

**Privacy & Security Tiger Team**  
**Draft Transcript**  
**June 4, 2012**

## **Presentation**

### **Operator**

All lines are now bridged.

### **MacKenzie Robertson – Office of the National Coordinator**

Thank you. Good afternoon, everyone. This is MacKenzie Robertson in the Office of the National Coordinator. This is a meeting of the HIT Policy Committee's Privacy and Security Tiger Team. This is a public call and there will be time for public comment at the end. The call is also being transcribed, so please be sure to identify yourselves before speaking. I'll quickly go through roll and then ask any staff members to also identify themselves. Deven McGraw?

### **Deven McGraw – Center for Democracy & Technology – Director**

Here.

### **MacKenzie Robertson – Office of the National Coordinator**

Thanks, Deven. Paul Egerman?

### **Deven McGraw – Center for Democracy & Technology – Director**

He won't be on the call today.

### **MacKenzie Robertson – Office of the National Coordinator**

Okay. Dixie Baker? Dan Callahan? Neil Calman? Carol Diamond?

### **Rebekah Rockwood – Markle Foundation**

This is Rebekah Rockwood for Carol.

### **MacKenzie Robertson – Office of the National Coordinator**

Thanks, Rebekah. Judy Faulkner?

### **Judy Faulkner – EPIC Systems – Founder**

Here.

### **MacKenzie Robertson – Office of the National Coordinator**

Thanks, Judy. Leslie Francis?

### **Deven McGraw – Center for Democracy & Technology – Director**

We heard Leslie. She must be on mute.

### **Leslie Francis – National Committee on Vital and Health Statistics**

Here.

### **MacKenzie Robertson – Office of the National Coordinator**

Gayle Harrell? John Houston?

### **John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, John. Alice Leiter?

**Deven McGraw – Center for Democracy & Technology – Director**

Alice is on leave for the summer.

**MacKenzie Robertson – Office of the National Coordinator**

Okay.

**Gayle Harrell – Florida House of Representatives**

Gayle Harrell's on.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

David McCallie here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, David. Wes Rishel? Micky Tripathi? Latanya Sweeney? And are there any staff members on the line?

**Joy Pritts – Office of the National Coordinator**

Joy Pritts.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, Joy.

**David Holtzman – Office for Civil Rights – Health Information Privacy Specialist**

David Holtzman, OCR.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, David.

**Gayle Harrell – Florida House of Representatives**

And Gayle Harrell is on now.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, Gayle.

**Kathryn Marchesini – Office of the National Coordinator**

Kathy Marchesini, ONC.

**MacKenzie Robertson – Office of the National Coordinator**

Thank you. Okay, Deven, I'll turn it back over to you.

**Deven McGraw – Center for Democracy & Technology – Director**

Terrific, thank you very much, MacKenzie. What we are going to do today is to continue to try to hit as many of the questions and the request for information that were prioritized for the Privacy and Security Tiger Team of the Health IT Policy Committee, and they were prioritized for us to resolve. If we are able to get through the questions that are a priority for us, and hopefully we will. We will take on one of the questions that was suggested to us as a secondary question, it had been teed up in your slides, and it involves the condition of whether or not NVEs should be prohibited from using or selling de-identified data for commercial use. But since that question was not given to us as a priority we will get to it if we can at the end. But we did make slides for it because members of the Tiger Team, on a previous call, expressed a desire to take that question on if time permitted.

We welcome members of the public who are on our call today. We very much appreciate your participation and your interest in what we do.

This is our last call before the Health IT Policy Committee meeting, which is on Wednesday, when all of the recommendations from all of the working groups on the questions of the NwHIN governance RFI are to be considered, and so this is really our last shot to do the best that we can with the questions assigned to us and the recommendations that we can put forth. We had previously discussed issues involving meaningful choice and authentication and encryption, and we had some discussions about the language and circulated to all of you some modifications and clarifications based on the previous discussion. I am hoping not to take those on in this call today unless one of you has a burning desire to take something up or has an issue with the language that we circulated, in which case we will. But we have some other substantive issues to try to take on today in the areas of notice and matching and query and response, among others, and so, again, if it's a minor wordsmithing issue please send it to us off line, but if it's substantive on issues of meaningful choice authentication and encryption, the language that was sent to you late last week, now would be the time to raise that.

Hearing none, thank you all very much, and we will move on to the issue of notice. And for those of you who are not on line, I'm on slide number five in the deck. The condition is Safeguard 5: "An NVE must make publicly available a notice of its data practices describing why IIHI, which is Individually Identifiable Health Information, is collected, how it is used, and to whom and for what reason it is disclosed." And there are a number of questions that are related to this condition which are set forth in your slides. We actually started to discuss this set of questions and this condition on our last call, and got, I think, a little spun around about whether notice to people about data practices needs to play the same role as, say, an accounting of actual activities with data. And so what I tried to do in formulating the straw man response here was to look at what the Federal Trade Commission had recently said about notices to consumers and privacy policies in the commercial space, and also some of the discussions that I've been privy to in the Information Exchange Workgroup about what's really the role of notice, and essentially drafted this straw man response, which is both trying to take advantage of those more recent discussions, but also covering some of the recommendations that we have previously discussed on the issue of notice patients, keeping in mind that the notice of data practices by an NVE would be relevant both to its participants and entities that might want to take advantage of its services, as well as of course to patients.

And so what we have recommended in our straw man response for your consideration is that NVEs should provide really a layered notice, something that is quite short, a one to two page summary of actual information sharing policies and activities, with of course an opportunity for interested individuals or NVE participants to obtain more specific details if they want them, such as through a Web site link or a contact who can answer more specific questions. The summary notice should cover categories of information versus each and every instance of data use and disclosure, and ONC should do further work with stakeholders to determine standardized categories and terminology for information uses by NVEs. And there's just a note here that this is consistent with recent FTC recommendations on consumer privacy, which call for privacy notices to be clearer, shorter, and more standardized to enable better comprehension in comparison of privacy practice.

And then we have a couple of other pieces to the response, again largely based on things that we've said before. The notice should be written in plain English, but also at the reading level of the average patient. This is really specifically for patient notices, and be presented in compliance with applicable laws with respect to language and disability. The notice should include uses and disclosures of de-identified data per the Policy Committee's previous recommendations, which we had issued with respect to intermediaries, of which NVEs would qualify. And then NVEs should be required to disseminate their notices to participants in the NVE and post the notice on their Web site, and this is consistent, I think, with some of the threads of discussion from our previous call.

That's essentially what we have prepared for you as a straw man response, and I'm interested in your reaction to it, and we should discuss that now.

**Leslie Francis – National Committee on Vital and Health Statistics**

I liked it, Deven.

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

Deven –

**Leslie Francis – National Committee on Vital and Health Statistics**

You get my vote.

**Deven McGraw – Center for Democracy & Technology – Director**

Thank you, Leslie.

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

Deven, this is John.

**Deven McGraw – Center for Democracy & Technology – Director**

Hi, John.

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

I'm looking back at the original document that was sent out which had the entire 14 pages, it looks like you've changed the straw man response between what was on the slides and what was on that document.

**Deven McGraw – Center for Democracy & Technology – Director**

The only thing that we did was to remove some of the rhetorical text, which we can put back in, so what would happen was there was some rhetorical text about not surprising the patient and transparency being an important element of fair information practices, and we removed it from the slides, not because we necessarily thought that the language was in some way controversial at all, but we couldn't figure out which question it answered. And our recommendations, when they're presented to the Policy Committee, unfortunately we will not be presenting the Tiger Team's recommendations as part of a separate presentation to the Policy Committee, but instead we will be chiming in with our recommendations in response to specific questions after the RFI. And we just couldn't figure out a way to squeeze it in, but if people feel it's important we'll figure out a way to squeeze it in.

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

My opinion is that I think, as for Leslie, I think this is actually clearer than what I think was in the straw man response before, and more focused.

