be reconstituted fairly
9 frequently depending on the clinical situation of the
10 individual.
11 MR. DeCOUTEAU: There's nothing technically
12 that would stop us from doing what you describe. In
13 fact there are industries out there that use things
14 like digital rights management to do exactly what
15 you're talking about.
16 The question is being able to deliver that
17 consent directive and bind it to the patient's data
18 without --
19 DR. KIBBE: Would you define that digital
20 rights management for us. Just very briefly in your
21 own terms?
22 MR. DeCOUTEAU: In my own terms?

1 DR. KIBBE: Yeah
2 MR. DeCOUTEAU: Well basically the data -- I
3 buy a piece of music from ITunes or whatever. And with
4 that comes the payload of the music itself. But
5 there's tag on it that I've purchased it someplace in
6 the cloud of software that's managing it. This would
7 be true for the medical industry where my clinical data
8 is bound to some policy, packaged, stored in multiple
9 sites and every time someone tries to open it, it goes
10 out and looks at my policy first to see whether or not
11 I have rights at that moment in time to explode that
12 document and view it.
13 So the problem with that is who's managing it?
14 What software do we need to have in each clinical
15 location to make it work? So that policy has to be
16 computable. There has to be a shared encryption
17 capability of that document that's known throughout
18 multiple organizations and so on. So it's a huge
19 problem.
20 DR. KIBBE: It's not even conceivable.
21 MR. DeCOUTEAU: It's not unconceivable, but
22 it's a huge problem. That's one issue. And this comes

1 up all the time in our group.
2 The next logical step is to something like
3 this.
4 The second one is how do we manage these small
5 organizations, these small mom and pop physician traps
6 out there. I live in Montana so the physician I see
7 doesn't have a $200,000 electronic health record
8 system. He doesn't have a suite of software developers
9 or anything of that nature to go out and build this
10 stuff. In fact, he doesn't even know what this really
11 means to him and his patient population at this point
12 in time.
13 So how do we manage that? Well, we do that by
14 basically consumer quality appliances that puts the
15 policy engines in a box that's an affordable way that
16 can look at the requestor and the responding
17 organization and make a decision based on that
18 consumer's choice. That's where we need to go. We
19 need to put all of this in a box someplace so the mom
20 and pop physician can go out and plug it in, manage it,
21 not necessarily be a software engineer to do it, but to
22 be able to turn it on in their environment.

1 DR. KIBBE: In the interest of time for the
2 other folks to respond.
3 MR. DeCOUTEAU: Oh, I'm sorry.
4 DR. KIBBE: We only have two minutes. Thank
5 you, though.
6 MR. SHELTON: So, David, your question would
7 require about 20 minutes to answer from my perspective
8 and I'm debating whether to just through it to Monte
9 and give you a quick response to your last question as
10 we unpack it. Monte, do you have a quick response or
11 do you want me to try to just answer some of the other
12 stuff?
13 MR. GIBBS: Feel free, Robert.
14 MR. SHELTON: So you're hypothet started with
15 there's the complexity of the job is made more
16 difficult by the fact that the policies needs haven't
17 been set.
18 And in our case, we actually didn't start with
19 the policy needs. In my testimony I said that we
20 started long before high tech. We started, in fact,
21 before HIPAA. The objective here from our perspective
22 is search for confidential documents.

1 If we think about something we all use in this
2 room. We all use search engines. We use Gooma. We
3 use BING. We use a search engine in our everyday
4 activity. The fundamental need that we've been
5 building towards is to allow confidential documents to
6 be searched and located, which relies not on a HIPAA or
7 a high tech policy, but relies upon introducing a new
8 element, a data element and in our view, a bureau that
9 is sought to determine whether this searcher has the
10 right to know the answer to their search before the
11 search result is served to them.
12 And I would agree with my colleague to the
13 left that it makes greater sense if each provider
14 location, if each technology vendor does not have to do
15 that on their own but they could borrow on the
16 technology that exists at a central level.
17 It would be far more affordable. It would be
18 far more controllable. It would be far more reliable.
19 And so we're driving towards that vision. And
20 when you list the data types and the places they're
21 held, I would add to it, Google and Facebook and
22 Twitter and a lot of other places the data is coming

1 from that have to be taken into account by this model.
2 MS. McGRAW: Thanks very much. Ioana?
3 MS. SINGUREANU: So first, I'd like to
4 summarize some of the demonstrations that we've seen
5 today and the major capabilities that we've seen today.
6 So we've seen systems where the consent was implicit I
7 would say and you will have an opportunity to correct
8 me. Where the exchange is initiated by the patient and
9 they control the information and the consent is
10 implicit in the fact that they will disclose
11 information to a specific provider.
12 Then we say another approach, actually, I
13 think, Private Access and HIPAAT would basically
14 provide a way of sharing consent directives, perhaps
15 maintaining them centrally and reusing them across
16 applications. And please do correct me if I
17 misunderstood that.
18 And finally, I think, Duane, you talked more
19 about a situation where we have a federated consent
20 where the patient is going to have an agreement with
21 each organization that may produce or share their
22 information.

1 So I see this at a high level as being three
2 different approaches and we'll have a chance to
3 elaborate a little bit.
4 Another thing I took from the discussion the
5 standards are there. It may be useful to have them
6 constrained more clearly to be applicable in
7 healthcare, maybe there are some improvement that could
8 be there. But generally speaking there is no lack of
9 standards to support our needs.
10 Then I would like to ask you now in terms of
11 an assumption. Is it fair to say -- and I'd like to
12 give you an opportunity to confirm or deny this rumor
13 -- that your assumption in your leading edge systems is
14 that all of the information is computable, that it's
15 segmented based on standard based computerable codes
16 and structures. Is that your assumption? Is that an
17 intrinsic assumption of your demonstration that we have
18 clean data, it's not legacy, it's after time, T zero,
19 when full use criteria come into effect and people are
20 adopting standards? Or is it a highbred? And would
21 you like to start?
22 DR. JONES: Thank you. Our assumption is, of

1 course, is the data and the source systems is anything
2 but standards based and segmented. So in order to
3 facilitate the creation of that environment, we have
4 this whole notion of this data aggregator which either
5 can sit inside a very large enterprise or to David
6 Kibbe's point, can sit in a Healthcare Information
7 Exchange so that information can be pushed from this
8 babble of disparate systems.
9 Use the rules engine to actually create
10 instantiateable ring-based documents with vocabulary
11 translations. Therefore you have the best of all
12 possible worlds. Now, if you have to return documents
13 as they were sent in to you, be my guest. But
14 otherwise, you do have the semantically interoperable
15 computable information.
16 So we've knocked ourselves out to create that
17 environment and in order to make it affordable we've
18 put that in the open source environment. In the LGPL
19 so that enterprises of whatever size can adopt software
20 as a service. Not from us, necessarily. But from
21 people who know how to do this, either small or large
22 organizations to service practices of any size, bring

1 them into the same logical environment.
2 MR. SHELTON: Monte, I'm going to give you
3 this one. I'm going to let Monte respond to this one
4 if that's okay.
5 MR. GIBBS: The short conclusion is that
6 again, anything but the information, where it resides,
7 its format, standards application could not be more
8 disparate if it tried. And on that basis our approach
9 doesn't conclude form based privacy settings and entry,
10 but our sustainable vision is to enable semantic based
11 rules and the collection or intake of this for more
12 intelligent conditioning of the existing data. There's
13 simply too much information out there to try to get it
14 to make this cabin crossing adoption standard apply
15 wherein existing data is standardized. Some existing
16 data is non-standardized, some is non-uniform, some of
17 its analog form, paper form, digital standard machine
18 readable. The whole spectrum is in existence.
19 Our objective, our obligation is to allow for
20 the enablement of that service of the application of
21 privacy directives and consent management against any
22 of that media in any form that it exists. This will

1 take a considerable amount of time for this type of
2 evolution to occur. But we can at least circumspect
3 that the grain of the directive enforcement is based on
4 the structure of the documents. And our oncology has
5 been engineered to be extent that it could handle that
6 very approach and say we can condition this field, this
7 value, this attribute in selectivity, enable redaction
8 and label the selection and the conditioning of data to
9 happen across a very wide spectrum that has almost no
10 uniformity.
11 MS. SINGUREANU: Thank you.
12 DR. JONES: Our approach is that data is not
13 clean. In fact, in our NN development DoD, we actually
14 created a common access data lair, an abstraction that
15 allows the data to be represented and then semantically
16 constrained away. I believe this is true for any EHR
17 system that's currently out there. That there is some
18 translation occurring and for us to be able to do
19 things like reaction or manipulating that data in any
20 such way requires it to be semantically constrained.
21 So it's an issue.
22 MS. SINGUREANU: It's an issue.

1 MR. TERRY CALLAHAN: I want to make sure I
2 understand the first question. I think I do, but let
3 me give you the response and if it doesn't seem
4 appropriate then maybe ask again.
5 MS. SINGUREANU: I can restate it quickly. So
6 is there an assumption built in or are we assuming that
7 the information is semantically clear and coded using
8 standards or as the other speakers indicated, your
9 system would perform whatever translation from local
10 codes to standard codes, from local structures to
11 standard based structures so they can apply the rules
12 consistently?
13 MR. TERRY CALLAHAN: The granularity if I
14 relate it to the granularity that we use. If, for
15 example, we're using HL7. Of course there's a lot of
16 information in HL7 so if we're using HOL7, then of
17 course it's there. If we're talking about something
18 like permissions, of course, HL7 has permissions too,
19 so we use those. We also use things like dates. So as
20 long as we know the structure of the date the way it's
21 presented, then we can use date. So even though that
22 in itself is not a standard as such, it's still

1 something that can used quite universally and in
2 combination with these other attributes also. Did I
3 answer your question? Yes.
4 MS. SINGUREANU: Sure. Yeah. Actually, I'd
5 like to go on to my next question, if you wouldn't
6 mind, Terry.
7 MR. TERRY CALLAHAN: I have one more comment.
8 MS. SINGUREANU: Sure.
9 MR. TERRY CALLAHAN: You mentioned about the
10 different models. I think we would agree that the VA
11 model and ourselves is almost identical.
12 MS. SINGUREANU: Okay.
13 MR. TERRY CALLAHAN: I think one exception is
14 perhaps at the moment we're using XTSB also with CDR2
15 and I'm not sure if otherwise the architecture is the
16 same.
17 MS. SINGUREANU: So yours is a model where the
18 consumer will express a different consent with every
19 organization. There isn't one centralized --
20 MR. TERRY CALLAHAN: Well, it doesn't have to
21 be centralized.
22 MS. SINGUREANU: It doesn't have to be

1 centralized.
2 MR. TERRY CALLAHAN: No. And also there's the
3 ability for the privacy officer or the administrator to
4 go into the GUI, their GUI, and create a very very
5 detailed consent policy also.
6 MS. SINGUREANU: Actually, I'd like to ask you
7 the next question regarding the exchange of consents.
8 How is that encoded? If it's addressed or it's
9 exchanged.
10 MR. TERRY CALLAHAN: Yes. So the exchange of
11 the documents is all as per XTSB. So I'm not the
12 technical person to give you that detail, but I know
13 that that is a provision under XTSB. So for
14 publishing, subscribing and for notifying -- anyway
15 under XTSB it's well defined.
16 MS. SINGUREANU: I think yours is simple.
17 MR. DECOUTEAU: It is. We're moving towards a
18 CDA R2 and expressing that in XACML.
19 MS. SINGUREANU: So internally is XACML, but
20 when you exchange you're exchanging a CDA R2. Any
21 preference in terms of implementation guide?
22 MR. DeCOUTEAU: None at this point.

