

**HIT Policy Committee
Transcript
June 6, 2012**

Presentation

Mary Jo Deering, Ph.D. – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Dr. Agarwal?

Madhulika Agarwal, MD, MPH – Veterans Administration

Here.

Mary Jo Deering, Ph.D. – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

David Bates?

David Bates – Brigham & Women’s Hospital & Partners Senior Vice President for Quality and Safety

Here.

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Christine Bechtel?

W

She’s in the restroom.

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

How’s that for no privacy here? Neil Calman?

Neil Calman -The Institute for Family Health – President and Cofounder

Here.

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Rick Chapman? Patrick Conway? Art Davidson?

Arthur Davidson – Denver Public Health Department – Director

I’m here.

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Connie White-Delaney? Paul Egerman?

Paul Egerman – Businessman/Entrepreneur

Here.

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Judy Faulkner?

Judy Faulkner – EPIC Systems - Founder

Here.

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Tom Greig? Gayle Harrell?

Gayle Harrell - Consumer Representative/Florida – Florida State Legislator

Here.

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Charles Kennedy? David Lansky?

David Lansky - Pacific Business Group on Health – President and CEO

Here.

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Deven McGraw?

Deven McGraw – Center for Democracy & Technology – Director

Here.

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Frank Nemecek? Marc Probst?

Marc Probst – Intermountain Healthcare - CIO

Here.

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Joshua Sharfstein?

David Sharp – Maryland Healthcare Commission

David Sharp for Josh Sharfstein?

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Latanya Sweeney? Rob Tagalicod? Scott White? Okay, back to you Paul.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

All right, thank you Mary Jo. And thank you to all the members for attending this meeting. This is going to be a busy meeting, but a very exciting meeting. We're going to spend most of our time providing feedback to ONC on their RFI for the governance mechanisms and we have a special guest, arriving around 2:30, who is the UK Secretary of Health, Andrew Lansley. So, he's going to be also talking to us about some of the new programs he's started in the UK, which I think will be very relevant to our work. So, I think that's going to be a valuable contribution. So, let me just review the agenda. We're going to start out with Steve Posnack talking about the RFI. I think all of us have attended his webinar, so we all know the overview. He's going to focus a lot of the attention on the areas, and particularly sort of the high level concepts and what they're looking for in our feedback to them. So, that's the concentration of his remarks. Then we're going to spend the next several hours, now that may seem like a long time, but for 66 questions, that ends up being 2-3 minutes per question; which is a challenge. Just to put that in

perspective, that's about 2 minutes for the workgroup to summarize and about two 30 second comments. So, we're going to have to work... pardon me?

M

... good at 30 seconds.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

We're good at 30 seconds, right. So I hope you'll forgive me for trying to keep us on task, because in fairness and to be respectful of both the ONCs request for feedback, getting no feedback won't be a service, and in respect... to respect all the hundreds of hours that have gone into providing feedback, we need to be very concise in our statements. So, I'll talk a little bit more about that when we get to that point. But first, what we're going to do is, Steve is going to give us an overview, concentrating on some of the areas where there may have been some misunderstandings or a lack of the appropriate focus, in terms of our comments, and that'll be a good setting for our discussion. And as I said, after we finish with this work, we're going to have an update from Rob Anthony about the Meaningful Use statistics, a brief one this time, with a more expanded one next meeting. And then followed by Secretary Lansley's comments at the end. All righty, any questions? Let me also do the minutes. Did you review the minutes and does anybody have any updates?

Christine Bechtel – National Partnership for Women & Families – Vice President

Indiscernible.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay, do you want to submit them afterwards? Okay, so Christine has some edits. Anybody else? Okay, I'll entertain a motion to approve.

W

So moved..

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

And seconds? Any further discussion? All in favor?

Men and Women

Aye.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Any opposed? Very good. Okay Steve, take it away. And Farzad's going to join us around 10 o'clock.

Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst

This is almost like a television production today with hand offs from Mary Jo to you and then to me. So, thank you for having me. As I'm sure... as Paul mentioned, hopefully you've caught one of my other stellar presentations and I have been... this is probably the one I've done the most out of any of the other presentations, which may be an indication of its importance and I think it's complexity in the areas in which we have a lot of policy debates to still happen. Yes?

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Before your stellar presentation, I forgot to do a logistic... a housekeeping logistic which is, because we're going to be short on lunch and we're just saying we'll be short on time for lunch, they have arranged for us to be able to purchase lunch ahead of time. So, you would have gotten a menu selection, and please get that in if you want to participate in that lunch. Thank you. Sorry Steve.

Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst

That's fine. So, to begin. I'm going to... this is kind of a stock presentation that I've given a number of times, but as Paul mentioned, I'll be stepping through some of the more important facets where hopefully before you begin your conversations, you can keep these in mind and it can ground people in at least the perspective that we're coming from and that we tried to express in the RFI and its preamble, in a way that was at least clear to us, but as we have seen from always reading the regulations and requests for information that we put out, what's clear to us may not be clear to you. So, here to do a little bit of voice over; I think as folks have seen, in terms of the level of detail and the amount of questions that we asked, we approached to this with a little bit of humility and not knowing all the answers, which is why it's a real important point, before we all jump into the rulemaking bus, that we all have the same map and we know which direction that we're going in. So, really we're at the point where we're looking directionally to see if we're all looking at the right endpoints and that's what we've tried to express in the RFI, kind of in a nutshell, and where you are at this point in time in terms of the policy discussions. And really, it's a unique opportunity to help us shape the proposal that we could subsequently include in a Notice of Proposed Rule Making.

So, all right, here's our statutory authority. I would note here, and this is one of the things that I've heard a lot of discussion about in terms of maybe differences in how ONC is approaching this versus how folks may be interpreting the approach that we laid out in the RFI. The statutory authority that we've got in the HITECH act requires the National Coordinator to establish a governance mechanism for the Nationwide Health Information Network. And so, as I've given my presentations, I've tried to note that it didn't say, "the National Coordinator shall govern the Nationwide Health Information Network," and so we see a distinction between govern and a governance mechanism and we've been focusing on, true to the statute, the mechanism construct and what a governance mechanism would look like. So, as the RFI explains in greater detail, we have approached implementing the statutory language by asking where can ONC uniquely add value and so in setting up a governance mechanism, what is ONC uniquely positioned in order to be able to provide to the industry. So we've laid out a multifaceted approach, as many of you as part of the workgroups have seen, going through all the questions, in terms of what an effective governance mechanism would include.

And so a general point that I'd like you to keep in mind as you have these discussions today, about the specific deliberations from each of the workgroups is to keep in mind that we are looking to create foundational structures and processes that would be necessary to support nationwide electronic health information exchange. And so that's what the mechanism construct is about. At its core, the governance mechanism that you see in the RFI is not necessarily about one particular form of exchange, or method; it is about putting in place the policy and technical building blocks that would make all forms of exchange take place, and support all forms of electronic health information exchange taking place. You'll also see that we have packed in a lot of the prior discussions that the HIT Policy Committee has had, the HIT Standards Committee has had, that you've issued recommendations on. I hope you feel like your work is continuing forward in some form or another. We've translated that and stitched together a lot of the history of the Nationwide Health Information Network experience, so to speak, since 2004-2005 into this RFI and so, as we've gone through the chronology and other elements, in putting together the conditions for trusted exchange that you'll be talking about, that's really where we tried to embody a lot of the discussions that have happened thus far.

All right. So what is the Nationwide Health Information Network, always good to have a reminder; this is how we've described it for the past couple of years, a set of standards, services and policies that enable secure health information exchange over the internet. And, that's really where we're trying to accelerate electronic health information exchange through the governance mechanism that we would put forth. So, we've included our rationale in the RFI for why we think now is the right time to act, to establish a governance mechanism. Obviously we expect that there will be a lot of discussion, a lot of analysis that needs to take place and so, there's no better time than now to get started with that, because this as element is part of the overall ecosystem and environment for electronic health information exchange that we think is going to be necessary to support all of the healthcare delivery reforms that... and novel

payment methods and other types of IT infrastructure components that will really make healthcare be delivered in a high quality and efficient manner.

So I'm not going to dwell too much on these slides because I've touched on them in the other presentations that I've given in the workgroups that you've been part of that have been blessed with my presence to give you a presentation as well. I've covered a lot of these together. On the overall objectives for the governance mechanism, we've tried to articulate that we'd like the governance mechanism to be able to enable a more competitive and open market for electronic health information exchange, to make it more efficient for entities to exchange electronic health information in areas where states and other types of consortia have already approached establishing governance. We hope that we can relieve some of the burden that they've taken on through this governance mechanism that we've established in order to take on some of the potentially disparate approaches that they would be pursuing in the absence of any national guidance. And so, again, we would seek to use this governance mechanism to help lay the foundation to support future stages of Meaningful Use that may include more comprehensive and robust information exchange related requirements. And then finally, to just work with the HIE marketplace to coordinate and guide the maturation and evolution of technical standards and implementation specifications.

Okay. So, when I talk about the governance mechanism, and I've tried to boil this down and so practice makes perfect in terms of the presentation; so, I think I've gotten to a place where I can articulate what the governance mechanism is in two points; the mechanism that we are trying to establish includes a validation process, and I'll discuss that in a little bit more detail, and a standards classification process. And those are really the two elements of the governance mechanism; and that's really what the RFI touches on. And so as part of the validation process, within that there are conditions for trusted exchange that would be the rules of the road. There would be the actual mechanics, entities, the structure, the process for trusted third parties to be validated to the conditions of trusted exchange and then there would be this other process to keep track of the conditions for trusted exchange, introduce new ones, retire old ones. And so, I lump all of those into this validation process that would be one prong of the governance mechanism.

And then the second prong is really for your sister committee or brother committee, the Standards Committee where we see the need for an open, transparent, iterative, deliberative process to mature interoperability specifications, to really lay out a roadmap for the industry at large. And that is the second prong that the governance mechanism would include. So, the scope of the RFI, and it primarily focuses its attention on entities who would facilitate electronic health information exchange on behalf of providers. So, these would be the ones that would come forward and prove and demonstrate their conformance to conditions for trusted exchange; and that is the primary scope of the Request For Information and the potential governance mechanism and the validation process that we've included. So in this case here, we discuss a voluntary framework, so we're not mandating, we don't intend or we didn't expect to have a mandatory process that would obligate everyone that's exchanging electronic health information to go forward through this governance mechanism, to be validated through this process; we want to make the validation process an attractive value-added proposition for all the participants in electronic health information exchange.

So, one of the feedback comments, and as you go through your discussions today, is really thinking about the value proposition for the governance mechanism in the validation process. Because if it's not going to be valuable to entities that are facilitating electronic health information exchange, then, we need to rethink some of the elements that we've laid out in the Request For Information. Because we don't want a situation where we build it and no one comes. So, as I mentioned before, the governance mechanism we've laid out is multifaceted in order to meet the diverse needs of different stakeholders out there. One of its facets includes the adoption of the conditions for trusted exchange, the ability for entities that would facilitate electronic health information exchange as trusted third parties, to become validated and establish the formal existence of these trusted third parties as what we call the Nationwide Health Information Network Validated Entities. So, NVEs for short, which is... you have a couple of new acronyms and abbreviations to play with in your discussions, enjoy. It's fun to come up with them as well.

So, this facet anticipates that many healthcare providers will rely on trusted third parties to facilitate electronic health information exchange on their behalf. Whether it be directed push type of method for electronic health information exchange or bi-directional query oriented methods of electronic health information exchange, our vision for the validation process doesn't preclude either one of those; there's just an instance where, at the point in time as we produced the RFI, there's a certain level of maturity in some of the policy discussions that have occurred thus far. So, I think I will continue on, so as not to eat up too much time.

To ground folks in, the three categories of conditions for trusted exchange that we have; we have safeguards CTEs, interoperability CTEs and business practices CTEs; and I won't go into any detail in the descriptions of these. There are 16 CTEs addressed in the RFI of which many have questions associated with, and, these are not meant to be an exhaustive or inclusive or comprehensive set; they're the best 16 that we had ready, that we had discussed, that we felt we could get policy direction on at the present time, to see where folks stood. So, if there's something missing, that's another area where again your feedback is going to be very much appreciated. We also, in terms of feedback that I've heard as I've given presentations, I would call out that again, we have a list, it's just a list of 16 conditions for trusted exchange that we think have potential. We foresee the need to package them into logical, and I'll repeat packages, where a grouping of CTEs could be packaged for a particular use case or policy objective, and then a different grouping of CTEs could be packaged for another use case or policy objective. And, you can foresee the need for different policies to be present for directed or uni-directional push type of transactions and other types of policies to be available for bi-directional query oriented exchange. And so, especially when you get into the safeguards related conditions for trusted exchange, you'll see some of those merge into that list. It's not to say that we expect or would anticipate or had intended that an entity coming forward to become an NVE would have to get validated across all of them all at once.

So, I'm not going to delve into the conditions for trusted exchange that we've listed, these are more for your reference here; they'll come up again as many of the workgroups discuss their deliberations. Just to ground folks since I know folks have gotten tripped up on this, the S or BP or I is just a shorthand to keep track of the conditions for trusted exchange, so you see S-1, S-2, that's to stand for safeguard CTE S-1, safeguard CTE 2, etcetera, etcetera. So we have 10 safeguard CTEs, we have 3 interoperability conditions for trusted exchange, and then we have 3 business practice conditions for trusted exchange that we've included thus far. The business practice ones are a little bit different, I think, in terms of the discussions that folks have had over the course of time; a lot of us focused on privacy and security orientated policies, a lot of us focused on interoperability. The business practice ones have focused attention on NVEs relationships with each other and how they participate in this health information exchange ecosystem and the activities in which they would support electronic health information exchange.

So we have some eligibility criteria that we listed as potential pre-conditions, so in order for an entity, a trusted third party to step forward to become validated as an NVE, we threw out a list of potential pre-conditions that we were considering. Again, this is not meant to be inclusive, exhaustive or comprehensive from a standpoint that all of them would be required in a potential rule making. We wanted to see which ones resonated the most with folks commenting on the RFI. With respect to the potential entities that could facilitate electronic health information exchange, again, we saw that there could be a variety of different organizations that could be considered trusted third parties that would be performing this kind of third party role and providing services to exchange electronic health information on behalf of providers. And so, we just wanted to give folks an idea that we weren't trying to preclude any type of entity or include any type of entity that shouldn't be included.

So from the validation perspective, and this is an area where a little bit of clarity also, I think this stems from the Governance Workgroup's original discussions a year or so ago, couldn't land on a particular term to describe what it meant to prove conformance with the conditions for trusted exchange that we now call them so, there was this general concept that the proof in the pudding would be validation. And so, a trusted third party would be validated as meeting these conditions for trusted exchange. As folks have noticed, the scope and tenor of the conditions for trusted exchange really focus on organizational behavior, the people, practices and how that organization functions, as well as the technical capacities of that organization and in the fluency in different interoperability requirements. So along those lines, under

this umbrella of validation, we saw that there could be at least two prongs to the validation process; there would be proof through testing and certification that an entity had met conditions for trusted exchange as well as accreditation, which we have in our context, conceptualized as looking at an organizations business practices and processes.

And so, you could foresee testing and certification of technical aspects for the conditions for trusted exchange being a way to satisfy the condition for trusted exchange as opposed to the entity itself being certified, per se. So, use of something that would be certified and tested would be a way to satisfy the condition for trusted exchange. And so, I just wanted to tee that up for folks to make sure you understand the distinctions that we've tried to make in the RFI. Another thing that has been a little bit confusing to folks, if you're familiar with the permanent certification programs for the structures and processes that we've established thus far, we have, for the permanent certification program, laid out a single accreditor that would determine the competency of multiple validation bodies and so, to make this analogous to the permanent certification program, we have a single accreditor that determines the competency of multiple certification bodies that then certify products, the EHR technology in this case. So, translating that over to governance, we'd have a single accreditation body that ONC would delegate some authority to, to determine the competency of the bodies that would then go out and validate different trusted third parties abilities to conform to the CTEs. So, that's how the kind of delegation of authorities and flow works in terms of replicating the certification process.

Okay, so I'm not going to dwell on this. As part of the first prong, the validation process for the governance mechanism, we think there would be a need to update and retire the conditions for trusted exchange. The most important thing here would be just keeping in mind the classifications that we've established in terms of emerging, pilot and national. This is something that we've replicated over in the technical standards classification process, that would include this annual review process to help identify and roadmap how the maturity and adoptability of technical standards and implementation specifications. And then finally we've included discussion in the Request For Information about monitoring and oversight. We see this as a shared responsibility among the entities that we would delegate some responsibility to, as well as the trusted third parties that would be conforming with the conditions for trusted exchange and then finally, since we are operating in a healthcare environment, there are a lot of other regulatory paradigms that we need to keep in mind. And so, the Office of Civil Rights primarily with respect to the HIPAA Privacy and Security rules, this is an area where you've seen in the conditions for trusted exchange that we've looked at the electronic health information exchange environment and said, what's different here, which is a question that we've asked, that many of you have asked on different advisory committees, whether it be NCVHS or the American Health Information community. I'm going all the way back there, you know, that we've asked what's different, what's the delta between the rules that exist today and the electronic health information exchange environment; where do we need additional protections or where do we need something different because the scope of the policy deficits that we have needs to be addressed in a different way. And to that, you'll see where we've tried to build on some of the concepts in existing regulatory paradigms and where we've explained some differences that we've seen based on the ecosystem that we're talking about.

So that's it. I'm going to be around so I can chime in where there are questions, but I don't want eat up any additional time that you may have.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

No, that was perfect. Steve, thank you very much. Any pressing questions on... so, we have two pressing questions. Judy?

Judy Faulkner – EPIC Systems - Founder

Yeah. One is about being certified for an NVE; in other words, if it's voluntary, then why would people do it but if it's not really voluntary in the same way that meaningful use is voluntary, it's voluntary, but if you don't do it, you're not going to be in good shape. So, I would like to understand more about what voluntary means. And the second comment I have is, I'm confused when I read through this about, as we think about the different entities that could be an NVE, some of these things seem to refer to one or the other, but aren't applicable to all. In other words, okay, here's... an NVE must publically make available a

notice of its data practices. Well, that makes sense if they're using an EHR vendor, then it makes sense for the customer to do it. But the customer isn't the user, the healthcare organization isn't the NVE in the way you described it. The NVE is a software vendor, but the software vendor isn't going to advertise or make publically available to the community. So that's where I'm getting mixed up in a number of these things when I go through in my head, is it an HIE repository, is it a vendor exchanging with another vendor or with itself or is it the customer, the healthcare organization user; and, I think every single one of them kind of needs which group is this focused on.

Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst

Okay, to the first part. We've... ONCs approached this in a way that we can stand up again the structures and processes that would be necessary for entities to be validated and to be designated as Nationwide Health Information Network Validated Entities. We included in the RFI that we could see subsequent policy objectives being met through leveraging the existence of the NVEs. And so, the analogy that I've used, and I always use analogies and then they never play out as I hope, simply would be like the Energy Star Program. And so, appliances and electronics go through the Energy Star Program, they get the designation and then Congress could decide, we want to establish a tax rebate program for folks that adopt... that purchase Energy Star Products. Similarly, we would just be focused on establishing the process by which the widget could come out essentially, and there could be this designation of an NVEs having met the conditions for trusted exchange, that could then be leveraged by other policy objectives, by other programs, whether it be a state or whether it be the Federal government, through a variety of different areas where... whether it be reporting, if we had a set of conditions for trusted exchange that the Federal government thought were all that would be necessary to report data to them, then they could subsequently include in whatever regulatory process or procurement lever that entities that would be reporting to them would need to have this designation. And so we see that our ability to create this designation through the governance mechanism then being able to be leveraged by others.

To your second question, I think it's a fair point and something that we've been trying to work out as well. We didn't want to preclude, in advance, any type of particular entity from being considered to be an NVE. We have been looking, and I think the first function test here would be, is the... are they serving as a third party, facilitating electronic health information exchange and if they are, then they could potentially be an NVE. And then I think your question is really at what level are they performing that action. So that's...

Judy Faulkner – EPIC Systems – Founder

It's different all over the place, depending on who it is, at...

Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst

...reflecting those differences is, I think, some of the feedback that would help us further shape this.

Christine Bechtel – National Partnership for Women & Families – Vice President

This is Christine. I have two, hopefully quick questions. One actually is coming directly on this point so, in terms of who would be an NVE, is it only entities that are facilitating information exchange on behalf of a provider, or is it their doing... because if I think about Federal agencies or the Medicaid Program, there are elements where they'll share health information, but it's not for the purpose of treatment, care delivery, things like that. Is it broader than just sort of on behalf of providers, or...

Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst

I think our initial focus has been on, at least accelerating electronic health information exchange among providers, but I don't think that we had intended purposely to exclude that potential.

Christine Bechtel – National Partnership for Women & Families – Vice President

Okay. And then my second question is, you did a nice job laying out sort of who would do what and I think where I fell off was, you have a process to update and retire CTEs, a technical standards and

certification process and monitoring and oversight; who does those processes? What's the body that does those?

Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst

For which one?

Christine Bechtel – National Partnership for Women & Families – Vice President

Well, I'm asking about all three; so who updates and retires CTEs?

Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst

Okay. So that... I mean, the presumption here would be that the conditions for trusted exchange would be established through regulation, like certification criteria today, and so we're hoping that there would be a process outside of formally adopting the conditions for trusted exchange that the evolution of CTEs could occur. And so that would be a process that would be facilitated by the Policy Committee, by other groups that could consider how the electronic health information exchange environment is evolving, where a new condition for trusted exchange may be necessary. Similarly, with the standards classification process, that's an area where we expected to have some regular check-ins with the Standards Committee and SDOs, etcetera to see where things really stand from a roadmap perspective.

Christine Bechtel – National Partnership for Women & Families – Vice President

And then those, either the agreed upon or evolved or updated either standards or conditions of trusted exchange would then get fed to the accreditation body and then the validating...

Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst

Yeah, as they would go through the subsequent processes.

Christine Bechtel – National Partnership for Women & Families – Vice President

Great. Thank you.

Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst

Yup.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Thank you, thanks again Steve. Farzad?

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

Hello. And apologies for being late. I want to thank everybody again for the focus on this really critical issue. It is, I think, we've talked about what's it going to take to get acceleration in information exchange, trusted exchange, in anticipation of Stage 2 in 2013, and certainly by 2014, the same way that we've seen the acceleration in adoption in Meaningful Use in Stage 1. And I wanted to take a second to, before we dive in to all the nitty gritty details of the 66 questions and the technicalities, to take a breath and think about what this is all about; that at the end of the day, electronic health information exchange just works, that it shouldn't require long negotiations, it shouldn't require an army of lawyers or PhD informatics. Much as we love informatics as specialists to be able to have healthcare providers exchanging information with each other. They shouldn't have to think about it. And we recognize that reaching a goal that's that simple needs a lot of complex discussion and investment and we think that a critical part of that is a foundation of common and consistent policies and standards upon which that trust can emerge. The trust that health information is going to be protected in a similar manner at a floor, the trust that the entities that facilitate exchange will have similar, properly implemented technical requirements and

importantly, the trust that the marketplace works for the customers, not only for the sellers of the services, but also for the customers and it works for the patients.

This was brought home to us last week when 40 of our state grantees gathered in DC to discuss how to accelerate exchange to support meaningful use, and there's been a lot of exciting progress. The grantees are doing a lot of work around the standards that we've worked together to establish consensus around, the consolidated CDA on the content, the direct protocols for transport. But one theme that came up over and over again was, without having common policies and rules for things like certificate issuance, the things like authenticating providers and querying directories, each of their implementations risks being its own walled garden. And there are ways and there are activities underway for them to have contractual or other negotiations between them, to have more of a flow of information between their boundaries; but it's not viable. What we heard over and over again is there needs to be a common floor before we can have a viable and scalable approach to support exchange across the nation.

So, as the workgroups wrap up their detailed analysis of the RFI, I'd like to ask you to consider as part of this important discussion today these two big picture questions, to bind together all of this detailed feedback. If ONC could adopt a common set of requirements for entities that would facilitate electronic health information exchange on behalf of providers that could immediately support Meaningful Use Stage 2 and ultimately other forms of exchange. Question 1, What would those common set of requirements, the minimal set of requirements need to be in order for those entities to engage in electronic health information exchange without a separate agreement with each other? Two, How should the entities have to prove that they've met those requirements? I think if we can narrow down, make sure that at the end of the day we have the answer to these two questions, to these two fundamental questions, we will have made a great deal of progress. Thank you.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Thanks Farzad. That's really good advice...(indiscernible) and so when we get down into the details, and we're wrestling with do we need to solve it, I think we need to return back to these two principles. So I think we're... presumably Farzad's been hearing from the states and locales where they're really having a slow slog of it, really the hard problem and if we can deal with some of these hard problems at a national level, then we'll free up that time for each of the locales and really create an acceleration of the whole process. That means we can't actually skirt the hard issues, because those are the ones that are causing the slowness. So we have to get to those, but we want to avoid the details that either the markets going to play out or they can agree at a local level, so not get bogged down in today's discussion. This is an RFI process, so we'll still have another chance at the NPRM process, so we won't necessarily have to get true consensus the way we try to drive towards in our comments, because just a discussion is input in their NPRM proposal making process. Neil, you wanted to say something?

Neil Calman –The Institute for Family Health – President and Cofounder

I wanted to ask a question. So, I guess the question is about your use of the word floor again. Because when we're developing these standards, we constantly run into situations where we can create a floor but it doesn't stop other people from advancing standards that are beyond, that create inoperability, in- interoperability when we're trying to create interoperability. And at the local level, we run into these issues all of the time, all the way down to like the hospital and the provider level where people have created different rules and different standards and so how do you contemplate this sort of model and are we really trying to say what we're trying to develop are standards and we're hoping people aren't going to pile things on top of this that make it more difficult for people to exchange.

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

My sense Neil would be that there are two different categories of pile-ons on top of the floor. There are those that actually help us do new things, greater things. So, if on top of the floor that is sufficient right, for directed exchanges, whether it's a push or a directed query, if there's a minimal set of requirements for that, but it doesn't address the needs of what we would need to do because we don't have consensus, we don't have workable approaches potentially around say, patient identification. If someone wants to go above and beyond that and say, well in our community, we're ready to try one out, we're ready to try out

an approach for this, and we will build on the standards, and we will extend the standards and we will try something out and we will report back. And I think this is the key part of it, we'll report back and we'll be part of a nationwide conversation that says, these are the questions, there's three ways of going about it, I don't know the directories, right, you could do it as an L-DAP, you could do it as a microformat, you know what, we're going to try the microformat approach for directories here, in this area. You guys didn't give us clear recommendations on which one to do, we're going to try one and we'll report back, and we'll learn from it collectively. That's good, because we need to have these emerging or immature standards or protocols, where there's insufficient consensus, the way we're going to get to consensus is by gaining knowledge about where people have actually tried to do it.

But on the other hand, if there are... so that's one category, where its building on top of, and that's good and that's kind of blazing the trail for the future, recognizing that they may have to backtrack if they end up in a... right, because if they go off the main trunk, they're trailblazing ahead, they may have to backtrack if the approach they're using doesn't work or scale. The other category might be things where it's really just unnecessary, and there we hope that having a Federal floor will give strength to people who say, why are we doing all this, the Feds have said this is okay and to have that be a driving function for simplification and for reduction of complexity.

Neil Calman –The Institute for Family Health – President and Cofounder

Just as a follow up, I just think that we should stop using the word floor, because it really implies that we're building something on top of it, and what we're really saying is that we're trying to get people to adopt the standard that we're creating and not build additional standards on top of it that, as you just said, may not be necessary.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Maybe I'll offer a little compliment to what Farzad said. So, he talked about innovation without violating the "floor," I'll just use that for temporary purpose. And the other way to look at it, it's a constant tension of course, but to the extent that we do an exceptional job in describing a compelling threshold or floor, that would invite people not to have to violate it, and that's... an example of the meaningful use framework is a floor, people can build it... but it's turned out to be a very useful floor and platform... maybe that's actually a better... platform to build useful functions, in particular the engage patients, for example. So, does that make sense?

Okay, let's start again. Let me try to set a few rules of the road for our discussions, just to have a floor... yeah, so, if we're going to make this two minutes per question, we're going to have to be very speedy, so the workgroup... the folks who are describing their workgroups feedback, it's got to be absolutely very concise in their presentations of that, and that's literally 1-2 minutes. And when we make comments, if we could in turn be very concise and parsimonious in our words, then we can try to entertain as much discussion as possible. We need to... we're going to start out trying to look for areas where we don't have a lot of differences of opinions, so we can start making progress and show that we can. But then there will be times when we want to work on some of the hard issues, so that we can create a compelling platform upon which it will reduce the rework being done at each state and locale and be a very solid, robust floor or platform on which to build these policies. So, that's sort of our goal.

My apologies for trying to keep us on time because if we don't get to something then it literally just doesn't go anywhere, and that would be a disservice to both ONC as well as to all work that's put in. So with that we're going to start with Governance, and we have an additional constraint, John is assuming the role of chair of the RWJ Hospital and he has to be off to that, so we have him for the next one hour in person and a little bit by phone after that. So, Governance Workgroup, of course, had the large share of the governance questions, as the primary, and sometimes sole commenter. So he's going to present some of that information and we'll try to move forward, sort of item by item or cluster by cluster, so we continue to get a track record of progress. Thanks. John.

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

Thank you, it's a pleasure to be here and just to put a point on that, I was elected Board Chair last month, this is my first Board meeting at 4 o'clock in New Brunswick, I thought I ought to be there, so, I really do apologize. I think I'm going to start off a little bit, skipping ahead to question #3, because this could be a very short report if you don't agree with us on question #3. And that is, "How urgent is the need to nationwide governance approach for electronic health information exchange?" We started off with saying that there is a need for rational nationwide government exchange, that actually exchange is happening and it's not being prevented by the lack of such a thing, but what we're seeing is that the disparate efforts at the local, regional, statewide effort have increased the cost and burden substantially in doing exchange, and fragmentation of governance methods and approaches have increased the time, cost and the complexity of exchange to exchange governance. We think that the framework should be lightweight initially, leveraging the Federal governments coordination function. So, that's sort of the first question and...

M

(indiscernible)

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

I would hope. We're good. Okay, so let me move forward to say that we had some overarching comments that as not to repeat what Farzad has mentioned, and I was remiss in mentioning the other members of the workgroup, and those members are Laura Adams, Laura Bailyn, Christine Bechtel, Neil Calman, Tim Cromwell, Doug Gentile, Jonah Frohlich, Leslie Harris, John Houston, Arien Malec, Michael Matthews, John Mattison, Holly Miller, Wes Rishel, Jan Root and Judy Warren; and thank them, the put in a lot of time in three different subgroups.

Nationwide governance is needed to reduce the cost of exchange, eliminate the need of redundant local or otherwise limited governance. We felt that that's important to state as part of the overarching comments; however, because the technology is still nascent, government should not restrict innovation and should be responsive to the evolution of the process of exchange. So, we are suggesting that there should be a balance, recognizing there's not yet a mature health informatics marketplace where market checks and balances could limit anti-competitive behavior, so some intervention to protect the public interest is required. The workgroup recommends that ONC develop more information on market forces and continue and closely monitor the HIE connectivity space to ensure that consumer interests are protected. That's our recommendation for an overarching statement. Okay, good. Hm, what does that mean?

M

It's seating the rest of our comment.

W

Well get into the details.