**Deven McGraw – Center for Democracy & Technology – Director**

Okay, good.

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

I think the only thing I would add is that on slide seven I think that the one thing we might want to think about is, is there a method by which not only does the notice get posted on the NVE Web site, but one of the things I know that some HEs do, including my own, is that we actually have an addendum to the notice of privacy practices that when you participate in a HE, and I guess in this case an NVE, that the participants would be able to post that notice along with the notice of privacy practices, whether that's something that could be worked into this or whether it's worth doing.

**Deven McGraw – Center for Democracy & Technology – Director**

Would you want to recommend that we require NVEs to make a postable notice available to their participants, or that that would be an option?

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

Making it available I think is the right wording, but I think it's good that whatever notices are there are something that could be used by the individual participants to better inform their patients. So yes, what we do is make a one page addendum that the participants are intended to post with their notice, so if you had ... language I think it would be helpful.

**Deven McGraw – Center for Democracy & Technology – Director**

Okay, that makes sense to me. Does anybody have any objections to that? Any other –

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

This is David. I just have a question for clarification on slide seven, the second bullet point the notice should include uses and disclosures of de-identified data, blah, blah, blah, and the word “include” there I assume means in addition to notices of identified data, right?

**Deven McGraw – Center for Democracy & Technology – Director**

That's what was intended.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

Okay, I missed that the first time through and read it as that the only notice was around what you did with de-identified data, and clearly that's not what we intend.

**Deven McGraw – Center for Democracy & Technology – Director**

We can make that more clear.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

“Should also include,” or something like that.

**Deven McGraw – Center for Democracy & Technology – Director**

I just put the word “also” exactly where you said it.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

Oh, good.

**Deven McGraw – Center for Democracy & Technology – Director**

That makes sense, David. Thank you for pointing that out. We want to be clear.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

Otherwise I think it reads nicely.

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

Yes, I agree.

**Deven McGraw – Center for Democracy & Technology – Director**

Terrific. Anything else?

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

We should move on before we discuss it too much.

**Deven McGraw – Center for Democracy & Technology – Director**

Yes, okay. I'm down with that, John, thank you. The next thing we had teed up in the slide for you today was on the condition related to digital certificates, and we had included in your original slide deck some background material that indicated the continuing struggles that ONC is having in determining whether our previous recommendations that ask for organizational level certificates, a high degree of assurance that the organization is who it says it is, and connection to the federal bridge, both to provide that high level of assurance to piggyback on a process that's existing, as well as to enable data sharing with federal partners, that those recommendations that we had issued and that the Policy Committee had endorsed, a question about whether that is feasible to do continues to be a sticky one to try to pin down in an evolving landscape of authentication policy generally, much less where the federal bridge might be headed. And so we actually do not have sufficient additional information for the Tiger Team at this time that can really enable us to make any further progress on this recommendation.

I think that ONC is still hopeful to be able to leverage federal bridge certification in the way that we had indicated for organization level certificates, and so they don't necessarily want us to come up with another set of recommendations for digital certificates, but in the time allowed for this RFI we just haven't really been able to pin down the information that we needed to. And we had, in our original slide deck, sent you some slides with a really brief summary of some of the issues that are being considered, but ultimately on a co-chair call this morning decided that we should hold off on addressing this recommendation further until ONC has sufficient time to do more information gathering and to figure out whether our original recommendation is in fact doable, which means that that recommendation from the Policy Committee stands as a recommendation to ONC that can influence the RFI. But obviously they're the ones who have to implement it at the end of the day and have to figure out whether it's implementable. Joy, I don't know if you want to –

**Joy Pritts – Office of the National Coordinator**

All I wanted to do is to tell people that we are very actively investigating this issue, that there are some organizations that are attempting to implement this, there are issues that are arising as a result of that implementation, and we are trying to nail all of those items down. It is a work in progress, although we've made a lot of progress in drilling down and finding out where the potential sticking points might be. So we are really getting to the point of seeing, as we would need to do with something, making a recommendation like this, how whether or not this would work in actual implementation.

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

This is John Houston. Just one point of note is this needs to be done, though, ... because I think the states are going to go off and start doing their own thing in this regard.

**Joy Pritts – Office of the National Coordinator**

They are already, John, and after doing that some things are coming to our attention that, when I say "all due diligence" we're having at least once a week, if not twice a week meetings on this issue, where we're identifying new issues and sending somebody out to go and track down what the answer to that issue is and bring it back. We're at a place, though, that I am very adamant that we are not going to rely on representation, where people say they're doing something and this is how it works. We are investigating that to find out what the actual practices are as opposed to just the rhetoric.

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

Basically there's a lot of people trying to go out and develop key infrastructures and stuff, and it seems like there's going to be a lot of duplicate effort and inconsistency if somebody doesn't get something done quickly.

**Joy Pritts – Office of the National Coordinator**

Well, there is that, John, but I think what we've also found is that there's what I heard referred to in the past as some vaporware, where people say they're doing "X" and then when you actively drill down the representations that are being made are not necessarily 100% accurate.

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

Sure, I understand.

**Joy Pritts – Office of the National Coordinator**

So we really want to make sure that when people say you can do a certain thing, that that is absolutely correct before people start trying to implement it.

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

Great, thank you.

**Gayle Harrell – Florida House of Representatives**

Yes, I want to jump into this too. I think this is an absolutely critical piece in order to make sure that we have that public trust out there. And being able to do this, being able to be part of the federal bridge and use that validation is very, very important. States are going to start doing this, I know there's lots of discussion in Florida on this right now, on how we're going to do this, so I think it's critical that ONC move forward with this, do whatever we need to do to make sure that we know the capabilities out there and how far we can possibly go and make sure it's, number one, doable, and that it truly serves the purpose that it serves, because this is a key component.

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

Can we make a general recommendation that we feel that this just needs to be done quickly and we agree with the need to get it right?

**Deven McGraw – Center for Democracy & Technology – Director**

Yes, I think we can. I think we can note that we certainly have a set of recommendations on here that we've put out previously that we think are the right way to go, but we know there are some operational issues that ONC is working to resolve and that we want them to do that as quickly as possible.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

Deven, this is David. At risk of opening a discussion which we probably don't want to have, can I ask on question?

**Deven McGraw – Center for Democracy & Technology – Director**

Yes, of course. Go ahead, David.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

I don't have the language of our previous recommendation, but are we recommending that it specifically use the federal bridge, or are we recommending what I would consider maybe to be a better way to phrase it, that it be acceptable to federal partners?

**Deven McGraw – Center for Democracy & Technology – Director**

I believe our recommendation was the latter, but we may have said more specifically cross-certified to the federal bridge.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

The reason I bring that up is because there are multiple ways, apparently, to be trustworthy to various federal entities other than just the bridge. So it may turn out that certificates that are eventually chained to someone who's a member of the federal bridge set of certificate authorities is the right answer, but it could be that there are other ways to do it. I don't think we believe that there's any specific magic in the federal bridge, we just want high trust, high security, and trusted by federal partners.

**Deven McGraw – Center for Democracy & Technology – Director**

That's right.

**Gayle Harrell – Florida House of Representatives**

I have a question for you all. When you're saying "high trust" –

**Deven McGraw – Center for Democracy & Technology – Director**

Not the security framework of high trust.

**Gayle Harrell – Florida House of Representatives**

Yes.

**Deven McGraw – Center for Democracy & Technology – Director**

... trust.

**W**

I know that ... . That piece I understand. But there are different security frameworks and certificate authority frameworks used to determine high trust, high versus medium in different ways, so at its highest level you're talking about national security level ... and I assume that that is not what this group is looking for.