1 MS. SINGUREANU: Okay.
2 MR. SHELTON: Monte, it's yours.
3 MR. GIBBS: Well, our approach is based on
4 XACML now and we're moving toward adaption of XSPA as
5 well. So XSPA relative to CDA and CCD is obviously the
6 future in CCR as well that we envision.
7 DR. JONES: As you've correctly observed in
8 the system that we have designed for a number of our
9 customers. Inside that system consent is implied by
10 the explicit action of the participants. However, once
11 things leave the system, we can package up the
12 information including a developed of a consent form
13 that can be accompanying information out of it. We
14 have no control over the enforcement.
15 MS. SINGUREANU: Since this is very new
16 software and you're on the leading edge, and I know
17 your software is open source. If you can say just a
18 couple of words about how it's licensed and how it
19 could be reused by other organizations.
20 DR. JONES: I'm sorry. It's LGPL, which is a
21 vendor friendly license meaning that when we work with
22 organizations and we're asked to do custom coding for

1 them, we actually give them two separate prices for the
2 same work. Are you going to contribute it to this open
3 source? Lower price. Are you going to package this as
4 something that only you can use? Much higher price.
5 So most of our partners who are in the
6 university or government space are very interested in
7 contributing to open source. There are some partners
8 who really want to work on their own little thing and
9 we're glad to help them do that and that's a separate
10 plug as a proprietary plug in.
11 MR. SHELTON: In our case, we've only released
12 in beta as of now. The implementations that we're
13 working are contract implementations where the
14 objective is to accomplish a goal for the user. And so
15 we're being compensated for the total package of the
16 delivery. In the long term, we're viewing the Bureau
17 as being a model that would be our pricing model. So
18 we have an estimation of under five dollars per year
19 being the cost to use the Bureau services.
20 MS. SINGUREANU: Thank you.
21 MR. DeCOUTEAU: The software I demonstrated
22 today is openly available through OASIS. The Policy

1 Engine that we utilized in Dallas, Texas is part of the
2 NN Connect -- Open Connect release and it is freely
3 available in its binary form. So you can go to Open
4 Connect and you connect to Open Source and you'll be
5 able to download that. And that's the piece that
6 actually executes the XACML policies.
7 MR. KELLY CALLAHAN: HIPAAT is not right now
8 set up as an open source, but as Terry indicated, some
9 of the interfaces and so forth we'd take a look at
10 minimal cost. That said, we realize that there's a lot
11 of trepidation right now when it comes to regular
12 licensed models and so forth. And that's why we're
13 looking strongly at Software as a Service to make much
14 easier, especially for large and small.
15 MS. McGRAW: Well, done. Melissa.
16 MS. GOLDSTEIN: Again, I've talked to many of
17 you before about your products and I'm very impressed
18 by all of them. I'm not a technology person so my
19 questions are focused on technology, but not to the
20 extent that theirs will be.
21 My first question is for Mr. Shelton. I am on
22 my institutional IRB, so I'm fascinated by the idea of

1 translating what you are doing now in the clinical
2 research sector to clinical treatment. When we get
3 studies on the IRB where researchers are proposing to
4 delve into medical records to decide who might be
5 appropriate for their studies and who may not, our job
6 is to protect the subjects and to look into the privacy
7 and security of the data. Except that goes through
8 expedited review on the IRB and typically, does not
9 require consent from the patients.
10 What I'm interested in is how you think of
11 this as translating to the clinical environment where
12 you are getting consent from the patients to begin with
13 to have potential researchers look into their data.
14 MR. SHELTON: Okay. I think I understand your
15 question. So if I'm not responding to you then just
16 rephrase your question. It's not an attempt to avoid
17 it.
18 First off, the history of IRBs was associated
19 with safety of the patient so they were looking for the
20 things that could happen to a patient that would be bad
21 to them during the course of the research project.
22 When HIPAA was adopted in 1996, the treatment

1 payment and operations got some exemptions and for
2 research purposes the IRB, the traditional IRB process,
3 was extended to create an exception to HIPAA, which was
4 if an IRB has reviewed the disclosure of the date then
5 that would substitute for the patient's consent. So
6 from a --
7 MS. McGRAW: Can I interrupt you? Can you,
8 Melissa rephrase your question so that it's more
9 technology specific?
10 MS. GOLDSTEIN: Thanks. Yes. I was going to
11 do that. What I'm interested in is translating what
12 you are doing now into a clinical treatment
13 environment. So you're piloting it currently, but with
14 clients who are researchers. Is that correct?
15 MR. SHELTON: Correct.
16 MS. GOLDSTEIN: And with patients and so there
17 is what you have done, from your testimony and from our
18 conversation before, is that emails have been sent out
19 to people or advertisements have been sent out to
20 people to sign up as Private Access account holders.
21 And then, those people who are the patients or the
22 subjects somehow connect. Right? So what I'm trying

1 to understand is how this will be translated into a
2 provider where consent means something different.
3 MR. SHELTON: The back end that we've created,
4 the source of the Bureau is functioning the same in
5 both environments. The ontology we've created, the
6 data ontology, the system architecture is contemplated
7 to go across any dimension.
8 It's the user interface and the purposes by
9 which that user is involved that are varying. We have
10 presently on the boards, October 1st is our date for
11 HIE turn on. We are by August 1st looking at including
12 enrolling in passing data to Google and Microsoft. So
13 the development cycle that we're on contemplates
14 serving these other market segments.
15 Now if want the how, then Monte needs to
16 answer the how.
17 MS. GOLDSTEIN: No. That was good. That's
18 what I was looking at too. Okay. My other question is
19 for more of you. And it's really about your pilots,
20 the pilots that you are using in different
21 environments. We think about scalable. Are they
22 scalable to small practitioners? Are they scalable to

1 small groups? But I'm also thinking about translatable
2 and replicable. And I suspect that there are unique
3 circumstances in each of these areas that you have
4 chosen to pilot? Right? San Diego. The Netherlands.
5 Ontario. And I'd like to know why there and why do you
6 think that it will translate to other places?
7 MR. SHELTON: Well, in respect to North
8 America, Ontario actually has one of the more stringent
9 privacy legislations. In Ontario, the acronym is
10 PHIPAA. What do you know? But anyway --
11 MS. GOLDSTEIN: I think I should jump in so we
12 don't get yellow carded. I'm not looking for policy
13 explanations of the policies in place. I'm looking to
14 I guess your technology fitting there versus your
15 technology fitting in other places. Why? Why will it
16 be replicable?
17 MR. SHELTON: From our standpoint, it's really
18 the same anywhere. In other words, EHRs are common,
19 the same EHRs that we deal with in Canada are in the
20 U.S. and Europe and so forth. So I think the fact that
21 it's based on the same standards and the fact that what
22 we're offering is just a simple request and response,

1 it would be the same anywhere.
2 MS. GOLDSTEIN: So why did you pick Ontario?
3 MR. SHELTON: Well, Ontario is home base for
4 us for one.
5 MS. GOLDSTEIN: San Diego?
6 MR. KELLY CALLAHAN: I can't answer that
7 specifically. But I would say the fact that both the
8 patient populations between VA, DoD and Kaiser
9 Permanente made perfect sense to initially pilot in
10 that location. And now they're moving forward into
11 Virginia and so on. Our capabilities, the things that
12 I've described in my demonstrations are actually not
13 geared for full implementation until 2011. It's going
14 to take that long during the development cycle to get
15 these capabilities within the systems.
16 MS. GOLDSTEIN: Thanks. Netherlands?
17 DR. JONES: Well, I hope I didn't mislead you.
18 The Netherlands is only one project we have. There are
19 other projects in advance of that. We have a
20 collection of primary care physician groups in the
21 Midwest called Novia Care Clinic and Bravura Systems
22 has implemented an electronic health record for those

1 clinics on our technology. And they've been live since
2 February of 2009. So we're beyond pilot. That's live
3 use. I really described the Netherlands because it had
4 this very stringent privacy regulation. Let me go on
5 to say that the Transcend Project is also in live use
6 and it covers 18 academic medical centers across the
7 United States collaborating in the I Spy Breast Cancer
8 Trial.
9 We have a group in Manhattan that is actually
10 worked out how to exchange information between doctors
11 offices and major teaching centers regarding
12 preoperative admissions and the paperwork involved in
13 that, again, using our platform.
14 And finally, we were selected as the
15 technology for the Electronic Clinical Data Repository
16 for the National Health Group in Singapore, which will
17 cover three and a half million patients.
18 So, indeed, we've gone from small practices to
19 national level in our own implementation. So we're
20 rather confident that it's generalizeable on the same
21 code line.
22 MS. GOLDSTEIN: Okay. Thanks. And now I'm

1 going to go back to my line of questioning this
2 morning, which was perceptions of the products among
3 both users or clients and the people, the patients, the
4 consumers. So I'll start at that end again, since you
5 just explained such a wide breadth of knowledge here.
6 Do you know -- have you surveyed them? Do you know how
7 they like it? Do you know if establishes trust among
8 the patients, that sort of thing?
9 DR. JONES: We haven't surveyed them, because
10 again, we're like, if you'll pardon the expression,
11 we're like "Intel Inside." I'm looking at the
12 computer. We're Tolven inside.
13 So the partners are the people who face the
14 brunt of it with the single exception of the Transcend
15 Ice (ph) By Trial Project, which we're the sole
16 technical implementer. And after the first training
17 session, we received a series of emails from people in
18 training session, including one from your classic and I
19 speak as one of the former -- your classic academic
20 surgeon saying this is the best blah de blah de blah
21 thing I have ever used, as a user.
22 Now that was great because this is complex

