

**Governance Workgroup**  
**Draft Transcript**  
**November 5, 2010**

**Presentation**

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Good afternoon, everybody, and welcome to the HIT Policy Committee's Governance Workgroup. This is a federal advisory committee, so there will be opportunity at the end of the call for the public to make comment, and just a reminder for workgroup members to please identify yourselves when speaking.

Let me do a quick roll call. John Lumpkin?

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Present.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Mary Jo Deering?

**Mary Jo Deering – ONC – Senior Policy Advisor**

Present.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

John Glaser? Laura Adams?

**Laura Adams – Rhode Island Quality Institute – President & CEO**

Present.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Leslie Harris? Christine Bechtel? Christine is on. John Mattison? Girish Kumar? Linda Fischetti? Michael Matthews?

**Michael Matthews – MedVirginia – CEO**

I'm here.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

John Houston? Carol Diamond and Wes Rishel will be joining late. Tim O'Reilly? Mariann Yeager?

**Mariann Yeager – NHIN – Policy and Governance Lead**

I'm here.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Elliot Maxwell?

**Elliot Maxwell – ONC – Expert Contractor for Health IT**

Here.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Adam Eighton?

**Adam Eighton**

Here.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Anyone else, please? Okay. With that, I'll turn it over to Dr. Lumpkin.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Great. Thank you. Well, why don't we go to the next slide? Just so that those who are listening in on there, this is the list of the members of the committee. What we want to do today is just to give a little bit of background of how we got to the point where we're at right now. The next step will be then to talk a little bit about the feedback that we got from the workgroup and blog, and this will give me a good opportunity to just clarify something about the term that you will see on our slides where it says NW-HIN for the Nationwide Health Information Network. This does not reflect the fact that there is a new name for what has previously been called the NHIN. It is just shorthand that we're using for the governance committee to talk about the health information network that we are describing the governance process for. The Office of the National Coordinator, I'm sure, when they have come up with a new name, will find the appropriate venue in order to make that announcement.

After we talk a little bit about the workgroup and the blog agreement, discuss the results from the assessment of existing mechanisms. We're going to consider some potential governance roles, and then talk about the focus, which I'll get to in a little bit, about where that led us to the area where we need to start to really nail down what we're going to recommend in just a couple weeks to the policy committee.

Just to refresh, the next slide, what we've done in the first phase, we conducted an environmental scan, which began with input from members of the workgroup, and then we had a hearing on September 28<sup>th</sup>. We heard from a broad group of individuals, including those who were currently engaged in exchange of health information through an HIE. We heard from the state of Minnesota, which already has legislation passed. We also heard from some other venues that are engaged in exchange, for instance in the finance arena, and some other models of governance from the National Quality Forum. From that hearing, we got information, as well as from those who submitted information in writing.

As a result of that, we developed a set of recommendations that were presented to the policy committee on the 20<sup>th</sup> of October. The first component of those recommendations were the nine sound health information network governance principles followed by the framework with the four areas, and we essentially did that by focusing in on what governance should cover. We got a positive response from the policy committee, and based upon that, we've gotten some input from the small group, and have begun to plow forward in trying to develop our final recommendation as to who and how this governance process should be developed.

The first component of that was to assess whether or not existing mechanisms are appropriate for the health information network governance process, so what's out there and how well does it fit. This includes looking at what entities are in place, whether or not they met the broad scope. Were they consistent with our principles? Could they be brought to scale? Could they actually, if these entities are in existence, could they meet the fullness of what would be required in the conceptual model of governance?

Now just to give you an example what I mean by that is that under the DURSA, those organizations first engaged in the health information network. The initial version of the DURSA focused in on every entity would be a member of the coordinating committee. That obviously would not be something that could be scaleable. Subsequent approaches to the coordinating committee are looking at the concept of having a more representative coordinating committee that would not include every single participant in health information exchange, and that may be a more scaleable model.