**Deven McGraw – Center for Democracy & Technology – Director**

I don't think so. I do recall that in our conversations what we wanted was to use the regular old adjective of "high" degree of assurance that the entity is who the entity says it is, but without necessarily having the word "high" translate in a matrix that says if it's at this level thou shalt do X, Y, and Z for authentication purposes in terms of the level of proofing that one needs to go through. I distinctly remember us saying, look, we want there to be that level of trust where the entities can have assurance that that certificate matches the entity who it says it is, but not high to the degree of national security necessarily.

**W**

Was this sent to the Standards Committee for that particular issue?

**Deven McGraw – Center for Democracy & Technology – Director**

I don't recall whether it was. But in order for us to be able to ... something on this question, here's what I'm suggesting, that we say that the principles in our previous recommendation of high degree of assurance that the entity is who it says it is and ability to exchange with federal partners, which at the time we concluded meant connection to the federal bridge, are still things that we want to be achieved, but we understand ONC is working through some of the details on this, and obviously certificates at the organizational level, which we have said previously, and that we need this issue to be resolved soon.

**Joy Pritts – Office of the National Coordinator**

When you say organizational level, you mean the healthcare organization, not the intermediary?

**Deven McGraw – Center for Democracy & Technology – Director**

That's correct.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

Right. The intermediaries in this case would mostly not be possessing of a certificate. They would merely be handling the transactions on behalf of the people who possess the certificates.

**Joy Pritts – Office of the National Coordinator**

Right, managing them.

**Deven McGraw – Center for Democracy & Technology – Director**

Managing them.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

Although there would be NVEs who become entities that are creating new healthcare aggregates that would in fact be essentially healthcare organizations, and they might have their own certificates.

**Deven McGraw – Center for Democracy & Technology – Director**

Right. Certainly there will be organizations that might play NVE roles.

**W**

Yes, yes.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

Right.

**W**

But for –

**W**

But your focus there is on the entity that the information is being sent on behalf of –

**Deven McGraw – Center for Democracy & Technology – Director**

Right.

**W**

... right?

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

Right, and being requested on behalf of. The requestor has to prove to themselves as well as the sender, in a sense, the querier as well as the provider of the information. Boy, these words are all so overloaded. I apologize about the word “high” in “high trust.” I should have said “level of assurance.” We tried in this committee and the Standards Committee to specify a specific NIST level of assurance, and we really weren’t able to be definitive because there are so many different use cases. But in general we were talking about something close to level 2 level of assurance.

**Deven McGraw – Center for Democracy & Technology – Director**

Right, but given that those NIST levels were designed for individual user level authentication it didn’t translate very well. I distinctly remember having that conversation.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

The problem here is that these organizational certificates in and of themselves aren’t terribly useful until they are accessed by an individual who uses his proxy access to that organizational certificate to vouch for himself. So you really do have to consider the individual level of assurance as well. We haven’t gone to that level in our recommendations, but in practice if you don’t have secure log-in, in your organization, then the organization certificate is somewhat meaningless.

**Deven McGraw – Center for Democracy & Technology – Director**

Well, that’s right. But we’ve also, in previous discussions, said that we would rely on the organizations themselves to do their duty under the security rule in order to identity proof and properly authenticate their individual users.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

Right. I’m just saying that has to be present as well in order to have a trustworthy system.

**Deven McGraw – Center for Democracy & Technology – Director**

Right. That’s right. I think we got that in the recommendations that we had.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

Yes, we covered that earlier, way earlier.

**Deven McGraw – Center for Democracy & Technology – Director**

That's correct. So essentially what the slides that we had sent you had, because we were so hoping to have a more conclusory discussion on digital certificates, had some additional slides, but I'll circulate some of the language that we've talked about that refers back to our previous recommendations and the overarching principles that we wanted to be sure that policy would honor and that we would urge ONC to work to resolve this issue ASAP. We'll get that around to you, because we hadn't really developed a straw man on that because up until two hours ago we were still hopeful that we might actually have more information to be able to make more progress. We took those slides out of this deck that we're using on the call.

For those of you who are following along at home, that was essentially old slides 9 through 13, so now we are on slide 9 on your screen, and for those of you who are following along on the deck that was previously distributed it's slide 14. It's on the issue of matching. This is Condition Interoperability – 3: “An NVE must have the ability to verify and match the subject of a message, including the ability to locate a potential source of available information for a specific subject,” and there are two questions that have been prioritized for us. Should we adopt a CTE that requires NVEs to employ matching algorithms that meet a specific accuracy level or a CTE that limits false positives to a certain minimum ratio and what should the required levels be?

And question 50 is: What core data elements should be included for patient matching queries? And what we did for this was to develop a straw man response that was based very much on the recommendations that we had on patient matching that came out of the hearing that we had, and there are two elements to the response here. The Tiger Team previously observed that the use of any particular data fields should not be required for matching as choice of fields to match depends on a number of factors, including the purpose of the data access. Consistent with past recommendations NVEs should have a process in place to evaluate the effectiveness of their matching strategies and achieving matching accuracy on an ongoing basis and use such evaluations to internally improve matching accuracy. We did not specify a particular numeric threshold for matching because based on the testimony that we had heard in our hearing, the appropriate level of matching accuracy and whether you err on the side of sensitivity or specificity was dependent on the purpose for which you were seeking to match patients' data would be different, for example, when you were matching for treatment purposes versus potential other secondary uses.

Now, having said that, what the Standards Committee Patient Matching Power Team did was to take our recommendations and actually be quite specific with some recommended thresholds when the exchange is for treatment of the patient. And there actually is in the governance RFI some language on this where the Power Team assumed that in the case of near time direct patient care specificity was more critical than sensitivity and a specificity of at least 99.9% and sensitivity of 95% would be an appropriate range for ensuring a high level of matching accuracy and accountability. And so I think what we need to consider is whether we want to stay in the space where our previous recommendations were on matching, or whether we want to, again, I'm going to go back to these questions consistent with specific questions, actually recommend that the algorithms meet a certain accuracy level and that ONC set this accuracy level, and we can either agree with the level from the Power Team or just tell ONC they should set a specific level that NVEs should be required to measure and to meet.

What do folks think about this?

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

This is John Houston. I'm concerned about setting specific levels because I think it depends on the environment. It may be very easy in certain cases and incredibly difficult in others and I would hate to put some figure in place and find out later that it really is almost arbitrary or doesn't reflect what realistically can be done. I'm not in favor, personally, of recommending those thresholds without doing a lot of detailed work on what those thresholds might be, and again, depending on the part of the country they may differ.

**Judy Faulkner – EPIC Systems – Founder**

This is Judy. I agree with him.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

This is David. We had a debate about this on the NWHIN Power Team last week, and on that call there were at least three members who had been on the original Patient Matching Power Team, Marc Overhage and Chris Ross and myself, and I think that was the three of us, and we on this more recent go around basically agree that the specific numbers are not applicable. We don't know enough about what is achievable, we don't have standardized ways to actually make these measures, and given that many of the algorithms are proprietarily protected there's no way to validate the accuracies, so I think we've also agreed to back off on specifics.

**Deven McGraw – Center for Democracy & Technology – Director**

Okay.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

I think we'd agree with what you've said.

**Joy Pritts – Office of the National Coordinator**

This is Joy. Do you have a recommendation about, I know this wouldn't necessarily go on the RFI, but about the next appropriate steps?

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

We didn't get into a deep debate on it, because we ran out of time, but one of the things we discussed was the question of transparency should be added to this response, meaning that a given NVE might, as part of their transparency notice, if applicable, provide information about their sensitivity and specificity matching. We didn't reach that as a conclusion, but we certainly debated that, under the assumption that transparency means people will compete to do a better job. Second is we talked about the possibility of ONC sponsoring work to develop testability strategies for these sensitivity and specificity measures, for example, the creation of de-identified but representative data sets that you can run through your system and score yourself, even if you don't expose your algorithm you can say here's a standard test set that's statistically similar to certain well known populations and then you can use that to validate. We didn't reach that as a concrete decision either, but that was certainly a part of our discussion.