1 data entry in a domain deep field. Quite by chance,
2 the system I described in Indiana, I happened to meet a
3 friend of a friend of a friend who was a friend of the
4 member of the board of the Novia Care Clinics that
5 said, they just can't stop talking about your system.
6 So the doctors are very happy there.
7 But, no, we don't we don't survey it. We are
8 not a marketing organization. We're really bad about
9 that. We're just technical.
10 MS. GOLDSTEIN: Thank you. We only have
11 almost three minutes. So, I guess, quick answers.
12 MR. SHELTON: We have Alan Weston as a board
13 member and Alan works for the Harris Survey
14 Organization so he wouldn't let me out of the room
15 unless we were surveying consumers. I guess the
16 statistics I would give you is that you're correct.
17 We've been targeting emails at people and seeing
18 whether they adopt or not. We're at about 40 percent
19 adoption, 40 percent adoption on invited people. Of
20 the consumers that respond to how did they like the
21 experience, roughly 75 percent have said that they
22 found it easy to use, intuitive, the kinds of answers

1 we would like. The remainder said it was very good as
2 opposed to excellent in that regard. And roughly 90
3 percent have said that they trusted the system and they
4 would pass it on to family or friends. So we're
5 getting the right sort of statistics to roll out from
6 here further.
7 MR. DeCOUTEAU: In our group, we're not really
8 concerned about end user usability at this point.
9 We're concerned about creating the standards for
10 interoperability between two organizations exchanging
11 healthcare information. And that's why my counterparts
12 here keep mentioning XPA (ph) standard. That's
13 basically what we demonstrated today.
14 We are working towards building the
15 capabilities, the user interfaces, and the
16 administration functionality into a product that would
17 ultimately be reference implementation for OASIS and
18 usable to any organization.
19 MS. GOLDSTEIN: Thank you.
20 MR. TERRY CALLAHAN: Yes. I think the time we
21 gave that the greatest attention was during the pilot
22 because we had no idea what we were in for. And I did

1 answer this, I think, earlier in a different way. But
2 we were, again, quite surprised at how much people
3 preferred it, not just did not, not like it, but they
4 preferred it, which was quite a surprise to us.
5 And so I don't recall any objections quite
6 frankly. Some were neutral, but if they weren't
7 neutral, they were positive. So I think that's the
8 best I could say.
9 MS. GOLDSTEIN: Thank you. I appreciate that.
10 MS. McGRAW: Thanks very much, Melissa. Okay.
11 Dr. Peel.
12 DR. PEEL: Well, first I want to ask you to be
13 really consumer friendly with what you've presented.
14 Would you make sure and send screen shots of everything
15 that consumers get to see, because you all can sense
16 where people actually enter things. Because people in
17 every state want to see what consents really look like.
18 And so I think, I'm not sure about all of your systems,
19 but I think you all had some of those shots in some
20 cases. But really, a complete set is very, very
21 important for Americans to be able to see what the
22 consents are going to look like for them. So that's

1 one thing I want to start with.
2 Okay. So, Tom, first I wanted to say
3 congratulations on a PHR that is totally patient
4 controlled. We like that very, very much. And I just
5 want to point out to the audience, both here and in the
6 States, that PHRs vary widely. And so one of things
7 that Patient Privacy Rights did with a grant from the
8 Rose Foundation was we developed a PHR report card.
9 You can see it up on our website and you will see the
10 grades range from A to F. So, buyer beware.
11 So since Tom, the business models for
12 infrastructure vary greatly and you're not giving this
13 away free and you're not selling data, what exactly is
14 your business model?
15 DR. JONES: No. We are giving it away free.
16 DR. PEEL: Oh. Okay. But not because you're
17 selling the data? Okay.
18 DR. JONES: No. No. It's open source code so
19 the software is available. So how do we make money?
20 We started making money the first month of business
21 because we supply services. We decide to be Linux and
22 Red Hat at the same time. So we have a dot org (.Org)

1 that is responsible for the code. It has a separate
2 board of governors and dot com (.com) that's
3 responsible for commercial services.
4 And those include Informatics consultation
5 including clinical work flow. They include custom
6 coding and include support. So that people want to say
7 that they are working on a certified supportable open
8 source platform from Tolven. Not something that
9 somebody's done anything with.
10 And those three chains of revenue are enough
11 to keep us going. So the dot com supplies the dot org.
12 DR. PEEL: That's good. I've got one question
13 for you. I know that -- I think are giving these
14 systems to -- you're partnering with large companies.
15 Could a single patient get a Tolven PHR or a single
16 doctor?
17 DR. JONES: No.
18 DR. PEEL: Do you anticipate that?
19 DR. JONES: No. This all has to be done
20 through a sponsoring enterprise sponsoring Software as
21 a Service. If we did it, we would be setting up a
22 Tolven.Com that would supply those things and we have

1 not done that.

2 DR. PEEL: Okay. Thank you. Robert, first of

3 all, I want to congratulate you on setting the gold

4 standard for the future of genetic and sensitive

5 research. And getting a little bit at your points,

6 Melissa, when we have a vibrant instantaneous and

7 dynamic consent, we no longer need IRBs to give

8 permission for who can look at our records. And your

9 story, of course, I don't know how many know this,

10 Robert, but what you did to protect your own son is

11 going to give every person the possibility of being

12 able to protect their own children's sensitive

13 information. So I admire where you come from. And, of

14 course what we really like that what you've created is

15 a real time dynamic consent and this is the end of the

16 blanket advanced consents. So congratulations to all

17 of for doing those.

18 One of the things I was going to ask was how

19 soon are you going to get your system used for EHRs and

20 hospitals and HIEs, you already answered that. And

21 then, you were talking about that your system is going

22 to be very inexpensive. How inexpensive? Do you know

1 yet?

2 MR. SHELTON: All of our performers are based

3 upon $5.00 per patient per year on average total use

4 that comes from a variety of sources and I showed the

5 model in the demo that said that the data seeker would

6 potentially be required to pay something for the data

7 that the data holder is vending to them or selling to

8 them.

9 DR. PEEL: That sounds great.

10 MR. SHELTON: From our perspective, we would

11 hope that we are a percentage of that receipt of money.

12 So in order for this -- I guess one of the things that

13 we've contemplated is that in order for systems to be

14 self sustaining and to have the ability create this

15 technology, there has to be a return to the technology.

16 There has to. You can't just be a call center. It

17 also has to create revenue. And so we contemplate that

18 over a period of a year, we will realize $5.00 on

19 average per patient per year. And that's our revenue

20 model.

21 DR. PEEL: Thank you. That's great. One

22 quick question. Do you know when the privacy layer is

1 gong to be fully ready? Do you have a time estimate on
2 that?
3 DR. JONES: I have a CTO in California who has
4 a detailed milestone chart on his board and I have a
5 price tag associated with building the whole platform.
6 And the roadmap is a 24-month roadmap to build out full
7 functionality and to serve 25 million people through
8 it.
9 DR. PEEL: Thank you very much. I'm sorry to
10 cut you off. I have so many questions for the rest of
11 the people too. But thank you so much.
12 Okay. Duane. First of all, congratulations
13 on actual electronic consent patient interface. Again,
14 this is what we want to see. And of course we love
15 that this is open source and free. And the other thing
16 that I was impressed with was you recognized what a
17 burden it is to patients to have to have consents all
18 over the place. So help me recall. Did you develop
19 this system in response to a particular law? I think
20 that there is some kind of federal that requires the VA
21 to do some segmenting with data sharing. Is that
22 right?

1 MR. DECOUTEAU: No. We were responding the
2 AIQs cases. This drove the development of our
3 interfaces.
4 DR. PEEL: All right. And so just to be clear
5 again, for the public, because I'm so excited that the
6 public can see all the wonderful things that you have
7 done. Can the systems that you've developed be used in
8 private hospitals across the country? Could they be
9 used in smaller doctor's offices, smaller practices?
10 MR. DeCOUTEAU: Again, the development was
11 part of an Open Source Initiative and that some of the
12 components, some of the vendor components, are freely
13 available.
14 DR. PEEL: Thank you. Thank you very much.
15 Hi Terry and Kelly. I got a couple questions for you.
16 Congratulations on demonstrating that there is
17 auditing. You may know this. Many of the larger
18 vendors don't want to do auditing and are trying to
19 push back the time tables for creating accounting of
20 disclosures. So that's really wonderful.
21 I noticed that you said in your testimony that
22 in 2007, you had a bundled consent and auditing

1 solution and I guess this really gets back to the
2 screen shots. We would like to see what the consents
3 were that you created in that bundled package. And
4 also, in 2008, you mention that you were working with
5 patients in North Carolina. Again, could we see the
6 choices that the North Carolinians got? I think that's
7 very important.
8 And then, how am I doing? Oh. Better than I
9 thought. Okay. I've got some of the same questions
10 for you all that I asked the last panel, which is now
11 that you have these robust systems which you have built
12 that allow consents and segmentation -- and I
13 understand, Tom, that your product can be turned into
14 an EHR, correct? Okay. So the stimulus bill created a
15 new right, that if patients pay privately, they should
16 be able to prevent their information from being sent to
17 insurers and others for claims and for healthcare
18 operations. And I want to ask each of real quickly,
19 does your system offer that? Tom?
20 DR. JONES: Yes.
21 DR. PEEL: Okay. Robert?
22 MR. SHELTON: It wasn't in our use case.

1 DR. PEEL: Okay. Duane?
2 MR. DECOUTEAU: I can't answer that question.
3 DR. PEEL: Okay. All right. Kelly and Terry?
4 Yes. That's in your system? Great. Okay.
5 And then the other thing that we're very
6 interested in -- of course it's also a new law
7 requirement in high tech and a new consumer protection
8 is because you have a consent system, do your consents,
9 do you make sure that there is consent before the sale
10 of any PHI? Tom?
11 DR. JONES: Well, again, it's unnecessary
12 because there is not consent needed. The patient takes
13 the explicit action to send PHI out.
14 DR. PEEL: Okay. Yeah. And you all don't
15 sell data. Yeah. Robert?
16 MR. SHELTON: Yes. I guess implicitly.
17 DR. PEEL: Huh?
18 MR. SHELTON: Yes, implicitly.
19 DR. PEEL: Okay.
20 MR. DeCOUTEAU: Technically, there's no reasn
21 why we couldn't. The policy hasn't been written for us
22 to do it.

1 DR. PEEL: Okay. Well, it's in the law. It's
2 a matter of law whether the policies written or not and
3 it's an important -- that was -- just so you know, that
4 was a really big deal to consumers to stop the sale of
5 their data without consent. So we hope that everybody
6 will pay attention to that.
7 Terry and Kelly look busy. Does your system
8 make sure that consent is obtained before PHI is sold?
9 MR. KELLY CALLAHAN: We have the tools. We
10 have a module for purpose of use, so it can be
11 architected, it can be used that way.
12 DR. PEEL: Okay. Great. And I think I asked
13 specifically -- well, Tom and Robert addressed the
14 important question of expense because we hear a lot.
15 Oh, doing consent is just going to be way too
16 expensive. Yours is free. Yours is $5.00 a month.
17 MR. SHELTON: An average of $5.00 per year.
18 DR. PEEL: Five dollars per year, oh, excuse
19 me. Better than I thought. Okay. And Duane, would
20 you please address the expense question and then--
21 MR. DeCOUTEAU: I don't think I can.
22 DR. PEEL: You can't?