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

We're going to get to the details. So let's dive right in to question #1, "What categories comprehensively reflect it?" We thought that the three categories that were reflected in the CTE, safeguards, interoperability and business practices were good, but there was one level that was missing in general, which is that... we recommend that the governance process should first focus on establishing and defining the policy objectives in and across each category and that subsequently should be a process for identifying the detailed accreditation, certification criteria that would achieve these policy objectives, and which would then be validated by accreditation or the certifying body. The policy objectives are likely to change only slowly over time whereas associated standards implementing and accreditation and certification may be subject to more rapid change. And so the rules should describe a specific process for developing, maintaining and revising accreditation and certification criteria associated with the policy

level CTEs , which may be different from validation of the CTEs themselves. And we go into a little bit more detail there for you to read.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

So, when a secondary group is speaking, please just only do the delta if there's anything that...any contribution, does the IE workgroup have any deltas from what John stated?

Micky Tripathi – Massachusetts eHealth Collaborative

Hi, this is Micky.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Oh hi Micky.

Micky Tripathi – Massachusetts eHealth Collaborative

I don't know if John got this, we're going cover it in 56, but, addressing grievances was another area, but in general we agree with what John just stated.

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

And in fact, we agreed with their recommendations on grievances although we placed it elsewhere in the grid.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Any further pressing comments then?

Christine Bechtel – National Partnership for Women & Families – Vice President

My only question is, the framing around certification to interoperability, which consistent with Neil's point, I thought was a pretty important part of creating consistent exchange. So, I'm not sure I sort of fully understand how that got kind of less... I guess, what does it mean to be certifiable on a modular basis, because to me modules are EHR modules, I didn't get that.

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

And I didn't go into that detail. One of the overarching things that we discussed within the workgroup is that one size doesn't fit all, and so, there may be a universe of CTEs, but if a group is let's say, just doing push exchange, not all of those CTEs may apply to that particular NVE. And so that's really what we mean by modular.

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

Maybe this is related to a conversation we had to with the Standards Committee where the concept was that there may be packets that you may need, one packet to do one type of use case, one packet of business practices, safeguards and interoperability and an overlapping, but potentially different packet of CTEs to do a query model use case.

W

Which absolutely makes sense, I just didn't read the statement to mean that.

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

And we apologize for the lack of precision of our comments given that we had such a very short time frame, but hopefully we all are on the page in what we're intending.

M

This is a new one, we've got complete EHRs, we have modules and we now have packets.

M

If I understand the meaning, it's really what's relevant to this particular... yes, okay.

M

It's a subset of the total that is... it's a relevant subset is really what you're talking about as opposed to a module. It's a relevant subset.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

That's correct. So, are we good with this response?

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

Okay, moving on to question 2, "What kind of governance approach?" And we grouped together this comment with questions 2, 4 and 7 and we referred to this a couple of other times. So, I will be able to pull them all together, that the success criteria we thought was important to first define what success looks like, and that the objective of the criteria to identify approach includes things such as being cost effective in establishing interoperability and trusted exchange is participative and accepted by a broad range of stakeholders, including consumers, raises the levels of standards and interoperability maturity in the healthcare system and within and among NVEs, and is sufficiently flexible to allow for dynamic changes in the market and technology and helps states fulfill their responsibilities to their citizens without having to create structures of their own. A voluntary approach would be sufficient if, as the workgroup expects, other incentives are tied to them by other public entities... other Federal agencies that would tie things such as exchanging with the Federal agencies or companies that make validation a condition of their business activity. We also re-affirmed the nine principles that are stated in the RFI, as recommended by our Governance Workgroup and approved this August by....

M

...sort of recount what you said. I think what you're doing is adding additional considerations for the overall objectives for a governance approach and in a sense your voluntary approach also ties in nicely... aligns well with what Steve described in the Energy Star; so you have other things that regulate the other side, you know, whether there's any financial benefit of being energy efficient; same thing, this is a voluntary criteria, but other drivers may force people to take advantage of this voluntary certification.

M

Right.

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

A good example of that actually, concrete example, was in the proposed rule for Stage 3 Meaningful Use; we said you could either use certified electronic health record technology or an Nationwide Health Information Network Validated Entity essentially.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

And does the IE Workgroup have any deltas on top of what John mentioned?

Micky Tripathi – Massachusetts eHealth Collaborative

No.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay. Agreement with these principles that John talked about in workgroup?

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

And we believe that those principles address question #4, they don't specifically address question #5, but the answer to question #5 is yes, based upon what we just said for questions #2, 3 and 4. And as well

as... and that brings us to question #6, and that is, "How can we ensure alignment between the governance mechanism and existing state governance approaches?" And we believe that acceptance alignment with state governance approaches should be a success criteria, as we talked about under question #2. In addition, existing and future grants have voluntary and other policy levers to encourage alignment with national framework. And there were comments by IE.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Any deltas Micky?

Micky Tripathi – Massachusetts eHealth Collaborative

No, I think the only... I don't know if it's a delta, it's just we also thought that the government could certainly play a role in the orchestration of various policy levers that are short of an outright mandate to participate that could strongly encourage registration.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay. Any comments and this is a body between, it's basically a cluster between questions... from questions 2 through 6? I think it's reinforcing the importance of this and the importance of the Federal role and just contributing a bit more principles in coming up with the approach. Larry?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

So, Larry Wolf. A quick comment that's really a general comment, not just about this piece, and that's this seems to be the Spring when the flowers that are blooming are requests for Kindred to participate in health information exchanges all over the country; and what's striking how different the agreements are we're being given by these organizations, all over the map in terms of their level of detail and their level of sophistication and so, there really is a strong need to get consistency in the agreements, even in the framework of what should be in the agreements, as well as the specific technologies being used.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

So, we need to do a good job. David?

David Lansky – Pacific Business Group on Health – President and CEO

I wonder, the expectation of the voluntary network will be successful in a pull, because other policies pull users to this model. I wonder Farzad or others if there's a likely commitment on the part of Federal agencies to do their part of that and say that we will require all data exchanges under the auspices or in response to Federal programming...to be consistent with this approach and compliant with the CTEs and so on. And if that were the case...if that were not the case, it would not be the kind of accelerator of adoption...

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Could you do something about the... I think Micky may be the only one there that's speaking.

Micky Tripathi – Massachusetts eHealth Collaborative ?? I thought David was speaking??

I guess where I was going with that is perhaps in our comments, we may want to say that we think it's important for the Federal government assert that they will be a driver of adoption of these policies by their requirements that they impose through their programs.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay.

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

It would...

M

Paul?

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Let's see, Farzad's got a comment and then Micky.

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

I would be curious to here, Micky and John and potentially others perspective of what David just stated, that without the Federal government kind of exerting an all hands on deck policy push on using and requiring these designations that there is likely to be insufficient market demand... market business case for such a designation.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Micky?

Micky Tripathi – Massachusetts eHealth Collaborative

Yeah, the first thing I wanted to clarify is that I'm a vegetarian, so that was definitely not me getting a hamburger ordered. The second thing... I think in general Farzad, to your question to David's, I mean, we didn't... there was no conversation in the workgroup about it being something that we thought that the strong... the very strong orchestration by the government was necessarily going to be required to make it work. Can you hear me?

M

Right.

Micky Tripathi – Massachusetts eHealth Collaborative

But, on the other hand, all of this, there's lots of interdependencies related to the strength of the CTEs, so as we'll discuss later, we did feel that there would probably be a lot of participation, assuming that there wouldn't be large barriers to whatever accreditation process there is and there was a certain amount of flexibility and reasonableness related to CTEs in general. So, I think the hard thing to sort of... the hard thing about answering just in general is that all of those things are interrelated; if there's a very, very high bar on CTEs and on participation in general, then it will take a larger amount of orchestration by the Federal government to make it work.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

John, did you have any other...okay. And Micky, I knew that wasn't you, I was saying that you were the only line that should be open.

Micky Tripathi – Massachusetts eHealth Collaborative

Oh, okay. Thanks.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay, any other final comments? Gayle?

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

Thank you. The only comment I would like to make is that states are already moving in this direction and that there's legislation pending in various states and there will be further legislation coming up, I'm sure, in this next year. So that we don't want this to get to the point where you have so many regulations across different state entities, the more quickly we move with this, the better; and going through the RFI process, going through the NPRM process takes a significant amount of time. So, I think perhaps we need some direction from ONC out there to states, through RACs and other mechanisms and state legislators to let them know ahead of time, what is foreseen, because we're going to see a rash of things, we're already seeing it, there is already a clamor in communities for this in various states. So, I think there needs to be some education process as to the direction that ONC is going on this now. We're at a critical crossroads because things are really starting to move too forward...fast, very rapidly, and then you're going to have the problem where you have governance coming out of the Feds, but yet you

already have state laws that require certain things. The same thing is true across privacy and security regulations. So, we need direction coming out of ONC to precede this to some degree.

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

That's an important point and I think the RFI is an important step and the meeting like we had last week with 40 state Health Information Exchange grantees and HIT coordinators is part of that process, but, I agree.

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

But that needs to happen at the legislative level as well, because that's where the laws are made.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

All right, John.

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

Great, which leads right into question #8, I skipped #7 because we said that was part of the package. Question 8 which is the role of ONC and I think here we felt that there were a number of roles so we think it's critical, specifically in endorsing and adopting CTEs and publishing guidance facilitating input from the various FACA committees on revisions and creating new CTEs and retirement, selection and oversight of the process of accreditation, overall oversight of entities and processes. Further believes that ultimately oversee the process for selecting and overseeing an accreditation body and, should play and arbiter role for any disputes that may arise between actors, and that gets to the recommendation by the IE Committee on dispute resolution; that ONC produce operationally defined descriptions of CTEs for updating and clarifying those definitions and to encourage that other private entities may have a significant role to play in adoption and use of standards, as we've suggested, through various incentives.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Good, thank you. Christine?

Christine Bechtel – National Partnership for Women & Families – Vice President

So, my question is around point number 2, around the day-to-day validation oversight of NVE should fall to private sector entities. What happens when there is a bad actor or violation? I mean, I assume obviously we have Federal law, HIPAA and other things that can come into play, OCR even, but in terms of okay so you didn't comply with this standard or this principle, and there may not be a legal remedy in that respect, so in the absence of legal remedies, what happens and who sanctions the NVEs who aren't playing by the rules of the road?

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

We felt, and we'll actually mention this in one of later recommendations, that there needs to be a spelling out of the process that would include the role of these validation bodies... entities, in not only doing the initial validation, but verification of some of the things that would be self-attested, that there needs to be a process to identify when someone is not doing what they said they should do and the authority to de-accredit somewhere in that process, and remove them from the list of accredited NVEs.

Christine Bechtel – National Partnership for Women & Families – Vice President

Thanks.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Any other comments? Good, thank you.

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

Okay, moving on to #9. So this has to do with the issue of voluntary validation, which we felt was not entirely clear, so, since we didn't think it was clear, we decided that we would have in mind what we thought it was and then made our comments related to that. And the workgroup believes that a voluntary approach to validation will only work if there are sufficient incentives to encourage widespread participation, such as requirement by Federal agencies that exchange occurs only with NVEs that have been accredited, incorporation of status into memorandum of understanding, safe harbors and financial incentives. And we had two recommendations; the recommendation that the adoption of CTEs should be voluntary and that for entities such as HIOs and HISPs that wish to be recognized as NVEs, adoption and compliance with CTEs should be mandatory. So, you don't have to be an NVE to do this exchange, in certain circumstances, but if you want to be an NVE, then CTEs should be mandatory.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Good, comments, questions on that? Very good.

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

The question is, should the validation process be variable based upon the CTE. We believe that the answer to that question is yes, and further, that validation methods may be mutable over time, allowing for changes in methodology to accommodate changes. So, as a principle we recommend that certification process would generally be most appropriate for CTEs that focus on standards and specifications which accreditation processes should be adopted for policy and process CTEs. Accreditation for policy and process CTEs should be initially done through self-attestation; however, ONC should consider a more formal accreditation process, including audits and site visits, especially with CTEs that don't carry with them civil or monetary penalty implications or penalties for which there are no other formal compliance processes. Also ONC might accept accreditation by other bodies such as the Joint Commission or EHNAC. Questions or comments on this?

M

I just have a little bit of a concern or a comment that there's a lot of words here, there's a lot of words here, there's certification, validation and accreditation, but to me when you talk about certification, the way we use that for the Meaningful Use Program, it was a very... it's like objective, it's attest, and there's no dispute at all, you pass it or you don't; either the thing works technically correctly or it doesn't and you talk here about people self-attestation, and then some other validation process, that's all pretty murky to me, in terms of who does that, how all that's going to work.

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

Well, it's going start out that way, because there are certain business processes that organizations will say, yes, we do follow various privacy rules. That's not something that you can do a test implementation and test them against. But, what we're suggesting is, is that when you do the initial accreditation, that that not be the end of it, that there be some process of monitoring which may include audits and site visits to verify that that is, in fact, occurring and that's what we would expect the accreditation bodies to be engaged in.

M

Can you give me some examples of entities like that accreditation entity like that that exist right now, that do that kind of work? Are you talking about like JCAHO kinds of audits, is that what you're talking about?

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

Yeah, JCAHO is an example. Any hospital has any number of requirements that they have rules and regulations in place and that they are being implemented and then JCAHO will come in during their site

visit and say, okay, let's see the regulation and let's pull a sample set of charts, to see if, in fact, they've been followed.

M

So you envision something similar to JCAHO, some body that's going to come in and audit and do this with every single NVE.

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

I think that the analogy with JCAHO may be a little bit more difficult at that point, because most of us who have been through those audits think about them as being overly impressive but there does need to be some means of validating that NVEs are, in fact, following through on the policies that they attest that they are following through on.

Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst

(Inaudible)...I'm at the end of the table here, I don't know if my mike...

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay, go ahead.

Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst

So, I think this gets back to the second big picture question Farzad asked, about how do they prove that they meet the condition for trusted exchange, and at what level of burden of proof, what is it? And is it that someone goes on site and checks them out, or is it self-attestation and so there's a difference there in how do we squeeze out the value that we're looking for from a trust perspective, depending on that spectrum of analysis, in terms of how the accreditation would go. Does that help? It's not an answer to your question per se, but just kind of framing it?

M

Thank you.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay, David?

David Bates – Brigham & Women's Hospital & Partners Senior Vice President for Quality and Safety

I also wanted to come back to Farzad's second question to us, because I think this is really an important thing, and, in Europe, as best I can tell, the key thing that enabled data exchange on a widespread basis was really some fairly rigorous conformance testing. So there was one entity that was set up that basically did conformance testing, and, that was not certification, it wasn't pass/fail, you tested whether you could send a specific piece of data and whether it could be understood. And it seems to me like we need some element of that if we want to get to where we want to go.

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

Yeah. So, our recommendation is for those things that can't actually be tested that way, that they should be, but that other components, like the business processes can't be tested that way.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

(indiscernible). Gayle?

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

One quick point I think we to really think about is if you want the public to have trust in these NVEs, you have to have some mechanism for compliance and for testing, to make sure that that attestation does really represent what they are doing, and that there is a process. Now who is going to do that, and where does that happen and on what level is still undefined.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

So one of the questions, you know, it's sort of a trust and verify, and the question is whether you... I think I heard a couple of comments saying you should do this all the time for everybody versus, more like an IRS audit where there is a randomness to it where you just feel like you really need to comply all the time, even though you may not be assessed every time, all the time.

David Bates – Brigham & Women's Hospital & Partners Senior Vice President for Quality and Safety

I guess I feel like it's the beginning, you just need to make sure that it's working. We've studied several data exchanges and the scenario that Farzad described is exactly what we find. So, within entities, data exchange works great and we can move data around and across entities, in every data exchange that I've studied, it just has not worked that well and people had trouble just passing even basic information back and forth and the lawyers did eat up three-quarters of the dollars that were allocated.

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

And this conversation actually takes us into #13, which is the next one on...

Christine Bechtel – National Partnership for Women & Families – Vice President

Before we go to 13, although that was really smooth, I wanted you to know... really nice... (laughter)

M

Well, he's the board chair...

M

...blame the cat.

Christine Bechtel – National Partnership for Women & Families – Vice President

But the thing... the only thing that does make me nervous, I completely agree there should be some kind of site visits, even something a little more rigorous. But, the only thing that does make me nervous, and I'm not sure that I know the answer, is the business practice piece; what are your business practices, what are your policies; self-attestation yeah, I mean I see how we got there, but I'm wondering if there are some other things that they can do to prove, look here are our policies and they are consistent. But, somebody's got some eyes on that as opposed to the body itself saying, ah yeah, we do that, but they've got to back that up somehow, something a little more rigorous I think, and having this recommendation reflect that, with respect to business practices and policies would be helpful for me.

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

I don't think we would say, check the box yes, I meet the CTE; but, we would expect that there would be some documentation to the accreditation entity that they do have the policies in place. But, having the policies and following them are different things...

Christine Bechtel – National Partnership for Women & Families – Vice President

Yes, I agree.

Jan Root – Utah Health Information Network

This is Jan Root from UHIN, can I make a comment?

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Who is this?

Jan Root – Utah Health Information Network

This is Jan Root...

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

She's one of the workgroup members.

Jan Root – Utah Health Information Network

Yes, from the Utah Health Information Network. I just want to mention that there is already an existing industry standard for health information exchange. It exists on the clearinghouse side, which is still PHI, and it is EHNAC and all the major clearinghouses are accredited through EHNAC, it is accredited every other year, it is incredibly rigorous. It does involve a self-attestation, we're just completing ours for our HIE and our clearinghouse business here. Each is about 160 pages long, just for the self-attestation. There is a site visit and that is an industry standard on the administrative exchange of health information. So, there has been a lot of work already done on this. Just wanted to make that point.

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

Christine, I also wonder if depending on the CTE, there may be somewhere crowd enforcement is sufficient, that you don't need... so the example that I think about in my career, and I think John, maybe you had a similar experience was, when we were doing the Smoke-Free Air Act in New York City. we didn't need to do a lot of site visits to bars to make sure that there wasn't smoking there because for every person smoking there, there were 8 other people who were non-smokers who would call the complaint line and say, there's someone smoking here and I don't like it, right. So, when we're talking about business practices, the counter party is in a great position to assist in enforcement of those business practices. Some of the internal security issues may need more, there's not going to be transparency or visibility on that other, so, I think we have, particularly on the business practices, there may need to be less central enforcement and openness to complaints.

Christine Bechtel – National Partnership for Women & Families – Vice President

And I think that makes sense. Do we have... would they have a complaint line to call, so to speak.

M

That's the comment about grievances.

M

Um hm.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

So let me try to summarize where I think we are, and then I want to pose one question. One is, I think we're in the trusted verify kind of mode. The second is that the kinds of conformance testing will vary by the CTE and the organization. And the question I'd like to pose is the sentiment of the group of how close to every time all the time versus more of a more randomness kind of... subject to a more random kind of audit. So those being the two more polar extremes, where is the group, towards, and David Bates' proposal was maybe more towards one side early on, and then relaxing. But, just a sentiment of the group, let's say... let me just start with the closer to the true conformance, best conformance testing as you can for everybody virtually all the time, yes, early.

Christine Bechtel – National Partnership for Women & Families – Vice President

Early, I think.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

So who's more in favor of that side?

W

Initial?

Christine Bechtel – National Partnership for Women & Families – Vice President

Yes initially.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

One, two, three, four. Okay, so I'm going to describe our main _point_, and we may have another refinement. So, the two extremes are, one is we test everyone against CTEs to the extent we can...

W

Paul, keeping in mind that we've already said that the CTEs may need to be tested differently for different things, right? So maybe the same approach isn't necessarily necessary for all of them.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Right, but the goal is to really test everyone to the extent possible versus the other pole is, sort of it's more relying on self-attestation may be too weak, but with a more random kind of audit, so, it's a real trust, but verify periodically; so those sort of describing the two poles.

W

And that we're....

W

(Indiscernible) Farzad said about the...

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

... crowdsourcing; it would be more like that, if we did that for all the CTEs, yes...

W

But we're talking mostly about the kind of technical specs and standards, less so about the policy stuff that you can't do through conformance testing is what I heard.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Well, you can go back... you can visit, like JCAHO, so you can visit, you can ask, you can look at the documentation, you can look at evidence of compliance by random chart pulls, for example. So, there's something... there are some testable things; you can ask people, on the job. So, there are ways to verify.

W

And we're talking about initially, as this approach comes out, not, of course, forever.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Yes, we'll talk about the... correct. It certainly can change, but the initial rule.

M

Can I... just really quickly. So, we're dealing with trust in an area of extremely sensitive information. So I was thinking about the FDA, they put a stamp on beef, don't they, somebody puts a stamp on beef...

M

...USDA.

M

...USDA, they put a stamp on beef, and if that fails, which it does occasionally, it still seems to be able to work, there would be process that the country is okay with. I'm not sure, if this fails, how many times it can fail, where it has absolutely no validity, because of the type information. So, when we talk about those two polar extremes, if I keep that in mind, I'm leaning toward higher degrees of regulation. But, I don't know the practicality of that. So, there's a lot of issues in between there. Sorry.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

And that's an opinion on the one side. And so I'm trying read the sentiment of the group because I think ONC would appreciate that opinion. So...

Judy Faulkner – EPIC Systems Corporation

Comment on the other side.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Yes, okay.

Judy Faulkner – EPIC Systems - Founder

And that is, that I think so far watching what we've done in this area, we see people who meet the letter of the law and get certified, but really doesn't work. And so I'm wondering whether in fact, the actual... if we spent more time focusing on, if it doesn't work, report it, then we'll check it out, stamp it and yet we haven't encouraged people if it doesn't work report it, so that the actual... allowing crowdsourcing or whatever, may, in effect, be closer to what we really want to get than a validation process that misses the point.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Those are well stated positions. Let me just sense, and it's neither going to be 100% one way or the other, so, where is the sense, initial... with the initial final rule, do people weigh on, the right half or the left... and I didn't mean that by... I can almost... now I can't use that in.... so, the side towards more complete conformance testing for everybody or more towards crowdsourcing and whistle blowing and that kind of thing.

M

I'm having trouble voting because I would vote for a lot of conformance testing for some things, but the exact opposite for many other things. I mean, any situation in which the crowd sort of approach will work, I'm all for that. But then there are some other things for which I don't think it will work.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

So let me state it that way then. Where possible, more towards....

W

Where necessary...

M

Where applicable...

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

...where applicable and necessary, conformance testing, and I'm using testing loosely, it's sort of... it could be involved with site visits, for everybody to get this designation or more relying on attestation and crowdsourcing? So...

M

Stated that way Paul, I don't see the conflict.

M

Yeah, I'm not seeing the conflict on your...

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

So, we've found a way to state it, anyway. Okay, very good. Thank you.

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

So, on #13, which also gets to the issue that we were discussing which is, "Should there be an eligibility criteria that requires an entity to have a valid purpose?" Our response is no. We felt that the entity should not be required to have a valid purpose because first of all, we felt it would be hard to define an effective... a definition that is effective for all appropriate uses and purposes, because again, we're talking about an evolving technology and process, and that we felt that this would place an unwarranted constraint. We did, however, recommend that we should consider having that purpose be public, so that each company would state their intended purposes. We also felt that having a "valid purpose" would not likely deter inappropriate exchange so, it would hamper the development of the field and not necessarily stop the bad apples.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay, any discussion on that one? Okay, very good.

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

Okay, the question is, "Should there be an eligibility criteria that requires an entity to have prior experience, or certain number of participants?" We basically felt no.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Any disagreement? Neil?

Neil Calman –The Institute for Family Health – President and Cofounder

Well just in terms of doing an on-site sort of validation for those things that need it, I mean, imagine the Joint Commission going to every doctor's office in America. If these are really small entities that are... we're not going to be able to do that. So, I think we're going to need to...

W

A single doctor's office would not be an NVE Neil. These are for the intermediaries.

Neil Calman –The Institute for Family Health – President and Cofounder

No, but a single... but what? A single network of... these are all...

W

I mean, I think we're aiming at the entities that sit in the middle and facilitate exchange...

Neil Calman –The Institute for Family Health – President and Cofounder

I was using that as an example...

W

(Indiscernible) language of the RFI.

Neil Calman –The Institute for Family Health – President and Cofounder

I was using that as an example, but in the community where there are seven different entities, you might not want to go through that level either. I mean I wasn't...

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

I think that this is... there's a cost associated with being an NVE, this is not a free thing and I think that there will be marketplaces that would tend to restrict that, particularly in small communities. So, we don't know what that number is, so, I think it would be difficult for us to project onto the system right now to say that there should be some baseline number. Okay, anything else on the... All right, good.

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

Question 15, "Are there other eligibility requirements?" We did not recommend others, but we did recommend that we look very closely at the one that stated that an entity would not have had civil monetary penalties, criminal penalties or damages imposed or have been enjoined for a HIPAA violation within two years prior to seeking a validation. We felt that the HIPAA validation component particularly would be problematic. So, I'm a large multi-hospital entity, we do exchange amongst my hospitals, and one of the hospitals in Collinville, Illinois has a breach, a HIPAA violation because one of the employees looked at somebody's record that they shouldn't have looked at. We immediately identified it through the audit trails, we took action and we sanctioned that individual. Technically, we would have had a HIPAA violation. We don't feel that that should be a disqualification, rather that they have policies in place to identify and that they have procedures to identify the bad actors and take action against them, we think it would be adequate.

Deven McGraw – Center for Democracy & Technology – Director

I have a comment in this regard. And I agree with you John, for that level of a HIPAA infraction. But I want to remind the Policy Committee that probably 2 years ago, we adopted a recommendation as part of Stage 1 of Meaningful Use that said, if you have been, I'm going to use the word convicted, but that's really only relevant in a criminal term, but if you've been found liable for a significant HIPAA violation. That means at the level of willful neglect of the law or a criminal violation, that you would not be... and you've been fined or have agreed to pay a monetary settlement in lieu of going through the civil monetary phase, that you would then not be eligible for a Meaningful Use payment; and this would apply at the enterprise entity level, and not due to the inadvertent actions of one rogue person.

So, we very carefully consigned it to the highest level of violation and said, you know, you're not really meaningful using if your significantly in violation as an entity of HIPAA. And we actually did put that forward to CMS. CMS took the position that for Meaningful Use purposes, they didn't want to mix apples and oranges, in terms of compliance with HIPAA versus eligibility for a payment. When I read this in the RFI, I thought, maybe it's better phrased as, if you're an NVE business associate that's been significantly in violation of HIPAA to the point where you're being fined, maybe you really shouldn't be eligible to be part of NwHIN. So, I think that's essentially what the IE Workgroup comments were intended to reflect. We just sort of landed on this yesterday and we didn't have time to resurface what the exact language was that the Policy Committee had previously recommended.

M

And that's not inconsistent with our conversations.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Neil?

Neil Calman –The Institute for Family Health – President and Cofounder

For how long? For how long are you excluded, forever, until you can prove compliance...

W

Yeah, I mean that's a good question. I mean...

Neil Calman –The Institute for Family Health – President and Cofounder

...and the other thing I'd just point out is...

W

... I mean, it shouldn't be a lifetime ban necessarily.

Neil Calman –The Institute for Family Health – President and Cofounder

... yeah, and the other think I just want to point out is that the victim is not actually the exchange. This is like the bus driver speeding and so nobody has a way to get to work, and all of the patients who are expecting their information to be able to be exchanged, are there. So we have to replace the bus driver and part of our mechanism here has to figure out what we're doing with all this information that's now locked up, that can't be exchanged when people are expecting it to be exchangeable. So...

Deven McGraw – Center for Democracy & Technology – Director

When people only have one bus, that's clearly a problem. I just don't like subjecting them to the 95 mile an hour bus driver...

Neil Calman –The Institute for Family Health – President and Cofounder

We all don't either, but we need to figure that piece out, I think.

Christine Bechtel – National Partnership for Women & Families – Vice President

But it does say within two years, prior to seeking, right, so... I don't know... I mean, which would mean basically if you got found in the last two years, you have to wait a year and then one year goes by and you're in, right?

W

Yeah, I forgot the two years is in here, the two years was not reflected necessarily in our previous recommendation... this seems reasonable.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Judy?

Judy Faulkner – EPIC Systems - Founder

I have a question on this, and I think we discussed it before, but if you can help me with it. The Kaiser example where they had the octo-mom and I think it was 16 people violated their rules because they had very strong policies, they found that out right away, they fired everyone involved and they were fined \$250,000.

W

They were fined by the state of California.

Judy Faulkner – EPIC Systems - Founder

That's what I was going to check.

W

They were not fined by HIPAA authorities. So that was more a violation of state law. I think if we focus on Federal provisions, we might be in...

Judy Faulkner – EPIC Systems – Founder

Thank you.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Paul Egerman?

Paul Egerman – Businessman/Entrepreneur

I guess my opinion with this issue appears to be similar to what the workgroup said, which was sort of like, if you've paid your fine and you've done your time, you're done. It's like there's not... we shouldn't be layering additional penalties on these people, especially arbitrarily when we don't know the impact. You say, then you can't be an NVE for two years, well maybe there's a real need for an NVE in a particular region of the country and we create a problem inadvertently with the statements. I just... if I understand what the workgroup said here, I agree with it. This should not be... we should not be layering on some penalties as relates to prior HIPAA violations. That's not where we should be right now, in this discussion, in my opinion.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Well, just because you agree doesn't mean that it's not understandable. (laughter)

Paul Egerman – Businessman/Entrepreneur

I agree with what you just said.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

(Indiscernible).

M

I wonder if there are other useful enforcement or alternate management options here that would apply; so if you're in trouble and you're the organization; that there's an option for some trustees of some kind to come in and take over the running of the NVE for a while, to say, we've brought in some trusted people to make this happen because it is needed in the community. We do that in other settings where the function is needed, the healthcare provider, we pull out the old management, put new management and say, we've got to provide these services, but the old guys we don't trust and so we're going to put some new folks in, let them run the organization for a while and at some point, the original management can reapply.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

So I think we have enough comment in support of the workgroups proposal and some additional commentary on it.

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

So, moving on, 16, "Should there be eligibility that are tax-exempt under 501(c)(3)?" And our answer is no, that we don't recommend that it just be limited to tax-exempt entities. Question #17, the optimal role for stakeholders. We feel that they have a role in many of the phases, we list them all here under the recommendation, I won't go into the detail.

Christine Bechtel – National Partnership for Women & Families – Vice President

So, it's Christine. Did you guys think about at all calling out specifically that NVE as an accrediting body should be encouraged to have consumers and governance rules at that level, not just for the overall mechanism, but more specifically, there are grant requirements, for example, for the Beacon communities where they need to have consumers engaged in governance. Did you think about calling that out in particular?

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

Our last item there, consumers have a very important perspective that needs to be considered, including in governance. Does that cover that?

Christine Bechtel – National Partnership for Women & Families – Vice President

Well, it's very broad. So, right, and so I think, what I'm asking is, did you think about the various levels of governance that are operating here, which is, obviously you have... consumers have the ability to have input into the regulatory process and in the Policy Committees and Standards Committees, things like

that. But beyond that, when we're talking about creating an accrediting body, and then all of these NVEs, that one requirement for, I forget now what we're calling, accreditation, validation might be around making sure that they have some consumer involvement in governance.

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

We didn't get granular into defining what we thought consumer engagement should be, but we felt that it should be at all levels.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Great. Thank you.

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

Okay. Question 18, monitoring and oversight...I want to make sure I was still in the right place...that we felt that the monitoring enforcement methods should rest on robust validation, and I think we just had a fair bit of discussion about this and that we make recommendations that these mechanisms should be included in the governance rule. But we did not take a position on how granular the rule should be in defining those mechanisms.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Any other comments? Okay.