**Deven McGraw – Center for Democracy & Technology – Director**

I actually distinctly remember that we had a lot of recommendations on this topic that did include ONC building an evidence base on what worked in matching and understanding more about what was needed to achieve accuracy, which is not exactly the same as what you said, David, but does talk a bit about understanding more about what works and what doesn't.

**M**

That makes sense to propose.

**Deven McGraw – Center for Democracy & Technology – Director**

Yes.

**W**

Yes.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

This is David again. There's a gap in the current architecture that the NwHIN Exchange Derivative project, the Connect-based projects are using, it's based on the XCPD transaction. There are a number of us technology wonks who think there's a gap in the architecture on how those services are being used in addition to some limits on the way the data fields are being used, in addition to the fact that we don't really have a standard agreement on how to measure accuracy, sensitivity and specificity, so there was some debate that we've had off line, a couple of us, about an S&I framework type exercise to get a next round of best practice consensus in the community of people who do patient matching, which might involve improvement in testability approaches and the like, so I think there's a lot of room for ONC activity here, without specifying specific numbers in this RFI.

**W**

Okay, I think that we should pursue this beyond this call as to where it makes sense to turn the attention next, particularly in light of the fact that many of the algorithms are proprietary and we won't be able to use those.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

Right, right. I'd love to be in that conversation. I've had it with Arien and Wes and some others, as to whether we're ready to start something like that, but I think certainly there's interest in something a little bit more along the lines of consensus best practice, S&I framework style, than regulatory.

**Deven McGraw – Center for Democracy & Technology – Director**

Right. We could add then to the straw man response of reiteration of our previous recommendation that was fairly generically worded about ONC helping to develop the evidence base about what works and disseminating best practices and strategies without necessarily directing it to the S&I framework or necessarily to further Policy Committee work, although that may be the way that that gets propagated forward. But we can at least mention that in our set of recommendations, that specific numbers are not the way to go. Instead, we need to be doing a lot more work to figure out what works, how to measure it, and how to get out the best evidence.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

How about, Deven, something along the lines of language that suggests that this is an area of rapid evolution and that best practice approaches are more appropriate than specific numerical targets?

**Deven McGraw – Center for Democracy & Technology – Director**

Yes.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

One of the things that's being debated is if we shouldn't use Social Security number above and beyond the usual demographic fields then what other identifying numbers are available, and there are a number of entities that are experimenting with things like cell phone numbers, credit card numbers, driver's license numbers, and the like. I think no one has an answer to that yet, but there should be a lot of experiment in the field to see what works and what works with acceptable privacy.

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

That brings up the first bullet, which is on the slide that's up on the screen now, which is I know that they're asking whether there should be specific fields or what fields should be used, but I would agree that we need to be flexible. But to the last point, which is the discussion about things in lieu of social number, should we make the recommendation that we aren't specific as to what should be used, but renew the earlier recommendation that Social Security numbers should not be considered, because I know there are exchanges who have thought of using Soc numbers.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

I'd hate to make that –

**Deven McGraw – Center for Democracy & Technology – Director**

Yes, I actually don't think we said that.

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

I know we talked about it.

**Deven McGraw – Center for Democracy & Technology – Director**

Yes. I think we said something a little more generic like this isn't resolved through a single shot solution like the use of a single universal identifier, of which the Social Security number could be one.

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

Right.

**Deven McGraw – Center for Democracy & Technology – Director**

I'm happy to add that in here as well, although it's not a question that was specifically asked. Well, okay, so maybe the previous question on the issue of whether there is a specific data, what core data elements should be included, that arguably gets to the point.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

I'm wondering if the things like a hash of the Social Security number or a hash of the driver's license number might turn out to be useful and acceptable. I hate to get real specific in regulatory language.

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

Yes.

**Deven McGraw – Center for Democracy & Technology – Director**

Yes. I think that's fair, but I think reiterating that we think this problem has multiple aspects to it that will need to be fixed and it's not a question of just having one common identifier that everyone uses. Again, if we stick with what we said in the past, where we at least know that when we have time to put a lot of thought into it that's where we landed, and I think it's really interesting that where we were before still in fact sounds like the right strategy to use to move forward. This is another one that we'll get language around to folks. It will be on a very quick turnaround, though, since the Policy Committee meeting is Wednesday.

I lost my Internet connection for about two seconds. Can the Altarum folks either take us to the next slide or give – yes, thank you all. The next is a question on query and response, and we're on Condition Safeguard 10: "An NVE must have the 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." And the two questions that are asked under that condition for us to try to resolve are: "What method or methods would be least burdensome but still appropriate for verifying a treatment relationship, and are there circumstances where a provider should be allowed access through the NVE to the health information of one or more individuals with whom it does not have a treatment relationship for the purpose of treating one of its own patients?"

This was a tough one for us to come up with a straw man response, because we have not really directly dealt with query response models in the Tiger Team. But we have touched on some of the issues that are raised by query and response models and so in that spirit tried to take some of those discussions and create a straw man in response that we thought doesn't necessarily address all the specifics of the questions that might be helpful. In the context of provider to provider exchange, the Tiger Team previously recommended that the requesting provider at a minimum should provide attestation of his or her treatment relationship with the individual who, and we're missing a word here, sorry, who is the subject of the health information exchange. Again, the Tiger Team has not previously addressed specifically query and response models, but in the spirit of provider to provider exchange and requesting parties being asked to attest the treatment relationship, NVEs should require providers to attest that a treatment relationship exists or is in the process of being initiated, and then perhaps, since attestation is probably the least burdensome way to do this but is subject to less certainty than folks might ideally like, we queried whether NVEs would periodically audit their own participating providers for compliance with attestation requirements and that NVEs should of course be transparent with participants about the purposes for which information can be exchanged using the NVE, which of course we have really covered in notice in transparency. So again, given where we have come previously to issues that this set of questions raises, this is what we put down as a straw man response, but I'm very interested in your feedback and whether there is more or less that we want to say here.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

Deven, this is David. A couple of questions.

**Deven McGraw – Center for Democracy & Technology – Director**

Yes, and then I heard John.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

One question is, the word "consent" or "authorization to share" or any such language like that is missing here, and I find that somewhat confusing because it's not sufficient merely to be in a treating relationship, you need to have consent. Again, it may be different depending on the circumstances. I would hate to imply that the treatment relationship is sufficient to access the data.

**Deven McGraw – Center for Democracy & Technology – Director**

I think that given our recommendations on meaningful choice don't necessarily require a patient's consent above and beyond what the law might require in certain exchange models, where the NVE is really just the facilitator, I don't know that it would be consistent with those recommendations to say with the consent of the patient. But certainly we can refer back to recommendations on meaningful choice and that meaningful consent to be obtained in circumstances where the exchange model dictates that consent is required or the law requires it.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

This is David again. For directed exchange, yes, I totally agree and we worked through that and carved out the directed exchange specifically to account for that, but are you saying that in a query model that the only criteria would be a provider has a potential treatment relationship?

**Deven McGraw – Center for Democracy & Technology – Director**

I think, David, that it probably depends on how the query model works. Our trigger for consent was about whether the decision to disclose the information was still in control of the data holder, so if you're getting a query but it's basically a request for information that you as a provider decide whether or not the data goes, that's arguably still a directed exchange, it's not pushed, it's pulled by request but the information is not released without the decision making power being exercised by the data steward, as opposed to a query response model where the function of obtaining the information happens more automatically without an inter-meeting decision being made by the data holder. And that can happen in a centralized database, but it can happen in a federated edge server type model as well, and our trigger was based on is the control over the decision to disclose lost?

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

Right, and it seems that that control over the decision to disclose is not captured by the notion that the provider is in a treatment relationship.

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

Can I suggest a little language tweak in the second bullet. You say a treatment relationship exists and that all other regulatory obligations have been met or other – what's that, I'm searching for a word or a phrase.