1 MR. DeCOUTEAU: I mean this is a government
2 development, but --
3 DR. PEEL: Oh, yeah, yeah, yeah, yeah. Okay.
4 You're right. I'm sorry. Right and it's open source.
5 So, Terry and Kelly, how expensive are you?
6 MR. TERRY CALLAHAN: Well, first of all, open
7 source is not free.
8 DR. PEEL: Right. It costs to maintain it. I
9 get that. We get that. Consumers get that.
10 MR. TERRY CALLAHAN: So as per our testimony
11 though, you can basically it scales for the similar
12 costs as EMPI or anything else that needs to be present
13 in an HIE or it can be available Software as a Service
14 for minimal cost.
15 DR. PEEL: Minimal cost? Okay. This is not
16 like a break the bank thing.
17 MR. TERRY CALLAHAN: No.
18 DR. PEEL: Putting consent in place. Okay.
19 That's really important for us to know. I'm trying to
20 thing if there's anything else because I have 34
21 seconds. Actually, I'd like to flag thing, which was a
22 number of people said the consent policies came first

1 from the jurisdiction or the community, then from the
2 facility and then the patient got what was left over.
3 To use that is kind of the opposite of how these
4 systems should be built. But I'm not allowed to talk
5 about it. Okay. Bye. That's it. Thank you.
6 MS. McGRAW: You squeezed that one in under
7 the wire. Okay. Terrific. We'll now move into
8 questions, comments from the Tiger Team members and I'm
9 going to head in the clockwise direction and continue
10 with my circle. So we'll head this way. Go ahead,
11 David.
12 TIGER TEAM DISCUSSION
13 MR. MCCALLIE: I'm going to ask a simple
14 question. Basically the same one I asked the first
15 group which is around interoperability. You all have
16 different approaches, different policy decision points
17 and different policy access control points. If you
18 were all to be deployed in a large state like Florida
19 or something which has maybe thirty different regions
20 where data is controlled and you had to interoperate
21 with each other so that policy could be defined across
22 the system and patients could manage their data

1 regardless of where it lives, how much work would it be
2 and how feasible is it to become interoperable?
3 So at least three of the panelists have
4 referenced using XACML and some subset of the IAG
5 standards. So specifically to the XACML users since
6 you are closest, probably, I'd be curious, what would
7 it take to work together in an interoperable fashion
8 and take into account the cost of integration of your
9 systems into EMRs and/or HIEs, the other systems that
10 would be out there. So there might be dozens of
11 different vendors that you have to interface with. How
12 standard are these standards?
13 You've basically said you didn't need anymore
14 standards. We also heard that the standards need to be
15 constrained better. But how close are we to being
16 truly interoperable? Maybe start with the VA, because
17 I think you guys probably have pushed that the
18 farthest.
19 MR. DeCOUTEAU: Well, our core standard or the
20 two standards of XPA (ph) allow us to interoperate
21 between healthcare organizations. And are constrained
22 as far as the objects that we trade between those

1 organizations through HL7. So we have those components
2 in place right now. There's probably a little more
3 work that needs to be done as far as exchanging
4 policies between organizations. Those polices need to
5 be computable. And that means that there needs to be a
6 common language. We've XACML. Many other people have
7 chosen XACML as their core policy language. We have
8 JBoss down there at the end.
9 So at the end of the day, for us to exchange
10 data regardless of where it's at, those standards have
11 to be in place. And we've done much of that work
12 already as far as XPA is concerned.
13 MR. McCALLIE: Are we close? I mean I'm in
14 the standards committee. At some point in the next
15 couple of years, we'll probably be making a
16 recommendation about the standard to use for these
17 purposes. Are we ready to do that?
18 MR. DECOUTEAU: Our work describes the minimum
19 set of attributes necessary to make a decision between
20 exchanging organizations. So if you layer that layer
21 ANHM (ph) on top of that have some additional
22 attributes, because they're a different implementation.

1 Right?

2 And Indirect will have their attributes. So

3 the minimum set provides us with the interoperability

4 capability and also provides us with the ability to

5 extend that standard and interoperate now with these

6 implementations.

7 So I think we are -- I think we're here.

8 MR. McCALLIE: So, Terry, how hard to hook

9 your two systems up so that they could talk to each

10 other and share policy and enforcement points in a

11 region.

12 MR. TERRY CALLAHAN: I just got permission.

13 We've actually been evaluated by the VA. We have shown

14 interoperability and we and other companies also have

15 used the same XACML and XPA attributes to be able to

16 communicate. Is that it?

17 Like I've got in regards to Florida, your

18 question was the best way to do it from our

19 perspective. So certainly the simplest way to do it

20 would be to have a common consent management validation

21 service for the State. And then have the individual

22 EHRs make a request to get a response. That would be

1 the minimum, that's all they would have to do in actual
2 fact to be able to get a response, to send a request
3 and get a response. And if they followed the XACML XPA
4 standard, then, of course, they will all be standards.
5 And as I may have mentioned earlier, from our
6 perspective, we've already developed what we call our
7 JAVA Consent Validation Interface, which is just that.
8 It takes the proprietary attributes of an EHR and makes
9 them standardized in a request, in a response.
10 From there, of course, there's different
11 variations. You could have centralized consent
12 management and distributed access control. So
13 certainly the best service to the small EHR company and
14 physician is just to make a request and get a response.
15 I mean it's the least expensive for these groups who
16 are all concerned about it.
17 MR. McCALLIE: So if we have the technical
18 interoperability, you mentioned the lack of -- or at
19 least the need to develop further computable policy. I
20 think you mentioned working on ontologies to represent
21 the entities that might be expressed in a rule. Are we
22 close on the rules themselves? How likely is it that

1 the rules could be made interoperable so you don't have
2 to write your policy for each target vendor?
3 MR. DeCOUTEAU: That would be my preference,
4 that the rules themselves are interoperable. Clearly
5 that would make implementation all that much easier.
6 That a given policy is applicable to all patients.
7 MR. McCALLIE: Right.
8 MR. DeCOUTEAU: If we could do that, we'd be
9 done.
10 MR. McCALLIE: So how close are we to that
11 point?
12 MR. DeCOUTEAU: Our group is just now
13 beginning to work on the ontologies on the XACML site
14 for XPA. And one of the use cases that I'm focusing on
15 is the care team. These are the people that take care
16 of me from a clinical standpoint. I have a doc, a
17 primary, a cardiologist, so on and so forth. And these
18 are the people I want to have access over time. So
19 things like that, we're working on. But it's not
20 happening -- it's not available to us right now.
21 MR. McCALLIE: Okay. I probably used up
22 enough of my time so thanks for those answers. That's

1 very helpful.
2 MS. MCGRAW: Ellen.
3 MS. FLINK: I'm probably going to open up a
4 little bit of a can of worms, and some of you I have
5 spoken with about this issue. But I have to bring it
6 up with respect to the whole consumer choice issue and
7 data segmentation. We have a population of finers
8 whereby laws including federal and many state laws,
9 which basically allow minor patients to choose consent
10 or have consumer choice with respect to health
11 services. But that information cannot be combined with
12 those services for which parents provide consent on
13 behalf of their minor children.
14 And so we talked about standards being in
15 place today. I am curious about what potential
16 solutions from a technical standpoint or what standards
17 would have to be in place in order to appropriately
18 segment those two records or the information that's
19 attached to the minor versus the information that's
20 attached to the parent on behalf of the minor. Anybody
21 want to take it?
22 DR. JONES: Well, I have to take it, because

1 in the Netherlands there's a gradation of minor access
2 to electronic health systems. There's one set that
3 applies up to age 12, another set applies to age 12 to
4 16, another set applies to 16 to 18. At 18, you become
5 an adult. So, in fact, we've had to work the Risman
6 (ph) Net organization to say, these are the steps that
7 have to be taken in order to make that transition
8 between each one of those phases.
9 So at the lowest level, under age 12, the
10 minor -- I mean the parent has access to and manages
11 the minor's electronic health information up to age 18
12 where the minor becomes completely independent. And
13 then there are gradations in between. So it's very
14 complicated and I'd be oh, so happy to walk you through
15 all of it, but it's tedious. But, there again, it's an
16 example of working with an existing policy.
17 The real problem that we will always face is
18 lack of a crisp articulation of the policy of the
19 environment in which we're establishing the
20 implementation. Given that, we can do it.
21 MR. SHELTON: Monte, do you want to answer
22 that and also, if you could -- we didn't get a shot at

1 David McCallie's question, which I think we'll tie
2 together a little bit in terms of the adaptor series
3 and where we are in terms of connecting to other EHRs.
4 MR. GIBBS: Well, I think one of the primary
5 differentiators and benefits of our ontology is the
6 fact that not only have anticipated this, but we have a
7 separation at present between the account holder and
8 the subject and an ontology that has the separation of
9 authority and subject. So this is, in fact, to address
10 the question directly. It's in practice. It's capable
11 and achievable right now between the ability if you're
12 currently an adult to have a associative policy
13 associated with a subject who is a minor.
14 And this is the benefit of when you anticipate
15 consumer driven models and behavior models based on
16 instances of what real world individuals -- situation -
17 - what real world situations have to be translated to
18 the ontology of technical infrastructure that enables
19 that to happen. But this is not an exotic condition.
20 MR. SHELTON: And, I guess, one thing would
21 tell is the context. We went on a nationwide
22 recruitment effort to find this CTO. This is a person

1 who worked with children's data for children gaming
2 sites, that has been involved with that type of
3 environment where there's specific rules associated
4 with that use. Remember, I said, we were looking at
5 this as a couple inches wide and five miles deep. The
6 ontology needs to pick up that. And if the ontology
7 inherits that capability, then the capability is not
8 hard to render to the user with the right user
9 interface.
10 MR. GIBBS: A highway internet.
11 MR. TERRY CALLAHAN: As I recall, New York
12 state is an opt in model or express a consent model.
13 So in that particular case, the parent, of course,
14 would have to give consent to have the healthcare
15 information of the minor shared. That would be step 1.
16 Then the minor, of course, would come in after
17 that and they would then restrict access to certain
18 healthcare information. So I think when the parent
19 puts that in, the ideal scenario, of course, their
20 particular consent, the policy that they are putting in
21 for the minor would terminate at the age of majority.
22 Whereas the minor's would start whenever they start

1 theirs, it would go on endlessly.
2 The important thing there is that when those
3 two policies are looked that the one for the minor is
4 adjudicated first, would be the critical component of
5 that, I would suggest. And, of course, they'd both be
6 done in a standards fashion in any case.
7 MS. McGRAW: Joy wants to follow up on that.
8 MS. PRITTS: A very short response, please.
9 So does the system automatically compute the minor's
10 age so that in two of these systems so that the
11 policies change automatically and that the provider is
12 not required to have to address it?
13 MR. TERRY CALLAHAN: It does not, but it
14 could. That would not be a big thing to do.
15 DR. JONES: It does in our system. In fact,
16 remember the provider has nothing to say about it.
17 It's the personal health record and it changes in the
18 sense that there is a notification that comes up on the
19 activity list that says, the policy is going to change.
20 Your minor will now be able to go through a wizard to
21 say that they're going to do X, Y, or Z at this age.
22 And that is computed from the date of birth.