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

Number 19, here's where I mentioned before we talked about the issue of remediation and we have recommendations that that should be a component. Number 20 that the... we felt that there should be a... that NVEs should be required to clearly and publically display their validation standard and with the... perhaps with the expiration date, which we recommend later, should initially be 2 years.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Questions, comments?

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

Okay, which is in fact, the exact next recommendation. Two years, initially, and then as we get more experience and the validation process becomes more mature, that time frame may change.

M

I'm sorry to go back to question 17, I just want to understand. Christine had asked about kind of more granular recommendations on whether in addition to the statements that I see here, that the majority of the governance representatives and so forth, but, did the workgroup think anything specifically about whether, for example, it would be appropriate to have an explicit requirement around consumers on the governance mechanism or boards for these certifying bodies or whether that would not be consistent with the workgroups intent here?

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

We did not discuss that.

M

Okay.

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

Okay, our next question, if you will turn to page 25, this is what, for those of you who may come from corn country, which I do, they call volunteer corn, which is a shoot of corn that's sitting in the middle of a soybean field; no one asked it to be there, it just volunteered. It's not considered to be a good thing, but we just felt we had to comment on that, particularly that there are many commercial purposes that involve de-identified data that are appropriate and we support the phrasing in S-5, but we don't agree with the phrasing in S-6. We recommend that a general principle of local autonomy, governance rule should apply to exchanges between NVEs, the local rules would need to be respected.

M

And how does this apply to S-6?

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

Let me pull out my grid...

M

Which is page 25, which is the de-identified health information for any commercial purpose?

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

We believe that there may be commercial purposes, let's see... I'm confusing myself. Let me read this through again. There are many commercial purposes that involve de-identified data that are appropriate. And the workgroup supports S-5, which says they must make publically available a notice of its data practices, describing why identifiable health information is collected. But, that may involve, in that notice, that they will be using that data for commercial purposes, which would contradict S-6.

W

So, I think it's an open question whether we open up S-6 at this time, because there were lots of workgroups who weighed in on it. I was a little bit worried that our comments were not reflected here, but I see they are, in another question that's related to S-6 and S-6 is a meaty one, so I defer to the chair as to whether we take that all on now...

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

And having made my statement, I'd be happy for that conversation to occur after I leave... (laughter)

W

I think what the Governance Workgroup has said here is not... is also reflected in some of the other commentary, so, we certainly could defer it or take it on now, but John doesn't seem all that wedded to being part of that discussion. So...

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

We'll move on to something that requires less time...

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

Okay. We're on... that brings us to page 36, which is... so our comments and IE had a number of comments... well, let me just say that on 52, 53, that our comments are reflected by IE's comments and so I'd be happy not to cover those, at this particular point, as I look at the time and realize it's time for me to hit the trail. Our comments on 54 are not contradictory to the IE ones, but, on what should an NVE be permitted to impose requirements on another NVE. And basically, Neil's not here, so, we see this designation as being a floor, that there may be some other agreements between NVEs that would be required by state law, that could be reflected in an agreement between those NVEs.

M

We'll come back to it.

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

Let me say that under 55, that we had some discussion about, and this comes up, which is that there should be metrics, they should be aggregated. We could not reach agreement on what level that aggregation should be; whether they should be aggregated at the local level and then sent up at a higher level, or whether they should be sent de novo up to a higher level and then aggregated at that point. But we felt that some sort of metric should be there, that were aggregated.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Do you want to go ahead with the other comments Governance wants to make.

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

We had some comments on S-10, which you can read, which is that... I'm sorry, page 39, which was under the question on 38, I'm sorry, which is, "Which CTEs would you revise or delete?" I think all the workgroups had some comments. We have a table that we submitted. I think when you walk through those STEs, you can see our comments, but basically, that the preferred set liability on S-10, which is the CTE that refers to the NVE must have a means to verify that a provider requesting an individual's health information through a query and response model, has or is in the process of establishing a treatment relationship with that individual. We felt that that is difficult to implement, that this is something that's required more at the level of the provider and the responsibility should remain there instead of at the level of the NVE.

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

John, the requesting provider or the supplying provider? Because under HIPAA, my understanding is, the responsibility is entirely on the supplying provider. And they may not be in a position... they may be in a worse position than the NVE to judge that.

M

Except for the transfer the whole chart, remember, it is permissible to transfer the whole chart, but the requesting should use their judgment in terms of minimum necessary.

W

Except in treatment...

M

Except in what?

W

Minimum necessary does not apply to treatment of an individual.

M

Yeah.

M

So that if I'm fishing for patients?

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

This is the example here that people use, I think Indiana Health Information Exchange, for example, there's a request for a record and they can look at whether it's ADT transactions, whether it's

prescriptions written, or other artifacts, to say, the person requesting the information on this patient, we have reason... we have artifacts, reason to believe that they actually have a treatment relationship with this person. The information exchange can do that, and therefore, based on that knowledge, they can flip the switch to allow that access, which otherwise would require, in their model I think, to know that the person for example, has consented to that information. So, this is a way of saying, there's controls on who gives the information, but if there is access to that information, should there also be controls on who can... can anybody pull down information on anybody else in the query model. Or, should there be either meaningful choice demonstrated or a treatment relationship. And this I pursuant to the privacy and security Tiger Team's recommendations to us, so I don't know if Deven you want to say more about that.

Deven McGraw – Center for Democracy & Technology – Director

I only know, this is... we did say a fair amount about this in relation to that specific CTE and so, this is... maybe a bit of an artifact of allowing John, while he is able to be here, to be able to present all of their recommendations; but, our sort of counterpoint to this isn't in this section, it's somewhere else, so. I mean, if we want to open that discussion up, I'm happy to go there.

M

You don't feel strongly about it John. (laughter)

Deven McGraw – Center for Democracy & Technology – Director

Okay.

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

So, I think we'll defer to Deven's presentation on this. The next two items that I wanted to talk about was on 56, related to the... I'm sorry, let me just find it, 58, which is the question about "Should the above CTEs, as well as any others considered, be packaged together for purposes of validation?" And we just went back to the earlier comment that no one size fits all and that the bundling, the parceling should reflect that. And then, on "What process should we use to update CTEs?" We have a fairly detailed comment, but it really goes back to our earlier comment that not all the CTEs are the same, that policy, which we recommend should be part of it, a policy statement, would be expected to change less frequently than those specifications that may be closer to the technology. And so, that each of the CTEs would have their own time frames for review and renewal or change, if that is necessary.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Judy.

Judy Faulkner – EPIC Systems - Founder

Quick question. One of the things we've seen is that sometimes the validating bodies get way behind and there's a long wait time. If a long wait time means that data about patients is not being exchanged because even though some of this is voluntary, there will be other things that make it very important to be certified and that's going to impede exchanging data. I think that you should focus on what if the accrediting bodies are behind, and then what do we do about exchange then?

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

Well, our recommendation really relates to the fact that we think the policy pieces ought to be in rules, and if you look at the detail here, we're saying that some of the other ones that are more likely to be changed, we should look at a non-rule process to enable them to more rapidly reflect a changing field. And I think that doesn't exactly get to your question, because when we say that somebody can be validated for two years, even though the rules of exchange may change because of technological advances or changes in understanding, that validation would be in place, that gives you a little bit of easement to make the changes that reflect changes in the field.

Judy Faulkner – EPIC Systems - Founder

I'm just saying leave them broader than that, which is not just the repeated after two years, re-validation, but even the initial, since we've seen wait times on other validations, I do think that because interoperability is so important, it might be important to figure out what do you do if you're behind... if those validating bodies are behind.

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

We did not discuss that, but I think that that's an appropriate point for ONC to consider as they're developing the rule.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

So I think we just have 61 and 62, which may be quick, right?

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

Basically we felt that "should we permit validation bodies to provide for validation to pilot CTEs," yes. And then the last one, "should we consider a process outside of our advisory committees," we thought that the FACA process was very important and played a critical role.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay, any comments on that? Thank you John. (applause) And you'll be on the phone if we have any pressing...

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

And as soon as I get in the cab I'll dial in and if there's pressing need, I'll try to listen. I apologize, there's a tunnel in Baltimore where phone service doesn't work, so if you a question at that point and I don't respond, I apologize.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

We do know that the tunnel is no longer than one mile.... So, thanks John, thank you very much.

M

And I hope you're not taking a cab to Baltimore.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay, so just for calibration, that's about the pace we need to continue, with the exception of we built a little reserve, but I know that there are about four questions where there's going to be more than 2 minute discussion. So, I'm trying to make sure that we get that, because those are the hard questions that somebody... it would be nice if we could settle at the Federal level. Okay, so let's go back to where John left off in the Governance... if somebody knows that number right away, that would be helpful...

Deven McGraw – Center for Democracy & Technology – Director

I think we're on question 22. And actually, we might actually skip to question 23, because question 22 we swapped with the HIT Standards Committee, so we don't have a workgroup set of comments to deliberate. Yes, that was page 16.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay, so wait, are you saying that 22 sort of there's no official comment...well I mean...

W

It's going to come through the Standards Committee.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay. So we'll go to 23.

W

Right.

Deven McGraw – Center for Democracy & Technology – Director

Right, the IE workgroup weighed in on this, so Micky, if you're on the line.

Micky Tripathi – Massachusetts eHealth Collaborative

Yes...fumbling with the mute. So yeah, I think the only comment that we had on this, and Deven please elaborate if I don't... if I cut it short, was just that we had noticed in the listing of a bunch of HIPAA requirements, that there was one section in particular, 164.314 is not included and we didn't really understand (indiscernible)... we just didn't have an opportunity to have a really full, robust discussion of it, but we just wanted to flag that.

Deven McGraw – Center for Democracy & Technology – Director

This is another one where the Standards Committee is expected to be taking the lead on addressing this question. So, we didn't talk about it.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

And the next one then is 24.

Deven McGraw – Center for Democracy & Technology – Director

Yeah, so here, both the Tiger Team and the IE workgroup weighed in on it. This is... we're on page 17, "What's the most appropriate level of assurance that an NVE should look to in directly authenticating and authorizing a party for which it facilitates exchange?" One of the things we noticed is that the CTE is framed in terms of authentication, but it actually covers both identity proofing and authentication, just as... since it's an RFI, we get to make comments like that. But we did say, again, our recommendations, which the Policy Committee has endorsed previously is that there be a high degree of assurance in authenticating parties for which it facilitates exchange, but that that notion of high degree of assurance doesn't necessarily need to translate into sort of NIST framework where thou then shalt have, you know, the token, in order to authenticate.

Remembering that we and the Policy Committee recommended that authentication for exchange among entities take place, and the digital certificates be issued at the entity level, and then each entity is of course responsible under HIPAA for authenticating its own users. So of course an NVE would need a process for authenticating the entities, for which it exchanges and if you have an NVE that is dealing directly down with individual users, then of course they would need to authenticate them as well. And then Micky, you had some stuff here too.

Micky Tripathi – Massachusetts eHealth Collaborative

Yeah, I think in general we're pretty aligned on that. The only other thing that I would note is that one of the topics of conversation that we had was that in many health information exchange organizations who have tried to do this, have gotten tripped up on this issue of trying to reconcile differences in authentication requirements among entities and so we would expect that would be an issue as well among NVEs, and just note that it will be important to try to minimize these differences so that those differences don't become a barrier, and we couldn't really come up with a better answer than that. But, just acknowledging that there are going to be those differences, the importance of trying to minimize those differences as a matter of policy and also wanting to also balance that it shouldn't produce undue burdens on other NVEs that would disrupt exchange services in general.

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

This is Farzad. Mindful of David's comment about Federal levers, the Federal Bridge which relies on and leverages the NIST levels of assurance, while we don't need to get into the weeds, certainly beyond my capacity to understand about what the Federal Bridge process, in terms of organizational versus group versus device certificates and so forth. But, are you making... are you silent on or are you making a statement against having a clear concordance with something like a NIST level 3 assurance?

Deven McGraw – Center for Democracy & Technology – Director

I think it's difficult to say because those levels and much of the historic Federal Bridge certification has gone to individual users...

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

Understood.

Deven McGraw – Center for Democracy & Technology – Director

And we have always felt very strongly that it's going to be much more efficient and effective for exchange among entities if they are permitted to do entity level authentication, entity level issuance of certificates with each entity then responsible for distributing the information appropriately and authenticating individual users. And what your staff, and the Tiger Team have continued to struggle with, is whether the Federal Bridge infrastructure that we had hoped to rely on, both to provide the level of assurance that we seek, as well as to allow entities to exchange readily with Federal partners. It's still a bit of an open question as to whether that can actually occur. And so we have another set of recommendations here that we should be resolving this as soon as we possibly can, but unfortunately, yeah, it's like... Joy Pritt, we were laughing with Joy because ultimately like we're digging way down into the... you folks are digging way down into the mud on this one and there's a lot of uncertainty.

We're presenting a different set of use cases to them than they're accustomed to dealing with, and I think there's a strong desire to accommodate that, but whether it can... and lots of vendors, lots of certified bridge authentication services saying they can do it. And yet, sort of when you get down to it, operationally can this happen, could you set it up tomorrow and actually execute it; a lot of uncertainty about that. So, I mean, we remain open as a Tiger Team to continue to talk about this with you all, but, from the timing of the RFI, we weren't sort of able to say, here you go. But the principles that we had decided and that the Policy Committee endorsed of when and entity exchanges with another, we want a high degree of assurance that that entity is who it says it is, and is not being spoofed and it's perfectly fine to leave to those entities the responsibility of authenticating their individual users. And ideally we want people to be able to exchange with Federal partners. How do we wrap that all together ideally, piggybacking on current processes if we can; and it's that last piece we have really tried to chase down and it's been very hard.

M

Micky, anything to add on the Federal bridge side?

Micky Tripathi – Massachusetts eHealth Collaborative

No. So, we did, I think it's under a separate question, did recommend that participation or certification with or interoperability with, however we're going to term that, with the Federal Bridge, is an appropriate thing to have as a part of the requirement. But I will say, with the caveat that the framing of that discussion was more about interoperability from a technical perspective, with an infrastructure and not about whether, if Federal Bridge participation means adherence to a particular level of assurance, rather than saying that there are requirements in the Federal Bridge that would adhere to different levels of assurance and then you choose which level of assurance and then follow the Federal Bridge policy or infrastructure requirements related to that. We didn't sort of break it down into sort of that fine granular discussion.

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

Can I ask Deven, on your... on the authenticating only at the... identity proofing only at the entity level, is that because you think the NVEs are operating between entities...

Deven McGraw – Center for Democracy & Technology – Director

Um hm.

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

... or do you... okay, if that's true, then do you see a need for a prescriptive approach of identity proofing and authenticating at the individual level? Think of it as the weak link.

Deven McGraw – Center for Democracy & Technology – Director

I don't think we... I think we thought that there were sufficient legal incentives already in place through HIPAA that would place... organizations are already liable for ID proofing and authenticating their own users and that that was far better than anything we could come up with from governance that would set potentially a higher bar, but Paul has something to add on that.

Paul Egerman – Businessman/Entrepreneur

The issue there is, again, this is sort of rehashing the prior discussions with the Tiger Team, but, it's really information exchange from one electronic health record to another, and as a result, that's why we saw the need for strong entity level authentication. When we look at large organizations like for example Sutter, we felt that Sutter would be responsible for making sure that the clinicians were appropriate who were accessing their electronic health record. So that's why we focused on the entity level.

Deven McGraw – Center for Democracy & Technology – Director

Right. And so presumably, if someone from Sutter represents themselves from Sutter and queries and is, in fact, not properly credentialed, it is in fact Sutter's legal obligation; not the NVEs.

Paul Egerman – Businessman/Entrepreneur

The way it would work would be through Sutter's electronic health record, from that health record through to the other NVE or whatever.

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

Okay, so for the purposes of this exchange and the governance over NVEs, that may be an appropriate response. Do you think that there's a role, really trust at the consumer patient side for providing clarity, which means also reducing either rework or the inconsistency from one entity to another, for having Federal guidance about identity proofing and authentication at the individual level?

Paul Egerman – Businessman/Entrepreneur

I guess, it's a good question. Are you talking about individual patients or are you talking about clinicians?

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

Clinicians. There may be HISPs who do the direct all the way to the twig there of the user, and do enable that model. Let's take that as an example.

Paul Egerman – Businessman/Entrepreneur

That might be a query response situation, I suppose.

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

Well, it could be that the HISP deals with individual providers who have gotten a DEA credential for second factor for ePrescribing, and they want to use... they happen to... I'm just laying it out, they want to use a very decentralized approach that goes into their, I don't know, their email client, and they want to service that and they want to be a HISP that exchanges messages. Or, it might be that it's the... the HISP is Kaiser Permanente, wants to be a HISP, wants to be a nationally validated entity and they have authentication of their end-users; they're a HISP and they also authenticate their end users. I guess, do we want to... I don't know that while we need to have the organizational, I don't know that we necessarily meant to preclude the individual.

Deven McGraw – Center for Democracy & Technology – Director

Right. And I'm not sure we did either, but I think maybe, and we didn't get into this depth of discussion. I mean, the turkey part with some of these query response questions is that we never had, as a Tiger Team, dealt with policies for query response prior to this RFI. And we were constrained in the time and you'll see it reflected in some of our responses, to sort of trying to tease some of these issues out for purposes of the RFI. So, that was one challenge. I think what really needs to be thought through is whether the current legal infrastructure under HIPAA, where NVEs are really business associates and not necessarily liable for authentication and identity, at a physician level, so that, I'm trying to think through quickly, if an NVE made a mistake, right, and somebody was using an ID to query information from that NVE or another NVE, who would be liable for the misappropriation or misuse of that data under HIPAA? That level of liability doesn't typically attach at the business associate level, unless the participants have essentially made that NVE responsible for it, then they violated their business associate agreement which then the regulators can... But in terms of sort of... I think what we're trying to do is balance sort of, at what point does the NVE set the standards because there's not a sufficient legal framework in place under HIPAA and customarily, when we've approached this issue, we've said, entities should remain responsible for the actions of their users. When you start to talk about NVEs taking on a roll that is where the entities arguably have less responsibility... where the entities have less responsibility and the NVE is taking on more, that's a significant paradigm shift that I don't think we had time to thoroughly think through.

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

I just want to remind us of the key question I asked in the beginning, is this something that if it's present... if it's not present, will require these NVEs to try to enter into bilateral agreements with each other where they try to ascertain well, who has the liability if I send it to you and you give it to somebody else who wasn't the person I meant to send it to, right? Or, do we need that to be included in the framework so that we remove the need for these troops of lawyers.

Deven McGraw – Center for Democracy & Technology – Director

It's a good question and I would want to know, how existing exchanges have sort of dealt with that... and whether that's been a source of a problem for entity to entity level exchange.

Paul Egerman – Businessman/Entrepreneur

So, to get back to the question that's being asked her, which is in question #24, the appropriate level of assurance, I guess the way I'd summarize the Tiger Team's discussion is, we considered at an entity level, we wanted a high level... high degree of assurance at an entity level, we liked the concept of the Federal Bridge, but we ran into technical problems with that. With respect to individual clinicians that you Paul and Farzad are asking now, that was not considered by the Tiger Team; however, I would speculate that similar to the view of the entity level, they would also want a high degree of assurance. So, whether... and that's the extent that we can answer the question now. I mean, that might be the same as like the DEA certificate, but it's simply a fairly high degree of assurance would be necessary. Is that a fair...

Deven McGraw – Center for Democracy & Technology – Director

Yeah, I mean, I think it's a fair point; but I guess I'm...

Paul Egerman – Businessman/Entrepreneur

...I'm just trying to answer the question.

Deven McGraw – Center for Democracy & Technology – Director

Yeah, although I think we moved a bit beyond that to some of the other issues that are related to this, which is to say, and back to Farzad's original question which is, to what extent is the lack of a clear authentication standard for individual users within an NVE infrastructure, is going to create issues for exchange that we would need to resolve it so that people wouldn't have to contract to resolve those issues. It's Farzad's question, which I... we did not address, it's an interesting one. And that's why I said, is it a barrier today to just rely on HIPAA? Which is essentially what we said, and Paul is saying yes. So.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

For this purpose, I think that answer is factoring also, considering my time, it may be something that the committee goes into more detail in, because it's something that plagues the rest of us.

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

I think that...

Deven McGraw – Center for Democracy & Technology – Director

We're here for you...

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

Yeah, and, as much as I said we can't get into the weeds, this is one of those issues where you got to get on... as you said, in the mud, under the weeds, in the roots.

Deven McGraw – Center for Democracy & Technology – Director

We figured this one was probably coming back, but this is as much as we could do on it...

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

And it probably would make sense to... there are some standards issues around here as well.

Deven McGraw – Center for Democracy & Technology – Director

Yeah, there might need to be some joint conversations, so...

M

We don't want everybody to get in the swamp, we might...(laughter).

Deven McGraw – Center for Democracy & Technology – Director

...just let us stay there.

M

Just a very quick comment, I think this does have to be in the framework, you know, to go back to Farzad's question, but, I think it can be delegated to the NVEs.

Deven McGraw – Center for Democracy & Technology – Director

Right, but delegate... I think the question is delegated with a more clear standard.

M

Exactly.

Deven McGraw – Center for Democracy & Technology – Director

And what would that be?

M

And that is what is needed. Yeah.

Deven McGraw – Center for Democracy & Technology – Director

Okay. Okie dokie.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Good, that was one of the issues...

Deven McGraw – Center for Democracy & Technology – Director

Tough ones?

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

So, that's good, no that's good.

Deven McGraw – Center for Democracy & Technology – Director

But it's related to question 25 as well, which is "Whether the indirect approach satisfies trust?" I think that the question is, is it just this sort of series of questions as well as question 27... I'm on page... okay, so really it's just question 26 is related to the same concept of whether you can just rely on the entity, can you flow down the responsibility, do there need to be additional standards. And so, it's one, and the IE Workgroup was remarkably close to where we were as a Tiger Team, so I think we'll just have to do some further work on both of those. So.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

26?

Deven McGraw – Center for Democracy & Technology – Director

27. Oh no, 26, I'm sorry. So now we are on 27, which is page 19. And this is related to the CTE regarding meaningful choice; and the question is, "In accommodating various meaningful choice approaches, opt-in, opt-out or some combination of the two?" Of course you remember that we said choice is meaningful, what your default is, in or out is less important, as giving people opportunity to make a decision with good information. "What types of criteria would we use for validating meaningful choice? And considering that some states have already established certain choice policies, how could we ensure consistency in the implementation?" And our response here is to reiterate a few things, the few decisions that the Policy Committee had come to previously. Again, it is about meaningful choice or meaningful consent, which we have a footnote here that we think those are the same, and that the elements that make choice meaningful, and that consistency in an approach, whether again you default to opt-in or opt-out is not as important as meeting the specific criteria, which also could be what is used for validation purposes. Like, do you have the process in place that can ensure all of this.

And, so an NVE then again is required to apply this policy with respect to the data sharing that it performs or facilitates. It's not responsible for complying with everyone else's policy. So, under what circumstances do you release data, either because it's being pushed at the direction of one of your members, or it's being queried. And you follow your policy and the other NVE will follow its and there isn't any reason why that all has to be the same. That's what we said on that question. We have other things to say about choice, but they come up in other circumstances. Micky, you had something to say about this here.

Micky Tripathi – Massachusetts eHealth Collaborative

Yes, and we're on, I just want to make sure I'm on the right question here...

Deven McGraw – Center for Democracy & Technology – Director

We're on page 20, we're on question 27.

Micky Tripathi – Massachusetts eHealth Collaborative

Yes, okay. Yeah, I think in general the only other layer that we would put on it is that we as a workgroup felt that the NVE should not be required to be the organizations that are obtaining and documenting and recording and storing the patients consent preference, that if certain NVEs choose to do that, for practical reasons or because that's a part of their business model, then that's fair enough. But that should not be a requirement, and we did have a lot of conversation about whether that would implicitly make that the full burden of providers. I think where we landed was that if we said that it was a requirement on NVEs, it actually would shift that entire burden to the NVE and we'd rather see an approach that allows the market to determine where that responsibility would most appropriately land. And, it's probably going to vary by market.

Deven McGraw – Center for Democracy & Technology – Director

Yeah, although we had some similar questions about whether and who would obtain the choice and document it, and our responses to that is in question 30. So, we might have to defer that piece of the conversation until then. So...

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

So, further discussion on this particular CTE in question... So, it's largely where the NVE is not in a position of re-disclosing, it would not really need the consent, the meaningful choice, the meaningful consent would apply to essentially the person gathering the information.

Deven McGraw – Center for Democracy & Technology – Director

Well, we're making it available through the NVE. I mean, the concept of re-disclosure is a bit of a slippery one, and it's actually... the only place in Federal law where you'll find it is with respect to substance abuse regulations. State law again, usually governs the actor; so if your disclosure and what happens to it after you send it somewhere else is not a re-disclosure, but that entities disclosure. So, because of the way we regulate this, we regulate it on an entity basis, not... the protections typically don't follow the data, except under some... there may be some state laws that do that, it's a very rare approach, substance abuse treatment do follow the data.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

So I misused the term re-disclose, it's when the NVE discloses it and it's not under the direction of the source, it could be the patient be the source, but, have I said that correctly?

Deven McGraw – Center for Democracy & Technology – Director

I think so, yes. I think.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Yes. Marc.

Marc Probst – Intermountain Healthcare – CIO

Just two things as I've been listening, I wanted to comment on. I guess one, weren't the patient and the management of that consent, I mean if it's happening at every provider and the NVE isn't the person consolidating that, boy it puts a lot of requirements on the patients to manage those consents, because they could change and they could change based on a certain type of care. And that's just a general question. And then the comment is, is there any kind of a chain of accountability in this process with the NVEs? In other words, you pull or I push information into the NVE, is that the right term? Okay. At that point, do they... are they accountable for that information and I the provider am no longer, because I know my reputation's going to get harmed either way, but... I can see when I take my money to the bank the banks responsible for it when I give it to the bank. If the NVE isn't, who is taking accountability or who's addressing through this process that whole chain of accountability, because it's going to get passed off four or five times, potentially.

Deven McGraw – Center for Democracy & Technology – Director

Personally, I think it's incredibly tricky, particularly where... depending on where we vest accountability, right. So even with respect to HIPAA, as between covered entities and business associates and the subsequently down the food chain, you're probably going to always fight about where the error occurred, and how do you trace it back ultimately from a legal responsibility standpoint, notwithstanding sort of where from a public relations standpoint people will or will not be held responsible. In a voluntary governance structure, we're trying to set up a different set of rules that might hold NVEs more accountable for them... than they necessarily would be as business associates, for the actions that they are taking and the exchange that they are facilitating. But, there's only a limited set of tools that we can provide, in terms of how we hold them accountable, we kick them out of the NVE, we suspend them, we file a grievance, whatever are the sort of further discussions on how this process lays out. But I think, I mean, I think it's tricky, I think it's really tricky. And it's...

Marc Probst – Intermountain Healthcare – CIO

But it feels like we're addressing it through authentication or patient identification, which are appropriate, I mean, I think that's right. But I don't hear the conversation or any set of policies around accountability for the data. Maybe there shouldn't be, maybe that's something we can't address, but it's something that feels missing in this whole process to me.

Micky Tripathi – Massachusetts eHealth Collaborative

Marc, this is Micky.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Go ahead Micky.

Micky Tripathi – Massachusetts eHealth Collaborative

The only other thing I would add to that, to your two questions, and we're struggling with this in Massachusetts elections, they were struggling; we're resolving this in Massachusetts by sort of thinking of this as being specific to the use case. And so, for example, in a directed exchange kind of architecture, where that's all you're doing, the responsibility I think both for the... the question is, who is a party that is providing access to another party and in a directed exchange model, that is the sender. And so, it solves that in that kind of model, it's appropriate that that be the locus of accountability, and the locus of the management of a patients consent preferences. As you move to the higher functioning kind of exchange model where you have automated query retrieve, then the access to that is being really determined, in many ways... or enabled, I shouldn't say determined, but enabled by the NVE and in that case, I think that you're going to want to have a centralized coordination and management of consent preferences on par with current technology, to really understand how you could even do that in a practical way and have it be automated.

Deven McGraw – Center for Democracy & Technology – Director

Yeah, I mean one of the tricky parts, taking my Tiger Team Chair hat off for a second, I think one of the tricky parts of this RFI is that we're trying to create a bigger universe, and yet it's far easier to set policy on use case basis.

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

I think you're right and going to back to the packet... package concept, there may be NVEs that we should either make clear that we're talking about them in the context of one package or another. Or, if we want to really start with cone this down say for Meaningful Use Stage 2, what is... which is, let's make sure we have the starter set for the directed exchange, including potentially directed query, as well as directed push. Those two may have a largely overlapping set of CTEs, make sure that we get that core simple set of CTEs, starter set, clearly articulated, even if the complexity of the further use cases requires further conversation. I want to be sure at the end of the day, the most minimal CTE bundle is clearly articulated.

Deven McGraw – Center for Democracy & Technology – Director

And reflected in another response of ours is the idea that we struggled as a Tiger Team with these privacy and security policy issues and we were only able to reach some conclusions when we narrowed our universe to exchange for Stage 1 of Meaningful Use. Treatment and care coordination, some reporting to public health authorities and some reporting of aggregate data to CMS, by combining that universe, we got comfortable with a set of policies that the Policy Committee also endorsed. Broadening that out and trying to say that the same framework works for that is almost impossible to do, but I like the... I think we certainly would see some of the recommendations that we have had made more easily incorporated into an NwHIN governance structure, if in fact, it had that kind of a focused applicability, at least initially. You can always build on it, what does it look like to begin with?

Micky Tripathi – Massachusetts eHealth Collaborative

So, Deven and Farzad, would that be consistent with an approach that I think we're going to come to when we come to the question on standards, and you'll see in our comments there, an approach that would essentially say that there are CTEs that can be bundled or packaged to use Farzad's word, for a particular use case and NVEs would sort of decide, based on the use cases, would they want to enable which CTE bundles they're going to adhere to, or try to get accredited for.

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

Yes Micky, I think in the future state, there may be a variety of designations that, it's kind of like labeling on the EHR certification program, you know, I do these quality measures, right. I support these use cases and organizations and could be validated to either. But the other part of this is a staging issue that it may be feasible or most feasible to start with the smallest set and to make sure that we can have clarity on moving forward on those, even if the more complex NVEs still we have lack of consensus around or on the standards.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Oh, David.

David Lansky – Pacific Business Group on Health – President and CEO

This is a really helpful distinction that Deven's raising for me, and what I'm doing here is listening for the use cases that are not the initial ones, which are the data aggregation, benchmark and feedback registry uses, device failure identification, revisions and so on, and where PHI will be transmitted from an NVE to another user and the questions of patient meaningful consent and so on are distal, both in time and structure. And so I'm trying to listen to avoid adverse consequences of what we just talked about. I think the caution I'd raise at this point is that it may not be that there is a set of simple cases and then more complex cases, but that there are different cases, and that we can't assume that the starter set correctly set the conditions for different kinds of uses. So, I guess I like the idea of packages of CTEs applied to a certain set of use cases, but not that they're necessarily hierarchical or build necessarily the foundations and building on top of them. So, maybe somewhere in this process we should articulate this bundle, maybe these 18, this bundle of CTEs apply to this use case, they may or may not apply to X, Y, Z use cases, and come back to those X, Y, Zs when we're able.

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

Clearly some S-1 should be foundational to all, others may be unique.

David Lansky – Pacific Business Group on Health – President and CEO

One word of caution that's on my mind, especially in the California Registry work is that, as we know from HIPAA, there's a lot of misunderstanding in the real world. So whatever we might say in this room or in the regulation may not affect how hospital lawyers decide to behave and we're spending literally more than years getting individual hospitals lawyers to work through data use agreements and so on. And so whatever comes out of this process we're discussing today, will have a set of adverse consequences and behavior and if this is perceived as a third layer of compliance after the common rule and HIPAA, now we

have this set of compliance perceptions, may not even been right, anything we can do to minimize that, because we're really clear about what it does and doesn't apply to would be very helpful, I think, in the field.