**Deven McGraw – Center for Democracy & Technology – Director**

Yes, so in other words you're saying you want to directly insert the requirement to be consistent with the meaningful choice requirements of NwHIN, as well as any applicable federal or state law.

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

Exactly, so something that captures the fact that, yes, ... is an opt out state and it automatically flows if the patient has a ... but other states are opt in and there's consent requirements in certain states, and so I'm trying to think of a way to say that so that we don't step on the states' rights issues.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

We've already crafted our ... words on that in terms of meaningful choice and maybe we just reinsert those here.

**Deven McGraw – Center for Democracy & Technology – Director**

Yes. I think it's a good idea. David, it didn't even occur to me that somebody could read this set of responses and not realize that they were intended to fit together with previous recommendations on meaningful choice, and that we should make sure that those are conjoined in the set of recommendations. Because you're right, I don't want anybody to think that, oh, you just have to attest to a treatment relationship and you can get any data that you want.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

Yes, that was my concern is that by introducing this new notion of tracking treatment relationship we might be perceived to creating some sort of trump card, a wild card. But having said that, I do have some questions about the treating relationship independent of the consent issue.

**Deven McGraw – Center for Democracy & Technology – Director**

Okay, go ahead.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

That is that I think that in some of these NVEs there may in fact be valid use cases where data can be queried that isn't involved in a treating relationship. So, for example, de-identified data in purposes like research or quality measures or improvement of business operations and the like that are covered under perfectly valid HIPAA constraints, where the NVE may in fact not actually just have provider treating customers, and we would want to account for that, I think. Now I know that there's this other question about not using de-identified data for commercial purposes, but even if it's non-commercial, even if it's just a safety institute or something, you're going to have users that have authorization under law to access the data that you somehow excluded because they don't have a treatment relationship.

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

But is that what's going to happen in a query and response environment, because treatment, that's a very easy thing to defend. Once you start getting into those other types of uses that's a whole different discussion and potential set of rules and limitations.

**Deven McGraw – Center for Democracy & Technology – Director**

Let me ask you if it matters to you if it's just about what you as a provider can get from the NVE that you have joined as a participant and fully understanding the rules, this is the HE or the NVE that you've joined that you pay a fee to or whatever are the circumstances that designate your membership, versus your right to query data from another NVE for purposes other than treatment. Does that make a difference?

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

I think it's an open question as to what the full scope of entities are that will want to become NVEs. And if we think of it only in terms of today's exchange and direct, yes, that probably works okay. But I don't envision that that's where this would stop. I think this could refer to things like, for example, query health, you could have a query health aggregator node that wants to be trusted under the NVE ... of trust but which is dealing entirely with de-identified data for public health and research purposes, and Sure Scripts might want to become an NVE.

**Joy Pritts – Office of the National Coordinator**

This is Joy. I think somewhere along the line we've lost the context of the original recommendation, and it may be in the RFI process. But originally when you were talking about this issue you had isolated yourselves to the treatment context.

**Deven McGraw – Center for Democracy & Technology – Director**

We did. ... for Stage 1 of Meaningful Use.

**Joy Pritts – Office of the National Coordinator**

Right, and so there are all these other issues that you were going to address at some point, but when you were limiting your discussion to the treatment context, these were the things that you were saying that you would want to see. So it was a more limited conversation originally.

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

Why don't we keep it in that context then, rather than –

**Deven McGraw – Center for Democracy & Technology – Director**

Well, one of the things that we can do is acknowledge that our previous recommendations, which deal with meaningful consent and deal with attesting to a treatment relationship, assumed an exchange environment for Stage 1 of Meaningful Use, which is largely treatment, some public health reporting to public health authorities, and quality reporting of aggregate data to CMS, so nothing beyond that. This condition seems to assume, in fact, that the exchange is limited to those purposes when in fact exchange may in fact be highly desirable for other purposes but we don't necessarily have policies on being able to access data on a nationwide basis from NVE to NVE for purposes beyond the Stage 1 criteria, and that we would need to think those through before we would expand that universe, don't you think?

**Gayle Harrell – Florida House of Representatives**

This is Gayle. I want to jump into this because I think this is a key issue as to who has access and what that relationship is. I'm very, very uncomfortable when we're opening up a discussion without some serious thought beyond the treatment relationship or potential treatment relationship. I think we need a whole lot of public input into that.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

This is David again. I certainly agree that there are certain roles that NVEs will play for which treatment relationships are going to be ..., but the way the RFI is structured NVEs are a broader category than just those, and we can say we don't think it should be, but the way it's structured now it's a broader category.

**Deven McGraw – Center for Democracy & Technology – Director**

Yes.

**Judy Faulkner – EPIC Systems – Founder**

This is Judy. A few years ago we talked about a carve-out to having a treatment relationship, and that was for newborns, where you may have to, in order to make sure your newborn is going to be healthy, access the record of the mother, who is not the patient.

**Deven McGraw – Center for Democracy & Technology – Director**

Okay.

**Judy Faulkner – EPIC Systems – Founder**

Remember when we did that a couple of years ago, Deven?

**Deven McGraw – Center for Democracy & Technology – Director**

Yes, I'm trying to remember if we had a specific – I definitely remember it coming up in conversation, I'm just trying to remember –

**Judy Faulkner – EPIC Systems – Founder**

I think there's a question about it in the RFI ... question.

**Deven McGraw – Center for Democracy & Technology – Director**

If anything I'm just going to take the slide back to the questions that were assigned to us, are there circumstances where a provider should be allowed access to the health information from one or more individuals with whom it does not have a treatment relationship for the purpose of treating one of its patients, and –

**Judy Faulkner – EPIC Systems – Founder**

I almost wonder whether this should be a break the glass type of situation, because we might not be able to think of it all, where in fact, you've got to go through something that you know you're going to be prominent, people are going to know about it, but you're doing it in order to make sure that you save a life and maintain the health of a patient in a critical time.

**Deven McGraw – Center for Democracy & Technology – Director**

Right, although in that case you would have a relationship with that patient because you're trying to save that patient's life. I think when you're talking about whether you can query NVE, for example, to find the data on all the patients that have the same condition as the patient in front of you in order to treat her more effectively, that's a circumstance where I think we need to think it through from a policy standpoint a little bit more, but certainly I recall that we've discussed the newborn issue where the patient is the newborn but there's relevant data in the mother's file –

**Judy Faulkner – EPIC Systems – Founder**

Yes, exactly. That's one thing. I think another thing is eventually we're going to want to be able to have a rare disease and be able to check to see who else might have it, not necessarily look at the record but maybe have the caregivers talk to each other. So that's looking things up, but it isn't necessarily doing anything about it.

**Deven McGraw – Center for Democracy & Technology – Director**

Right, and then there's the question of how identifiable does the data have to be in order for you to be able to learn from it. But I think this takes on some bigger questions that I think we can't resolve in the short time we have here, but just to acknowledge that our recommendations were largely about exchange for treatment purposes. We did talk about the newborn context, and that should be reflected here. There are, however, circumstances under which we want to make exchange available for other types of purposes. The Tiger Team has not taken that on yet from a policy perspective and the fact that the RFI sweeps fairly broadly suggests that we need to.

**Judy Faulkner – EPIC Systems – Founder**

And we should. There's one other minor thing, and that is it keeps saying that the provider has to attest, two things, it could be that the provider or the provider's delegate, because very often it might be someone other than the provider who is tasked with the job of doing that.

**Deven McGraw – Center for Democracy & Technology – Director**

Like a nurse or a PA.

**Judy Faulkner – EPIC Systems – Founder**

Yes, right. And then secondly, sometimes that can be done automatically. In other words, the system can say this patient has a scheduled appointment and it doesn't need to actually have an actual attestation.

**Deven McGraw – Center for Democracy & Technology – Director**

Okay.