1 MR. SHELTON: And ditto from our systems
2 perspective, there's four qualities that we think are
3 absolutely required in order to deliver this product.
4 And it's the identity, the privacy, the security and
5 the traceability. As soon as the identity is real and
6 is known to the system, it can be calculated to act
7 automatically based upon a rule.
8 MS. McGRAW: Wes.
9 MR. RISHEL: So we got a new timer? Okay.
10 MS. MCGRAW: Actually, we're running slightly
11 early, so I have not been leaning on you all not to be
12 piggish with time.
13 MR. RISHEL: Here I was trying to --
14 MS. McGRAW: But remember there's a whole
15 other side of the table over here that you'll have to
16 answer to.
17 MR. RISHEL: I understand. I was trying to
18 get Alan to ask one of my questions, but it didn't work
19 so.
20 Just one question. And I admit I don't fully
21 understand all of the different points that are
22 involved in this discussion. There's policy

1 enforcement points and there's other kind of points,
2 but is there somewhere in these systems a database that
3 contains all the things that I don't want people to
4 know about me? Could you explain how the policy can be
5 enforced without that database existing?
6 MR. DeCOUTEAU: I'll take that one. Okay. So
7 during the healthcare information exchange, the
8 requesting organization in that request across the
9 network, it asserts who I am. I'm Dr. Bob. What role
10 I have -- physician. What functional role I have.
11 Maybe physician as well. What permissions I have. I
12 can search. I can bring up the laboratory -- this
13 within my own organization.
14 MR. RISHEL: Just to be sure. I'm talking
15 about the consumer now.
16 MR. DeCOUTEAU: Right. But I'm telling you
17 how that decision is able to be made outside of where
18 the data actually lives.
19 MR. RISHEL: All right.
20 MR. DeCOUTEAU: So what happens is that that
21 request, that information about the requestor and the
22 subject patient are consumed on the responding end.

1 They're consumed --
2 MR. RISHEL: I really need you to speed up.
3 Okay. Is there a database or not?
4 MR. DeCOUTEAU: I'm drawing the picture here
5 for you. So what happens is that that information is
6 consumed. It's sent down to the policy engine. The
7 policy engine looks at it, goes out and gets the
8 patient consumer choice in whatever form.
9 MR. RISHEL: Okay. Where does it get the
10 patient consumer choice?
11 MR. DeCOUTEAU: It's either stored in an XDS
12 repository. It could be in a database. But basically,
13 it's brought back into a form that the policy engine
14 understands.
15 MR. RISHEL: So that place, where it just got
16 is a list of all the things I don't want anybody to
17 know about me, right?
18 MR. DeCOUTEAU: Right. It is my policy.
19 MR. RISHEL: Yes. Okay. Thanks. That
20 answers my questions. All right. I'm sorry --
21 MR. DeCOUTEAU: But it does not include the
22 clinical information.

1 MR. RISHEL: Oh, I understand. I understand.
2 I just think that if there was one thing I wouldn't
3 want to get out, it's that I don't want people to know
4 that I'm might be schizophrenic. That's all. Except
5 for my other ego, I would like him to know.
6 That's policy. I agree. I'd like to
7 stipulate, based on what we heard today that there are
8 standards in place that can communicate rules that have
9 been implemented in open source code and that have been
10 used by a few organizations for some subset of rules.
11 Okay.
12 I think I heard in answer to David's questions
13 that for the variety of rules we might want and
14 particularly the variety of rules we saw in
15 demonstrations today, many of the ontologies may not
16 yet be standardized.
17 For example, I saw the ability to restrict
18 information based on department. I'm not aware of a
19 standard oncology for department and if there were one,
20 I'm almost sure that no hospital in the world uses it.
21 Unless I have errored in what I just said,
22 that most of the standards exist for expressing rules

1 and doing the transactions to resolve rules, but the
2 ontologies are still a work in progress. Unless I'm
3 wrong on that, I'd like to go this notion of a quality
4 engine in a box. Because that is the idea that is
5 probably most relevant to an assessment of how quickly
6 technology could be rolled out in the healthcare
7 environment, which is complex.
8 So, Duane, I think you were the one who
9 brought it up. So could you describe to me what it
10 would take for an existing EMR that is a developer of
11 an existing EMR whether it's a hospital or a vendor to
12 get all of the ducks in a row to interface with that
13 quality engine. For example, what ontologies would
14 have to be introduced into the EMR in order to create
15 -- to allow that appliance to do the policy resolution
16 for me?
17 Somehow, it seems like the policy has to know
18 something about the data that's coming out of the EMR,
19 right?
20 MR. DeCOUTEAU: Correct if you're planning on
21 constraining access to specific portions of that data,
22 that data has to be semantically constrained. So your

1 example of department, the use of department in a
2 policy decision point is arbitrary. It's not to say
3 it's not right. It's just someone's opinion.
4 So the data itself has to be constrained. So
5 some EHRs may not be able to get there. It may be cost
6 prohibitive to provide them with he capability to
7 redact specific portions of the clinical record.
8 However, things to control access to specific
9 users, specific roles, organizations, locations and
10 things of that nature can all be layered on top of the
11 existing electronic health record without a wholesale
12 replacement of that record.
13 MR. RISHEL: Well, I think that's a very
14 important point.
15 MR. DeCOUTEAU: Yeah.
16 MR. RISHEL: For us to recognize that there
17 are many policy issues that are not specific to the
18 clinical data.
19 MR. DeCOUTEAU: That is correct.
20 MR. RISHEL: That could be implemented with an
21 appliance with no necessary modifications to the EMR
22 and a relatively limited set of ontologies that have to

1 be built.

2 MR. DeCOUTEAU: Absolutely. That's absolutely

3 correct.

4 MR. RISHEL: Right. That's good. It may be

5 that the seventh allele of the schizophrenics might not

6 be one of those.

7 MR. DeCOUTEAU: That's a problem.

8 MR. RISHEL: Right. Yes. Good. So there was

9 a stated assumption here from Tom that the process of

10 accepting data into a clinical database could create a

11 completely semantic representation of the data. And I

12 believe that was to back up the point that it would be

13 better to do these queries out of that database and out

14 of the source systems.

15 I'm having trouble accepting that just on the

16 basis of everything I know about the mapping that goes

17 on today and the amount of actual information that a

18 physician wants to see that is right now coded in text.

19 Or a clinician wants to see this code.

20 DR. JONES: You've got me there. Well, then

21 my answer to you all earlier on was to say we will do

22 everything possible to process electronic documents to

1 create semantically interoperable data. But we always
2 preserve original documents in whatever form including
3 scanned documents and jpgs. So that if that the query
4 you want to have, that's fine. But insofar as is
5 humanly possible, we will create the semantically
6 interoperable database, but --
7 MR. RISHEL: Or computerly possible.
8 DR. JONES: Yeah. Yeah. Computerly possible.
9 So it's got to come in -- if it comes in in gibberish,
10 it'll come out a gibberish. And that's okay by us. I
11 mean, you may remember the history of the previous
12 company I was with where we got terribly prissy about
13 what had to come in. We decided, no, no, you got to
14 bring them in there. You've got to have the potential
15 for having all the data in one place. You hope that he
16 majority exist in semantically interoperable place in
17 space. The other thing you've got to make sure of is
18 if comes in in something else, you have to have an
19 indexing system, probably rules driven or at least
20 rules aided indexing system so that those documents can
21 be segmented according to the preference of the
22 enterprise. So that when you reveal things, you can

1 reveal or send out either from a segmented document
2 hold or from the interoperable -- semantically
3 interoperable data hold. Does that make sense?
4 MR. RISHEL: Yes. Thanks. So one last
5 question --
6 MS. McGRAW: And make it quick, Wes, we've got
7 to get to the other side of the table.
8 MR. RISHEL: Right. So in the environment
9 where the consumer has the ability to enter
10 information, how does the fact of a minor's having been
11 emancipated get entered? How would that information
12 get into the system?
13 MR. TERRY CALLAHAN: Again in the system that
14 I described, it's outlined by law. The emancipation is
15 age related. It's the clock ticks and that's what
16 happens.
17 MR. RISHEL: I'm talking about the situation I
18 just drew. How about in this country?
19 MR. TERRY CALLAHAN: I just wonder if anybody
20 has a different answer for --
21 DR. JONES: Certainly in the scenario that I
22 described. Then, of course, if it ended with the

1 parents -- with the date that parent put in as the age
2 of majority, then, of course, would that not answer it?
3 MR. RISHEL: The Court can order that a minor
4 is emancipated before the age of majority as far as I
5 know the parent gives up the control of their data at
6 that point. I'm just wondering where would you put
7 that information in?
8 MR. TERRY CALLAHAN: Well, if I understand the
9 question, when you create the consent directive, of
10 course, it has a beginning and an end date. So it can
11 be until revoked or a specific date. Does that answer
12 your question?
13 MR. RISHEL: Well, I better let other people
14 go.
15 MS. McGRAW: Yes. We'll have to move on.
16 John.
17 MR. HOUSTON: Deven.
18 MS. McGRAW: We have another almost half an
19 hour so I have not short changes you. No worries.
20 MR. HOUSTON: Excellent. I actually have two
21 questions and one of them deals with listening to all
22 your testimony, it's great that you give the patient,

1 the consumer, the opportunity to provide consent for
2 these releases and the like. But I guess the question
3 I have is it seems like all your models are based upon
4 some idea that the consumer is front of a computer and
5 that they provide some type of computer based consent.
6 And I guess the question I have is how do authenticate
7 or identify the user and ensure that that person is who
8 they purport to be rather than somebody masquerading as
9 the user.
10 There are a lot scenarios I could go into
11 where that does happen today. And yet all your models
12 really depend upon a high degree of trust that that
13 user is who they say they are.
14 DR. JONES: Sorry. Some of our partners have
15 suggested that they're going to be biometric
16 identification in terms of thumb print. That's one
17 possibility. The fact that we're totally web based
18 does not mean you have to be in front of your own
19 computer in your own home but that can actually have a
20 kiosk, a web enabled (inaudible) do it from the
21 library.
22 Spoofing, of course, is always going to be an