Deven McGraw – Center for Democracy & Technology – Director

Amen.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Very good. So, that was a helpful discussion. So, we're on 29 now?

Deven McGraw – Center for Democracy & Technology – Director

Yes, I believe we are.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

We're like essentially keep... I mean it's sort of bundled with 28, 27 and 28?

Deven McGraw – Center for Democracy & Technology – Director

Yeah, they're bundled together so again, what we had basically done with all of these meaningful choice questions was sort of to reinforce what we had said previously, which is to say, it's not about opt-in or opt-out, it's about meaningful choice. And when choice is triggered depends on your model of exchange. Assuming a confined set of purposes, we assumed, for which you'd permit exchange in the first place, right. So, it's who has the decision to release the data is ultimately... because the patient shouldn't be surprised by any of that. And then ultimately, in terms of the question of can the choice be... can the process of giving patients choice be delegated to providers. We always said, in our initial recommendations, that providers would have to play a really strong role in securing consent from their patients in our choice model as we described it, right; because you have to have an opportunity in advance to say whether or not you want to be part of something, regardless of whether the default if you say nothing is you're in or you're out. And so, we did see the physician playing a role in saying, is it okay for me to share your data with this NVE, and so the physician in that model would play a very strong role in both obtaining and documenting choice.

Having said that, certainly there could be NVE models where the NVE would have to be responsible for making that documentation; and it probable depends on exactly what they're doing, how the data's being held, stored, how the exchange is being facilitated as to who's kind of responsible for getting the patient to say yes; and when it needs to be documented, for documenting that. But the physician will likely... because the physician is who the patient trusts, the locus of trust, is that the Paul Tang principle or is the patient not being surprised, or it's both. The physicians will have to play some sort of role, but obviously the NVEs are either primary in terms of documentation, or strong supporting role in facilitating those conversations.

Paul Egerman – Businessman/Entrepreneur

I'd like to add one thing which is, it's also... question 30 is an example of a comment that Judy made earlier. It's a little confusing when you read the question as to what they mean by an NVE, because NVE might be a provider, right? So NVE could be, for example Kaiser or Sutter, in which case they... it's not so much an issue of delegating the responsibility, because they have the responsibility, because also provider, I agree with...in like the way HIPAA divides it, it includes entities in the definition of a provider.

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

I want to ask if you have already considered or if you haven't, if you might consider the directed query use case. So, we have the directed push, we've got that; we have the use case that Micky described around automating the request so that without the knowledge of, intermediation of the sender, the NVE retrieves the information or holds the information in response. The third model is somewhere between those, is the directed query where it's for unplanned care, but the request goes point to point to a known end-point and the response can be non-automated, it could be a manual process of reviewing, oh, I got this, just as people get today. I got this request from this other provider, they say they want it for this reason, then

maybe they have whatever consent approach they have and it's not an automated response mediated by the NVE. It is mediated by the end-organizations the NVE is rather thin in that respect. Would the meaningful... how would that be treated in response to... I understand now what you're saying about directed push on one side, automated query response on the other side; where would directed query fall?

Deven McGraw – Center for Democracy & Technology – Director

So, with the caveat that we didn't take that model up specifically, the principle... the core concepts embedded in our original recommendation were about where is the locus of decision to release data. And when it vests in the NVE in an automated way, that's where the patient could be surprised, and that's a model that triggers choice. Where the provider, who is the locus of the patient's trust, still has the decision making authority to release, which is how I interpret model 3, then that looks more like directed exchange, it's just, how did the exchange initiated, did it initiate from the push or did it initiate from a response to a request. But it was still my decision to release, based on what I know about the patient and my own obligation is to comply with whatever laws are in place regarding consent, if I have them.

Micky Tripathi – Massachusetts eHealth Collaborative

Micky. I would agree with that.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Thank you, I think that's an important point to add. Judy.

Judy Faulkner – EPIC Systems - Founder

Another use case I wanted to bring up to make sure that's called off to, and it's what we call the magic button. And the magic button means that you have one group, usually in the same community as another group, and they have a button into that other groups EMR and it goes the other way too. So, you are really creating almost a different kind of OHCA because it's not on one system, but they're becoming a virtual OHCA. And I'm wondering... and it works effectively...

M

That means you're direct...(indiscernible)

Judy Faulkner – EPIC Systems - Founder

And it works effectively in helping patient care. I'm sorry, what did you say?

Paul Egerman – Businessman/Entrepreneur

I think that's what Farzad called directed... is case directed query, right?

Judy Faulkner – EPIC Systems - Founder

Directed query could also be going through the whole interoperability checks, this does not.

M

It's more like an OHCA.

Judy Faulkner – EPIC Systems - Founder

It's more like an OHCA.

Deven McGraw – Center for Democracy & Technology – Director

Well if it is an OHCA, so for those of you who don't remember, and OHCA is a HIPAA concept of an Organized Health Care Arrangement. Essentially you do have to be doing more than just record-sharing in order to be an OHCA; you have to be holding yourself out jointly to the public as being in some sort of joint system, and I think there's even something about, I don't think you're required to share financial risks. But there are some indicia of being an OHCA that includes holding yourself out to the public as being in some sort of joint arrangement. And so, the way that we ended up framing our recommendations, again with the issue being who's deciding when to release the data, it's either in the providers decision making control or it's in the OHCA's decision making control. But I think if all you're

doing is creating a button, the magic button, where I can pull from you and you can pull from me automatically; again we never took up that use case specifically, but if the concept is don't surprise the patient, and patients trust their own providers... but again...

Judy Faulkner – EPIC Systems - Founder

I just think that as we go through all these things, that might be another thing to be keeping in mind, because it works effectively...

Deven McGraw – Center for Democracy & Technology – Director

Magic button. Okay. I mean the idea is again, to be facilitating exchange but in a way that people will trust, and sometimes instead of going back to what's actually happening here and to what extent are we disrupting the arrangements that patients have typically relied on, is a good way to frame initial discussions about that.

M

I think another thing... an attribute of an OHCA though is, there is some agreement. So, for example, hospital and medical staff, it's almost an obligation, so that's something that would not necessarily pertain to these two magic button holders.

Judy Faulkner – EPIC Systems - Founder

We just wanted to make sure that, as we do all this, we don't invalidate because of one of these... a magic button use case.

M

I mean, I just wanted to support that. I do think it's important to look at that use case, because to get to value, that's the kind of thing that we'll need to have.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

It's really the clinical trading partner and we have to facilitate that somehow. Other comments? Okay.

Deven McGraw – Center for Democracy & Technology – Director

So we have no exceptions...

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

Could I just...that's one where I don't think we need to rely on governance to clarify the... to facilitate the flow of information between those two entities...

Deven McGraw – Center for Democracy & Technology – Director

Right, because they can make an agreement.

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

We can be assured that they've already discussed their... they've already that their teams of lawyers discuss... yeah like, we're not saving them any lawyer time, they've figured out how they work together. So, I think while it is an important use case, I think it's probably outside the scope of what we're trying to do here in enabling.

Judy Faulkner – EPIC Systems - Founder

As long as they know it and their lawyers don't decide that because of some rules here, it has to stop.

M

You know, we've just done a couple of these things and our lawyers keep getting involved, even though we've...

M

I bet they would.

M

So, I think some statement in the framework about kind of what standard language you have to have, I think will be helpful.

Deven McGraw – Center for Democracy & Technology – Director

Ready?

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay. Yes, please.

Deven McGraw – Center for Democracy & Technology – Director

Okay. So we didn't have a response to question 31, which is would we create any exceptions to the CTE, we don't see any. So now we're on page 22, question in context. So now we're all the way up to safeguard 4, "an NVE must only exchange encrypted IHI." We actually thought that this was redundant of S-1, which makes all addressable implementation specifications under the HIPAA security rule, required. Encryption of data in motion and at rest is an addressable specification that is rendered required by S-1 and therefore this one is repeating that and you don't need it. And one of the... we got also sort of wound up in whether an encrypted channel versus an encrypted message, or a secure channel, like what is sufficient and ultimately we decided we don't have to drill down on that because guess what, it already got decided in S-1 and the Standards Committee is going to handle that one. And we also have four members that are on the Privacy and Security Workgroup of Standards, so, ultimately that one was easy. Micky, you had something on here though.

Micky Tripathi – Massachusetts eHealth Collaborative

Yeah, it was really... it was just about transparency, that we felt that it was appropriate to have a CTE related to NVEs being transparent, certainly the expectation that they're going to adhere to HIPAA but being transparent about data exchange that could be outside the purview of HIPAA, for example, we felt that that was appropriate to have as a part of the requirement.

Deven McGraw – Center for Democracy & Technology – Director

Okay. So the next several questions I'm going to propose...

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

How many are there going to be?

Deven McGraw – Center for Democracy & Technology – Director

Okay, so this is on the topic of notice, it's question 32, 33, 34 and 35 and 36.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay, then let's... this is a perfect time to break for lunch, because it's scheduled for this time (laughter)... It worked. And we're scheduled to resume at 1. Is anybody keeping track of the number that we've already passed?

W

We have 61 questions, we're half way... sixty some, we're half way through.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Well, I mean, we've not done them all... you're right, we've probably done most of the ones... so we're about half way, which is exactly half... but we probably have 3 gnarly ones to go. Is a half hour reasonable for the lunch break, particularly since we've brought in? Okay, so then we can resume at 12:45, and we'll just keep going. Thank you. Good job everybody.

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Operator, would you open the lines please and would everybody take their seats please and we'll start. If everybody would take their seats please, we'll start. And operator, you can open the lines please.

Operator

All lines are now bridged.

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Operator, can you confirm that the lines are open?

Operator

All lines are now bridged.

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Thank you very much operator. Paul, we are live.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Wonderful. Thank you everyone, thank you everyone for a very productive morning, and we hope to continue the pace, which we'll have to in order to finish on time. We're going to finish our work by no later than 3:10, to give Rob a chance to go over the update for the Meaningful Use and by 3:25, we'll turn it over to Secretary Lansley. Farzad asked me to talk a little bit about the Committee, and we'll do that a little bit before. So, we were leaving off on page 22 with question 32 and Deven.

Deven McGraw – Center for Democracy & Technology – Director

Yeah, so I'm going to propose that we bunch together all of the questions related to CTE S-5, which is the requirement for an NVE to make publically available a notice of its data practices, describing why IIHI, which is Individually Identifiable Health Information, is collected, how it is used, to whom and for what reason it is disclosed and the IE Workgroup had some comments on this as well. But, the way that the responses are chunked up to the different questions, it doesn't flow as well. So, essentially what we said here is yes, absolutely an NVE should have a notice about its data practices regarding IIHI and actually, it should be noticing its data practices with respect to de-identified data, too. And this is consistent with a recommendation that we had already made as the Policy Committee, that intermediaries or HISPs, should be transparent with their customers about what they are doing with de-identified data as well. We have recommended that this be a layered notice so that there's something short, and easy for folks to understand, that summarizes actual information sharing policies, as opposed to what you are permitted to do, which is what HIPAA currently requires, and that there be links for people or a capability for people to obtain more details if they want it.

And the summary notice should really be in categories, not, we disclose to X entity for this reason, but disclosing for treatment and care coordination, you know, sharing information for these purposes and that ideally, there might be some further work done on what these standard categories of disclosures ought to be. And this is consistent with what the Federal Trade Commission has recently said in its report on consumer privacy in the commercial space, which is, that for notices to be able to be effectively compared from a... in terms of comparison purposes, you ought to try to standardize the categories as much as you possibly can, and we thought that was a good idea. The notice should be posted on the website and provided to the NVEs participants and the NVEs should also make that notice available to its participants to share with its patients. We similarly said, again, if this is notice that the average person is going to have to be able to read, it needs to be comprehensible at a reading level that the average person can understand and using common languages for the community that is served, as well as be accessible to persons who have disabilities.

And so that covers a lot of the questions and again, I think there are some consistencies with IE. I'll let Micky respond on top of that, but that's essentially...Paul, did I leave something out?

Paul Egerman – Businessman/Entrepreneur

No, I think you did great. The only thing I would add is, a lot of these sort of notices right now, especially like privacy notices and consent notices before you do a procedure, tend to be written and oriented in such a way as to protect the healthcare organization. And what we're basically advocating for is a transparency notice that's oriented towards the patient or the consumer, and written in a way that a consumer can understand, that that's important and the standardization is critically important. It wasn't in our... recommendations, but my personal view is ONC could go so far as to sort of say, here's a standard format, so you can make it easier for a consumer to compare, you know, this is the information you get from one place versus another. But anyway, that's the main concept, transparency notices oriented towards the patient or the consumer, as opposed to protecting the organization.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

(indiscernible) attest to that is really the no surprises rule. In a sense, if you're not going to be transparent to the patient, if it's not written for the patient, then of course they're going to be surprised, even if you told them, in some sense. Other comment....Yes, Neil. Micky.

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

Paul, this is John Lumpkin, I have a comment.

Deven McGraw – Center for Democracy & Technology – Director

Hang on a minute.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

You want to add something Micky?

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

This is John Lumpkin.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

It's who?

M

John Lumpkin.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Oh, hi John. Go ahead.

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

Hi. Just a brief comment that the Governance Committee has a little bit of concern that if the "to whom" should not require the publication of a list of its customers and members, but that may require...may be a declaration of the class of individuals that... with information...

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

I didn't quite get that.

Deven McGraw – Center for Democracy & Technology – Director

Hi John, this is Deven. So, that sounds like that a notice about data practices shouldn't necessarily be translated into a requirement to disclose a customer list?

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

That's correct.

Deven McGraw – Center for Democracy & Technology – Director

Okay. I think we on the Tiger Team focused more on the purposes for which data is exchanged than the types of participants that would be able to participate in the exchange at a categorical level, so we certainly didn't drill down to the level of identification of specific customers, but it's an interesting question.

Paul Egerman – Businessman/Entrepreneur

And this is Paul. And my reaction to what you just said John also, it depends on again what this NVE is, what kind of organization it is. I can understand what you're saying if it's like a vendor, that they would want to keep their customer list secure. But if it's an IDN or an HIE kind of organization that's a non-profit organization, I don't understand why there would be any concern about publishing that...

Deven McGraw – Center for Democracy & Technology – Director

...about naming the participants.

Paul Egerman – Businessman/Entrepreneur

...about naming the participants, and generally transparency is a good thing.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

I guess I have a similar reaction. And so for example, it would be a surprise to the consumer if they found out that this NVE was selling it to, I'll just pick an industry, drug, that would be something that would alert them and have them look... if it was a surprise to them, then I'm not sure it should have been done by our other principles. Neil.

Neil Calman –The Institute for Family Health – President and Cofounder

So, two questions. First of all, what... don't we... isn't there some specification as to reading level, because average patient means 50% of them are going to be below the reading level at which we're producing this document. Don't we have like a... is there something now where we, you know use third grade reading level or something like that as kind of a standard that we would want this to meet?

Deven McGraw – Center for Democracy & Technology – Director

We didn't discuss it in detail. I... Gayle said fifth grade, I thought fifth grade was sort of standard for reading level when you're actually trying to communicate with folks as opposed to third. But, I think...

Neil Calman –The Institute for Family Health – President and Cofounder

I guess it depends on your population...

Deven McGraw – Center for Democracy & Technology – Director

I think it does, yeah. Your population has to be able to understand it, is kind of the rule of thumb.

Neil Calman –The Institute for Family Health – President and Cofounder

Well, whatever, average is probably not the word we want to use.

Deven McGraw – Center for Democracy & Technology – Director

Okay.

Neil Calman –The Institute for Family Health – President and Cofounder

I forgot what my second comment was. It'll come back.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Any other comments about those two questions.

Neil Calman –The Institute for Family Health – President and Cofounder

Oh, now I remember...

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay, Neil.

Neil Calman –The Institute for Family Health – President and Cofounder

Sorry, what are the standards in terms of when these practices change and you have tens of thousands of consented patients already, and somebody then decides that a new opportunity has come for them to use their non-identifiable patient information for some new use. How does that work when you've already consented all the patients?

Deven McGraw – Center for Democracy & Technology – Director

So, I think it again depends on what you've consented them to, right? So if you have described at a categorical level generally, and again we said we should do more work on what these categories are, so that they're actually... people understand something when the category is conveyed, it's not perfect, but listing every single use is also going to create a notice that no one will ever read. But if you're adding a whole category, you have to change the notice and let people know, and we... if that changes the circumstances under which you got meaningful consent from somebody to share their information, you need to go back and approach them again. Because we called for transparency as part of consent, so, if you are making a significant change in data sharing, in terms of the types of categories, categories of information sharing that you're getting into. And again, we probably need to do a little work on what those categories are, but it shouldn't actually be that difficult, I think there are pretty common buckets that we can land on, that would necessitate a change. An addition of one customer versus... not so much.

So let's say you're an NVE and your notice says, we allow... our participants, our healthcare providers, and we facilitate exchange among them for treatment and care coordination purposes, and we also fulfill our members obligations with respect to public health reporting to their entities. And, we do not disclose any de-identified data. And then they decide, for one reason or another, that they're going to engage in a business model that involves de-identified data. So under our standards, certainly from a notice standpoint, you would need to notify your customers and the public about that change, because it's an addition of a category. In terms of what we've said about meaningful use... I mean, meaningful choice, it's a little less clear, because we framed most of our discussion on choice with respect to the exchange of identifiable information, and when those categories change, versus the use case that I just suggested. But here... I'll do, you know, we've added payers to the list of people who can query our NVE, and as a use case. That arguably changes the dynamic and people ought to know it, and probably should be re-asked about whether they still want to participate.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Art.

Arthur Davidson – Denver Public Health Department – Director

Yeah, I think that this is now raising some concern for me about how, if we limit ourselves to this first use case, which was about, as Farzad was saying, about direct, query back, about the individual patient, and we establish a consent that basically excludes some of the public health and population health value of sharing data of the NVE, that it may result in an unintended consequence that we should really consider how far we want to wait... how long we want to wait... or how far we want to go with this process without considering what might be an adverse outcome. Because I'm sitting here thinking okay, I'll wait, I'll wait, I know it'll come, it will happen, because I trust all of us are interested in population health, learning health system, all that. But, if we do this one use case at a time, it may then result in all the consents being redone. So, I'm wondering if we should add to this individual use case at this time, some population based approach to using the data through the NVE.

M

I thought actually one of the scope... the proposed scopes was Stage 1, which of course does include population public health.

Arthur Davidson – Denver Public Health Department – Director

But, we don't really hear much about that in these 18, is it 18, criteria.

Deven McGraw – Center for Democracy & Technology – Director

Right, they don't. The 18 criteria kind of presume, in many respects, either, depending on how you read it, a huge, broad landscape of exchange for any purpose whatsoever, or, in the case of some CTEs, treatment.

Arthur Davidson – Denver Public Health Department – Director

Right, and it only deals... it just says treatment, it doesn't say operations...

Deven McGraw – Center for Democracy & Technology – Director

...just in one...

Arthur Davidson – Denver Public Health Department – Director

, it doesn't say about quality, it doesn't say about...

Deven McGraw – Center for Democracy & Technology – Director

Yeah, just in one though Art. And so, essentially what... part of the discussion that we had before lunch was to say, it will be easier to craft a set of CTEs and policies that would apply, again as part of NwHIN, and how NVEs interact with one another and in order to create a trust environment so that they will exchange data among one another or be able to share data for certain purposes. If we say, for Stage 1, or even propose Stage 2 of Meaningful Use, those exchange elements are the sort of focus of the use cases that we're going to do for NwHIN Stage 1 of governance. And hoping to kind of grow it as we add on additional circumstances to that. So, I don't think public health was left out at all, but there are some consequences to narrowing the universe, and I think David kind of alluded to these in one of his prior comments, which is, that there's a lot of secondary uses for which we need to have robust data exchange, but that raise a more complicated set of policy questions that we haven't really completely grappled with as a committee, but for which there's baseline policy in the law. But certainly with respect to standing up a governance infrastructure that supports some basic exchange needed to meet meaningful use, there are some population health uses that would clearly be included.

Arthur Davidson – Denver Public Health Department – Director

So if... I thought I heard you say Deven, that if you sign something for sharing your data for a specific purpose and then we decide, or the NVE decides or the organizations that participate in the NVE decide that there's a different use case, there's a potential you'll have to go back and re-consent all those people.

Deven McGraw – Center for Democracy & Technology – Director

Well, that's correct. However, we in part because again, our concepts of meaningful consent mean that the person being asked to consent has some basic understanding of what's happening to their data. Again, with respect to exchange through an NVE that... where the decision making control from the... so we're talking about what the NVE can do, not what an individual provider can do with his or her own data.

M

Bur a governmental...

Deven McGraw – Center for Democracy & Technology – Director

This is the crux of consent, right, if you don't want to surprise the patient, and you lay out to them the circumstances under which their data can be exchanged, in particular models of exchange where their own provider, who they've depended on to exchange the data, and make decisions on their behalf, is no longer in that decision making capacity and somebody can query the NVE and get my data for some purpose that I didn't fully understand. That's where we based choice; and if you sort of add a purpose for which you're network can be queried, or data can be pulled from it, it just goes without saying the people need to have an opportunity to decide whether or not they want to be part of the new arrangement.

Arthur Davidson – Denver Public Health Department – Director

There's no question, I'm in total agreement with that. It's not about consent, it's about limiting the consent to the individually identifiable health information, absolutely we need to have consent, they need to know where it's going. But for the de-identified data, that's where I think if we short sell that on this initial consent, we may really have a big problem in trying to achieve all the secondary uses that David was referring to earlier.

Deven McGraw – Center for Democracy & Technology – Director

Right, right, right. And Art, I will say that what we have said as a committee to date, and we're about to have a big discussion about de-identified data, if we're going in order; what we have said as a committee to date is that the consent recommendations that we have made apply to individually identifiable health information.

Arthur Davidson – Denver Public Health Department – Director

Yeah, I'm with you.

Deven McGraw – Center for Democracy & Technology – Director

We've said that when you're sharing de-identified data, you should be transparent about it. But that's not sort of part of... and I think my use case probably messed up that... my example that Judy asked me to give, probably, I can see where that would have been confusing. Our consent recommendations were... did not extend to de-identified data and I think we need to have a much conversation than we probably have time to have today, to get to that, if we were going to do that.

Arthur Davidson – Denver Public Health Department – Director

And just to add, you said when you're sharing de-identified data, you have to be transparent and transparency on sharing de-identified data also includes identifying who you're giving that de-identified data to.

Deven McGraw – Center for Democracy & Technology – Director

Um hum.

Arthur Davidson – Denver Public Health Department – Director

The transparency is not just a category, we give de-identified data to other people, that's not transparency, it's here are the people that we are sharing the de-identified data with.

Deven McGraw – Center for Democracy & Technology – Director

Specific to the company or specific to classes of actors...

Arthur Davidson – Denver Public Health Department – Director

Specific to the company.

Deven McGraw – Center for Democracy & Technology – Director

We did not discuss that at the Tiger Team.

Arthur Davidson – Denver Public Health Department – Director

That's... I think that's what we did discuss.

Deven McGraw – Center for Democracy & Technology – Director

No we didn't. Because I can tell you, I probably would not have agreed to that. That to me is like a customer-sharing list, as opposed to saying we share de-identified data with pharmaceutical companies, we share de-identified data with companies who share data with pharmaceutical companies. That's different than saying, I have a specific customer that I have to be transparent about. I think that's a bigger discussion.

Arthur Davidson – Denver Public Health Department – Director

Okay.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay, so we have some comments teed up, let me remind the committee that we're on a time frame and also this was not one of the ones that was controversial, so...

Deven McGraw – Center for Democracy & Technology – Director

This is just about notice people... (laughter).

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Just keep that in mind. I think I saw David, Judy and Larry.

David Bates – Brigham & Women's Hospital & Partners Senior Vice President for Quality and Safety

I want to just support Art in this, and I feel like even at the beginning we have to include some of this as an opt-in thing and we, I think pretty clearly need more conversation, because I can't imagine disclosing a list. I just can't see how that would work, personally. Or, every time you identify some new public health department that you're going to go back and ask everyone to consent again, that's not going to work.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

You can't support a list of individual organizations to share with or a list of classes?

David Bates – Brigham & Women's Hospital & Partners Senior Vice President for Quality and Safety

A list of individual organizations.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay, so that wasn't... so Deven's proposal was classes of use. Judy?

Judy Faulkner – EPIC Systems – Founder

I just want to hit the re-disclosure and daisy-chain effect because I just need a little bit more clarification what you've said about re-disclosure before. So, a patient going to my healthcare organization knows what I do with that data. But then the patient's data is then sent over to another organization, what can that other organization do with that data, because you just said it was controlled substances before, and then, if I'm connected with the whole country through these various categories, then isn't the patient... doesn't really the patient have to know where every organization can send stuff to?

Deven McGraw – Center for Democracy & Technology – Director

So generally what happens today, if data's being shared, is my doctor sends my information to your institution for... because I'm being cared for, for treatment, for whatever. Once you get it, it becomes part of your record and what you do with it is subject to the laws that govern your use of data. So this concept of sort of re-use or re-disclosure, assumes that there is kind of an independent legal operation that floats with that piece of data versus a set of legal obligations that constrain your institution in what it can do with data once it gets it and presumes that you're getting it for a purpose for which you're authorized to use it.

Judy Faulkner – EPIC Systems – Founder

But then I as a patient might not know where my data ends up if...

Deven McGraw – Center for Democracy & Technology – Director

Well, I mean, and that is absolutely true and I think that's inevitably, in sharing data, it's one of the reasons why consent doesn't do such a great job at protecting people's privacy; because the most you can do is say, once your permission to share it with X, Y and Z, what they do with it further is subject to some set of laws or not subject to any set of laws at all. And that's part of the transparency process and people make decisions about whether that's a risk that they want to take or don't want to take. I mean,

we sort of don't... the only exception to that is in the concept of... that I'm aware of, is in Federal law with respect to substance abuse treatment data. Once you receive data that's covered by those rules under part 2, you actually can't treat it like other data in your record, and if you want to re-disclose it, you have to have the patient's consent in order to do that. There are special protections on that data for reasons of making sure that people are comfortable enough with the data sharing environment that they will actually seek treatment. And so there are some additional consents. But, it's not, again, we're trying to make it as clear to people as we possibly can, which is a challenge, what might happen to their data once it's disclosed, but there is a limit to that. And that's one of the reasons why it's good to have some laws about what people can do with data, so that it's not an open-ended paradigm, that's just subject to that initial consent for people to share it.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

For the people who are taking notes, could we at least flag that there's an educational.. I don't want to say requirement, I mean, it would be....

Deven McGraw – Center for Democracy & Technology – Director

I mean the meaningful consent is all about transparency, and we said that...

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Except that this transitive kind of thing may not be as clear with the first disclosure, and so we just want to make sure that they... that is included in the meaningful consent, because, this is... it becomes transitive by the way we're describing it. And Larry.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

So, let me shift a little bit back to something I heard in Art's comments I wanted to pick up on, which is, I think we need to think about a framework for de-identification. And that part of what we're doing in this first round of getting consent is to lay out to people that, we have concerns about the data that's about you, that's identifiable to you and that we also have interest as a community and potential commercial interest as a provider or an NVE making money off the data, in using the information about you both for your benefit, in terms of improving health and for a bunch of other reasons. And that that education process around how data gets used, I think really should take on the question of de-identification because this is not like the privacy things I get from my banking companies that say, all of our related companies are going to use your data any way we want and we know it's you and we're going to market to you and all that stuff.

This is de-identified, so other than technologies to re-identify it right, we're basically saying you're now part of a big pool, and you're helping advance either the commerce of healthcare or the health of healthcare, do you want to buy into that or not. And I think that broadly that's a discussion to happen very early on, and it doesn't depend so much on the list, other than as for examples of who it is we're selling the information to. Because I think about, sort of, what I feel is the right thing with data.gov where we're saying, we want to encourage a lot of reuse of information and that we should really be looking at this as part of what we're trying to get done here. And bring that into the early part of the discussion and not say, too complicated, we're going to wait, because I think this is a really key piece of what we're trying to accomplish.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Let me see if I can summarize where I think we're ending up. The question is, should the NVE be... would the NVE be able to accurately disclose all the activities it may include in the notice, and should some type of summarization be permitted. I think we're in agreement that the NVE should disclose the classes of use that it is purporting to get meaningful consent around. One thing we're uncovering is something that is probably not well understood by the patients and consumers, is the transitive nature of... the implications of the transitive consent, once it goes to the person... the organization you're agreeing to, that organization has... it can do anything lawful that it wants to do, and as people understand that, that's part of transparency and part of education. So, is that... and that I think would capture public health and what Larry said, and everything, except for what Paul might have said in terms of naming individual organizations. Is that fair? Okay, next.

Deven McGraw – Center for Democracy & Technology – Director

Now we're in the related question, CTE 6, of whether an NVE should actually be prohibited, an NVE, from using or disclosing de-identified health information to which it has access for any commercial purpose. And we were secondary on this question on the Tiger Team, so I feel like I should defer to the IE Workgroup, which is primary on it, and then I'll add our comments.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

This is page...which question is this?

Deven McGraw – Center for Democracy & Technology – Director

I'm on question 37 which is page 25...

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay, so we jumped...

Deven McGraw – Center for Democracy & Technology – Director

Did I skip one?

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Yeah, I think you skipped a number, right?

Deven McGraw – Center for Democracy & Technology – Director

No, I lumped all the notice questions together.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay. We're further than we thought.

Deven McGraw – Center for Democracy & Technology – Director

Yes.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay. Okay, Micky you want to give first read?

Micky Tripathi – Massachusetts eHealth Collaborative

Sure. So this... we did spend a fair amount of time on this question and we concluded that we thought that condition S-6 as written would have a chilling effect on many existing and emerging business models, many of which we couldn't really name, but we thought in general that overall it would be chilling to the market and to NVE participation in general. And we would recommend that instead of prohibiting the use or disclosure of de-identified information, which is the way S-6 is written, that NVEs instead be permitted to disclose de-identified information only according to a set of principles. So, as permitted under business associate agreements; when uses are disclosed in a public notice, granted that we're still discussing, you know, what that public notice would look like; when the information meets de-identification standards, and when the NVE prohibits downstream recipients from re-identifying patient information. So, according to those four principles we would recommend that NVEs be permitted to disclose, not according to those four principles, but subject to those four principles, and we just note that our recommendations are to the best that we could understand them, consistent with the recommendations by the FTC in a recently released report that was cited there.

Deven McGraw – Center for Democracy & Technology – Director

I don't know, is John on the phone, because Governance Workgroup had something on this, too.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

John Lumpkin, are you still on the phone.

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

Yes in fact I am.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Would you like to comment on this from the Governance point of view.

W

Paul, I think he's driving, so, but we are on page 25.

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

Can you hear me?

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Yes we can.

John Lumpkin – Senior Vice President and Director, Health Care Group, Robert Wood Johnson Foundation

Okay, yes. So, I think the comment that I had mentioned before is that we felt that there were commercial purposes that are appropriate and so that a strict reading of S-6 with...would be a chilling effect.