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

Deven, towards that point as well, does this imply that there should be a contractual vehicle already in place with providers, such as a DURSA or some other agreement, that also in addition to attestation per se legally obligates that provider to only access information for express purposes that are identified in the agreement?

**Deven McGraw – Center for Democracy & Technology – Director**

I believe that the attempt to create conditions of governance that would apply to all NVEs who voluntarily subscribe to them is an effort to avoid having to execute mini DURSAs for every NVE to NVE exchange. It doesn't obviate the need for the NVE itself to have business associate relationships and very clear agreements about what it will and will not do with data with its own participants, but then would be binding on anybody else who would request data or connection services through the NVE, but the idea is to try to avoid having to contractually create the relationships from an NVE to NVE basis.

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

I'm just wondering whether there's a way to have some federal or some standardized terms that when you decide to participate in an NVE that they automatically attach, so you almost have this fabric throughout the United States that applies, if that makes sense.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

I think that's one of the goals here is to set these criteria high enough so that the trust level is there so that you can have these conversations nationwide without additional contractual ... conversations. But my guess is that this will evolve into something that had some common root trust that everyone adheres to but then in specific use cases you're going to have to adhere to more rigid constraints, some of which might be DURSA like, but not necessarily require direct contracting.

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

I wasn't saying it had to be direct. I'm just thinking of a way to put –

**Deven McGraw – Center for Democracy & Technology – Director**

I'm just wondering, Judy, I totally see your point because attestation is just a tool of signifying that there's a relationship in place, and I think we can wordsmith this to say that when the exchange is for treatment purposes certainly the provider who's requesting the information, that there should be some way of indicating that there's a treatment relationship or a pending treatment relationship. So whether that's done automatically through the system through appointment scheduling or through some form of attestation is –

**Judy Faulkner – EPIC Systems – Founder**

Sure, in many cases you can figure it out.

**Deven McGraw – Center for Democracy & Technology – Director**

Yes, we'll certainly try.

**Judy Faulkner – EPIC Systems – Founder**

Yes, right.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

This is David. I would agree with that and just say the language might be something along the lines of "take means to ensure that" rather than get an attestation. The other thing is that it may well be that the NVE delegates that to the client application, so it may be that the NVE somehow has to assure that the client has done that gating, but it may not be actually mediated by the NVE services. In other words, an EHR connecting to a local HIE, the EHR may have in place mechanisms to prevent inappropriate access to the patient's record and subsequent access to that patient's data in the HIE, and it may not be the NVE per se that does that.

**Deven McGraw – Center for Democracy & Technology – Director**

Okay, that makes sense to me.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

"Take means to ensure that," which to me comes back to the consents and permissions things really, ensure that the data's being used legally.

**Deven McGraw – Center for Democracy & Technology – Director**

Yes, I think that's right. All right, we have some wordsmithing work to do on this, but I think we have the spirit of consensus around this one.

**Judy Faulkner – EPIC Systems – Founder**

This is Judy. Was there a topic that flew by about basically whether we should be doing rules of the road across the whole country, or that each NVE should be doing this on rules and relationships? Did that fly by, or did I get confused about that?

**Deven McGraw – Center for Democracy & Technology – Director**

No, it didn't. We didn't get assigned the question on how to do governance and do it, and whether there should be rules of the road. I think the theory of the RFI is that NVEs, as their business associates, as their participating providers, that there will be a set of rules that they come to agreement with, with respect to their own internal, not internal to one organization, but internal among organizations served by an NVE, decisions about purposes for which data can be exchanged, etc., etc. What the RFI is attempting to broker is a set of rules of the road for exchange across NVEs.

**Judy Faulkner – EPIC Systems – Founder**

Right, and that's important.

**Deven McGraw – Center for Democracy & Technology – Director**

Yes, yes. The Governance Workgroup got most of those meaty questions but as a Policy Committee member you'll be able to weigh in on all of that.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

This is David. I broached the subject just briefly, but what I was getting at is slightly different, which is that in some of the other workgroups that I'm on that have been addressing these things is the ... and somewhat consistent notion that there are CTEs that all NVEs would have to meet and then there's a subset of CTEs that may be protocol specific, depending upon what the NVE actually does, that may be different depending on what you do. So an NVE that only supports directed exchange would have a different set of criteria than an NVE that supports a query response exchange, but that everyone would have to meet core sets of trusted identify proofing and the like so that you felt comfortable connecting.

**Deven McGraw – Center for Democracy & Technology – Director**

Right. I think that's right, David. And it's not entirely clear that the RFI yet makes those distinctions very clearly.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

No, no, it doesn't. It consistently doesn't make those, and we've been consistently trying to say it should.

**Deven McGraw – Center for Democracy & Technology – Director**

All right, let's try to get to the last couple of ones here, if we can. The next two have to do with the circumstances when an NVE assembles or aggregates health information that results in a unique set of IIHI, which unique is not defined, but which I take to mean the NVE has repackaged data or collected it in a way that it's not just the data that came from the provider, but it's something unique that perhaps the patient could not get from the individual provider. And in that circumstance condition S8 says the NVE must provide individuals with electronic access to their unique set of IIHI, which is in the same way that covered entities have an obligation under HIPAA to provide electronic access to electronically stored data in a designated record set for their patient, and I'll just skip ahead. S9 then says that when you have this unique set of IIHI then the NVE must provide individuals with the right to request a correction and/or an annotation to this unique set of IIHI.

So essentially what's going on here is they're taking two of the core rights of HIPAA that apply to covered entities, which is the right to request access to your health data and to get an electronic copy of it when it's held electronically, and the right to request an amendment or an addendum to health data and asking that the NVE do this for patients in cases where they are assembling or aggregating data that results in a unique set of IIHI. And the questions that are asked here are, question number 40: what are the further parameters, if any, that should be placed on what constitutes a unique set of IIHI? And then the questions on condition S9 having to do with a request for correction, if the NVE honors it what is the impact that such a correction have if the corrected information was accessible by healthcare providers and not used solely for the NVE's own business processes? And then are there circumstances where an NVE should not be required to provide individuals with the ability to correct their IIHI?

And essentially what we had said, we didn't address this issue specifically, although we certainly did endorse the right of individuals to receive copies of their health information electronically, both as a Tiger Team as well as the Policy Committee, with respect to meaningful use criteria and similarly with respect to being able to request an amendment and to have information added by the patient pursuant to HIPAA. We wanted to make sure that the EHRs would have the capability to do that through the certification process, but this is a little bit new in terms of its applicability to an NVE. Personally, I think if we can land on the right definition of when something is unique it seems like the right thing to do, this is my own personal viewpoint here, for patients to be able to get this from an NVE that's actually assembling and creating unique data that the patient couldn't otherwise get from the healthcare providers. That would be something that the patient should be able to access and have corrected in accordance with HIPAA's current rules on amendments.

But what do folks think about this? And forgive me for glomming these two together, but they seem very similar and I think that's the only way we have a hope of dealing with them in the time we have left.

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

This is John Houston. I'm trying to envision a case where the NVE would ever have unique information that wouldn't be available through a provider somewhere, because I look at this and it scares the heck out of me, the fact that you're going to have these NVEs out here having to work directly with patients. My thought is, is that if this ... is going to exist I think that a provider still should have some roles such as acting as the agent of the NVE in order to accommodate these requests, because the provider can do two things. One, they can ensure that the patient is who he or she says they are, do some identify proofing, and also act as a middleman to help accomplish any of the request for information or any type of corrections that might need to be performed.

**Joy Pritts – Office of the National Coordinator**

This is Joy. I think part of the rationale behind this was that at least in some of the models the NVEs will create a longitudinal record of an individual that may have information in it that doesn't relate to that particular individual and it won't be the provider who's creating that kind of a record, it would be the NVE doing that. So how does the individual make sure that the records, the information that's shared about them is indeed their information, or we move information that is not related to them.