1 issue as long as you're limited to name and password
2 and people are careless about that. So if you want to
3 have other metrics, you do so. But we enable either
4 question and answer biometrics, that kind of stuff.
5 Again, it is going to be to the taste of the sponsoring
6 enterprise as to how they wish to have that enforced.
7 MR. SHELTON: Monte, do you want answer about
8 ID verification?
9 MR. GIBBS: Yes. The first thing I would say
10 is that our technology is performed by the process,
11 which is by establishing a hearing our models
12 specifically our model of the Privacy Bureau, you have
13 an obligation toward security and validation. And that
14 is not a one time event. That is a not a user name or
15 password. That's not a single instance. It is a
16 perpetual instance of technology being employed,
17 applied and repurposed over and over again and never
18 entrusting that the process has been completed. That's
19 a differentiator again through our oncology. We
20 utilize a third party identity verification system. We
21 limit the use of the trusted cookies and/or other forms
22 of protocol that can be spoofed and exploited and

1 hacked. Again, we've repurposed and constantly recycle
2 through the authentication focus, the way in which we
3 do multifactor authentication, our oncology enforces
4 the four levels of missed authentication, site keys.
5 In every instance what we're attempting to do is show
6 that's there is a demonstration of technology that
7 doesn't trust and makes no assumptions of trust
8 throughout the process, but does so in a way also at
9 multiple points. Not just when a consumer is sitting
10 in front of a computer, but at points by which they
11 receive treatment, the physician's office or other
12 location.
13 So intermediaries may come into the process,
14 but the technology enforces the standard for security
15 and authentication of the individual at every point of
16 contact every time.
17 MR. DeCOUTEAU: The model has to support only
18 a digital entry of the consumer choice, but also
19 possibly a paper delivery of a form that's been signed
20 and certified. The demonstration that I went through,
21 I acted as a privacy advocate for the patient because
22 these were complex clinical problems that she wished

1 not to disclose. So there needs to be some interaction
2 at some point where the patient's wishes are vetted
3 through somebody who is knowledgeable in this area. So
4 you're going to have that.
5 Certainly, there are some policy decisions
6 that can be made immediately. If a patient wants to
7 opt in, you're in. And do you want to control access
8 to specific sites? Do you know who you're being
9 treated by? You can select those. As far as
10 identifying who the patient is in these electronic
11 systems, clearly that's an organizational policy, the
12 level of assurance of identity for the VA is different
13 than that of the DoD. That's an example. That may not
14 be true. But it could be.
15 MR. KELLY CALLAHAN: I don't think we have
16 anything more in particular to add then our partners
17 here.
18 MR. HOUSTON: Great. Thank you. I hear the
19 example that the spouse that is maybe either divorced
20 or they're separated and the one spouse goes in to try
21 to -- knowing enough information about the other spouse
22 to enroll them in some type of PHR just to be able to

1 see what's going on. And so you hear those types of
2 stories and it's a concern that to make sure that we
3 really do understand who these people are who are
4 initially enrolling in these.
5 The other question I have is specific to the
6 VA. And like the VA, I actually brought smaller but
7 nonetheless, the organization I work for has 20
8 hospitals and it's quite large and many, many
9 information systems which pass transactions probably
10 hundreds of thousands of dates. And so, I could see
11 with a primary system where you could put certain types
12 of preferences in place patient-wise in terms of what
13 can be released, to whom and how and what type of
14 restrictions are in place.
15 But how does the VA handle the idea of
16 honoring those preferences and those consents as data
17 is passed between systems and potentially released
18 through departments. I guess the best example is that
19 radiology departments often do their own release of
20 information of exams, yet, most radiology departments
21 have their own radiology systems that are fairly well
22 self contained.

1 And so even if a patient were to come in and
2 at intake, at registration, say my preference is that
3 this type of information shouldn't be disclosed to
4 whomever or this type of information could be disclosed
5 to whomever. How do you deal with those other
6 ancillary systems and those ancillary releases?
7 MR. DeCOUTEAU: I don't know if I can answer
8 that question. I can say that in the current DoD, VA,
9 Kaiser Permanente implementation that all disclosures
10 are going through the Release Of Information Office.
11 Somebody is physically looking at that document and
12 approving it currently. That is changing in the pilot
13 demonstration. Internally, I can't answer that
14 question what's going on as far as the exchange of data
15 between --
16 MR. HOUSTON: My fear is simply that you lose
17 that logic as data flows between systems. And as we go
18 towards an electronic release, I guess, I'm just trying
19 to understand whether the VA has really thought and
20 able to think through how you handle that.
21 MR. DeCOUTEAU: Well, I can tell you what
22 we've been working on if that helps. Clearly, we

1 actually started XPA as a way of driving software
2 behavior within the clinical applications based on
3 policy. Our goal initially was to remove those
4 decisions from Software Developer and allow us to
5 change the behavior of the application through policy.
6 That was the first demonstration we did in 2008, was
7 literally driving behavior both organizationally and by
8 the patient of the existing internal application.
9 So XPA, the cross enterprise version of that
10 is just a logical extension of I'm controlling behavior
11 internally. Now I'm going to control it when I'm
12 exchanging data outside the organization.
13 So we haven't really moved away from the
14 model. It's all still service based. It's very
15 expensive to recreate software over and over and over
16 again to do the same thing. So that's what we did
17 initially.
18 Now has there been a lot of adoption of these
19 capabilities? This is something that occurs over time.
20 Again, these are relatively new standards and it is
21 what it is.
22 MS. McGRAW: Thank you very much. Sumit.

1 MR. RANA: Thanks, folks. I actually have
2 many questions but I am at severe risk of being red
3 carded by the folks next to me so I will keep this very
4 short.
5 I had a question for you Duane. As you were
6 talking about the consent capturing process, I think
7 you had implied that it anticipates future consent and
8 somehow is sort of future proof. And I wanted to ask
9 you what specifically technically have you done in
10 order to implement that. It goes back to what Wes was
11 asking you in terms of if those ontologies are not yet
12 defined, then how can we technically do that?
13 MR. DeCOUTEAU: Believe me this in an advanced
14 concept of treating the patient's policy or consumer
15 choice as a living directive. The example of
16 protecting the human genome basically utilizes an
17 outside clinically relevant source, in this case the
18 Genome White Association Study has a way of
19 interjecting new medical knowledge into the policy
20 engine.
21 And so what the patient creates consumer
22 choice, it says, I want to mask anything about

1 schizophrenia that may or may not be delivered today.
2 It may be delivered today or tomorrow. I want it
3 redacted from my clinical record. Well the only way
4 that you can do that is that the policy engine and the
5 policy itself stays current with the available medical
6 knowledge. So it's constantly going back and looking
7 at well, this patient's data has been requested from
8 Healthcare domain A. He wants you to control access
9 the genomic data. I'm going to go and look and
10 actually remap that patient's data against the most
11 current known medical knowledge and determine at that
12 point should I be redacting additional information.
13 And if that's the case then I do and I send it on its
14 way. What is it allows that initial intent by the
15 patient to be protected.
16 MR. SUMIT: I understand that part. And I
17 think this came up in the morning too which is then it
18 goes into who's the knowledge base who is maintaining
19 that and the rule sets around that.
20 MR. DeCOUTEAU: Right.
21 MS. HARRELL: Once again, time being of very
22 limited entity, I will keep my questions very short and

1 my comments. I want to make a couple comments first.
2 First I want to thank the Policy Committee and the
3 Tiger Team for putting this one today. I can't tell
4 you how informative it has been for someone who is not
5 a technology geek. And I thank all of those of you who
6 are for really being so informative and I really
7 appreciate that. And I'm excited about the art of the
8 possible. To me, this afternoon has been the art of
9 the possible.
10 But I'm a practical person. I want to know
11 the reality of the situation and Wes started getting
12 into this. I want to know when is this reality? When
13 can we start implementing policies and I think we need
14 to go down the policy road. We've been in technology
15 road, but we need to get to the policy road.
16 MS. McGRAW: Make sure you ask a technology
17 question.
18 MS. HARRELL: I'm going to. My technology
19 question is really how real is this? How many people
20 do you actually have in your systems? How many people
21 are using them? What are the problems? Is this
22 reality? Can we count on this and set policy to

1 implement it? How real is this?
2 DR. JONES: If you'd like me start. Not
3 nearly as many as I would like of course, but there are
4 probably 22 small practices, two to three physician
5 practice with whatever patients are associated with
6 that are using the Tolven based system for EHR and
7 they're expanding to PHR within this calendar year for
8 that patient population.
9 The Dutch situation I described to you and in
10 the documents it says probably no more than a hundred
11 people right now. It's expected to scale up to three
12 and a half million providing everybody is happy with
13 the way it goes and further policies are implemented
14 regarding things like agency and spouse and those sorts
15 of things, because right now, it's just individual.
16 Singapore is just being kicked off.
17 So in effect, it's new. We haven't had hideous
18 bumps in the road aside from those that the ones that
19 you brought up, which is how is the policy clearly
20 articulated so that the technical people could
21 understand how to implement it. That is one of the
22 bigger roadblocks. In fact, I would say that major

1 expenditures and expense are on the debates about
2 policy that have taken place to the extent that you
3 would like. The second would be interfaces when
4 important. And the third would be terminology mapping.
5 And we're able to help follow those, but it's work that
6 often get thrown back onto the customer, the client.
7 MR. SHELTTON: Monte, do you want to answer
8 the question for us?
9 MR. GIBBS: Well, I would first say that we've
10 emerged by condition. We just emerged from our data
11 program and have entered into the commercial stage or
12 the production line stage. So on that basis these were
13 enclosed beta programs and initiatives.
14 How many do we have? Not nearly as much as
15 the situation and the issue should require. We have
16 enough numbers to validate the business and validate
17 the assumptions of our technology and architecture.
18 But fundamentally what is required to help this is more
19 focus around the issue and the policy itself.
20 We have the capacity, the scalability, and
21 extensibility to do at this very minute, right now,
22 receive and to be able to administer effectively and

1 consistently up to a million users presently.
2 By entering into the stream for the PHR
3 integration the EHR integration that we're
4 anticipating and that's precisely what we anticipated
5 being able to do.
6 MR. TERRY CALLAHAN: Our initial
7 implementation is limited to a small pilot in San
8 Diego. Ultimately this technology will need to scale
9 to support all veterans which is roughly about 6.5
10 million, I believe. We're currently in development and
11 building all of the glue around this technology. So
12 it's more than just what you're looking at here. It's
13 the ability to provision a specific provider with a
14 specific role, those kinds of things to create the
15 translations necessary to be able to speak across the
16 exchange in a standard based way.
17 MS. HARRELL: Can you tell me how many -- when
18 you say small pilot and when is it going to be in place
19 that it's scalable?
20 MR. TERRY CALLAHAN: Well, I'm a technologist
21 so it's scalable today. But as far as fully being
22 implemented, not until late 2011.