Deven McGraw – Center for Democracy & Technology – Director

Okay, and then, this is Deven. And our comments, which are mostly found beginning on the bottom of page 26, we struggled to reach consensus on this. We did take this up last because this was not one that was prioritized to us, but a number of members were interested in weighing in on it, so we did, but it meant that we took it up at the very nth hour. But, I think there were strong opinions voiced and we tried to reflect them in the comments here. We had a difference of opinion. There were Tiger Team members that thought prohibiting NVEs from using or disclosing de-identified data for commercial purposes could eliminate a potential model of sustainability and any other entity not part of NwHIN would be able to do this under law, but the NVEs would not.

Defining what a commercial purpose in healthcare is can actually be a challenge... bless you Gayle... as healthcare entities must generate revenue in order to remain in the business of providing care. So, what is commercial in one context may... is probably mixed, versus defining something that is purely commercial and of little to no other public health benefit, population health benefit is a tougher thing to determine. However, there were other Tiger Team members who expressed concern that this really was about the trust between NVEs from one to another and that if an NVE was allowed to disclose data for... even de-identified data for commercial purposes, that that would... that for some NVEs, they would not want to share data with them. And because of the uses that can be made of de-identified data, which under law is basically anything, once it's de-identified, it slips out of coverage, certainly under HIPAA or any other law that I am aware of; it could be used in ways that patients would not agree with, or might arguably harm them from a discrimination standpoint, and could be used to create market advantage or disadvantage among competitors.

So, we were deadlocked. But we did agree that NVEs should be required to abide by HIPAA standards for de-identification and that they commit not to re-identification and bind their downstream recipients. That's something that we don't have in the law today that it would be nice to get, as part of NwHIN governance and of course, in terms of transparency, NVEs should absolutely be transparent about uses and disclosures of de-identified data.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay. Other comments from the committee.

Marc Probst – Intermountain Healthcare – CIO

Paul?

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Oh, sorry, Marc?

Marc Probst – Intermountain Healthcare – CIO

NVE to NVE, is there a BAA; what is the relationship between NVEs, relative to data use or anything.

M

I would guess that unless they're subcontractors...

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Shouldn't be an NVE to NVE, because that's beyond the BAA association (laughter). I got drawn into that one, thank you very much.

Deven McGraw – Center for Democracy & Technology – Director

I'm totally loving this conversation. This is really fun.

Marc Probst – Intermountain Healthcare – CIO

You're not handing off data from one NVE to another.

Deven McGraw – Center for Democracy & Technology – Director

Well, yeah, you could be.

Marc Probst – Intermountain Healthcare – CIO

Because that was one of the concerns you just outlined, as kind of this trickle through approach. So, if you have a BAA in place on how the data is going to be used, doesn't that answer the question, I mean, on the use of de-identified data?

Deven McGraw – Center for Democracy & Technology – Director

So, the members of the Tiger Team, a number of folks thought you know, if the participants in an NVE want to limit their NVEs use of de-identified data, they have a mechanism to do that and it's called the

Business Associate Agreement and they would prohibit it, because the data originates from the provider, not from the NVE. But then it was pointed out that sometimes NVEs have more market power than the individual participant and a desire of a participant to say, I don't want you doing this with the data that's coming from my institution, it may not be effective because it could be that the NVE is powerful enough to say, here are the terms of the deal, and sign it.

Marc Probst – Intermountain Healthcare – CIO

And that's their only alternative, is that NVE. Yeah, that would make sense.

Deven McGraw – Center for Democracy & Technology – Director

Yeah. And so, I think what ONC is sort of floating out there for public comment is that issue of uses of de-identified data such that we have to create this kind of prohibition in order to create the trust environment that will enable exchange from one NVE to another, on behalf of their member entities. And it's a tough one, because I can certainly see the rationale, but my biggest concern is that we are imposing something on NwHIN that the whole rest of the healthcare environment doesn't have to abide by. And so, we're significantly disadvantaging them in an effort to sort of build this trust.

Judy Faulkner – EPIC Systems – Founder

Can you explain that for a minute? So, if I'm a healthcare organization, I can sell the data, de-identified, as a healthcare organization.

Deven McGraw – Center for Democracy & Technology – Director

Yes.

Judy Faulkner – EPIC Systems – Founder

How many do that?

Deven McGraw – Center for Democracy & Technology – Director

I think it depends on the industry you're talking about.

Judy Faulkner – EPIC Systems – Founder

But I mean, right now, for provision of care, I don't know any who do that and I'm wondering whether, in fact, maybe there are, but I don't... my experience is it's very uncommon so that what we're doing is taking a situation that may be legally okay, but isn't done, moving it to a whole different group of organizations which don't have that same principles of care of the patient and allowing them to do something under the rubric of the others can too, when they don't really do it.

M

The reason that healthcare organizations, for the most part, don't do this is they have another source of revenue, right, which is from patients or from the payers, they have another source of revenue...

W

They also don't believe in it...

M

...that's right and if... the reason that I like what was originally written in this RFI to prohibit commercial use, is if you create these intermediaries where selling the data is either their only source of revenue or a primary source of revenue. Well then as a business, you sort of orient yourself to who your customer is and so if your customer is pharmaceutical companies, say, who buy the revenue... buy the data, then you try to figure out, well how can I get more of the data that my customers are going to want to pay for, and that's not quite the same as what we're trying to accomplish here, with healthcare information exchange. And to me, the issue is still... goes back to, what we want to do is we want to build trust and if we want to build trust and we want to have no surprises, I like the idea of saying, let's prohibit this sort of commercial use. Now we definitely have to do something to define what in the world commercial use means, you know...

Deven McGraw – Center for Democracy & Technology – Director

Right, and...

M

...that's a thorny issue, step back into the thorny issue...

Deven McGraw – Center for Democracy & Technology – Director

It's a very thorny issue. Yeah.

M

But we all have our own nightmare view of what that is, and somehow we need to figure out how to write that down.

Deven McGraw – Center for Democracy & Technology – Director

So I had... Judy, I'm just remembering that there are, in fact, business models for certified electronic health record vendors, where the price of the system for the provider is free. It's a fully certified system and... free meaning no out of pocket cost, but the way that the system gets paid for is by permitting the data, in HIPAA de-identified form, to be utilized by the vendor and sold. And so, in terms of sort of whether we would be foreclosing a business opportunity that's tied to the delivery of care, we could be, in fact, by saying this cannot happen, as a business support.

Micky Tripathi – Massachusetts eHealth Collaborative

This is Micky. I would just add, Deven, that it's not that there are many HR vendors who do this, it's not just the ones who offer it for free, but they offer it to their customers as an option for them to get a share of revenues back from the sale of de-identified data. So, it's not uncommon at all, there are more of a sophisticated HIE organizations have been trying to pursue this path, and I even know of some large provider organizations as well who they may not do it, to Judy's point, but in some cases that I know of, it's because they've been unsuccessful at doing it, it's not for lack of trying.

Deven McGraw – Center for Democracy & Technology – Director

Yeah.

Judy Faulkner – EPIC Systems – Founder

Well, as we've queried our customers, we find almost total disinterest, in fact, it's the opposite, they get angry when we talk to them about this. Because we've asked them that same question, do you want us to re-sell, and it is wham, no way. And that's going through a whole lot of customers.

Deven McGraw – Center for Democracy & Technology – Director

Yeah. Well, I just...as to the question about whether this is ubiquitous in the provider community, to date they have not been very rich stores of digital data. And so, the typical sources for this are elsewhere, where in fact the data stores are much richer and robust, but that's going to change as we digitize this data; and I think, we've sort of pinpointed the crux of the issue, what does this do to build trust, in terms of foreclosing a set of uses assuming we could appropriately define them. But what does this potentially do to the business model sustainability and environment when we've already agreed, assuming people are in agreement with what the workgroups have said, that we should protect this data more from re-identification.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

So let's go in order. So Larry and then Judy or Gayle and then Judy.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

So, let me add another wrinkle to the use of de-identified data. So, it's de-identified with respect to what. So we're talking de-identified with respect to the patient. But there's been some press around selling of data that has the provider information in it. And some states have, in fact, tried to prevent this, at least to my knowledge unsuccessfully, arguing that there's a provider privacy piece to this. And that if you sell to a drug company information on what drugs docs are dispensing, they get unfairly marketed to around their prescribing practices in ways that may be seen as...or at least not friendly. And so I wonder in our discussions about de-identification, if in fact there isn't a subtext here of organizations sort of being put in some kind of a review process they had no intention of being reviewed along, because data is now being shared that's about them, directly or indirectly. And I know that some of the HIEs that do use their data sets for research, have been very clear about protecting the identity of the individual provider organizations when that research happens.

Deven McGraw – Center for Democracy & Technology – Director

Yeah. Just for clarification purposes, de-identification is only as to the patients identity under HIPAA. It does not require masking or stripping or aggregating as to provider. It can be provider identified.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

I guess I'm bringing that forward as it may be a subtext to why today providers aren't doing this, because it puts them too much at risk for other issues, commercial or legal.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

I'd like to insert a comment before we have Gayle and Judy, which was Farzad's first principle, remember, part of the goal is to avoid every organization having to write their own BA, etcetera, put their own lawyers on to this tough problem, and if there is a way to do this at the Federal level, in the interest of the patient

consumer, then that may be a good thing. So, let me just throw that out to get that an additional test or comment. Gayle.

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

Thank you. I think this comes down to the whole trust level and in transparency, and you have to really make sure that the patient is understanding what the potential uses of that data is, and the transparency is a key component of it. So, I think that there needs to be some very clear rules of the road on this, if you're going to allow it. And, it needs to be extremely well stated in that notification, if it's going to happen. And it's the transparency element that can build that trust, and it's a key element. I think there are lawsuits now on the resale of that data that the Supreme Court's, I think, actually in some states have ruled on this and they are able to use that data, especially on providers. Now, if you're going to go down the road of individual provider information, I don't know that we have the authority to do that, under HITECH. So, I think that is something you know, you can do patient identification and de-identification, but I don't know that we can set a rule on provider de-identification.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Judy.

Judy Faulkner – EPIC Systems – Founder

Two things. One, one person I know just, I think he's a physician if I remember who it was, filled out something or other and he put in something about a diagnosis he had. Within a very short period of time, ads were coming to him as he would get into websites and things and Google ads about that, and he felt violated. And I think that we're not going to know the paths that are going to take that somehow that data is pulled out, maybe it's from the provider, maybe it's from ethnicity, maybe it's from job, maybe it's from location; where they can put things together and figure out how to target, I'm sure that they'll be able to do that well, and...

Deven McGraw – Center for Democracy & Technology – Director

(indiscernible), a diagnosis from a provider would be in the provider's capacity as a patient, and that would not be HIPAA de-identified data. They type of provider identity is to how many... how often do you prescribe ex-drug versus another, not that the providers aren't sometimes patients themselves, and then there's... HIPAA protection...

Judy Faulkner – EPIC Systems – Founder

Oh, I know that, no, no, no, that wasn't the situation; he wasn't as a provider, it was as a patient and he felt violated and I just think it could be too common that someone suddenly is getting bombarded with stuff that they thought was private and they aren't because of the ability that searches will have to figure out how to pinpoint smaller and smaller populations...

Deven McGraw – Center for Democracy & Technology – Director

That was not... just so you know, that's not de-identified data.

Judy Faulkner – EPIC Systems – Founder

No, I'm saying it was... having written many reporting capabilities and realizing when I write those reporting capabilities, theoretically on de-identified data, you can put information together to still target a very small population. And I've been on the coding side of that, realizing that that's a failure in the whole concept of de-identified data, you can get down fairly small. And so, I just thought his reaction to seeing that there was not... was indicative of how people feel, like you said, when to their surprise, something happened that they didn't think was supposed to happen. The other thing is, I think that, and I mentioned this the other day, if this data is for commercial purposes, the reason we're doing it so as to sustain these businesses is a weird reason. And there need to be other ways found, because I go back to, the more that this becomes a way, the more it's going to get out of control, I think. And the more that we say this isn't the way, other better ways will be found.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

I might relay a... there was a hearing at NCVHS looking at community data sets and one of the issue... actual part of the testimony came from Indian tribes, and I think the part of the learning point there is, I think we all are part of small groups, we just don't know it yet. If you think of how medicine is going. So, I think, that sort of opened my eyes in terms of thinking about "de-identified" there's... we're just all part of small groups, it's just a matter of time.

Deven McGraw – Center for Democracy & Technology – Director

Just keeping in mind that this is not just about sale of data for commercial purposes, this is about use of de-identified or aggregate data, by the NVE itself. So, even its own analytic capabilities for its business would be depending again on how we would define commercial, arguably prohibited by this CTE. It's not just about prohibiting the sale of de-identified data to somebody else for commercial purposes, it's sale or use for commercial purposes; and again, depending on how you use the term commercial... Again, I'm not, believe me, I'm getting the trust issues here, but I'm also fully aware of just how much the use of de-identified data supports a healthcare infrastructure and increasingly supports it. And I'm very worried about moving forward with a condition like this, without fully understanding the unintended consequences; even if I completely get why it would be in here, and why it's worth having a conversation about it.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Well, I think it's... okay, go ahead Neil.

Neil Calman –The Institute for Family Health – President and Cofounder

I guess, going back to Farzad's principle, by not saying anything about this, are we going to start hearing, well, the Feds allow this to happen, I mean, there's sort of the opposite effect, right? So, I think no matter what we do, we need to clearly articulate certain principles about this, we can't just be silent on it. I mean, I think that would be irresponsible.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

I sort of sense if there is any representativeness of this group, I think trust has certainly come up, and clearly that would surprise a goodly number of patients were they to find this was occurring. But, David.

David Bates – Brigham & Women's Hospital & Partners Senior Vice President for Quality and Safety

Okay, I just wanted to say, I think, from the comments, I think we're all more concerned about sale than use. I think fine with use within the entity, but sale is what makes us nervous, you get to the daisy chain, the Judy thing Judy is talking about and so on.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

So, I guess I'm hearing a different sentiment than is written here, let's say, well at least from the IE Workgroup. Let me get a calibration on that. So, are people in support of the CTE that says, "an NVE must not use or disclose de-identified data to which it has access for any commercial purpose of its own."

David Bates – Brigham & Women's Hospital & Partners Senior Vice President for Quality and Safety

I'd like a minute to say, maybe directly say sell, because I think that's what we're concerned about.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Well, what's a use that does not involve monetary gain? So then the question goes again, to either the provider or the patient would be surprised that, you know, I contracted you to get this to where I want it to go...

David Bates – Brigham & Women's Hospital & Partners Senior Vice President for Quality and Safety

They're developing an analytics approach that will help the practices identify high risk patients, for example...

Paul Egerman – Businessman/Entrepreneur

Alternatively, the NVE is owned by a pharmaceutical company, so, it uses the data it gathers for... right, that would be another way to do it...

Deven McGraw – Center for Democracy & Technology – Director

It does market segmentation in order to compete better with other NVEs in its marketplace.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

But interestingly, isn't that what the people who were on the trust side worried about? I mean, shouldn't there be a firewall that says, here's my function, I'm going to operate as an exchange NVE for this function and if there's any other thing I do with it, that's subject to separate meaningful choice. Okay, I've seen some nods there, so I mean, could we interpret or make sure that our interpretation of this statement is, an NVE, which they said at the beginning is focused on exchange of health information, so an NVE acting in its health information exchange function should not use or disclose de-identified health information for commercial purpose. Marc.

Marc Probst – Intermountain Healthcare – CIO

So what if the members of that NVE, the customers of it, people that are using it, all agree that that's an okay thing to do. So, as a provider organization, I'm using an NVE and I say, that's okay, I understand we're going to get the consent and it's okay if the NVE, I'll use the word sells, sells that data, de-identified data, for the purposes of that NVE. If we said what this outlines, they could not do that, even as an agreed group that are saying, yeah, we think that's okay to do.

Deven McGraw – Center for Democracy & Technology – Director

Right.

Paul Egerman – Businessman/Entrepreneur

And so I just want to make understand what you're saying, so the provider organization then will represent the desires of their patients in that statement?

Marc Probst – Intermountain Healthcare – CIO

Yeah, and we would have... I mean the provider organization would have to get the consent, they'd have to message that through that this is going to XYZ, I'm not even going to try this, NVE and that that's what the data would be used for. But as long as the consent was there and it was passed through and understood, it seems to me that the provider organization ought to be able to allow the NVE to do that.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay Art.

Arthur Davidson – Denver Public Health Department – Director

Another example would be the public health agency that wants to do an analysis of its jurisdiction and wants to know where people live and what the control is blood pressure for those who have hypertension, and where people live that have poor control. We could use the NVE as a vehicle to aggregating all that data, and the public health agency might pay the NVE to put that together. So, I think that gets back to what Deven was saying earlier, you know, is this part of the commercial operation of the NVE, and is that of value to society. I think it is. And that's not selling the data again, it's about using the data for a commercial purpose.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay, so let me try to accommodate both of these last two points in the statement... the draft statement I made. So to Art's point, that would not be acting as the NVE conducting health information exchange, you could hire the same group of folks to do something different that is permissible by law, to do something, but it wouldn't be them as functioning in the health information exchange role.

Judy Faulkner – EPIC Systems – Founder

So is the healthcare organization just selling the access to its data to a public health group? But they don't have the data without being health information exchange, they don't have the data, so, I'm not seeing the distinction.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

So, they could turn around and give...the public health department could turn around and give the NVE data, and have them perform an analytic function to the satisfaction of the public health agency, and that would be fine...

Arthur Davidson – Denver Public Health Department – Director

That is different... but they don't have the data, the public health... they want to use the HIE to create this geographic report...

Paul Egerman – Businessman/Entrepreneur

And my response to that Art is, I want to do that as a commercial purpose if...and use

Arthur Davidson – Denver Public Health Department – Director

Not or if...

Paul Egerman – Businessman/Entrepreneur

I would not because it's being used for a public health agency so, I somehow, even though you're paying for it... I know, it gets tricky.

Deven McGraw – Center for Democracy & Technology – Director

Here's another... on the same on, exact same analysis, done and paid for by the manufacture of the drug, but shared ubiquitously with the public health department...

Arthur Davidson – Denver Public Health Department – Director

That doesn't fit, because they're not... that wasn't something permissible under law, without consent.

Deven McGraw – Center for Democracy & Technology – Director

Yes it would be because... no absolutely it would, it's de-identified data.

Arthur Davidson – Denver Public Health Department – Director

But getting access to it...the public health department has a right to this data, the other party did not have a right to the initial...

Deven McGraw – Center for Democracy & Technology – Director

...as long as the data is de-identified, either by the entity before they share it with the commercial party or, if the commercial entity does the de-identification, they just need a simple business associate agreement that says, you're going to make sure this data meets de-identification standards and then once it does, here's where you can use it.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

So we are getting beyond... that's sort of HIPAA. We are getting beyond HIPAA because we're getting more people having access to this data and can operate on it, including de-identifying it, and then all of a sudden making it exchangeable with whomever, and that's actually the point of this discussion, I think.

Deven McGraw – Center for Democracy & Technology – Director

But, I do think that that use case really presses on what could potentially be lost by drawing a hard line here, which is that yes, if a pharmaceutical company is paying for that research, they're going to benefit from it from a commercial purpose with respect to the drug that they manufacture. But, many times, that data also ends up being used by public health departments, by research organizations, and it benefits

them, too. So, that's where the lines about what's commercial and not commercial get extremely hard to draw.

Judy Faulkner – EPIC Systems – Founder

... their customers on trying to figure out whether they wanted to it for those reasons, because I supported you exactly on that for a while, and I went to them with this, what turned out to be idealistic approach, and got pushed back almost 100% from the physicians saying that isn't the reason the pharmaceuticals want the data, and you're being idealistic about it, they told me, and usually they're doing it to figure out marketing approaches.

Deven McGraw – Center for Democracy & Technology – Director

Well, I mean, with all due respect Judy, I actually do talk to data mining companies on a regular basis and try to understand what it is that they do, so this is not... I think for good and bad, I don't think I'm coming at this with rose-colored glasses on.

Judy Faulkner – EPIC Systems – Founder

From the doctor's perception is what they told me.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

This might be... the other thing to think about is, this is a new area, it's also completely new for our patients and maybe over time there will be new uses that are acceptable. So, societies norms will change, which is why the surprise rule may change over time...

Deven McGraw – Center for Democracy & Technology – Director

Yeah, although Paul, you were... you're making an assumption that we know for sure that patients are uncomfortable with uses of their de-identified data when all of the survey research that I've looked at, it's all over the map, meaning a lot of people are quite comfortable as long as they're identity is protected in the data.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

So that's the second... let me go over to Neil's question, and I think the clause he's adding is... so in addition to no commercial use, the additional clause is, unless there's meaningful consent. So, if everybody... let's pretend everybody wants this to happen, then the meaningful consent would be an easy thing and there would be no reason to have a law that permitted something to happen as a default, without asking patients.

Judy Faulkner – EPIC Systems – Founder

But Paul, then will the person's data not be able to be shared if I'd get sick and have to go somewhere else, because I object to that?

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

No,

M&W

No. It's de-identified...

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

It's just the other stuff. So, this does not invalidate the permitted uses by HIPAA at all; what we're struggling with is the things that go beyond HIPAA, that are being made possible by both exchange and creating a new intermediary. The thing that the Privacy and Security Group did not cover at the time; the conduit thing was fine, we're now in that area... okay, somebody can have retained data, what should they be permitted as a default, as "floor" to do?

M

So what we're basically adding is a category of de-identified data that would come under consent requirements.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

That's basically what we're doing.

Deven McGraw – Center for Democracy & Technology – Director

Right, I mean, that's the direction you all are heading in, I personally am not comfortable with that, in part because we lose incentives to de-identify when we treat all data as though it raises the same degree of privacy risk for an individual. And giving people individual consent rights with respect to uses of their de-identified data. I mean, in terms of the work that we've done, you're not going to stop data use for these purposes, right? And right now it's happening with de-identified data, which has issues clearly, but doesn't raise the privacy risks for the individual that fully identifiable data. And if you start treating it as though it's exactly the same from a privacy standpoint, you lose the incentive that currently exists for people to bother to de-identify data; because it actually can be quite... you know, there's a process involved with doing it right that's not cheap.

M

Can I add something to that? This isn't just about privacy, okay? I mean we live in a country where race has tremendous implications and people were asking people to disclose information about race and ethnicity and people are reluctant to do that partially because they don't know what kind of sick researcher is going to find something that they can attach to race that has nothing to do with race, by just doing a statistical analysis on some data that they mine. And we're getting information from people that can be misused in very dangerous ways and I think it is the... it is somebody's right to consent to having their de-identified data used in research, and especially populations of folks who are subject to discrimination and have been the subjects of discrimination in our society. I don't see any reason why we should have the right to disclose their data. I think it functions in exactly the opposite way that you're saying. I think people are basically going to say, I don't want my data in any of that stuff, and some people, your surveys may show that 80% want it, but, the 20% that don't are the people that I'm worried about.

David Lansky – Pacific Business Group on Health – President and CEO

David Lansky...

Judy Faulkner – EPIC Systems – Founder

... most physicians and CEOs.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

David Lansky.

David Lansky – Pacific Business Group on Health – President and CEO

Well I think all this is very much premature to try to have a blanket policy in this area, that there are levels of granularity here that we're all wrestling with. The words even on the page commercial, de-identified, what's clinical data, we already have claims data being used for a lot of these aggregate purposes with a set of rules and lack of rules that are difficult. And a lot of this data is just claims data with more richness, from the point of view of these aggregate analysis, and I'm not saying that's a simple problem. But I'm really worried that we're entering a new age of data applications, some which are virtuous, of the kind we've been talking about, most of which cut across current ownership of data categories. That is, we've got VHR program and others, individual doctors, individual healthcare organizations, but most of this analysis is cross cutting those traditional control points.

This is going to be really complicated, and I'm nervous for the reason I think both Art and Deven have said, about coming up with a blanket policy of the kind that's in draft, which closes off most of the desirable, analytic purposes that I know my community is worried about, how to build integrated care, coordinated care, looking at the long term outcomes of care; a lot of things which require both identified

and de-identified data to be moved across these boundaries. And the NVE is the vehicle for doing a lot of that, so to start setting rules on day 1 that add to the difficulty of looking at patterns of care across settings and time, would be very worrisome to me, until we've really thought it through. We need to solve these problems, but I don't think we can do it with a single phrase in a proposed regulation.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Yes Gayle.

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

I've had my card up for a while down here. As we move into different methods of payment, and if you're doing accountable care organizations and you're doing a variety of mechanisms to determine what... how you improve outcomes, I think there's got to be... we've got to be very careful that we don't close the door to making some... and make very hard choices on this line. The key to me is transparency, is notification and consent and I disagree a little with Deven in that because we're opening such a new door in the use of de-identified data, that we have got to re-examine that whole ownership of de-identified data, and it's time that perhaps we do need to put some very special categories of notification and consent on the use of our individual de-identified data. So, this is a large conversation that's going to go on; definitions of commercial, what is commercial use of it, and really as you move down and look at how that's going to be used by many different organizations to determine payment, you don't want to preclude the good uses, just because people get scared of the word commercial. So, I think consent and notification and transparency are the key elements to being able to do this appropriately.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay. Let me try... let me see if there's an approach here that would be suitable to the group. One is to come up with a statement, a counter-proposal to the wording there and also with that is to have a preamble that describes the kinds of issues and controversies we're on the issues if you can't guess that highlights that because it isn't a simple thing, but one is at least to offer some kind of caveats to the statement that's there. The approach is to describe the issues, which I'm sure are not new to ONC, and the other is to put some draft words as a counterproposal to the CTE described. Would that be okay with people? No.

M

I kind of wonder if, as this is an RFI, if what we might do is simply have a response that we had a spirited discussion and here are some of the things that were said, and we do not have a consensus. I mean, that's useful information and if we summarize what was said and, it's an RFI, here's what was said and this needs a lot of work.

Judy Faulkner – EPIC Systems – Founder

What happens then, if we were to do that, is it out of our control and then it goes on and whatever the key...

M

...never in our...(laughter)

M

We've never been...

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

We may be part of the first, but we're never the last.

M

I think Farzad needs more guidance than that.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

I think that was Neil's point...

Judy Faulkner – EPIC Systems – Founder

It would be nice.

Deven McGraw – Center for Democracy & Technology – Director

Yeah, I mean, you know, this... I think that's the best we're going to be able to do in an RFI, but an RFI is an advance of a proposed rulemaking. So... and we may be asked to continue to flesh out different aspects of this as well as others where we didn't have sufficient amount of information or time to drill down, to deliberate in preparation for rulemaking, assuming the Administrative Procedure Act allows it. But I seriously don't think we're going to be able to wordsmith a CTE that we could get consensus on, based on the difficult issues at stake, all of which are... this might be the single most interesting conversation I've had about this set of issues, and I've had many. It's been incredibly rich, but it's very hard to say that you can land in a conclusive place, based on all of this.

M

The only thing I hear in comment is, we all would like to understand better what a commercial purpose is and so that that's a clear need, we need to have some definitions of that, but I don't think I heard anything else in common (laughter).

Judy Faulkner – EPIC Systems – Founder

Do you want to ask Paul?

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Is there agreement on the sense that there are certain types of de-identified information that people feel should be subject to individual consent?

Judy Faulkner – EPIC Systems – Founder

Or should it be done, that's what I think we need to ask... Should it not be done, should it be subject to certain kinds of ____ consent, or should it be done?

Neil Calman –The Institute for Family Health – President and Cofounder

How about...different levels; I mean, one would say, it can be done with people's consent. The other would say, we're saying it can't be done at all.

Judy Faulkner – EPIC Systems – Founder

And the last would say, it can be done without consent. Those are the three things.

M

But doesn't HIPAA define that already?

Neil Calman –The Institute for Family Health – President and Cofounder

No. HIPAA doesn't say anything about de-identified data.

M

But it's all okay as long as....

Deven McGraw – Center for Democracy & Technology – Director

No, once it meets de-identification standards, it sort of fall... it's no longer PHI and the HHS doesn't have the authority to regulate it.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Let me try to get at least some consensus around some of the concepts, okay. So one concept that we all agreed is, we need a better definition of what commercial means, commercial to who... money making for whom. Another one that Neil just raised, and let me see if people can agree to this is, whether... should we ask... call a question about what is needed... when meaningful consent is needed; it could be never, it could be always or it could be in certain circumstances. Are we... I think we actually could agree

on... it's possible we could agree on one of those three. I'll say it again. So, the statement here is a blanket statement and it doesn't involve meaningful consent at all. Okay, so that is one of the options. That seems to have generated a fair amount of pushback. Another option, the other extreme, is that you must always have meaningful consent and the third option is in the middle, which is, that there should be a way to define certain commercial uses that are okay with meaningful consent. Does that cover the span? David.

David Lansky – Pacific Business Group on Health – President and CEO

I still have a mechanical question, I don't understand how the NVE, which is one or more steps removed from the patient goes back to... with de-identified data, goes back to the provider who in turn gets consent for a new use.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

It's prospective, in other words, the provider would have had to already gotten, and that's a negation that the NVE has with the provider, what's permissible?

David Lansky – Pacific Business Group on Health – President and CEO

That's mechanically really dubious to me, but I'm...

Neil Calman –The Institute for Family Health – President and Cofounder

Well that's already...data, I mean, it's the same question.

David Lansky – Pacific Business Group on Health – President and CEO

We could have the data...but it's just an impractical environment to solve it in.

M

So Paul, maybe we need to focus on here is to identify the areas where there's an issue and pass that on to ONC to say, we talked about how do you have meaningful consent when it relates to de-identified, how do you have meaningful consent when it's about actions of the NVE in the future. The variability of interpretation around commercial purposes that it might not be for sale, it might be for operations of the NVE, it might be actually doing a public health function and it maybe to capture some of the richness of the conversation, and it's sort of key categories would be a useful thing to pass on.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

I mean, I'm sure this is not new to them, so, I would like to make that next contribution. So, if it is possible, and understanding that we'd have to consider the practicality of it to find ways, and find uses and disclosures, for de-identified data under meaningful consent, then that's the thing to work on. Because that's not what this CTE says, it is no use, with or without consent. So, are we closer to...

Deven McGraw – Center for Democracy & Technology – Director

So you're saying definitively find categories of de-identified data use for which we would impose consent or further explore whether there ought to be meaningful consent attached to all or certain uses of de-identified data.

M

I'd be fine with that.

M

Which one, she asked a question.

M

I know, but I'd be fine with her second statement.

Deven McGraw – Center for Democracy & Technology – Director

My framing is just slightly different, which is not... doesn't conclude necessarily that that's the direction, but that it gets further... that whether there are categories of uses or disclosures of de-identified data for which we would want to seek meaningful consent, it's something that should be further explored.

Paul Egerman – Businessman/Entrepreneur

...I mean is that meaningful consent...exchange, in other words if you say "no" I don't want this category, does that mean none of your data gets to the NVE?

Deven McGraw – Center for Democracy & Technology – Director

Well, I think that's something that would have to be part of the discussion, because I'm not sure that it's terribly easy in a de-identified data set to separate out who has said yes and who has said no.

M

Yeah, because I'm trying to think about it, since I'm the NVE, how do I know...

Deven McGraw – Center for Democracy & Technology – Director

Yeah, we're not supposed to know that...

M

... which data has been used for what purpose...

M

(Indiscernible)

W

Sure, you can...

W

You have one little field, do you want this disclosed or not?

W

Yeah, that's...

Deven McGraw – Center for Democracy & Technology – Director

No, it's more than one field, it's in fact 18 fields under Safe Harbor and if it's statistically de-identified, it's even slightly... it's more complicated.

W

...(indiscernible) do before you de-identify it, you have it with the patient's record.