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

I can certainly understand that explanation. That still takes me back to the thought that somehow the providers that participate with the NVE should have some responsibility or take some type of active role to act on behalf of the NVEs to help accommodate the patient's request for information and/or correction.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

This is David. I think the patient should have that ability. I think in many cases they'll go through a provider because that's the only way they'll be able to figure it out, but there will be times when the providers are just too busy or not interested, and in this era of patient empowerment I think ... is correct.

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

My concern is the NVE is going to be ill prepared typically to be able to handle those types of requests, and also how do you decide, again, going back to identity proofing for a second, the patient's identity, these NVEs become fairly virtual, where do you show up to do this. I think that the provider is in the best position in most cases to act as that agent of the NVE.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

But an NVE that's taking on the responsibility of creating a longitudinal health record for a person has taken on a deep responsibility and we'll have to match that with concomitant capabilities.

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

I understand building a record like that, but the NVEs are still, in many cases, very virtual in nature. The patient has a relationship with the provider and I would think that that's the best vehicle, in my opinion, to ensure that the record is straightened out. And as you said, there's a concomitant responsibility as a provider if they decide to participate with an NVE, that maybe these are the types of things that they also need to do in the event that there's some type of issue.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

I think there's a direct analog here to the credit reporting agencies, which fall tooth and nail to avoid having to have consumer access to their credit record. But it was only after consumers got access to their credit records that they discovered how incredibly many errors there are in those records, and only then did consumers have an avenue to do something about it, because you can't go to every merchant and say, have you ever submitted something about me in error to the credit agency? I don't see how you can avoid this.

**Deven McGraw – Center for Democracy & Technology – Director**

Yes.

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

See, I tend to disagree with you because I just think that practically speaking, in my opinion, the NVEs, they're very difficult for the patient to effectively interact with them, and I think providers are going to be in a much better position to do that.

**Deven McGraw – Center for Democracy & Technology – Director**

So here's what I'm going to suggest, because this is one of the things that we get to do with an RFI that we have less flexibility to do in other contexts, which is to be able to say that there are a number of us who very much support these CTEs being applicable to NVEs, but that some folks raise concerns about the NVEs lacking the appropriate relationships with patients and that it might not necessarily be ideal for patients to be able to get this information from an entity that they don't necessarily have a relationship with.

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

Yes, things like identify proofing and simple capacity to understand the interaction of the record. The other thing too that has to happen here, Deven, is that somebody may have to explain to the patient why the record's correct, it is the NVE ... having any healthcare background being able to help the patient sort through the record effectively.

**Deven McGraw – Center for Democracy & Technology – Director**

Right. But that's what I'm going to suggest that we do, only because, again, we have that leeway to do this with an RFI, and all of these responses will have to come up through the Policy Committee anyway.

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

I would agree with your recommendation.

**Deven McGraw – Center for Democracy & Technology – Director**

Okay. I'm going to do my best, John, to capture your concerns, but if you have a moment and you can shoot me an e-mail, that will help me articulate them better.

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

If I can remember what I said.

**Deven McGraw – Center for Democracy & Technology – Director**

Well, we also have note takers on the call, so between that and what you might recollect we'll do okay. Does anybody else have something that they want to add on this one?

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

This is David. I'll just make one, maybe it's obvious, self-evident point, but it might also be the case that certain NVEs actually synthesize data that is not available to any of the contributing systems, risk scores, suggested plans of care and the like. So it's not just a question of errors in the longitudinal record, it could be –

**Deven McGraw – Center for Democracy & Technology – Director**

That it's really truly unique data that doesn't exist elsewhere.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

Correct, derivative data that could have, it's like a FICA score in your credit agency. That's a synthetic value that has a very profound impact on you and if it's wrong you need to go and find out why.

**Judy Faulkner – EPIC Systems – Founder**

This is Judy. Do you see a future where it may have DNA data and rather than letting it sit there inertly it is actually interpreting the DNA data to what will happen to you down the road?

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

Yes. Some of the companies do that already.

**Deven McGraw – Center for Democracy & Technology – Director**

I think Judy has just suggested that 23andMe, why you might want to become an NVE.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

Yes, yes, deCODE, 23andMe, Navigenics, they all do that.

**Deven McGraw – Center for Democracy & Technology – Director**

Okay, we will reflect the discussion of the Policy Committee in our response to these questions. All right, we actually are able to get to the additional question on de-identified data that folks had requested that we be able to address and we've got a little bit of time, so let's go for it. I'm on slide 17, Condition S6: "An NVE must not use or disclose de-identified health information to which it has access for any commercial purpose." And the RFI specifically asks what impact this would have on evolving business models for NVEs and would the additional trust gained from the CTE outweigh the potential impact on these models and on what other entities might this have in effect. And so we've developed a straw man response based on some of the concerns that you all raised when we had our very first discussion of this RFI at the end of Steve Posnack's presentation of all of the conditions, and it also does reflect some of the discussions that I've been able to participate in with the Information Exchange Workgroup on this very same topic. But it's being revealed to you all in this form for the first time here, and basically what we have in the straw man is that prohibiting NVEs from using or disclosing de-identified data for commercial purposes could eliminate a potential model of sustainability. Other entities would be permitted to do this, again with de-identified data, since it's not regulated, whereas, this would be prohibited for NVEs.

Defining what is a commercial purpose in healthcare can be a challenge, as healthcare entities must generate revenue in order to remain in the business of providing healthcare. In other words, what's commercial and what is not in healthcare, instead of prohibiting uses and disclosures of de-identified data for commercial purposes ONC should instead require NVEs to commit to not re-identifying de-identified data and require NVEs to bind their downstream de-identified data recipients to the policy of no re-identification. This is consistent with some recommendations that the FTC made in its recent report on consumer privacy, and as the Tiger Team and the health IT Policy Committee previously recommended, and as we've stated in other parts of our response to this RFI, NVEs should be required to disclose uses and disclosures of de-identified data.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

Wow, I think you've nailed it.

**Deven McGraw – Center for Democracy & Technology – Director**

Whew! It's been so interesting to me the consistency of the discussion on the CTE throughout the workgroups that I've been able to sit in on and participate on. I have a colleague in our San Francisco office who's been covering the Governance Workgroup calls for this, I've been on these calls as well as Information Exchange, so again very similar threads of concern about understanding the intent of the CTE but being very worried about unintended consequences for it. So I just try to capture all of that in the response.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

This is David again. I think the key thing here is that what is illegal is re-identifying data that has passed the HIPAA standards for de-identification, that's what should be prohibited, not using data according to HIPAA standards.

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

This is John Houston. I fundamentally have a different view on this matter, because I think that there are a lot of other unintended consequences that can occur, and I have seen occur in healthcare, where de-identified data is identifiable down to the institution level or provider level and is used for a whole host of competitive or anti-competitive purposes. I have seen drug manufacturers try to use prescribing patterns to set pricing strategies. I have seen other types of medical supply providers use those for similar purposes. It takes away a revenue source even for providers themselves who maybe look at that data as having a competitive advantage when it comes to a few things like their research endeavors, and all the other things that may be intangible but value adds to the particular provider or health system.

**Deven McGraw – Center for Democracy & Technology – Director**

John, do you think on that latter point that NVE is supposed to be a business associate of its participants, that if the participating providers don't want it to be mining the de-identified data that they could prevent that from happening as a matter of local policy?

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

Honestly, I think we're going to have trouble with that now, although I'll point to a great example, there are a number of accrediting bodies out there today, societies like thoracic surgeons, or I forget which body it is, that in order to get accredited you end up having to become part of this, you have to subscribe to them. And they force a business associate agreement at you that gives them so many rights to the data on a de-identified basis, and then when you say, well, I have a problem with that, they say, then don't subscribe. And then the physicians come back and say, well, wait, I need this for my accreditation, so we have to do this. I think the same thing could happen with respect to NVEs as well. They know you need to be part of an NVE because of meaningful use and other things, but my fear is that it's going to be almost a contract of adhesion.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

John, this is David. I didn't follow. I got your examples and they make good sense, but your conclusion is that NVEs should be prohibited from any use of de-identified data?