1 MR. KELLY CALLAHAN: Of course, our objective
2 was to build the tools according to the standards,
3 which we did do and the standards are there and they've
4 been demonstrated the VA and others. So we're ready to
5 go so we just need somebody that wants to take the next
6 step with us.
7 MS. HARRELL: So you actually have no one in
8 the system right now?
9 MR. DeCOUTEAU: We've got a couple projects in
10 the can, but as far as an implementation standpoint,
11 we're in our own Phase 1 with a 24 hospital exchange
12 and another one or two projects. We've also over a
13 year ago showed as we're now allowed to say,
14 demonstrated interoperability with the VA and have had
15 an evaluation that way.
16 In addition to that there's a lot of other
17 things you can do. Quite simply, we've benchmarked our
18 products and so forth to know that it can scale to be
19 able to handle six, ten, twelve million population or a
20 jurisdiction of that size based on transactions,
21 anticipated transactions and so forth.
22 At some point -- ask us this question again is

1 six months time and we can give you more information.
2 MS. SWEENEY: I too want to thank ONC and Joy
3 and Deven and all of you who participated. But I did
4 have some couple questions. I realize that there is
5 tremendous variability on the panel in terms of what's
6 been deployed and what's still on the white board. B
7 But either way you still bring to us a lot of
8 thoughts and a lot of things that I want to push back
9 on you to hear your thoughts about it to see how you
10 would address them. So I just have three quick
11 questions.
12 One of them is this morning, all of the
13 systems had a provider in the middle, a provider who
14 acted as a proxy for the patient's consent and right
15 away a lot of issues came up. Like how can a patient
16 really be informed when a lot of times it wasn't clear
17 the doctor was completely informed with respect to the
18 technology trade offs of the consent.
19 We talked about the inference problem that I
20 might click off one field but there might be other
21 fields that can give away that information, an
22 inability to scrub the text and EMRs that are text

1 based. So therefore, I may have to block a whole area,
2 when I really just wanted a small part.
3 So, Robert, when he presented his system he
4 said well, the way he tries to get the patient informed
5 around this is through this referral system based on
6 trust. And the VA system sort of actually just hires a
7 profession privacy counselor who is going to sit there
8 and set the settings and have to make an appointment
9 with them.
10 Are there any other models or what have you
11 guys thought? Have you thought about how you would
12 address this?
13 MR. TERRY CALLAHAN: Just let me add that we
14 never get the PHI itself so we just get attributes so
15 we apply the consent policies against the attributes
16 that are being supplied to us.
17 If I understood your question about scrubbing
18 information ◆
19 MS. SWEENEY: Well the question is -- maybe
20 it's more clear with the second question too because
21 they're sort of related. So why don't I go ahead and
22 ask the second question and put them together.

1 But the issue is basically if we were to shift
2 a lot of policy towards individual consent which has a
3 lot of value to it and a lot of good things happening,
4 the question is, did we just create a false -- I mean
5 in some sense the overarching issue here is that I
6 create a false impression by believing the patient
7 could do a better job at some of the issues raised
8 earlier.
9 So, for example, paper choices were very
10 granular when we think about paper consent. Some of
11 it's just limited by the fact that it's paper. Some of
12 it's limited by how much the patient could get their
13 mind around. So technology clearly allows more
14 granularity. We even saw that in your examples. But
15 the granularity introduces complexity. A complexity
16 that we as humans aren't good at dealing with. That's
17 what the inference problem is about, that I can't my
18 head around all the places it could be. But yet, I'm
19 asked to make individual decision.
20 So if more granularity adds complexity but
21 less granularity gives me less real control and
22 therefore loss of data utility because I have to block

1 out more either in or out. How do you think your
2 systems -- what is the technology answer? Where are
3 the technology sweet spots or where to do you believe
4 them to be?
5 MR. TERRY CALLAHAN: So if I may say, the
6 first decision is one of the jurisdiction as to what
7 their policies are and to what extent they want the
8 patient to have control over access to their PHI.
9 The template that we showed you as an example
10 mimics quite closely to what a typical consent policy
11 would look like and if it doesn't, it can be changed
12 accordingly. So we can make that template look exactly
13 like a consent policy or consent document.
14 MS. SWEENEY: The thing you don't give me is a
15 technology benefit.
16 MR. TERRY CALLAHAN: Excuse me? A technology
17 benefit? You mean over paper?
18 Well there's a lot of benefits. First of all
19 you can record it centrally so it's available to
20 everybody as soon as it's entered. If you were to go
21 form paper to a template, you have a transcription, the
22 possibility of a transcription error. Once you have it

1 electronically, then, of course, you can also have
2 rules that are available with that document. Then you
3 have two available. And then the other thing is you
4 could make it very central. You can make it --
5 MS. SWEENEY: I understand, but I mean I was
6 after something different and maybe we should talk
7 about it later unless somebody else has a point to make
8 about the granularity problem.
9 MR. SHELTON: Well, I would just say, I've
10 been on various panels where people have questioned the
11 advisability of having high granularity. I personally
12 don't believe technologically that a consumer is able
13 to get their head around all the possibilities of
14 granularity unless there is some means of assisting
15 them. We've done the analysis. We've talked to the
16 consumers. We've seen the reactions and the consumers
17 will glaze over with the possibilities and be left, in
18 effect, with all the granularity in an opt in or opt
19 out.
20 So from our perspective, there has to be
21 assistance of some variety and you that I spoke this to
22 in my testimony and I spoke to how we've addressed that

1 through the guide system. And I'd love to take credit
2 for it, but where it came from was the ITunes selection
3 of music of how Apple has design to reduce down
4 millions of pieces of music down to what you would be
5 interested in seeing or listening to, based upon
6 finding someone who shares your interest in similar
7 types of music.
8 So the guide system seems to provide some
9 benefit. I'm hopeful that other vendors, other
10 companies, will take a look at it and we'll try to
11 improve upon it and we're watching what other people
12 are doing. I think the beauty of our economy, the
13 beauty of a competitive society is that when someone
14 comes up with an innovation, other people either copy
15 it or try to improve. And ultimately, you improve the
16 way the interfaces work.
17 Clearly, if we're going to have granular
18 consent, there has to be a capability to inform and
19 educate and get good answers from consumers, or else
20 I'll get another yellow card if I say the rest.
21 MS. SWEENEY: Last question, which is a very
22 simple one, it's related to what I was --

1 MS. MCGRAW: Yes. And can I ask the
2 respondents to try to be as direct as you possibly can
3 to LaTonya's question. Because we still have two more
4 members to get through and we're running out of time.
5 Thank you.
6 MS. SWEENEY: The last question consent
7 changes over time. So none of you talked about any way
8 that the data was tethered and or propagating consents
9 or anything like that. I don't know if you thought
10 about it.
11 MR. TERRY CALLAHAN: Yes. I'd like to take
12 that. In actual fact every time you create consent
13 policy, of course, that's recorded as you well know.
14 If somebody updates that policy, in fact what they do
15 is it's not just updated, it revoked and a new one is
16 provided and there's a complete history of that
17 provided in the system.
18 MS. SWEENEY: But the question is, the data
19 that just went out the door, there's no tethering to
20 that and now I don't want that kind of data out there
21 because now I know that that allele has a problem and
22 an inference and I want that old data -- at least let

1 them know that I don't want it distributed any further.
2 MR. TERRY CALLAHAN: Right. Well, certainly
3 the best way is to have a remote request and response.
4 In other words, every time you want to access that
5 information, it doesn't need to tethered. I mean it
6 can be tethered. We can do that. But it doesn't need
7 to be tethered. So if you just make a request every
8 time you want access, you're going to get the latest
9 consent director with a consent policy.
10 MS. SWEENEY: All right. But that's not how
11 your model worked.
12 MR. TERRY CALLAHAN: No. No. There was three
13 things we do. We have, again, a pdf that we can
14 provide. We can attach the machine readable document.
15 And then somebody if they wish because it's XTSD, they
16 can a subscribe if you wish or publish. So if there's
17 a new consent directive in our document in XTSD, we can
18 publish that to whoever received it initially.
19 MR. SHELTON: And I would just answer that
20 we've, I think again, just to point out things I
21 showed. The consumer did change their preferences
22 during the course of the five minutes that I demo'd the

1 technology. So the consumer was making changes during
2 that duration of time and that's what I believe a
3 consumer will do. So that dynamicism (sic) of the
4 system, I believe, ultimately has to be present.
5 You raise a great point if it's not tethered
6 back in some way, how does it get the update. And
7 rather than publish the update, what we're looking to
8 accomplish is at the point that the data moves or
9 proposes to move, it can reach to this place to say can
10 I share this with them? Well, if you've changed your
11 technology, if you've changed your privacy setting
12 during the duration of time between when you gave to
13 that to the party and when they are choosing to share
14 it, the answer would have changed from it used to be
15 use. It's now no. But the person that's wishing to
16 share is able to go get that answer at every moment in
17 time.
18 MS. DIAMOND: I'll just thank the panel. Both
19 of my questions have already been asked and I'll seed
20 my time to the gentle lady on my left.
21 MS. BAKER: Well, thank you. I've never been
22 called a gentle lady before.

1 Okay. My question has to do with how this
2 kind of segmentation is captured in audit records and
3 accountings of disclosure. Clearly an access is still
4 an access of identifiable patient information. So that
5 said, but if I were a provider and I were making
6 clinical decisions based on the information that's
7 available to me at the time, I would want that
8 disclosure record or that audit log to accurately
9 reflect the true access that I had when I made those
10 decisions.
11 So there's a concern if portions of the record
12 that were accessed and disclosed had been redacted or
13 somehow not available to me. So I'd like to know how
14 your systems accurately reflect what data they access
15 or disclosure actually involved.
16 DR. JONES: In the system I described to you,
17 of course the provider has a database with the copies
18 of the information the patient sent. That's what there
19 is. So decisions are made on that database. That
20 database is everything is in it is all it is when it's
21 there. So if anybody comes to an access of litigation,
22 they say, this is the information the provider had.

1 MS. BAKER: Even though that's not where the
2 audit or the disclosure took place.
3 DR. JONES: Correct. But if you want to go to
4 see what did the provider have available, that's where
5 you go.
6 MS. BAKER: But the person and the entity that
7 releases is the one responsible for the accounting for
8 disclosure and the audit. So their audit still
9 wouldn't be accurate.
10 DR. JONES: Well the PHR -- if you think that
11 the PHR entity which releases to the provider is an
12 auditable entity, then I agree with you. But, in fact,
13 all those disclosures are auditable as well because
14 it's XML documents that were sent by the patient to the
15 provider. Every one of them is audited. You know
16 exactly when it was sent.
17 MS. BAKER: Okay. Let me hear from the
18 others.
19 MR. TERRY CALLAHAN: Can I respond to that
20 please? So as we mentioned we find that he consent
21 validation service is a very good place to filter the
22 information that's required for the accounting of

1 disclosures. Assuming that what we do when a
2 validation request comes in, when we send the request
3 back, we send it back with an identifier and that
4 identifier goes with the request to the EHR so that
5 when the EHR then does disclose that information that
6 identifier is included in that disclosure log and goes
7 back to us and they're matched up.
8 MS. BAKER: The identifier of what?
9 MR. TERRY CALLAHAN: So the identifier of the
10 request, which includes, of course all the particular
11 information as Duane mentioned.
12 Then it goes back with a response to allow or
13 deny or to allow with override. And it goes back with
14 an identifier of all that information they just
15 recorded. So that identifier then is provided back
16 when it's actually disclosed. So when it comes back as
17 a disclosure, that identifier is in there and it's
18 matched up with all the other information that has been
19 recorded.
20 MS. BAKER: With the rules that were in effect
21 at the time?
22 MR. TERRY CALLAHAN: Yes.