Deven McGraw – Center for Democracy & Technology – Director

Well that's right, but again, if you've got an NVE model, where they've got the data, and the question is, they've got it per consent for identifiable uses and being... I mean, I just would want to explore it further, I don't... we don't do this today, so we're into new territory that I think we have to explore the ramifications of, but I think it's worth exploring, is what I'm saying.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

So let me... so Christine hasn't said anything, so let me have Christine say something and then we'll

Christine Bechtel – National Partnership for Women & Families – Vice President

Just briefly, I completely agree with Deven that this is something that needs more detailed work that we can accomplish, and I just want to put one thing on the table. I do think it's going to be very difficult to define either the kinds of data or the uses of the data that are okay and not okay, and we haven't covered things we haven't imagined... I mean, it's going to be difficult. Another way, and I don't know that this

would work, but another way to think about it for the workgroup might be to think about if the legal definition for commercial use is actually something to do with profit, that maybe you'd think about defining profit or saying, you know, can't be about profit, you can only do it at cost or something like that, so you don't get into... Now I want to throw this out because we have to think broadly, you don't get into all of these undefinable things that we're supposed to somehow define. But if I think about my role as a non-profit, and I'm not supposed to make a profit, but I can absolutely cover my costs in doing it, it changes the entire incentive structure. So, I just want to put that out, it may not be a great idea, but, I think it's worth thinking through.

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

I want to take us back to the package or kit concept of the use cases, and I think it applies to this one. I just want to make that explicit, so, if the NVE is enabling the kind of automated response to queries in which it has access to data, or even holds data centrally, then clearly this is something that this aggregation function, becomes something that may well be within their core operations and so forth. If, on the other hand, there is a lighter weight set of NVE functions that they're providing around providing kind of the pipes for the information to move, if they get access to de-identified data, it is not really centrally related to their function as a validated entity for information exchange. It may be fine, but it's something else they're doing, it's another line of business; and, it appears to me that then it doesn't matter if they're an NVE or a business associate, or an aggregator, or someone else doing some other service, right? But, we can... I'm wondering if there's something that guidance you can offer in terms of categorizing this as is this a CTE that is necessary for all use cases or only for some use cases where access to that information is kind of a natural part of their NVE functions; or it is some other line of business, in which case it's kind of they may be able to... they shouldn't be validated to being... I apologize for thinking out loud here but we're not doing... we're not discussing national validation conditions for aggregators. Someone else maybe does that, or someone else maybe... and maybe at some point...

Deven McGraw – Center for Democracy & Technology – Director

Nobody does that actually...

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

But that's not what we're talking about here, we're talking about what are the necessary conditions, the minimal conditions for trusted exchange. And so, I'm wondering if that would be clarifying when you're discussing the CTE, say, which models of exchange it applies to.

Deven McGraw – Center for Democracy & Technology – Director

I suspect that that would be enormously helpful. Again, we're sort of taking a set of CTEs that were not so narrowly circumscribed and as we talked about their sort of different sort of buckets use cases, ways we want to be more specific about different models. I think it... frankly I think this question will never be easy to resolve, but certainly easier if we're applying it to certain models where... you know, in terms of what exactly are we trying to govern, right, versus things that we'll leave to the rest of law to deal with.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

So, let me first try to define the problem... shape the problem a little bit more, just like Farzad would say. So, when we talk...

Deven McGraw – Center for Democracy & Technology – Director

I'm on like a 15 minute time frame... unfortunately health datapalooza, I've got to moderate a panel at 3 o'clock.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay, so let's try to do this.

Deven McGraw – Center for Democracy & Technology – Director

So, my apologies, but...

M

It only takes 10 minutes to get there, I just did it...

W

(indiscernible) (laughter).

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay, first let me... we have framed the CTE as dealing with the NVEs function in health information exchange only. Regardless of what this body of people do, this CTE only applies to the NVE health information exchange function. Can I... can we set that as what we're talking about?

Deven McGraw – Center for Democracy & Technology – Director

So, does it collect data or does it not collect data as part of the exchange function.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

It may or may not.

M

It may or may not.

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

If it does, it does so under different auspices than their identity as a national validated entity for information exchange.

Deven McGraw – Center for Democracy & Technology – Director

So, their NVE role is as an exchange facilitator, so they really shouldn't be touching data for that purpose at all...

M

They don't do data...

M

Right and it's moot, it's irrelevant.

M

It would be irrelevant under those conditions...

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

Just to, just to, just to, just again, put a point on it, what I think would not be useful is if someone said, oh, I'm a validated entity, therefore, as I'm transiting information, I'm going to skim some off the top to use for other purposes, right.

M

That's what this is saying.

M

But some of them are doing that as explicitly part of their model, they're hosting people's data...

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

That's what I'm saying, if you...

M

...they're providing federated use of the data

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

...that's exactly what I'm saying, I'm saying is, to... it depends on the model as to whether access to that de-identified information is implicit or accompanies the exchange model or if it's really, you know, could be packet sniffing for no other purpose other than... you know, it really does not further their role as an exchange entity at all, in which case, it is... whether it's appropriate or not, and I don't think we have to say here that a condition of trusted exchange is you don't do that, right. But my point is, someone else could do that under a separate set of business agreements and contracts. If you want me to be your data aggregator, let's become a business associate; and that's a perfectly valid business, to be someone's data aggregator, someone's quality measure warehouse, someone's analytic shop, that's a perfectly valid business. But this is not the way to do governance over those entities, that's...functions.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

So in a sense, if provider, if this organization says, I am an HIE NVE, I will do the following and I will not do this. If you want to have an agreement with me to do a commercial purpose, then there is a separate agreement, and oh by the way, I'm either certainly either will or will not get meaningful consent. So, this... so one way is to modify this statement is to say the NVE acting as a health information exchange will not use de-identified data for commercial purposes. That does not mean the organization can't have a separate agreement, but it does mean it would have to have a separate agreement. Would that be acceptable do you think?

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

That is truly problematic because at that point, at that point, you're taking away any need to notice or have transparency for the patient to know that their provider is then going to essentially sell...

M

No, no, the providers at that point...

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

...their data, in a de-identified way. At least if you have some parameters around the de-identified data within the NVE, then you... I would like us to see having an element of consent and an element of transparency.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Maybe, let me clarify. So, in the HIE function this organization would not be permitted to use de-identified data for commercial purpose. If the organization... if the provider organization wanted to have something else done with their de-identified data, they would have in their good conscious and following HIPAA, have to have decided either was allowed by HIPAA or they got meaningful consent.

Christine Bechtel – National Partnership for Women & Families – Vice President

But if the... I guess where I'm falling down is, if the NVE wants to use the data that they have as the NVE, can they do that?

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

No.

Christine Bechtel – National Partnership for Women & Families – Vice President

Okay, so that's... so you're saying, the NVE can never do anything for commercial purposes...

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Correct.

Christine Bechtel – National Partnership for Women & Families – Vice President

...with data, the aggregated data, but the provider organizations that are part of this, can do whatever they can do today under HIPAA?

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Correct. And if they want to do a function that's not covered by HIPAA, they will need to have meaningful consent. So, the way that I'm editing this CTE is to clarify that it's not talking about an entire entity and they get to do or not do something, it's in their HIE function, that NVE entity cannot do...

Christine Bechtel – National Partnership for Women & Families – Vice President

So the provider organization was also an entity, accredited or whatever, validated as an NVE, but as an NVE they have data from other provider organizations, can they just put their provider organization hat on and use all of that data only...no, you're saying only their own...

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

They can only do what they can do as a provider, and that's covered by HIPAA.

Deven McGraw – Center for Democracy & Technology – Director

Yeah, I'm really struggling with conceptualizing what it is that you're trying to suggest... you know, it's one line of business versus another line of business and it's okay for them to do it in this line of business, but not okay in the other one.

M

(Indiscernible)

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

...and you lose the transparency that we've already built in...

Deven McGraw – Center for Democracy & Technology – Director

And we've already said that NVEs will do a bunch of things, only some of which they'll be validated for. So, okay, for your validated services you're not doing it, but for your non-validated services you are ... same data or you have to ask for it again so you can do it in the other... I mean...

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

Let me try to restate what I'm hearing. There...this is not going to...any conditions of trusted exchange we put on for NVEs is not going to solve the broader problem, that some feel is a problem, of bringing more transparency to the uses of de-identified data more broadly. We know that, because not all the actors who are going to be among that are going to be NVEs or exchanging information. There's a separate tier of activity that we're not addressing through this conversation. However, in order to achieve the core goals of, "can these organizations be trusted," can we have at least these organizations be trusted to do exchange. The position you're saying is, at least for these organizations, it's important that there be transparency around what they do do, whether it's...you know, these organizations; whether it's part of their core business or not, their core business and so forth. And you would be loath to give that up because it doesn't relate to solving the problem of... more broadly, but it addresses the trust issue in these NVEs. That's what you're saying.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

That's a good point.

Deven McGraw – Center for Democracy & Technology – Director

But I'm also still struggling with the...

M

If we don't have access to de-identified data, then it's not an issue

Deven McGraw – Center for Democracy & Technology – Director

Well then it's not an issue, that's what I'm sort of struggling with is that we've sort of created a very narrow use case where we arguably don't even need the CTE at all...

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Right...

Deven McGraw – Center for Democracy & Technology – Director

... which is fine.

M

(indiscernible) sniff packets if you wanted to...

Deven McGraw – Center for Democracy & Technology – Director

Yeah, so packet sniffing I'm perfectly happy to say should not happen.

M

Well, it is a condition of trust and it is useful to explain this...

Deven McGraw – Center for Democracy & Technology – Director

Yeah, I mean, again we've narrowed it such that the only way that an entity under that sort of circumstances and with that sort of narrow use case would be able to use de-identified data is if they were packet sniffing or doing an end-run around or somehow being able to collect or amass de-identified data kind of that goes beyond their... or that might be part of their facilitator role, but is absent from it. So, you know, so certainly as narrowly as defined as we're talking about it, I think there's... it's hard for me to say why that would be problematic. It's also hard for me to say why this condition is needed, but, you know absent unscrupulous behavior.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Well, that does exist...don't think I'm forgetting...

Deven McGraw – Center for Democracy & Technology – Director

Yeah, no, well right, but I'm thinking of, you wouldn't even be able to be transparent about something like that because it would be so... the way you've described the use case, unless I'm missing something, the only way to be able to use or disclose the data for commercial purposes would be through some sort of nefarious way.

Paul Egerman – Businessman/Entrepreneur

Unscrupulous, nefarious stuff. I mean, you see how people do internet advertising, you just monitor your activity and then they make decisions based on that.

Deven McGraw – Center for Democracy & Technology – Director

But again, based on his narrow use case, you couldn't be doing that, the way that I understand it, is you've defined it so... in such a constrained way that it doesn't even seem like you would need de-identified data, or have access to it.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Let me see if people can agree with that, to have something that we can advance that reflects some of the opinions that we've heard about. We will also go through the transcript and try to enumerate all of the topics and concerns, just to catalog those for ONC. But most of them they've heard before, it would be helpful to make some kind of advance and... Jodi.

Jodi Daniel – Office of the National Coordinator – Director of Policy & Research

...something maybe as that... so I'm hearing that there is concern about what the right policy is because this sort of needs to develop over time, but concern about trying to narrow the use case too much and that kind of things happening outside of this narrow use case. And I'm wondering if maybe what, kind of an approach that folks will be comfortable with is, identifying the things that the Policy Committee actually cares about being transparent about and then requiring transparency on particular uses of the information...of de-identified information so that at least there's transparency about how the information is being used as a condition, as opposed to actually setting the policy and then over time, as we see what transpires, the conditions can change if there are things that are happening that folks are uncomfortable with.

Deven McGraw – Center for Democracy & Technology – Director

I mean I thought we had that, this whole discussion over the last hour and a half is whether we would go further than that.

Jodi Daniel – Office of the National Coordinator – Director of Policy & Research

Right. Okay.

M

Yeah.

Deven McGraw – Center for Democracy & Technology – Director

And many people do want to go further than that, that's what we're stumbling with.

M

And there's also agreement on the Policy Committee in terms of the requiring NVEs to commit to not re-identifying de-identified data. We got that two. Those are both really important.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Marc.

Marc Probst – Intermountain Healthcare – CIO

I'm just wondering a little bit about consent process. I mean even if it is according to that requirement, we're still going to have to have consent to send the data, right, and share the data within that NVE. So now I'm going to have multiple levels of consent; that I can send it through an NVE, but I also need consent that if I want to aggregate data with that same organization, there's going to be another level of consent?

Deven McGraw – Center for Democracy & Technology – Director

I think that's one of the issues to explore Marc, because certainly with respect to the recommendations on consent that we were able to agree to, it has to do with the type of NVE model you're dealing with and identifiable data. And then we did agree on transparency and we did agree on re-identification. What we've been discussing is whether there's also a role for consent for certain uses of de-identified data, and that's what we haven't had sufficient time to resolve.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Can I try the statement?

Deven McGraw – Center for Democracy & Technology – Director

You know what, you can Paul. The only reason why I'm mentioning this is we're listed on here at least another 5 or 6 times, and we're supposed to be done with all of these by 3:15.

M

Go ahead.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay. All right...

Judy Faulkner – EPIC Systems – Founder

Can I make a quick comment Paul?

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Yes.

Judy Faulkner – EPIC Systems – Founder

One thing that sometimes we see is that in some areas of some states, using a certain HIE is required and so, as we make these rules up, we have to realize that we're maybe not giving organizations a chance, we have to make them up very wisely for the organizations.

Deven McGraw – Center for Democracy & Technology – Director

And I thought that was not permitted under meaningful use, but for Medicaid purposes, but...

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay Deven, you want the... so we'll go back and we'll extract all of it, extract and summarize the comments.

Deven McGraw – Center for Democracy & Technology – Director

Okay, we're on page 27 and we can dispense with question #39, because the Standards Committee is handling it and we did not, this is the CTE involving high availability of services. So really we're on question number... the question set that begins with #40 and deals with two, I'm going to try to lump... are you okay with that Paul? So there's two CTEs S-8 and S-9 that have to do with the obligations of an NVE to patients when they assemble or aggregate identifiable health information that results...when they assemble or aggregate health information that results in a unique set of IIHI, Individually Identifiable Health Information, and when they do that, there are two CTEs that have been proposed. One is that the patient would be able to access a copy of that, because it's unique information and so presumably it's not necessarily also in the hands of their provider. And then the second condition is CTE 9, which deals with the patient's right to seek an amendment to that again unique set of information.

And on this set of issues, and I'm going to lump all the questions in under both of those conditions again, because they both deal with the circumstance when... which doesn't always occur, but when you have an NVE that's actually assembling or aggregating unique data, at least as proposed in the RFI. And on the Tiger Team we were quite conflicted about this. A number of Tiger Team members said yes, if there's unique data that's being assembled or created in this NVE, absolutely the patient should have the right to see it, to get a copy of it and to seek an amendment to it per the HIPAA privacy rule process, if they need to do that. But there were members of the Tiger Team who sort of felt like the NVE is not the entity that has the relationship with the patient, that the data...that the patient should deal with their providers and the originators of the data. There were some concerns by one of our provider members about what an NVE would do in amending data, that would not...that the provider would not necessarily be vetting, because any unique information created by an NVE would be sourced initially from the participants, and there was a high degree of discomfort with sort of ceding to NVEs this responsibility and taking it out of the provider's hands where they're sort of closer to the origination data source.

And so given those quite clear concerns, and yet a strong desire on the part of other Tiger Team members to make sure that patients could actually access data that is unique about them that's being assembled or aggregated by an NVE, we couldn't... we probably if we had a little bit more time, then probably been able to hash this one out, but, we threw in the towel, due to lack of time and that's kind of where we landed.

Paul Egerman – Businessman/Entrepreneur

So... the comment I would just add is the suggestion that Farzad made in previous discussion could be helpful in this one too, in other words, you take that data aggregation, you somehow do something different with that, then all of a sudden, maybe some of these things start to fall in place.

Deven McGraw – Center for Democracy & Technology – Director

Oh absolutely. I mean there were a number of folks who said, “yeah, I don’t know of an HIE who does this.” And some of us do know of some, but it’s very model-dependent, so, I think you’re right Paul.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

I’d like to jump in with a comment that keeps recurring, which is, over the last couple of years we’ve really shifted the model that we’re talking about. We went from in the early days of this, we’d have network of networks, there was a very strong sense that the exchanges were data repositories. And we’ve moved far from that model to lots of different kinds of connectivity, most of which doesn’t store data, but is really to facilitate exchange. I sort of feel like we’re sort of rethinking architecture one little example at a time, and probably outside the context of today’s discussion, we ought to revisit this with some coherence around what’s the architecture evolving to, because maybe that would give us better clarity around how to address these policy issues.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Christine.

Christine Bechtel – National Partnership for Women & Families – Vice President

I think on this particular... these two question sets, I think this is about conditions of trusted exchange and I think that means that consumers should have the ability to access a copy of the information that’s held about them and an ability to correct it. I understand the concern that there may or may not be a relationship with the NVE, but, I don’t think that stops people from asking for their information from their credit bureau, and I’m not sure any of us would describe a relationship with our credit bureau. And what we know just finally from our survey data is that when consumers can’t access and see the information that’s held about them, it creates an enormous amount of trust. So I think it’s actually very important to allow that... to allow both.

Judy Faulkner – EPIC Systems – Founder

One comment on that. What you usually have to do when you’re sending data to patients is different than when you’re sending data to healthcare people, so it does mean that the NVE is going to have to be able to translate things into lay terms, not just let them look at the data.

Christine Bechtel – National Partnership for Women & Families – Vice President

And I think that’s important and fine. These entities are to be trusted anyway.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

So where does that leave us in terms of, if you use... you separate the functions, then we actually don’t have to deal with this, and which are people comfortable using the separate the function?

Deven McGraw – Center for Democracy & Technology – Director

Yeah although, I mean I think it just begs the question though, when you have a model that aggregates and creates unique data sets, are you going to give patients the right to get the data or not? I mean, it’s clearly not a universally applicable NVE, but in that circumstance...

Christine Bechtel – National Partnership for Women & Families – Vice President

Right.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

But if you use... so they would not be acting as an NVE in that case, they would be acting as an aggregator and they have certain responsibilities, including...

Christine Bechtel – National Partnership for Women & Families – Vice President

Why wouldn't they be acting as an NVE though? I mean, if their model is such that they do actually hold the data and they are acting as the NVE...

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

They're not acting as an HIE function only.

Christine Bechtel – National Partnership for Women & Families – Vice President

Wait a minute...

Neil Calman –The Institute for Family Health – President and Cofounder

Well, they're aggregating the data in order to act as an intermediary and exchange.

Christine Bechtel – National Partnership for Women & Families – Vice President

Yes.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

That's interesting, I looked at it the other way around, they were exchanging in order to aggregate.

Deven McGraw – Center for Democracy & Technology – Director

It's both.

Neil Calman –The Institute for Family Health – President and Cofounder

It could be both.

Deven McGraw – Center for Democracy & Technology – Director

It's both. I mean, you know, so I've heard of models of exchanges where what gets developed is a summary record from disparate records and then that's what available to be pulled from the exchange.

Christine Bechtel – National Partnership for Women & Families – Vice President

And in that case, the consumer should be able to see it, either way, I think.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay. And that would... the NVE would be interacting directly with the consumer then, in that scenario.

Christine Bechtel – National Partnership for Women & Families – Vice President

Yeah, that may be the case.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay, and that's what you'd have to sign up for, if you were one of those.

Neil Calman –The Institute for Family Health – President and Cofounder

Talk about surprise...you go to the doctor and then you get a letter from some other entity that you've never heard of...that says...

Christine Bechtel – National Partnership for Women & Families – Vice President

I mean, but...I don't want to put David Sharp on the spot here, but I'm going to. But I mean, you guys in Maryland have talked about a policy where consumers can query, they can, you know, ask for a copy of their data from the exchange, but, I don't know that you have set up yet whether they would ask through their provider or directly of the exchange or both. But that is your policy already, I believe.

David Sharp – Maryland Healthcare Commission

Yeah, that's right.

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

And Neil, it shouldn't be a surprise because we already discussed that if the information leaves the provider's control, the patient should have meaningful choice about that. So, it can't be a surprise to them that someone else has the data if they were given informed choice about whether they want to participate in that.

W

Yup.

Neil Calman –The Institute for Family Health – President and Cofounder

It will still be a surprise.

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

Then it wasn't meaningful choice. If it's a surprise, then it wasn't meaningful choice.

Neil Calman –The Institute for Family Health – President and Cofounder

You make the choice in 2003 and get the letter in 2004 from somebody you don't...I mean, I'm not saying it's bad, but it does have... there is an element of surprise in this, you're dealing with an entity that you don't really know. So, that's okay...

Paul Egerman – Businessman/Entrepreneur

We did advanced education about this..

Neil Calman –The Institute for Family Health – President and Cofounder

I think we're okay there.

M

...about the transitive nature of their choice...

Paul Egerman – Businessman/Entrepreneur

And that's one of the things...

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Yes and that's one of those things.

David Lansky – Pacific Business Group on Health – President and CEO

Going down this path also may create a new set of entities who choose not to be subject to these constraints and a part of providers and others choose to create these alternative structures because they don't want the cost and burden of being accountable to the individual consumer or patient, I'm not sure... we should think that through a little bit. I'm thinking about the registry case where real-time registries essentially are going to be functioning in a data exchange role, pushing identifiable data back to participants, integrating data from multiple sources, but don't want to be in a position of managing a million patient direct contacts and feeding them individual reports from data that was originated from provider data capture. So they would try to excuse themselves from this regime. I'm not sure that's good or bad, but we should...

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

So did you consider some of this flavor in the discussion? Okay.

Deven McGraw – Center for Democracy & Technology – Director

Yeah, I think we should. I mean, that's what the beauty of an RFI, the richness of this discussion can get incorporated.

Arthur Davidson – Denver Public Health Department – Director

So Paul, I think I agree that NVE is not necessarily the best mechanism to get it back to the patient, so why don't we just say that there must be a mechanism to provide the information back and that that is worked out in the business model or the opportunity in each community. Because I just think that the NVE is not likely to be... they'd rather go back to their own doctor.

Christine Bechtel – National Partnership for Women & Families – Vice President

Right, and that's why I call it the example of Maryland, because it's... you know, they'll figure it out, but it doesn't necessarily mean that the NVE has to go through the cost, it doesn't mean... they'll figure one way or another out.

Deven McGraw – Center for Democracy & Technology – Director

That's a good point. That's a very good point.

Christine Bechtel – National Partnership for Women & Families – Vice President

We're not trying to dictate the practice here, the workflow, just the policy.

Paul Egerman – Businessman/Entrepreneur

...if you get the doc to respond to every new data that comes in will be a bit of a challenge too, I think.

Christine Bechtel – National Partnership for Women & Families – Vice President

We have technology, if I get a copy of my credit report...

Arthur Davidson – Denver Public Health Department – Director

No but what we're saying is here... they have a right to see the data and they have to go to some place to get it and it may not be the NVE, it could be their own doctor's office that does a query and brings back and aggregated record.

Christine Bechtel – National Partnership for Women & Families – Vice President

It could be a website too.

Arthur Davidson – Denver Public Health Department – Director

It could be it automatically goes to the PHR, I don't know what...

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay. We have approximately one minute per question going forward.

Deven McGraw – Center for Democracy & Technology – Director

All right, so we are on question 43 on page 29, "What method or methods would be least burdensome, but still appropriate for verifying a treatment relationship in the context of a query model?" And a CTE that says NVEs must have the means...bless you Gayle... to verify that a provider requesting an individual's health information through a query response has or is in the process of establishing a treatment relationship with that individual.

So, our response reflects an understanding of the RFI that NVEs could be engaging in a whole lot of different types of exchange, and we were very uncomfortable with thinking that you could use a query and response from an NVE for purposes beyond the sort of Stage 1 Meaningful Use criteria that we had landed on; which would mean you would most often be querying for a treatment or care coordination purposes. Maybe there would be some public health queries, and maybe the public health agency could query as well; but a limited set of kind of use cases. And so we certainly had to say at the outset that being able to use a query response model in order to get data for a broader set of purposes was not something that we had made policy on, and wanted to get that out very, very clearly. The other thing we wanted to make note is that with respect to whether you could query for a patient who wasn't necessarily your patient, that there might be circumstances where we might want to allow that. And one of the ones that we had previously surfaced as an example to the Policy Committee in our consent recommendations

actually involved the treatment of newborns, where it's often important to have information about the mother, even though the mother isn't your patient, as a NICU provider or a pediatrician. But, there's probably a limit to how far you would go with that; but certainly, when you're using it for treatment purposes, talking about sort of verifying that you have a treatment relationship with the patient that you're querying or there are other circumstances that exist where you should have the capacity to query, even though that's not necessarily the patient in front of you, and the newborn is the one example that we came up with; there may be others; that essentially you'd have to ask for attestation. And maybe require NVEs to periodically audit that, but there isn't really another more effective way to do it that wouldn't be more burdensome.

It also occurs to me as I'm saying this, that if and when we fix the authentication issue, it doesn't necessarily resolve treatment relationship issues, but at least pinpoints... gets us more assurance on whether we've pinpointed the right provider, which is certainly helpful to this conversation, although certainly does not solve all things. And Micky, you had some stuff on this one, if you're still there.

Micky Tripathi – Massachusetts eHealth Collaborative

Yeah, I'm here, I'm not sure if you can hear me.

Deven McGraw – Center for Democracy & Technology – Director

Yes. Yes.

Micky Tripathi – Massachusetts eHealth Collaborative

Okay. So I don't think Deven that anything we had on this one, I'd love to go back to the other conversation about commercial uses, but I'm not going to do that. I'm not sure that there's anything on this one that is different than anything that came out of the Tiger Team.

Deven McGraw – Center for Democracy & Technology – Director

Okay.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Any disagreement with what Deven said about 43?

Deven McGraw – Center for Democracy & Technology – Director

And I also picked up question 44 in the response. I'm lumping, even as we speak.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Good, very good. Okay.

Deven McGraw – Center for Democracy & Technology – Director

All right, well, you are now moving into the interoperability CTEs, which begin at the bottom of page 30. I will just say, in terms of the other things that the Privacy and Security Tiger Team weighed in on, it included the issue of digital certificates, which begins at the bottom of page 32, and that's the one where we have already sort of had a discussion, that we need to further drill down on. So, I think we've done that one already, I just wanted to give you a heads up about that. And then I think the only other piece that we have is on patient matching, and, we have a lot of other things to get to, so I defer to a chair. If I'm not here, I think our written comments speak for themselves and Gayle and other members of the Tiger Team who are participating in the conversations, I'm perfectly confident they can represent. So that means that we are on the transport methods, for which IE has the only comment here. So, it starts at the end of page 30, it's question 45 and the answer from IE is on page 31.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Thank you Deven.

Deven McGraw – Center for Democracy & Technology – Director

I'm out of here.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Good luck with the Palooza and come back.

Deven McGraw – Center for Democracy & Technology – Director

If it's still going on, email me, I'll come back. I'm supposed to be there until 4:30 though.

W

We'd better not be.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

No, we won't be here. Okay. Let's see, we're going to IE then. So, we're picking up on page 45... I mean, question 45.

Micky Tripathi – Massachusetts eHealth Collaborative

Right. So in general our comments were that if... the question talks about multiple standards and seemed to not be linked to the ongoing effort related to standards for EHR certification, and so, one linkage that we wanted to make was that if there is a determination that it's preferable for NVEs to support only one mechanism, or have only one mechanism be a part of the validation, that that ought to be adherent or aligned with the transport requirements included in the EHR vendor certification, once the 2014 edition is finalized. It didn't seem to make any sense to have that be living in a parallel world than what the EHR vendors are going to be certified for.

We wanted to recognize also that SOAP is used by many public health efforts, so to the extent that there is sort of a set of priorities around that, that that was recognized as being priority mode of transport. But, the third bullet... and to step back for a second, the recommendation from the workgroup would be that rather than require that NVEs necessarily support one or multiple transport mechanisms, going back to a comment that I made earlier, there was a pretty strong sense of the group that the NVEs should be left to determine which transport mechanism is preferable for the clients they serve and for the use cases that they're involved with. So, one could imagine a set of interoperability CTEs, for example, that are lined up with particular use cases; let's say at public health, lab results delivery, some re-document exchange and then, a set of standards or implementation guides related to each one of those, and, that an NVE would essentially choose which CTEs they would want to adhere to, and then make transparent or have NwHIN governance process make transparent, so that they're only having to be validated or certified against the use cases that make sense for them. With regard to...

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

Micky, a kind of clarifying question on this, are you saying that certain...the validation...governance process as a whole would provide for potentially different transport mechanisms for different use cases, for example, lab or public health; or that an individual NVE could choose, and presumably different ones could choose differently to facilitate a given use case in which case the... If I wanted to... if I'm a provider who's using one NVE, I would need to check with another provider, you know, kind of are you on the nice ATM network or on a different ATM network, in order to see if this is going to work?

Micky Tripathi – Massachusetts eHealth Collaborative

No, I think the idea here, and I don't think it's captured fully in the language, so I apologize for that. I think the idea that we had discussed as a workgroup was that there would be specific use cases and then the governance process, through some type of process, and maybe it's aligned with the process that's used for determining the standards for the EHR certification requirements, would for a particular transaction, let's say it's for lab results delivery, would specify that HL7 2.5.1, for example, is the standard for that, so that... so it wouldn't require that an NVE...that every NVE be required to meet that standard, but it would require that if they are going to deliver lab, they use that standard and that that be a part of what is made transparent and available for the market, so that those in the market understand which use cases each NVE is essentially qualified for under the NwHIN concept. Does that answer your question?

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

It does.

Micky Tripathi – Massachusetts eHealth Collaborative

So in recognizing this, and then the other point would be that for any use cases/standards/implementation guides that overlap with a meaningful use transaction that's specified in either the 2011, I forget which year that was, and the 2014 edition, that those be synchronized so that if there is an overlap there, that we use the one from the EHR certification so that there's no misalignment there.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay, great.

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

I would just ask then Micky, if the wording here could be word-smithed a bit to provide clarity around that, that it's not at the NVEs discretion to choose which mechanism they choose for which use case.

Micky Tripathi – Massachusetts eHealth Collaborative

Sure.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay. Go ahead.

Micky Tripathi – Massachusetts eHealth Collaborative

Okay, so we're on question 46. So this, I think, just goes back to the previous one. There's not necessarily any reason at this level to be for or against a secure RESTful transport, but the question would be, to having a process that would actually...because as we know, that's more an architecture than it is a standard right now, but to the extent that there is a process for validating that as a standard and having an implementation guide that is actually actionable that ought to be just like any other standard made available through this process for NVEs that choose the particular CTEs that would rely on that.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay.

Micky Tripathi – Massachusetts eHealth Collaborative

Okay. So moving to question 47, there didn't seem to be any concern, at least on the part of the IE Workgroup about whether VNS or L-DAP or appropriateness and sufficient in this case. There was a concern more about... you know, about this question of... about having one or the other, it think is probably the best way to sort of frame that. Again, I think it was more just a question of having it line up with whatever is going to be coming out of the certification process related to EHRs, so that to the extent that there are points of overlap, they are absolutely consistent.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

No objection on this end.

Micky Tripathi – Massachusetts eHealth Collaborative

Okay, question 48. I think we actually talked about this before when we were talking about the authentication. And as I said before, there was agreement that the interoperability CTE that ought to be consistent with policies of the Federal certification authority, but that they ought to be able to use a market-based approach with Federal guidance for establishing policies pertaining to organization or group digital certificates. So again, I know that there's sort of a big issue there, but there was a sense that the organization level certificate, barring any other policies in that regard, would be the appropriate level.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

So Art wanted to say something, I don't know whether it's this one or the one before.