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

I think for commercial purposes.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

What is commercial? Is staying in business commercial?

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

No, no, commercial meaning resell of data to pharma companies or to –

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

So Sure Scripts and others that have had court tested cases, all the way, I think, to the Supreme Court in the IMS case, right, of right to use the physician's identify for marketing purposes you would preclude NVEs from doing that?

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

I have a basic objection. Whether somebody can say I'm allowed to do that and get it into a contract that says I can do that, that's fine. It might be legal. My point is that these contracts can very quickly become contracts of adhesion because you might not have a choice but to join an NVE, and that NVE's going to say, hey, when you subscribe to us here's the way your data's going to be used, and then they're going to lay out all these de-identified data uses, which might include we reserve the right to sell your data to pharma, or whomever else. Or it might be that they can sell the data to anybody who might then use it for developing benchmarks in the industry for competitors doing marketing against you potentially.

**Judy Faulkner – EPIC Systems – Founder**

This is Judy. I agree with you. It makes me feel really funny. I'm just thinking, what would this look like, the headlines of the paper, which is we agree to allow reuse of de-identified data for commercial purposes because otherwise they may not be sustainable, so it's to give them an ability to be financially profitable. That's a weird reason. When I look at some of the things that can be done, let's look at de-identified data and back to the DNA example, so maybe you're looking at results that you get from ethnicity or for location or a bunch of other things, where you don't necessarily then get down to an individual, but you can get to groups of individuals, and that's what my worry might be.

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

And by the way, the other example too is if there are large health systems in one region would one health system be able to buy data and use it to mine for strategic, more than strategic planning, but to actively compete against another provider. Those things concern me.

**Judy Faulkner – EPIC Systems – Founder**

I think what's really interesting is there appears to be a trend of the payors buying HIEs, so as that goes what is the reason that they're doing that?

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

That's a different set of concerns.

**Deven McGraw – Center for Democracy & Technology – Director**

I think it is too. I think the difficult thing is that what essentially this condition is doing is prohibiting NVE, I mean, right now if the data qualifies as de-identified under HIPAA anyone can buy it and sell it and use it for any reason whatsoever. So it's a very open marketplace. This condition, if applied only to NVEs, takes them out of that marketplace, but nobody else.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

Right, that would be my point is if we don't like the fact that HIPAA allows providers and their institutions to be identified then we should address HIPAA.

**W**

Yes.

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

This is different because this is really a different phenomenon we're talking about here the way that data rolls off and aggregates and then to be disseminated by a third party that you might be obligated, you have, again, the contract of adhesion that you're forced to use and now they have your data and they're reserving all of these rights and you have no control as a provider over how they decide to use it on a de-identified basis. I just think this is a real challenge.

**Deven McGraw – Center for Democracy & Technology – Director**

Yes. I'm not disagreeing with you at all, John, that it's a challenge, but today ... could do this whether or not the providers on its medical staff agreed or not. There are electronic health record vendors out there who are using this as a business model in order to offer providers a cheaper way to achieve a certified EHR for meaningful use purposes, and it's a business that anyone can get into. I have similar concerns about certain uses of de-identified data, which it gets harder and harder to pinpoint regulate those in light of the recent Supreme Court decision, but having said that I think applying it to one sector of the marketplace without having overarching policy that really applies to many more actors is not necessarily the way to go about fixing it.

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

I just think we're opening Pandora's box.

**Deven McGraw – Center for Democracy & Technology – Director**

It's open, baby.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

It's already open. I'm looking for the –

**Deven McGraw – Center for Democracy & Technology – Director**

Who do we close it on?

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

Yes.

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

I understand.

**Judy Faulkner – EPIC Systems – Founder**

I kind of agree with John, because I think it's going to be harder to close it than it will be later on to open it.

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

The other thing too, when we started up our HE in this area we were with nine other providers, and this was one of the things that really we decided in our HE that the members had to approve all uses of data, even ... de-identified basis, just because of this, of concerns over how is data going to be used in a competitive marketplace and would providers be using it against each other in terms of marketing strategies and trying to take market share over. I just think it's something that has a lot of unintended consequences, to use the big term you used earlier, Deven.

**Deven McGraw – Center for Democracy & Technology – Director**

Yes. I can see that, and I'm actually glad to hear that in your particular circumstance you were able to exert market power with your HIE to control the uses and disclosures of data through your HIE, but I can appreciate that that kind of bargaining power might not be available in other markets. We're losing time and we still have to get time for the public, so I think that we have a real difference of opinion on this. I could in no way present it as a set of consensus conclusions, but I would like to reflect the basis of the discussion, both John and Judy's well-articulated concerns, as well as the straw man responses that at least David and I agree with. And again, the Policy Committee will have to consider that, along with the deliberations of all the other workgroups as well as the members themselves in trying to figure out what to do with this one.

**Judy Faulkner – EPIC Systems – Founder**

So are you going to leave that as open, then, Deven?

**Deven McGraw – Center for Democracy & Technology – Director**

Yes, I'd like to. We can just stay silent on it, or my preference would be to reflect the difference of opinion that we had on the call.

**Judy Faulkner – EPIC Systems – Founder**

One thing I would like to say from my own experience is that I see a healthcare organization, such as UPNC, take a different look at how they deal with their patients and data, than a third party group that doesn't have that same association with the patients. So it's hard to say that because the healthcare group could do it therefore others should be allowed to too, because I think they're two different situations.

**Deven McGraw – Center for Democracy & Technology – Director**

That's a fair point, ...

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

Deven, I agree with taking the latter approach, and I trust you to articulate the different opinions in a way that gets it out on the table.

**Deven McGraw – Center for Democracy & Technology – Director**

Okay, thank you.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

Can we say that we do agree with the specific language about prohibiting re-identification –

**Deven McGraw – Center for Democracy & Technology – Director**

Oh, thank you, David.

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

Absolutely.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

I think that that's absolutely critical. I agree that these others are valid points, I'm just concerned, as is Deven, that this is already the way the world works and to exclude NVEs from that space would be counterproductive to what we're trying to achieve here, which is trusted frameworks.

**Judy Faulkner – EPIC Systems – Founder**

We don't do things just because others do it.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

No, but –

**Judy Faulkner – EPIC Systems – Founder**

Your mom taught you that one.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

... data available out there.

**Deven McGraw – Center for Democracy & Technology – Director**

I'm calling my mother, Judy.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

Yes.

**Deven McGraw – Center for Democracy & Technology – Director**

Yes, I think we can, from a consensus standpoint, make the point that there should be prohibitions on re-identification that would apply, regardless of how the rest of this discussion on uses of de-identified data for commercial purposes comes out.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

It sounds good.

**Deven McGraw – Center for Democracy & Technology – Director**

All right, we're a little over time. I think we should open up the line for some public comment before we let folks go.

**MacKenzie Robertson – Office of the National Coordinator**

Operator, can you please open the lines for public comment?

## **Public Comment**

**Operator**

(Instructions given.) There are no questions at this time.

**Deven McGraw – Center for Democracy & Technology – Director**

All right, thank you all very much. We really made some pretty amazing progress, with very difficult questions, we've got a little bit of wordsmithing to do, which we'll get out for you to take a quick look at before we submit it for the Health IT Policy Committee's meeting on Wednesday. For those of you that I'll see there, I'll see you there, and for the rest of you, again, thank you and we'll have another topic to discuss the next time we talk.

**John Houston - University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics**

Thanks, Deven.

**Deven McGraw – Center for Democracy & Technology – Director**

Thank you.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**

Thanks.

**W**

Thank you.