1 MS. BAKER: I see.
2 MR. DECOUTEAU: This s a problem. This is a
3 problem with the current approach. The physician needs
4 to be able to recreate that document at any given point
5 on the consumer policy and consumer choice at that
6 point in time as well. If the physician chooses to
7 save the document that has had redacted information nin
8 the receiving organization, how do we let them know
9 that data has been redacted without delivering he
10 policies?
11 So there needs to be some kind of balance
12 between the patient being able to redact the data and
13 the physician being notified that some things are
14 missing.
15 We do all these demonstrations of XPA and
16 that's one thing we talk about in data redaction.
17 We're the people that started this thing way back in
18 2008, where the physician is able to infer that
19 something is missing and then goes to the patient ands
20 says, you need to change your consent policy to allow
21 me access.
22 So we have all those pieces that need to be

1 addressed. The auditing piece, the accounting of
2 disclosure, those are things that are relatively fixed
3 and available to us now in the technology (inaudible).
4 MR. SHELTON: I guess I would answer three
5 ways. One, when the data seeker is given a document,
6 they became a data holder so the document they received
7 is what they received. So the way that prove what they
8 had is because it's what they have.
9 Secondly the question of whether the redaction
10 or not is disclosed is not really a technology
11 question. It's a yellow card question from my
12 perspective. It's a policy question. It's an
13 institutional policy. It's a legal policy. It's
14 something that I think that when the technologies are
15 applied that various groups need to speak to. But
16 that's not a technology question.
17 The capability to redact is there. The
18 capability to notice the redaction is present. That's
19 what he technology is able to provide.
20 MS. BAKER: I think the technology has to
21 define how this is done. But the policy needs to
22 define how this is done, but the technology needs to be

1 able to do the timestamps and tell exactly what went
2 over there, because ultimately this is going to end up
3 in a court of law.
4 MR. SHELTON: Well, and the third point I was
5 going to make is when we showed the audit log, every
6 single step was made or was shown for the movement of
7 some packet of data. If you receive a federal express
8 package, federal express can say you got a package on
9 this date. And on the outside of the envelope, they
10 can tell you what is on the file folder, if you will.
11 But they don't know what's inside that packet. And so
12 the protection ultimately is the business records of
13 the recipient which will show what they received inside
14 the packet, the data packet itself, though, contains
15 not the data, but the metadata associated with it. And
16 that metadata is the consent based practice of do you
17 have a right to receive this.
18 MS. McGRAW: I think we are to the point of
19 our second public comment period. Judy, do you want to
20 do your magic?
21 JUDY: Sure. Anybody in the wishes to make a
22 comment please cue up to the microphones in the middle

1 of the room.
2 MS. McGRAW: Don't forget the rules. They're
3 still in place.
4 JUDY: Right. Only questions -- well, not
5 questions but comments about this hearing today.
6 MS. McGRAW: Technology only. Not policy.
7 JUDY: Right on. State your name, your
8 organization, a reminder that you have two mintutes.
9 And Operator if you would please tell those listening
10 of the phone and one the web how they might cue up.
11 OPERATOR: (Instructions.)
12 PUBLIC TESTIMONY
13 MS. McGRAW: Okay. We'll begin with the lady
14 on my left.
15 MS. WRIGHT: Is that me? Okay. I'm Robin
16 Wright (ph). I'm working as a volunteer with NCHICA in
17 North Carolina, Health Information and Communications
18 Alliance. Also the North Caroline HIE Legal and Policy
19 Workgroup.
20 My question has to from a consumer
21 perspective. And I know access to technology is not
22 free to me at my home. I would like to see access to

1 medical records be free. And I don't believe that
2 consumers will be engaged in this unless it is free.
3 They will not be reimbursed for any monies that they
4 would put forward for their medical records. And today
5 states charge different prices or states allow
6 providers of service to charge for paper copies. And
7 it can be very expensive, $10 a page. North Carolina
8 is $0.75. So think about that when you're working in
9 your group. And I hope that was enough technology for
10 you.
11 MS. McGRAW: Thank you, Ms. Wright. And we'll
12 go to the person on the other side of the room, please.
13 MS. HOGGLEMAN: Yes. My name is Lindsey
14 Hoggleman (ph). I'm and independent consultant and I
15 want to thank the Policy Committee and the Tiger Team
16 for their continued exceptional hearings and
17 testimonies.
18 I'm commenting today from the perspective of
19 an non-physician provider. And I appreciate the
20 comments about departments and ancillaries and where
21 that comes from. And I'm going to beware of the yellow
22 card, because I have no yellow cards for my children.

1 I can't get away from the comment made about -- I think
2 we need functionality within EHRs if we're going to
3 move to segmented data sharing mode where non -
4 physician providers are aware of the patients choices
5 and the patients consent. Because in a paper record,
6 confidentiality is the same across everyone. It's a
7 way of life and a way of delivering care. The consent
8 is only a form that's a signed piece of paper in the
9 paper record. And as we move toward segmented data,
10 that changes for every patient. And so I just
11 appreciate the comments on looking at other viewpoints
12 and how we deliver care from the non-physician
13 providers. Thank you.
14 MS. McGRAW: Thank you, Linda(sic). Operator,
15 do we have anyone on the telephone?
16 (No audible reply.)
17 MS. McGRAW: Okay. We'll go on this side of
18 the room again , the gentleman there.
19 MR. TRISIZE: I'm Tom Trisize (ph). My
20 background is one of I've worked for large Fortune 100
21 companies. I've been a Chief Information Officer and
22 Chief Marketing Officer.

1 As I look at this and how I frame today's
2 conversation, I think it's a good start. But the
3 paradigm that I look at is how good is the technology
4 of the abusers versus the technology of the
5 organizations that are represented here today. And
6 framing that in another way, I would say, as an abuser,
7 how worried am I about the conversation that's taking
8 place in this room today? And quite frankly, and I'll
9 throw it out there. It's judgmental, but I'm not too
10 worried. I mean my capability and use of technology
11 through aggregation of data over the internet through
12 piracy of data that's leaking out through doctor's
13 offices. Just from -- any you say, oh piracy, we've
14 got rules around that.
15 But a lot of what I can do as a piracy
16 aggregator, I can bring that data together and make it
17 look like it's a very legitimate face and then sell
18 that to marketing companies, drug companies --
19 MS. McGRAW: I'm going to interrupt you, sir,
20 because you're -- we're yellow carding you.
21 MR. TRISIZE: So my technology question is how
22 worried are you all about your direction of technology

1 against what the abusers are going to bring to bear?
2 MS. McGRAW: Great. Thank you, Tom. And the
3 gentleman on the other side of the room, please.
4 MR. PYLES: I'm Jim Pyles (ph) I represent
5 the American Psychoanalytic Association and the
6 American Association of Practicing Psychiatrists.
7 And I just wanted to thank the Committee. I
8 think the testimony today has been fascinating. And
9 the thing that I take from it and it's mirrored in some
10 of the written testimony is that protecting the right
11 of consent appears to be technological issue. It
12 certainly could be a policy issue as well. But we know
13 from the testimony of these gentlemen that it's doable.
14 And I found that pretty enlightening.
15 I was looking at the written testimony of Mr.
16 Shelton, I guess, where he says, "It has been said by
17 some that a robust system of highly granular patient
18 consents and detailed accounting for disclosures is
19 impossible or be unacceptably costly. And yet, one the
20 basis of our development average to date, I would beg
21 to differ." That's interesting and important to those
22 who practice psychotherapy, because the right of

1 consent is absolutely essential for psychotherapy to
2 take place because psychiatrists and psychotherapists
3 have to explain to the patient at the beginning of the
4 relationship what the parameters of privacy will be.
5 And if they cannot guarantee or assure the patient that
6 the right of privacy and consent will be in tact, then
7 the therapy simply can't take place.
8 Well, I guess one other observation is I
9 assume these gentlemen would not be developing the
10 systems they're developing if they did not believe that
11 the public was interested in it.
12 And finally, it does seem to me that from what
13 I've heard that the question is really comes down to
14 the policy, because if you draft the policy, they have
15 the capability to build to it. Thank you.
16 JUDY: Thank you, Mr. Pyles. Last chance on
17 the telephone. Anybody have a comment?
18 OPERATOR: Yes. We have a comment on the
19 telephone from Fred Bore of Meta Steward, LLC. The
20 line is open.
21 MR. BORE: My name is Fred Bore (ph). My
22 company is Meta Steward, LLC. I have participated on

1 several HITSB committees including the Consumer's
2 Preferences Tiger Team. I am presently participating
3 on a small HL7 Personal Health Records Workgroup. I'm
4 a member of Dr. Peel's fan club.
5 My ideal would be a single patient Tolven
6 system. Thank you.
7 JUDY: Thank you, Mr. Bore. Anybody else on
8 the phone?
9 OPERATION: None for the phone with a
10 question.
11 JUDY: Okay. Thank you. Deven, back to you.
12 MS. McGRAW: You really can't get anymore
13 succinct than that last comment.
14 JUDY: And I would to thank him for not having
15 one of those horns as a member of your fan club.
16 MS. McGRAW: I want to thank everyone once
17 again. There's been a lot thanking in a hearing like
18 this that I think this might be on the record as the
19 longest one that we've had of the policy workgroups and
20 standards as well. And for all of you for hanging in
21 with us for the entire team as well as the members of
22 the public. It's been a long but very interesting day.

1 We have a lot of information.
2 We will have to have the policy conversations.
3 We wanted to try to make this very focused on what the
4 technology can and cannot do. And we got, I think, a
5 good picture of where that is. I think there will be
6 some follow up questions that we'll ask from you.
7 Certainly if there's additional information
8 that any of the companies or any of the reactor
9 panelists want to provide, we'd be more than happy to
10 receive. Especially if you want to react to what you
11 heard today, we'd love to have it.
12 And so I just want to close by thanking you,
13 thanking the staff for all that you did to make this
14 possible and stay tuned.
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1 CERTIFICATE OF COURT REPORTER

2 I, JEFFREY MICKLE, the officer before whom the
3 foregoing meeting was taken, do hereby certify that the
4 foregoing meeting was duly sworn; that the hearing was
5 taken by me in stenotypy and thereafter reduced to
6 typewriting by me; that said meeting is a true record
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8 to, nor employed by any of parties to the action in
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