Arthur Davidson – Denver Public Health Department – Director

Yes, it's on 47. Micky, that last bullet there where you say as long as congruent with directed exchange, does that mean that we think that one NVE will speak to another NVE through directed exchange?

Micky Tripathi – Massachusetts eHealth Collaborative

That one NVE will speak to another NVE?

Arthur Davidson – Denver Public Health Department – Director

Or make queries from one part of the country to another?

Micky Tripathi – Massachusetts eHealth Collaborative

Well sure, why not?

Arthur Davidson – Denver Public Health Department – Director

Or is that the... I just wanted to know if that's the only mechanism we think will happen. Is connect not going to be part of this as well?

Micky Tripathi – Massachusetts eHealth Collaborative

Yeah, sure, it could be. There's no reason that it couldn't be. We didn't mean to exclude that, I think it just was the way that the conversation sort of unfolded.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

So you might want to provide some clarifying text, just to help Mary Jo.

Micky Tripathi – Massachusetts eHealth Collaborative

Yeah, no, I apologize for that, we didn't mean to exclude that.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

No problem.

M

Are we on 49?

Micky Tripathi – Massachusetts eHealth Collaborative

Let's see, ah yeah. So on this one it think the workgroup felt pretty strongly I think, that... we didn't think it was really appropriate to be establishing universal accuracy level or minimal error ratios or what have you, that there are certain cases in which the matching... in which the use cases aren't a part of what the NVE is doing and there seemed to be a fair amount of openness in the market. I think the Tiger Team has also been noted as well, and we're pretty aligned with where they landed, that it sort of too premature for any specification of accuracy levels at this time.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay. 50? Take 50 and 51 together.

Micky Tripathi – Massachusetts eHealth Collaborative

Let me just jump ahead here and make sure I've got this right.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Sure, David Bates wants to make a comment.

David Bates – Brigham & Women’s Hospital & Partners Senior Vice President for Quality and Safety

On 49, would it really be unreasonable to establish some sort of lower bound? I understand that things are getting better, but, it...

Micky Tripathi – Massachusetts eHealth Collaborative

Yeah, I don’t... if Paul is still there, I would love for him to weigh in on the Tiger Team perspective on this, but we had a pretty limited amount of time to discuss this, and I know the Tiger Team spent a lot more time on it and I wouldn’t want to just sort of characterize it. If we had had a very robust discussion on it and could say that the workgroup had a very clear view on whether there ought to be any sort of levels or specifications of accuracy or a lower bound. But I know the Tiger Team spent a lot of time talking about this.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

So Paul Egerman is not here right now, but I’m guessing there’s a market pressure to not be bad. Yeah, Larry.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

So, I’m reminded of the conversations we’ve had of this in the past and the higher concern was about data quality on the identifiers; so, if we’re not getting a good patient name capture, patient date of birth capture, patient address. You know, if we’re not getting good information about the basic identifiers on the patient, then the matching quality is going to be up in the air. And if we were to focus on something that was going to high reward, we should focus on getting good data and standardizing the data sets that we’re working with, rather than focusing on the algorithms at this point.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay, so I think we’re... does that cover 51 as well, the standards?

Micky Tripathi – Massachusetts eHealth Collaborative

Yes, I think it does.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

You want to go to 52 then?

Micky Tripathi – Massachusetts eHealth Collaborative

Okay. Yeah so, on this one we spent a fair amount of time talking about this one, and what we did was, we referred to basic general concepts of net-neutrality to help us think through this one. And the basic idea here, and it’s captured in the bullets, but the basic idea is, sort of following on that broader net-neutrality conversation, that’s happened sort of across many industries, is that there ought to be a basic sort of set of dial tones, whether you call it a floor, a dial tone, whatever it is, but the basic idea of there being a basic dial tone service that ought to be made available across NVEs, and for which no fees are charged and no other barriers placed; so that that core set of exchange capabilities or, dial tones, would be absolutely fluid across all of the NVEs. But that that framework should not prohibit NVEs from being able to charge and offer for charge value-added services, that would be on top of those basic dial tone services.

Now obviously there would be some work in determining what those dial tone services are, but one could certainly build on what the basic component of direct, for example, as being sort of one foundation for that, of being able to send/receive messages according to wherever we land on the 2014 edition for transport, plus access to provider directories, plus discoverability of security credentials. That might be at least three core elements and one can imagine building on top of that. And recognizing this to be dynamic, and so there’d need to be a process for revisiting and refreshing that concept of dial tone, because it could be that as we get to a place where business, legal and technical standards make query retrieve... more practical in the market, that one might want to add those things over time...right now. So in general, there was a strong sense that there ought to be this basic dial tone set of services that follow

on the net-neutrality concept, but not prevent organizations from going further with value-added services, if they are allowed to charge each other and still qualify as a validated entity.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Judy.

Judy Faulkner – EPIC Systems – Founder

We're on 52?

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

We're on 52.

Judy Faulkner – EPIC Systems – Founder

A question then for the use of software where the healthcare organization is sharing with another healthcare organization and it's not an HIE with a repository, some of the vendors will charge for that exchange, is this covered under that or not? Under certain circumstances.

M

Charge who?

Judy Faulkner – EPIC Systems – Founder

Charge their own customer.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Charge their own customer?

Judy Faulkner – EPIC Systems – Founder

But the customer could be an NVE...yeah, because we're getting in to that whole definition of what an NVE is.

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

I think this whole section is talking about how NVEs relate to each other, in their roles as NVEs.

Judy Faulkner – EPIC Systems – Founder

Well, earlier we were defining that an NVE could be as a software vendor and the NVE could be the healthcare organization, so, it is how they relate to another if you look at it that way.

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

Um, healthcare organizations like the VA might be NVEs, choose to become NVEs, large delivery networks. EHR vendors may choose to become NVEs, and provide NVE services. And this is meant so that no NVE need necessarily be the entire network end-to-end, which is the situation where unfortunately we have today, but to be able to have one endpoint use one NVE, the other endpoint use a different NVE. And this is talking about how NVEs talk to... not just talk to each other, but transact business with each other. So, I think that the main issue here is, in order... if I'm an NVE acting as an NVE and I'm passing a message to you on behalf of my user to you to deliver to your user, that passing the message should not have to be accompanied with passing a folded \$20 dollar bill also.

Judy Faulkner – EPIC Systems – Founder

Okay. However, it has been said that the software companies may be NVEs, and it has been said that if the definition of some of the NVE responsibilities are things such as you have to alert your patients as to what's going on, that the healthcare organization who is doing that using that software, is also perhaps an NVE. That's what was said earlier.

Micky Tripathi – Massachusetts eHealth Collaborative

But I think this was... of their role as an NVE, not as their role as a software vendor or provider organization.

Judy Faulkner – EPIC Systems – Founder

All right. Thank you.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay, that sort of covered 53 as well?

Micky Tripathi – Massachusetts eHealth Collaborative

Yup.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay, so we're on to 54.

Micky Tripathi – Massachusetts eHealth Collaborative

So the following... concept then we could have bundled some of these together, but this is basically saying that there shouldn't be any prohibitions on imposing requirements on other NVEs when we're talking about value-added services. But again going back to the net-neutrality concept, we did not want barriers to be created that are non-financial barriers, but are barriers nonetheless, to preventing the free flow of information for those basic dial tone services.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay. Okay, 55.

Micky Tripathi – Massachusetts eHealth Collaborative

Yeah sorry, let me just catch up to where we are here. Okay, so on this one, we had a little bit of conversation about it, and it's somewhat similar to other conversation I think we had earlier in the day which is, trying to strike that balance between an obvious societal interest in having transaction volumes and various types of information reported so that we can start to track it from a population level, what's going on. But, also wanting to be sensitive to the interests of any particular NVE who may see some of this data as proprietary and that this would then be a barrier for their participating. So, the idea was that the reporting standards ought to be transparent to both the public and the NVEs to ensure their participation, that it should be de-identified from an NVE perspective. So not reporting that it's this NVE in particular, but be able to aggregate at whatever level is appropriate; recognizing that there is a value in measuring the progress on a national, regional and perhaps even statewide level. But again, those levels of aggregation that don't reveal that NVE-specific information would be the concern there. And so, that would relate both to sort of the transaction volumes at an NVE level, and perhaps the type of transactions facilitated for specific NVEs. There was a fair amount of back and forth, I think, in the workgroup on this question, but I think that we have a fair degree of consensus on this point, once we talked it through.

M

Why would the NVE data be proprietary? I'm not sure I understand that one.

Micky Tripathi – Massachusetts eHealth Collaborative

I think it's related back to the question though, for example, revealing your customer lists. Once it starts to get down to that level, it could be that there start to be concerns about, what is being made available that might sort of have competitive consequences.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay. So now we're on to 56.

Micky Tripathi – Massachusetts eHealth Collaborative

Yeah, I think on this one, the only ones... the only one that we really had was the one we already talked about before, which was about a structure and a model for grievances, and I think a number of the other workgroups, both Governance and the Tiger Team identified this as well.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay. So 57.

Micky Tripathi – Massachusetts eHealth Collaborative

I don't think we had one on this one.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Ah, let's see, Privacy and Security... Paul's not here either... so there are no comments on the performance and service specs.

Micky Tripathi – Massachusetts eHealth Collaborative

Nope.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

And 58 is, should the above CTEs as well as any others be considered for the NPRM?

M

This is 58?

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

I think we already covered that actually. So we're jumping ahead as already said, to 63, perilously close to getting there.

Micky Tripathi – Massachusetts eHealth Collaborative

Yeah, on 63, not surprisingly, the best way to provide CTEs guidance on some stuff is to provide funding for pilots. No better way to get attention and to get focused attention, in particular. So, I think in answer to that question, what would be the best way to help facilitate the pilot testing and learning necessary, absolutely support pilots and think that funding specific pilots related to leading edge kind of concepts to test the market feasibility would be the best way to do that.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

...tossing in another thought here. Since we're talking about this being a voluntary process, and that we're imaging lots of other models evolving in the marketplace, perhaps this is a place where we might actually look to the marketplace to see what's evolved, so there may be examples "in the wild" if you will, of people innovating, trying out new things that we're going to be looking to identify. And so I think it shouldn't just be what are we inventing, but there should be an active scanning of the environment looking at models as they develop so that there's a chance for them to get recognition and bring them on board.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

This is not exclusive, of course.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

... to this. We shouldn't imagine that only things invented here count, we should, especially since we're looking for a voluntary program and we're expecting others to be doing things

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

Most things invented here weren't invented here (laughter).

M

Just debated.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay, 64.

Micky Tripathi – Massachusetts eHealth Collaborative

Did we have anything there, let me go back. I don't think we had anything.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

So we're now up to 66 then.

W

Is that the last one?

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

I think that's the last one...now we've got the new assignment.

Micky Tripathi – Massachusetts eHealth Collaborative

There are a lot of words here, but I think it's less complex than suggested by the number of words. So why don't I just summarize and I can just take this point by point. So the first one is that related to the cost of validating, and I think that in looking at it, holding everything else constant, recognizing that there could be a lot of movement around different CTEs and that would change the concept of what NVE validation would be. There's just going to be... there's a lot of variation out there, it's going to depend on the range of services offered by the NVE and which CTEs apply to these services. So it's very hard to say what we think the cost of it would be in general and could only really offer... and it shouldn't be a surprise that, unless the costs are reasonable and minimized wherever possible, that would just create a barrier to participation, unless there are other strong incentives to get organizations to want to do this. Sorry?

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

No sorry, go ahead.

Micky Tripathi – Massachusetts eHealth Collaborative

Okay. So, I think on this one there was a question on... let me just make sure I've got the questions right. Okay, so this was the potential savings to states or other organizations and whether that would happen. Well, in general, I think thought was that for those states that are going to... that in a sense there's probably three categories. One category is the states who either already have or are considering pursuing their own accreditation process, and to the extent that there is an overlap between what ends up becoming the set of CTEs in this process that would cost you the validation NVE, except if there's overlap. If there's complete overlap, then yes it reduces the cost and reduces the burden on them. The second category would be those who have not contemplated doing this and perhaps may not. This would offer, arguably, some kind of benefit, but there was no real cost that they were going to sort of have anyway, and so it doesn't necessarily reduce the cost.

The third category were those who are going to do this anyway and we thought that it was probably the case that you would see this breakout more functionally than anything else. What I mean by that is that as it relates to sort of think of business processes, safeguarding and the other category. But, it would be mostly in the... and interoperability, that it would be mostly in the safeguarding category, particularly related to privacy, that you could see individual states still feeling the need to have additional kinds of conditions of trusted exchange that are specific locally, because of the lack of alignment, with Federal and state law. But that we could see that it could provide some type of relief in terms of cost or burden, when you think about business processes and interoperability, which I think most states don't want to get involved in if they can avoid it.

There was a sense that... this is, I think, lumping 3 and 4 together, let's say, that in the... I should mention that the person who headed this subgroup with this set of questions, was himself with a vendor, so this is from a vendor perspective; that there was a sense that, again, assuming that the CTEs in general and the entire concept is at a level that doesn't have significant barriers in the way of cost and in the way of any significant... any individual CTEs that are seen as a barrier, but that in general the concept that it actually could be quite a spur to the market and that there could be hundreds, if not thousands of organizations that would ultimately seek to get this kind of NVE validation. In part, just based on, I think, an earlier comment that Larry Wolf made, that as Kindred Healthcare, for example, is looking across the country, that this type of process may not answer all of their questions, but the extent that it provides a floor, I know Neil doesn't like that word; but the idea that there being at least a floor that they would understand that every organization who is asking for their participation, if they were a validated NVE, knowing that would arguably help with their being able to move forward with thinking about... various types of exchange activities across the country.

Again, we did come back in this question to our pretty strong sense that having this prohibition of use on de-identified data would have a chilling effect. And so we offer that as a caveat, that adding that perhaps along the lines that were discussed earlier in the day, would be the one caution I would offer, that would make us really rethink whether we were going to have hundreds of thousands participating if we have too big an imposition of requirements related to the use of de-identified data for commercial purposes, without very clearly defining what the process is and what those terms mean. The very last question was, it's very hard for us to make an estimate on the application and reporting burden, because it's just going to vary widely. So, we didn't even want to offer anything there.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Well thank you for a great job at working on this cost issue, and I'm sure that the ONC is very appreciative of this work, because they have to go up and justify it to OMB. Any other comments on this? Okay, well thank you very much Micky. Oh Christine, I'm sorry, I didn't see

Christine Bechtel – National Partnership for Women & Families – Vice President

I probably had it pointed the wrong way. Just a few... I'm wondering on the funding, we haven't had that as a precedent for meaningful use in general, and I do believe there may be NVEs who are healthcare organizations and NVEs who are vendors who would be willing to step-up and do it without funding, so I'm wondering if you want to try that first, if it's just the pilot, to see if it works. So, that is my suggestion, that it's not maybe necessary to do the funding. And I want to comment on the comment about chilling effect on not allowing commercialization of the data. I do think that we have to separate it from when in fact healthcare organizations are going to be automatically charged for an HIE in their environment, that might... In other words, the healthcare organization has to have a choice. If the organization itself doesn't want to have their data commercialized, but they are charged for it, that puts them into a very awkward situation. And I have... I know of a number of organizations in that situation; they may not have to use it, but their charged for it, and I think that becomes a big problem, if they don't believe ethically that that's what should be done.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Yes, Larry.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

A quick closing comment. From talking to some folks involved with HIEs, one of the consistent requests I get from them is that ONC develop some kind of roadmap that says where they're going, so that sort of is their underlying question I keep hearing is, "okay so we see this RFI and we're imaging that there's going to be regulation, but is there an overall sense of where are we going, what's the macro architecture we're working under, what's the kind of the vision of where we might be in a few years." And I know some of this is, we want things to emerge in the marketplace, so I think that might be an acceptable piece of the answer. But, where in fact there is a specific vision or where this is going, so some of this is around is direct the only transport, and ONC said "no, direct is not the only transport." So some of this might just be reinforcing messages that are already out there, but I think that there is sort of a... There are things like we've spent a lot of time talking about today that are putting people on edge, and they're saying, "okay,

so if my business model is up for grabs, where are we going, what is a stake in the ground," if you will or a direction that's being set by ONC and can we get some clarity around that that's maybe bigger than a regulation... broader than regulation.

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

So, it's often said that you can't communicate enough, and we've, I think it's a good opportunity for those who are listening to hear it again; but I would refer them to the March Health Affairs article where there's a deceptively entitled article which is, "The National Strategy for Health Information Exchange," from the Office of the National Coordinator, which attempts to list this. I also note that we've been joined by Secretary Lansley, and we want to move into the next portion of our program. But I will summarize, very briefly, in terms of how this, and Secretary Lansley may be interested in hearing, what we're talking about today is an approach to beginning to support all three mainstays of the strategy for health information exchange. It is quite clearly not going to be a one size fits all, but by establishing a series of building blocks on standards for building blocks around content, around messaging and around transport standard; but also building blocks in terms of trust. This is a building block that helps establish structures where trust can emerge and we anticipate three different models, architectures as you put it, for information exchange to occur.

According to the needs of the situation, and all three are okay, and all three will draw on many of the same, but not an identical set of building blocks. Those three are first, ubiquitous directed exchange, directed push and potentially directed queries, where the endpoints are known. It's part of care that is directed by the patient, it's directed by the providers; I'm sending you a referral, the patient is discharged, all those transactions that currently take place inefficiently and with faxes and paper, as it is not smart data. So, that is part one, ubiquity of those capabilities including addressing, through this rule, some of the main limitations to its scaling that we've heard about. How do we deal with security certificates? How do we deal with open phone books and directories for identifying? And how do we deal with rules of the road for how that's going to occur? That is one band.

The second band is going to be more complex sharing of information including queries that pull information not from a single centralized approach, but rather from a multitude of local approaches, Affinity Networks, Integrated Delivery Networks, Health Information Exchanges, the noun, regional health efforts: a variety of ways, organizations that have sufficient trust to implement the query, broadcast query, pull approaches, which we hope will grow over time. They too will draw on some of the same building blocks around security certificates, around the rules of the road which may, as we heard today, be different, around the phone books and so forth.

And finally, and I think of particular interest to the Secretary, we are quite interested in a third model, which is not a business to business or business to community model of exchange, but rather mediated through the consumer themselves; information exchange mediated through the patient, where the patient can choose to be a centralized repository of one, they aggregate their information. If they wish to, they can assemble that information through ever easier ways of aggregating through blue button, automated blue button, pushes to their electronic medical home as it were and having them share information with who they please. Those are, as we have laid out, the three parts of our information exchange strategy; ubiquitous directed exchange, Affinity Networks that grow over time for query response and then a safety net, as it were, for those individuals who choose to be or have to be, unfortunately sometimes, the medium for their own exchange. So Larry, I urge your friends to read the paper, but that's the Cliff Notes version.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

And maybe if I could just offer a word of thanks to the committee members, the workgroups and all the hundreds of volunteers and volunteer hours in putting together such a rapid response to the RFI and for achieving our goal of getting through the 66 comments and getting, I think really we have only one that's a bit more outstanding, which is the commercial use, and we'll try to do what we can in terms of offering insights and feedback, and we'll certainly get a chance at the NPRM stage as well. So thank you very much for everybody's work on that.

Robert Anthony – Centers for Medicare & Medicaid

Do you want me to talk about...

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Rob, we have about 10 minutes, so, this is... we're going to have a much more expanded feedback at the next month, this one we're trying to hit the high points to share with the committee, but also to inform the Secretary on the success of the Meaningful Use Program.

Robert Anthony – Centers for Medicare & Medicaid

I'm actually a short of amazed that you guys are only 15 minutes behind schedule with everything you had to discuss today. I'm going to try and put you back on schedule. There's a lot more information in these slides for people than we're actually going to review, but I did want to make it available. I did want everybody to know that we'll have the slides there not only available on the website with this meeting appointment, but they are also going to be available on the CMS data and reports website from now on, so people will be able to take a look at it. So this is a status report of where we are officially as of the end of April and I have some draft numbers for as of the end of May, and talking a little bit about the attestation thresholds that we have for the Medicare EHR Incentive Programs for Meaningful Use, and I will go over some of the registration and payment data very quickly here.

The registration does continue to be fairly consistently high, last month we had about 14,000 providers who registered for the program, this month a little over 12,000; it puts us at a little over 238,000 as of the end of April; a little over 70, actually 71% of hospitals that are eligible to participate in the program have registered to participate in the program, and we are fast closing in on half, 50% of all eligible professionals being registered for the program at this point. So, in the past we've done a little bit of a chart line graph to show how things were, it started off when we first discussed it as sort of a hockey stick. We are sort of reaching the point now where it is more of a plateau, in this case that doesn't mean that the patient is dead, it means that the patient is surviving quite well. You can see 2011 we had almost 124,000 EPs on Medicare, almost 50,000 on the Medicaid side; and as you can see, we have some fairly consistent figures month to month, we get a little bit of a predictable bump in January and February because we have a number of people who came in before 2011 to attest who registered and attested either on the same day or very close to each other.

And this is just the overview of where we were with April Meaningful Use payments. All of the Medicare payments are for providers who are actually meaningful using EHR technology and hitting all of the objectives. Medicare paid about \$340 million in March alone to over 8,700 providers...I'm sorry, in April alone, to 8,700 providers. We paid about...a total of \$603 million payments, incentive payments in March, and we shall see when we add up the April and May, we're fairly close to that as well. So, we're being fairly consistent in the amounts that are being paid. We are still in April, and as you'll see in some of the May figures, processing some payments for folks who were being paid for the 2011 payment year. So, we're still seeing the end of 2011 and what Meaningful Use for 2011 actually looks like.

This is just a breakdown by specialty, I think most of you have seen something like this before. Not surprisingly, most of the Medicare participants are Family Practice, Internal Medicine. There isn't a huge number of change, but again, the encouraging thing is that we're seeing the number of specialties participating fairly consistent on this. Again, this other category looks rather large and it represents a lot of things; it represents people who haven't necessarily indicated a specialty to us, and sometimes it indicates some folks who are in specialties that are smaller...too small to actually make this list for us.

And then I did want to include here, just a month to month, so that you can see what the payments are. Again, we did this as a line graph before and you can see that we're sort of evening out on the number of payments with some hikes in the end of February or November/December, the two months following the close of the fiscal year for hospitals, but otherwise, we're sort of reaching an even keel as far as to how much we're paying each month in incentive payments. And this tends to hold true on the Medicaid side as well. We did about \$250 million in Adopt, Implement, Upgrade payments in March, and now we have close to \$200 million for both Meaningful Use and AIU in April for Medicaid, although as you can see, the number of Meaningful Use for Medicaid is fairly small. Partially this is because it's the first month that

EPs could have been meaningful users and partially it's because not all of the states have the systems up for people to actually do Meaningful Use Attestations. But, we're still seeing some pretty high participation rates on the Medicaid side; so, we've got a number of people who in 2012 are going to continue coming in for first year participation of Adopt, Implement, Upgrade. And again, this just shows the number of payments, month by month, on the Medicaid side and as you can see, we started with the then quite exciting, but now appearing fairly lowly figure of about \$700 some thousand way back in January, up to evening out at around \$81 million for eligible professionals and about \$117 million, just this month, for eligible hospitals on the Medicaid side.

So altogether, we've done about \$540 million as of the end of April. We have paid out, as of the end of April, a little over 94,000 eligible professionals and made about \$5 billion dollars in incentive payments. This is not a complete picture of what 2011 looks like and as you go forward, you're going to see both a 2011 program year column and a 2012 program year column so we can break out and we can see year by year which things are looking like, and we'll have a fuller sense of what 2011 actually closes on, as we go through the next couple of months. But we talked a little bit about this last time, and I just wanted to highlight where we are and as of this point 45% of all eligible hospitals have received an EHR incentive payment, either for Meaningful Use or Adopt, Implement, Upgrade. So that means that whether they are meaningful users or not, we have 45% of eligible hospitals in the country have made a financial commitment to having an EHR in place.

We have now approximately one out of every seven Medicare EPs are meaningful users of EHRs. Last time we reported on this it was one out of every nine. We're starting to see more and more coming in in 2011. We are at one of every 5 Medicare and Medicaid EPs total have made a financial commitment to an EHR so they've received a Meaningful Use or Adopt, Implement, Upgrade. And this figure at the bottom is holding steady, the percentage of Medicare EPs who are receiving an incentive who are specialists. Actually, we often hear the complaint from folks that this program is really geared towards primary care, but in fact, we have almost 60% of the people who are meaningful users at this point who are participating who are not primary care.

So these are just draft numbers for what we have for May. You can see a little bit of number downtick for Medicare EPs, it's only about 900 it looks like for May; that is sort of in line with what we saw last time, in 2011, and we'll be watching in the coming months to see if that holds true. A lot of people came in towards the end of the year. Obviously, people who are coming back for 2012, we won't see them until the beginning of 2013, because they will have to do their entire year. But for people who are coming in brand new to the program, doing their 90 days, these are really the people at the beginning of it and if 2011 was any indication, a lot of those people tend to come in towards the end of the year or the last quarter of the year. One of the payments we did make this month was for Medicare Advantage Organizations; we paid over 11,000 eligible professional incentives for Medicare Advantage Organizations, and that represents about 9 Medicare Advantage Organizations at this point. About 4,300 Medicaid EPs and 200 hospitals for a little over 16,000 providers paid in May, so an increase over what we saw in April, about \$550 million in incentive payments paid, which is consistent with what we saw in April, and puts us at a little over \$5.5 billion paid total for the EHR incentive programs.

I won't go through a lot of the attestation data, but I just do what to highlight, we've got almost 70,000 EPs at this point in time, almost 1,300 hospitals. The data that you will see has not changed significantly, we're looking through all of this to see what the 2011 Meaningful Use picture looks like. We do often get asked, well what does the data show us about the barriers that people face with Meaningful Use. And this is why we highlight this bottom number under EPs, the second bullet, for folks who are unsuccessful. Out of almost 69,000 eligible professionals who've attested, only 277 have been unsuccessful. And out of those 277, 167 resubmitted and were successful in their attestation. So, we really only have 110 EPs that have been truly unsuccessful and that means that the attestation actually isn't telling us a whole lot about the barriers that they're facing. However, we're going to talk a little bit next month about what some of the RAC data, what some of CMS' field survey data has told us about some of the challenges that people are facing. All of the hospitals have been successful.

As you go through this data, please keep in mind that there's very little Medicaid meaningful use data here, so we're really looking at a picture of meaningful use for Medicare, it may change as we get more Medicaid data, but as you saw from the other slide, there's only about 20 EPs that are represented in all of this data. I know you've seen this over and over again, overall we're seeing very, very high thresholds, but there are always people who are at the borderline on things, not a big difference between EPs in hospitals, not a big difference in specialties in how they performed. As I said, the data is going to be available on our website.

We did highlight what the most popular menu objectives were for EPs and hospitals to choose and we did highlight which were the least popular menu objectives. I think that there's not been a significant change from what we have seen in the past. But as you go through this, we did break out all of the recording objectives so you could see what the high thresholds really were. It looks like we're closing in on what the picture of 2011 Meaningful Use is. We are now at the tail end of folks that are coming in, we've included those attestations as we look at the averages and it doesn't appear that the people who are coming in at the end were performing significantly lower in any way than the folks who were coming in in the beginning. Again, as we discussed, it's not quite sure whether that means that once you're a meaningful user you're a meaningful user or whether these are the folks in 2011 who were most situated to come in and incorporate this as workflow. So, once we have this 2011 snapshot, one of the things that we're going to want to do is start looking at 2012, and the folks who come in for Meaningful Use, and see if that differs in any significant way. So, I won't go through all of these, but they are available on the ONC website, they'll be available on the CMS website. And I will say that from when we presented this last time, none of these values changed more than 2%, so, there really has been no significant change. And I think that was almost exactly 10 minutes, so...

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Very good. Thank you very much Rob for your outstanding...

W

I have a question.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Just one because I want to...

W

Just one quick comment, I know last time we had asked to get percentages of all eligible providers, all, so that we could put into context. You know, if you're saying 50% of all eligible providers have received some kind of payment at this point, you know, could you break that out across the board and just put another column in so we can see the percentages of all eligibles out there, especially in the specialties, you know, how many in the specialties, specifically.

Robert Anthony – Centers for Medicare & Medicaid

I don't know that we necessarily have a breakdown by specialty, numbers by specialty, but we would have a breakdown by all eligible professionals, and it was published in our Impact Analysis. And I do want to clarify, we have almost 50% registered, it's only about one out of five at this point, that have received a payment, whether that's Meaningful Use or Adopt, Implement, Upgrade.

W

Correct. If you can put that within the context of the report.

Robert Anthony – Centers for Medicare & Medicaid

Sure.

Judy Faulkner – EPIC Systems – Founder

You know what, that's referring to eligible providers. The provider denominator is... I think, especially if you look at... is much more than this number, so have you looked at back data at all?

W

These are people that are seeing Medicare, Medicaid patients, I'm assuming that's how you're defining eligible.

Robert Anthony – Centers for Medicare & Medicaid

Yeah, the definition of eligible professionals is people who fall within those different classifications that we have, primarily doctors of medicine and osteopathy, although I should say doctors of dentistry and dental surgery, chiropractors and so on the Medicare side. On the Medicaid side its physicians, nurse practitioners and so on.

W

I'm just wondering about the...

Robert Anthony – Centers for Medicare & Medicaid

And it would be folks that have some kind of Medicare or Medicaid patient population.

W

Right, so that's... so, I'm wondering if you have that data. So if we have a total of 238,000 providers, that 51% of eligible, we know that the number of providers in the country is more than 500,000 or 450,000, so I'm just wondering that percentage. You might not have that data because it's coming from CMS.

Robert Anthony – Centers for Medicare & Medicaid

Yeah. We didn't include that as part of our analysis. I'm sure that we could take a look at some figures from other organizations.

W

What would be interesting to see if there's any difference in terms of EHR penetration in people that are not in this cohort of EPs, but are providers overall.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

And the main result of that would be that the Meaningful Use... the Health IT incentive program is working, is increasing...

W

If we had the data..

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

...the increasing rates of adoption. But I'm not...I think we need to judge the program on what it's intended group that it's intending to reach, while recognizing that there are going to be folks who are not eligible for the incentives and we would not...

W

Well, and what might be fascinating is the people that aren't eligible are actually because they're not caring for Medicare and Medicaid patients, have a different demographic and actually have more EHR penetration. I mean, I don't know; I think it would be an interesting analysis and it would prove the impact if it showed more penetration.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Very good. Thank you Rob. At this point, want to give the Secretary some time, also wanted to provide you a little information about this group. So this is one of two Federal Advisory Committees that was created by the HITECH provision of the Stimulus Bill back in 2009, and it really is to...one of the main things is to promote the more accelerated adoption and Meaningful Use of Electronic Health Record and Health Information Technology more broadly, as you are doing in the UK. The group around the table represent health systems, physicians, clinicians, payers, health researchers, public health, vendors; so a very wide and diverse group and that's provided rich discussion for us. And I'd have to say... and people

generously donated the time, we have a marvelous relationship with the Office of the National Coordinator, with... more broadly and the amount that have been accepted of some of the recommendations we make, and the feedback has been wonderful, I would say. So, this has been a very high performing group.

Beyond the Committee there are workgroups that involve even a broader range of experts that contribute and feed up through the subcommittees, the Committee and contribute to the work and recommendations from the Committee. Just today we went through 66 questions that were posed in a Request For Information from the National Coordinator regarding Governance of the Nationwide Health Information System, and again had a very rich conversation about that. The types of things we have been working on, one of the biggest one has actually been Meaningful Use, because that's almost a \$30 billion dollar program. To put that in perspective, the previous Office was funded around \$50 million dollars a year. So this is a huge program, it's really moved the country, I think everyone would say. You've heard some of the success and the acceleration of the adoption and the use of this technology.

We also work on health information exchange, something that we think doesn't move without the public sector, so that's another big effort for us. Some of the foundational things like Privacy and Security, a concern throughout the world, is something we try to tackle head on, because as Farzad mentioned, data flows at the speed of trust. So that is something that we really work on. And then there's a clause in HITECH that sort of amounts to other duties as assigned, because it says any other HIE that helps quality and efficiency, have at it. So, we have a broad scope of things that we work on. But I think it's been a very mutually beneficial relationship we've had with the Administration, with the Office of the National Coordinator, and I'll mention the five categories of Meaningful Use, because it feeds right into your talk.

So the framework of Meaningful Use was around five categories. The first one is to improve quality, safety and efficiency of healthcare, but also to reduce healthcare disparity. Something that the systems weren't able to do before Meaningful Use, in a sense. The second one I think will appeal to you, which is patient and family engagement. So although this started out as an EHR initiative, we rapidly turned it to make the patient part of the health team and so they should have fair and equal access to their health information and the same decisions or tools that will help them be an effective partner. The third category is care coordination, something that doesn't happen almost without electronic systems, but, we still have to improve the electronic systems and their exchange of data to make it happen. And the fourth one has to do with public and population health. We're trying to create that interface and exchange so that almost in a bi-directional way, the public health system can know what's going on in the public and the treatment of individual patients can be informed by what's going on in the population. And finally, to reinforce the fact that privacy and security is foundational, that is a category that we have, part of a condition of getting your incentive payment. So those are the... I think that fits right into your remarks and it's a privilege to have you here and thank you very much.

Andrew Lansley CBE, MP – United Kingdom's Secretary of State for Health

Thank you very much, and thank you Chair and indeed Dr. Tang, thank you for the introduction. Thank you for the opportunity to be with you. I realize it's a particular privilege from my point of view to be here and the chance to hear a little of what you're doing, and indeed to read about what you're doing. And I know my colleagues who are here with colleagues from Department of Health and Human Services and your office and others, the opportunity to share in some of these issues; because while we have health care systems that obviously have significant differences in terms of how they're structured and funded, as you may begin now to look at what we've done over the last few years, and some of how we deliver, as you say, how we deliver greater quality, how we integrate care more effectively, how we mobilize information as a resource and how we empower patients. Those are things that are really not fundamentally about those issues.

From our point of view, we're aiming for a system that continues to be highly equitable, but one which achieves excellence, and achieving that excellence is not about a service which simply gives people the same thing, regardless of their needs or wishes, but something that's very responsive. You have a system which in many respects has been very responsive, but actually has found it quite difficult sometimes to be equitable. Now I think we're all aiming for the same thing, we're all aiming for something that's both highly equitable and something that is excellent, and not to sacrifice ever one for the other.

So, from my point of view, of course when you talk about trying to secure the benefits of increased investment in information technology to support health care systems, my predecessors certainly subscribed to that view and back in 2002, they set out on a path of a centralized procurement, because we have a central healthcare system... centralized healthcare system.

I'm afraid what it demonstrated, I picked up your Chair's view that a one size fits all solution was not the right answer and so indeed, it turned out to be. Our one size fits all systems simply did not deliver for us. We got some things in place, we got, for example a network across healthcare providers and family practices, a spine for the transfer of information. We've got a system for the transfer of digital images, we got a system for our ability to, for example, to process prescriptions, which we of course manage centrally. So we can do those things, because those are the sort of things you can really grab hold of as an IT system. But when it actually came to the functionality of empowering patients and clinicians, a top down system didn't respond to the users and you've got to have a user led system. So, over the last two years, we've very much been setting out to use the contracts we've got, to vary them to deliver something which is much more flexible and responsive to the healthcare providers themselves.

Now from my point of view, two years ago, when we came into office, what we set out to do amongst the range of things, by way of reform, was to put patients right at the heart of how we designed the future of the National Health Service. The principle we adopted, I didn't invent it, it was Archibald Picker who first said it was "no decision about me without me," and so, shared decision making between clinicians and patients is absolutely instrumental to this. Part of it, of course is nothing to do with IT as it were, it's actually about just thinking about this as a cultural response. And I think I would say that one of the things I think I have felt most strongly is that up until recently, we had as it were an IT strategy, we didn't have an information strategy. And what we published following all this extensive consultations on it, we published just over a fortnight ago, was an information strategy for the National Health Service.

So if I might just summarize what I think that is all about. Firstly, it's a recognition that the provision of information is a health and care service in its own right. You can deliver improving results through the system by the manner in which you use and mobilize information. What we're setting out to do is get the right information to the right people at the right time, in a form they'll understand and engage with. It's not just about access to information, it comes to the point I think you've been discussing greatly, it's not just access to information, it's about support and advocacy to people so that they can make meaningful use of this information; it means something to them, and they can use it for themselves; not just use it as providers, but use it as patients and families and carers.

Of course we have to join up systems, we have to share data standards. I completely understand and endorse the view which I think has been at the heart of the way which you've now been approaching things, is not to specify what hardware people should buy or what software people should buy, but the means by which they should be able to communicate and share data with one another, for the benefit of patient. That's what we need increasingly to do and create in that sense empowered consumers on the part of our family practices and our hospitals. We feel then we can use online and digital systems to transform health and care in the same way as any other business. I mean, it is a failing of the public sector sometimes to feel a bit like a convoy that moves at a pace of the slowest; whereas in the business community and the private sector, people move at the paces they are pulled by the faster ones. So we want a care system that has that. We want that sense of everybody moving rapidly, pulled by innovation and service innovation to make this happen.

We want therefore to take the technology we take for granted in the outside world to be applicable to the NHS, and that means making us very... it's a culture change for the National Health Service, because in the past the National Health Service has pretty much taken the view that if we require something, we will design it for ourselves, and we will apply it to ourselves, and we will apply it to our patients. And now we are literally looking for patients to take control of their own data and their own record, to be able to share it with other systems, hopefully to do so in a way, well intentionally to do so in a way which enables them to be confident about the quality of those systems. But also to be confident about their ability to control who has access, if at all, to their identifiable information and patient sensitive information. But that doesn't mean actually you can't share it with people; there's plenty of systems that are increasingly enabling one to share and access means by which records can be used more creatively for people to manage their

self-care and interact with their healthcare providers without necessarily even sharing their information with those websites and the like.

From our point of view, what we wanted... let me just summarize to you from the patients point of view, where it is we hope to be with the information strategy, wants to see this from the patients point of view. So, as a patient, I'm looking forward to being able to book my appointments and order my prescriptions online, repeat prescriptions online. I'm looking to be able to communicate electronically with my health and care professionals, and use my online services and IT services to improve my health. I look forward from our point of view, in our system, by 2015, everyone in England to be able to access their general practice record. We at the moment have a summary care report, which you may be familiar with, which is, I think, is in a sense something that is useable for the purposes of helping patients to be safe when they are being cared for. We managed, after two years ago, to get over what was clearly resistance, particularly among patients to this. We've now moved it to 12.5 million summary care records, we've got one in four, of patients. But, we've still have a way to go on that. But this is separate and different from everybody being able to access by 2015, what is in their general practice record.

Of course remember in the National Health Service context, pretty much everybody who is a patient is registered with a general practice; so by extension, pretty much everybody has, as it were, a general practice record as their core medical record. So test results online as well as other health and care records, as more care providers make them available to me. I should be able to access those online. I should be able to share that information with others who care for me professionally or informally. I will know how the information from my records, together with information about my own needs and preferences, will be shared securely between the professionals providing my care. So my care can be more joined up say for better, and an important thing from patients point of view they've told us, and I won't need then to repeat important information so often to different staff. This will enable us to have more integrated care; so wherever I go for my services, whether it be my general practice, my pharmacist, in a care home, an emergency department, professionals will be able to access the information they need about me. Obviously information that keeps me safe about allergies and the support I need, but they will also, they will have access to my care plan, my support needs, my expressed preferences.

The results of tests will be available rapidly and electronically to provide faster diagnosis and my NHS number, and we are hoping by... well, we're aiming by 2015, alongside this, to have cleaned up the system so everybody has a single NHS unique identifier number, so we can join up this system and ensure that care is more effectively and efficiently coordinated. I should be able to find information through a single trusted place; if I wish to, I should be able to go, as we have HS Choices as a website that is available. Through that, I should be able to access other websites that have good quality information that are not necessarily public sector. There will be other public sector sources of information, for example, the National Institute for Health and Clinical Excellence, produce nice evidence and nice pathways and increasingly that will reflect evidence-based quality standards and advice about the services and the quality of services patients should have a right to expect.

I should be able to get information relating to the different services that are available, to be able to make choice. We have a program of choice, the development of choice; for the moment patients can access across the whole of the country, they can access choice for planned operations. We're beginning to see that extending into access to choice in community services. I think from the United States context, we have, as it were, less choice, but we are expanding choice. But increasingly, of course, you need information to support that choice. So a lot of this is about extending the clinical audit and the information about the quality of general practice and the like, so that patients are able to make effective choices about the services that are provided to them.

I'll be able to leave feedback about my health and care experiences and one of the central outcomes that we're looking for, there seems to be a rule of five in these matters; the results we're looking for fall into five main categories. We're looking for a reduction in avoidable mortality. We're looking for an improvement in recovery following treatment. We're looking for an enhancement to the quality of life of patients living with long term conditions. We're looking to reduce avoidable harm. And we're looking to improve patients experience of their own care. Thank you. And in that latter respect, feedback about the

services that are provided to me as a patient are something which likewise should be very much part of not only of the NHS system, but part of the feedback system through private sector websites and the internet as well. So, we have, Iwantgreatcare.com and websites of that kind.

And not least, I think we should be increasingly confident that that data is not only used for my benefit, but is also used for the benefit of population health. So that's...and we have systems developing for linking up data across the health and care services for the benefit of delivering improving services, to see the quality and the variation of services. And of course, as we expose variation, so we drive improvement and we root out poor performance, and that is demonstrably happening. And the public have been very clear with us that they also accept, as long as their information continues to be secure and anonymized and non-identifiable, they are happy for their data to be used as part of research projects. So, we have the capacity in the National Health Service to arrange databases to link up, a large, 50,000,000 diverse population where we have a prospect of having very substantial, consistent information about a large population for research purposes. So, we're hoping to put all that together.

From my point of view, I'll stop now and happily take any questions. What I'm looking for is for patients to really feel that the service is not only accessible, and in truth, in the past, many of the measures of success that we have applied, have been about access to services; but one which is, from their point of view, goes beyond the fact that they can access the National Health Service readily to one which is really, from their point of view, effective at enabling them to take greater control of the service that is being provided to them. My experience with talking to clinicians is that for many clinicians, their clinical practice they completely understand at a personal level. But the conversation with patients, it's not simply taking a history, not simply doing the examination, ordering investigations, but understanding what a patient's wishes and expectations are, is an integral part of delivering the best care and delivering the best results. They know that in an individual and a personal sense, but they haven't experienced it as a system. A system hasn't been designed to do the same thing. So what we're really looking for is a system that enables us to do exactly that, is to understand that the best care is likely to be care that is literally for patients, where no decision is made about them without them.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

That's fabulous, I mean, I think that's so coincidentally in line with the vision that we... and so eloquently articulated, it's just wonderful. Thank you for sharing that.

Andrew Lansley CBE, MP – United Kingdom's Secretary of State for Health

I'd be very happy if any of your colleagues have points or comments or questions they'd like me to hear, I'd be happy to respond.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Neil.

Neil Calman –The Institute for Family Health – President and Cofounder

So, aside from using...

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Maybe if you could give the Secretary just a little bit about who you are, what you do, why you're here.

Neil Calman –The Institute for Family Health – President and Cofounder

Sure. My name is Neil Calman, I'm a family physician and I run a network of community health centers, urban and rural, in New York State. I guess my question is, as you sort of look at where patients get information on which they can make intelligent decisions, are you using the electronic health record in some way to facilitate their access to information that might be beyond what they get from their own physicians. Do you maintain a database, for example, of information on pharmaceuticals with a patient accessible information?

Andrew Lansley CBE, MP – United Kingdom’s Secretary of State for Health

Yes. In addition to their own record, their personal health record, which they should have access to, which... I mean frankly we will start with the general practice record. It will take time and will be a work in progress for a period of time, to bring essential information from hospital records into the general practice record, if they haven’t already been provided. And too often, there are limitations on the data that is provided even back to the general practices. But if we give them access to their health record, if we give them very effectively immediate access online to test results, if we give them immediate access to the discharge summaries from hospitals, that should, in effect, keep them up to date with their own record. Now in addition to that, you’re absolutely right, we should have a structure which allows them also to go out and look and say, “well, that’s what’s in my record, but what, given my circumstances, should I expect, and what do different providers do for me?”

So, increasingly we will be providing them, we’ve started that process, actually with the active coordination with the Royal College of General Practitioners, to publish data about the relative performance of general practices across the country. So people can look at general practices and say which, how well are they doing. We’ve extended the range of clinical audit on services in hospitals in particular, so that people can look at those services as well. But also they should be able to look at, not only private sector websites, but organizations like the National Institute for Clinical Excellence, are increasingly publishing quality standards. We hope to have about, probably about 170 quality standards by 2015, which cover the bulk of the main conditions that we provide guidelines to.

In addition, NICE [National Institute for Health and Clinical Experience], if you haven’t had a chance to look at it, I think NICE evidence and NICE pathways, each of them as accessible systems will give patients quite a lot of opportunity to look and say, under these circumstances, what does the evidence tell me, as a layman, about the nature of the condition that I have and the options for treatment and so on. Sometimes we will literally take that and make it specifically available. I launched last October the first eight sets of decision-making aids for patients working with clinicians. So, for example... and it’s quite interesting because I remember I was talking to a gentleman who had been passed the pilot on, it was localized prostate cancer was the decision-making aid. And he said to me, “Look I don’t... and the point about this and a point about the way in which the information was provided to me, was that I didn’t actually lack people to talk to, I could talk to my GP about it; my wife was a nurse, and that wasn’t the issue. I could go and talk to the consultant about it. The issue was, I wanted to have sufficient information in a form that enabled me to make the decision, because I did not want, if the decision went wrong, for somebody else to be to blame. I wanted to be responsible for it, I didn’t want to blame my wife, I didn’t want to blame the GP, I wanted to know that I’ve got good quality information that enabled me to make...” And that really for me encapsulated that sense of shared decision-making isn’t about just being told what the good information is and somebody else is still making the decision. It’s literally that transfer of responsibility and ownership of the decision that’s being made.

Neil Calman –The Institute for Family Health – President and Cofounder

Thank you.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

David.

David Lansky – Pacific Business Group on Health – President and CEO

I’m David Lansky, I represent large purchasers of healthcare, large companies, global companies, General Electric, Intel, those kinds. You’ve done wonderful things to move the patient reported outcomes field forward and by tracking four conditions and doing pre and post treatment outcomes for total hip replacements and so on, you’ve really moved things forward. We’re actually having a hearing here this week on how to capture patient generated data into this process, both the electronic health record, but also the production of quality measures of the kind you were just talking about. And I’m wondering how you see the work you’ve done on patient reported outcomes, beginning to characterize the performance of, for example, hospitals performing surgery and looking at their mid-term outcomes, and providing feedback to patients about the quality of outcomes they’re getting from those facilities with the EHR

strategy you're implementing and where do you see the patient reported outcomes piece going and growing and how does this fit in with the IT piece?

Andrew Lansley CBE, MP – United Kingdom's Secretary of State for Health

Hmm, quite a lot there isn't it. Well, thank you, I mean I think it is terrifically important from our point of view and fortunately, the latest data published just a couple of... just two or three weeks ago on hip replacements and knee surgery demonstrated improvements in patient reported outcomes, which is always very encouraging. Because one of the political dangers is, you're very clear about what results you want to focus on, but the results don't necessarily go in the right direction. But fortunately these results were going in the right direction. Patient reported outcomes, and that's very... from our point of view, very important to distinguish between, as it were, those patient reported outcomes that are the basis by which, in a sense, clinicians can look for specific evidence of clinical effectiveness and that's the sort of thing we're looking for in this particular context; so it will be things like short form reporting that enables one to ask what a relative, from the patient's point of view, relatively straightforward, objective questions. What degree of mobility has been restored? What degree of pain has been removed? Are you better or worse? You know, things that, broadly speaking as long as you aggregate across any decent population, you've got evidence. But in addition to that, patients and the public have told us very strongly that they regard the outcomes we're looking for are not only the patients report of the clinical effectiveness, but their experience of the care.

So for example, it immediately became apparent to me that yeah, we did have a survey, you know, we had surveys, but it turned out that the surveys didn't extend to any mothers giving birth; it didn't extend to virtually any patients with mental health problems; it didn't extend to any children under the age of 16 at all; it didn't touch learning disability services at all; it completely ignored end of life care. So there were whole ranges of places where actually, when you're measuring patient reported outcomes, you're not looking for something, and it's very difficult to define anything which is, in that sense, objective. You are looking for something which is subjective. So we've been designing a series of mechanisms for patients to report their own experience.

So for example, for mothers simply to tell us after a period of time, whether they were able to go home with a well-baby having had what they regarded as a good birth experience. Just tell us that, because if we were talking about results, we were talking about neonatal mortality which is important, but, doesn't really touch most mothers actual experience very much. And likewise with end of life care, you know, people would just shy away from it. But actually, going and talking to the families of those who had palliative care services, after about three months, and having a conversation with them about whether people looked after them, whether the services were properly integrated, whether the care was provided; and asking that just gives you so much information. And in a sense, from my point of view, it was.. in the wider community, in the same ways we take it for granted increasingly that we're applying new technologies to refashioned services, we take it for granted that the feedback we receive from our customers is integral to how we develop our services and how we improve them. So for us, that has to be the case as well. And so I think there's two sets of things there.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

I have a question. Paul Tang, internist in a large medical group practice. You mentioned how the people feel that they want information for their own care, but also for the benefit of the population. Was there sensitivity around privacy related to exchange of electronic information and if so, has there been some progression in thinking about how data movement and aggregation and use in research over time, and what may have caused potentially more receptivity to that use?

Andrew Lansley CBE, MP – United Kingdom's Secretary of State for Health

I think Paul to be fair, we're still just moving up from base camp on this one really. I mean clearly there was resistance and the administration before me introduced the idea of summary care record, but it had effectively stalled, because the general practitioners, family doctors weren't keen, they didn't see the value. I'm not sure they were all that comfortable about the security of the information. So, after the election, it took us a few months, but we did manage to get beyond all that and as I say, we're now twelve and a half million and counting reasonably rapidly.

But I think, if I were to go and talk to a cross-section of the British population at the moment, I think they would still feel uncomfortable about the long term possibilities across a thing as big as the National Health Service, large numbers of people could access their information. Every time anybody says to them, but it's password protected, they go, "yeah, I know, and people put the password in and leave it open." You know, so we've actually got to find ways in which these things...there are smart ways of doing this now, so people don't have long disincentives for entering their passwords. It's a bit like you put smart cars to pay, you know, are you literally there and if you're not there, then the data can't be accessed as if you were there. And we can do this thing, we know we can do this thing, we just need to make sure we build it into the system and make it happen.

Fortunately, from my point of view, what became immediately obvious from the survey work we did, was that if the public actually feel, for example where research is concerned, that even before the data is linked up and shared, it's been anonymized and is no longer identifiable to put in a structure they feel confident it can't be dis-aggregated and identify them, then they really believe in it, and they believe in the value of contributing to research. And that was a very encouraging thing, we're like 85% positive subscription to that concept.

Judy Faulkner – EPIC Systems – Founder

Hi, I'm Judy Faulkner, I work with an EHR vendor, and I was wondering, you spoke about the patients having access to the GP record and the discharge summary, do you see the UK moving very much to more of an integrated record where the GPs, the specialists, the hospital, the A&E all have access to all the data that's shared among them, for better care of that patient or do you think that that's not the way the UK is built and it won't happen.

Andrew Lansley CBE, MP – United Kingdom's Secretary of State for Health

It's clearly not the way we're built at the moment. I think we will get more of it, and to be honest, I think most of the drive for this will be from patients themselves. When patients increasingly will say, "yes I have access to my general practice record, it has on it the discharge summary from, and it has the test results when I was at the hospital and so on, but I know more happened, I know there's more in the hospital record than is reflected into this." And they will be out there demanding it; and we will be making sure when they demand it, they get it. And because it's a unique identifier, hopefully we should be able to make it absolutely expected that that data can and should be shared with patients.

Judy Faulkner – EPIC Systems – Founder

From the physicians point of view, will the physician in the emergency department, that's A&E right...

Andrew Lansley CBE, MP – United Kingdom's Secretary of State for Health

Yes.

Judy Faulkner – EPIC Systems – Founder

...be able to see what happened to the patient yesterday at the GP and will the physician be able to see the last hospitalization so the patient's physician can take better care of the patient.

Andrew Lansley CBE, MP – United Kingdom's Secretary of State for Health

Yes, it should be possible to do that. And happily, I mean, there are...we're now kind of building things less from the top down and more from the bottom up. So for example, I can go to hospitals in England and they have got a direct relationship between general practices and their own... in the hospitals. It's not routine, it's not generally the case, but we have examples where it is happening; so what you described Judy would absolutely happen under those circumstances. The A&E department would be able to look on the patient's record and see if there's been any immediate and recent change in their medical circumstances.

Judy Faulkner – EPIC Systems – Founder

Thank you.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Do we have time for Gayle to make?

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

One more question if you don't mind. Gayle Harrell, I'm a State Representative from Florida, I'm a Health Care Provider, I owned a mammogram center and also a large practice manager. So, I'm a hands on person, I mean, down in the trenches, hands on, and I have a lot of concerns on, as Paul knows, as Farzad knows, I am sometimes a voice in the wilderness crying on that level of practicality and also privacy and security. And I am assuming, I don't know, I'm not that familiar with how you are running your health information exchange and whether you're using a federated system or you have a repository, a national repository system of your records. But, for us here in this country, the privacy and security issues are probably the number one issue I hear from my constituents on an almost daily basis, as to what is going to happen to their private, very personal health information and it comes across the spectrum, you know, liberals, conservatives, doesn't matter, it's an issue. And I would really like to drill down a little bit on how you deal with that in your system and what mechanisms do you do to really assure the public on those privacy and security levels and what safeguards have you built in that perhaps we need to look at.

Andrew Lansley CBE, MP – United Kingdom's Secretary of State for Health

Well Gayle, of course we start from a different place from you; we start from a system which was established on the basis that there was going to be a National Health Service IT scheme. That was it, there was going to be one scheme for the whole country. So, 18,000 locations between general practices, a bit like your health centers would be, were, and are now located on that, and it's called a spine, it's The National Spine and they're all connected on it and technically speaking, all the data is held on National Servers. So, the general practices own the data.

Now, one of the central things that we're now working on is not necessarily to change the, because we've got, as it were, the physical infrastructure, we've got the hardware, the issue is, from the patients point of view, how is that information being shared and by whom is it being shared and why is it being shared. And that was completely opaque to them in the past, and it needs to be transparent. And one of the things I'm aiming for, and Fiona Caldicott, who's working on further work on information governance for me, will be reporting on this. We want to arrive, ideally, at information governance which ensures that in the same way as patients, as it were, trust their local general practice, and always have trusted them with that data, they continue to trust them with that data. That data may be accessed through the Spine in other places, but whenever that happens, patients if they want to, should know whenever that has happened, and in particular, you need somebody who is, as we would call it, the Caldicott guardian; the person whose job it is to say, why has somebody accessed my patients data. And of course if you aggregate to too big a population, you can't do that very effectively, because people have no idea who this patient is and why... all they can see is that the, as it were, the pro forma was met; whereas actually what their practice very often can do, is go beyond that and say, combine the clinical with the administrative. Which I have to say, is one of the central things I'm trying to do in my system.

You know, in the National Health Service, I'm trying to arrive at a position where clinical decision making, led often through general practice, is directly combined with decision making about the allocation of resources. But the same should be true for the use of information. Somebody, and it might be a practice manager, should be able to say, yesterday, which hospitals accessed information on our patients; and let's say, typically a general practice in England would have about, well there's about eight and a half thousand practices for about fifty million people, so we're talking about say 7 or 8,000 patients. Now, at any given moment, any day, actually hospitals aren't going to access more than a few dozen of those patient's data. So it is perfectly possible simply to look and say, "who accessed our patients data yesterday and why." And in most cases, they'll go, fine. Some cases they'll go...turned up at the emergency department last night, and this is an important fact and that sort of information is increasingly generating decision making in the community about how we manage patients more effectively in the community so they don't turn up at the emergency department on a regular basis. So, that's quite important. So, it's not just for the protection of patients, but it's for the improvement of the care of patients. But it certainly is a protection; if somebody has accessed the data of a patient and you can't

think they're not an inpatient, they're not an outpatient, they're not an emergency patient, why are they doing it and that kind of knowledge of patients is pretty central to this.

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

Thank you so much, Secretary Lansley. We really do draw on our Federal Advisory Committees and their workgroups. We have had meetings on average every other day for the past three years, that have been openly broadcast and a core part of that is to give an opportunity to the public to speak either in person or on the phone. So Mary Jo, should we open?

Public Comments

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Yes. Operator, would you please open the lines for public comment. Are you there operator? Well, if you can hear me on the line, if you are on the line, please dial 1-877-705-6006 and press 1 to speak, or you can enter a comment in the public comment field to the left of the presentation. Operator, do we have any comments? And if there's anyone in the room in the meantime who would like to come forward and make a comment, please do.

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

And I want us to have a good model of democratic processes for our guest, so...

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Yes, we'd like a comment from someone. I knew we could rely on Carol.

Carol Bickford – American Nurses Association

I'm Carol Bickford, I'm staff at the American Nurses Association. I want to ask you how you are integrating the various clinicians in the record keeping process. You've spoken specifically about the general practice and the hospital, but please share with us how you've accounted for the different clinicians, do they have unique identifiers as well, so that you can verify what care the registered nurse, graduate nurse is doing in your space, and other clinicians, the physical therapist, OT, so we can figure out who's doing the best care, the best way, the best outcomes.

Andrew Lansley CBE, MP – United Kingdom's Secretary of State for Health

Yes, thank you. We do indeed, through the...when people are accessing an NHS record, any member of the NHS staff will have their own personal identifier, so, we will know which patients identifying if accessing a patients record and for what purposes. I might say, the use of technology is...these are not things that are being mandated by us from the government, but there are hospitals who are increasingly able to know exactly where patients are all of the time in the hospital, and which staff are there. And this is, from their point of view, I have to say, a very effective mechanism from the point of view of managing the effective treatment for staff and of delivering safe care to patients. It begs questions about the degree of privacy associated with this kind of technology, but it is, I have to say, a very effective mechanism for managing care.

From the nursing point of view, the use of technology and the use of electronic health records in hospitals, patient administration systems as well, is increasingly being linked to re-designing the way in which nurses deliver care. So, for example, I was in Northwest of England back in January, talking to senior nurses, they had redesigned the way in which they delivered care and it was all around the proposition that nurses would always be entering any data relating to a patient at the bedside, entering once, entering it electronically, not going off and sitting at a nurses station and some of the new hospitals. I mean you may be well ahead of us on all this, but some of the new hospitals we're building, we'll literally have only single bedrooms, nurses will spend, in our experience, under those circumstances, will spend

probably 55-60% of their time with patients, whereas in the past we were looking at something like 35%. There won't be a nurses station, it just will disappear because they will spend their time with patients or talking to patients or talking to other clinicians, but doing it increasingly at the bedside rather than doing all of that data entry and data recordkeeping somewhere else. And I think from the patients point of view that's great, that's so much better.

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

We have no public comments on the phone at this time.

John Anderson - New Mexico Health Information Technology Regional Extension Center – Project Manager

Hello, my name is John Anderson, I'd like to make a comment if it's possible.

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Yes, I'm sorry. By all means go ahead.

John Anderson - New Mexico Health Information Technology Regional Extension Center – Project Manager

Okay, thank you. I found the talk around shared decisions in the UK extremely interesting, as it might apply to some of our needs here in this country. As we know, there was a lot of discussion today around HIE sustainability and how we move forward in that area and it seems to me that the three points of approach in information exchange tie into this in a way. If we have exchanges that can provide longitudinal records as a form of a patient health record, then that brings the provider into an area and a level of confidence where they are willing to accept that record and perhaps adopt that form of integration from the shared decision point of view, while at the same time, if it was something that was useful to the patient, they might be willing to pay ten dollars a year for that, and in some HIEs in this country, I know that that could actually pay their annual budget. I just wanted to share that information because I see some real synergy between what was just presented there and some of the things we were talking about.

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Are there any other comments please? Hearing none.

Andrew Lansley CBE, MP – United Kingdom's Secretary of State for Health

Can I, I mean clearly, part of what, was it John, John Anderson?

John Anderson - New Mexico Health Information Technology Regional Extension Center – Project Manager

Yes, that's correct, John Anderson. I'm with the Regional Extension Center out here in New Mexico.

Andrew Lansley CBE, MP – United Kingdom's Secretary of State for Health

Yes John, it's Andrew Lansley. Part of what you were saying of course, applies to the structure of American provision of healthcare, not in the same way to British. But, from my point of view, it's... I'm hoping that what you describe as a longitudinal health record is exactly what we're talking about, something which reaches right back, which is not short term, which sees a patient in the long term context, which supports the integration of care over a longer period of time. Because one of the things that I think we feel most strongly we need increasingly to do is to move away from thinking of healthcare as something that occurs only in episodes. It doesn't happen in episodes, healthcare is a lifelong commitment and the more we can encourage not only patients themselves to see it as something which is something they can be participants in over a period of time, that general practices hopefully see it that way already, but can be encouraged to do that more. But increasingly, of course, all the other providers should see themselves being integrated. Because we've tended to think of the integration of care as something that is about structural or funding relationships, when in fact, actually what we really should be starting from is saying, the integration of care should be literally the process by which we design health

and care services around the particular needs of patients. And our experience, I have to say is increasingly that it isn't about structural organizational change that delivers integration, it's literally the willingness of professionals to work together in order to make that happen.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

That's very good. We really appreciate you're taking the time, it's been inspiring. It truly has been and I think we learned a lot just about what you're doing there, and probably can apply it here, in our programs here. So thank you so much for taking the time.

Andrew Lansley CBE, MP – United Kingdom's Secretary of State for Health

Well thank you very much. I'm very grateful to you and I know there has been a very productive exchange between ourselves and the United States and I'm looking forward to more of it as time goes on, not least from your own endeavors, so thank you very much indeed.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

And thanks to the committee and folks on the phone and all the workgroups who participated in the work discussed this morning. Thanks and see you next month.

(applause)

Public Comment Received During the Meeting

1. What physicians do now is synthesize the patient's words into a succinct communication - how do we achieve that synthesis with all the data that patients might submit?
2. When a patient enters their data into the Electronic Medical Record, when is the provider legally obliged to make an entry as to their acknowledgment of the patient's entry (including date and time); and when is the provider obliged to make comments (clarification of facts, clarification of context, agreement of comment, proposed provider actions stemming from the patient's note) regarding the patient's entry. Also, is there an expectation that the patient be informed that the provider read and acted upon the patient's note. When provider notes are reviewed in the future, are patient notes (another source) supposed to be present along with provider notes? Are the consultants expected to have seen, read, and responded to the patient notes? Can the patient decide whom, among the care team, is allowed to see what notes (e.g. data segmentation)?