Once we've identified those existing mechanisms, we've compared them, and we can then identify the gaps and begin to address the issue for our recommendation on the 19<sup>th</sup> of this month on whether or not any new entity or entities are needed in order for us to achieve our goal of governance. Our charge is also to recommend that overarching governance process and to recommend how these functions should be implemented and by whom.

When we went out to the public, we did this in two ways. We submitted a blog post, which was put up on the ONC site on behalf of our workgroup, and we've also solicited information by e-mail. We asked a certain set of questions, which are, are there existing entities or processes performing a particular governance function, as we identified in our report to the policy committee on the 20<sup>th</sup> of October? We asked, does it accomplish the health information network objectives and principles, and can it scale to meet the needs? Then we asked what essential functions or activities are not currently addressed, but are needed now to overcome these barriers and to provide and to facilitate and promote the exchange carrying forward in the major overarching requirements that are they going to promote and engender trust in people who are engaged in exchange? Will they promote interoperability?

The next steps are to then identify should the federal government perform that function directly or delegate it? Delegate it to whom? If a new entity is needed, what type of structure and attributes should it have, which is the major focus for what we're going to try to accomplish today.

From that activity, we received 33 blog posts and 149 e-mail comments, which we are incorporating into our work. Those comments fell into a certain number of four areas, categories. One is categories of encouraging the use of clear and plain language. Other categories were related to the principles. There were comments that were related to technical components and direct responses to the questions. We received these 182 comments from general consumers, which represented the majority of the comments we received, small businesses. We received some from physicians, hospital administrator, from companies and from associations.

Basically the general feedback that we received, as I mentioned, there is a need for more education and governance using clear and plain language. I have to admit that when I talk to some of the people that I work with about what I'm doing in the governance workgroup, it's probably the first time since I did my internship in anesthesia that I put so many people to sleep. But what we know is that despite that that governance is critical to the functioning of the Nationwide Health Information Network to assure that it creates an environment for trust and that it promotes interoperability. So despite the fact that many people are not clear on what we mean by governance, the comment was that we need to try to explain this in ways that the public can understand.

The other areas of the feedback are that governance should have a strong emphasis on secure, assuring privacy and security, and that is a comment that the workgroup resonates with. We've emphasized that throughout all of our meetings and our discussions about the governance mechanism that only as long as you can assure privacy and security can you create the environment of trust that enables the exchange of health information.

The fourth area is that governance should leverage existing mechanisms where appropriate with specific suggestions to leverage the FCC, for instance, and state regulatory frameworks. That's consistent with what we heard at the hearing on September 28<sup>th</sup>. We also got suggestions for state and federal partnership, for national level policies and standards, particularly with input from the health information technology policy committee, and suggestion for some sort of national accreditation program for qualified entities.

Looking at that, and then based upon how we ... from here, there are basically three roles that I would like to focus the work of our workgroup in our meeting today to address. These three areas are looking at based upon a number of, again, the deliberations by the small group, our responses that we got back from public input, and the analysis that all led us to this particular point. Recognizing that we, as a committee, are not going to come up with a recommendation that will be comprehensive in the sense that it will cover every component of every aspect of governance. We're trying to focus in on the high priority areas where it's most important to insure the further development of the Nationwide Health Information Network. Those three areas are the federal role, including relationship to other roles, the coordination role, and the validation role.

Now as we get into each area, we'll see that there may be a variety of approaches for coordination and validation, and that there may not be a single pathway, although what we're going to try to do is to hone

this down as much as possible to a number of set of ways that this can be done. I would also remind that up until this point that we have set the framework for decision-making, but up to this point, we haven't made the decisions, and that's really what we're going to be doing today. What you're going to be seeing is a way to structure the conversations.

Let me move into the next slide, into the first area, which is the federal role. The federal role encompasses the Office of the National Coordinator's potential role and that of other federal agencies and respective responsibilities, which would be explored at a later date. We pretty much have heard through our work that there's a need for strong federal leadership and federal engagement, and that national level conditions for participation in the Nationwide Health Information Network are important and would be set at the federal level. These include eligibility criteria, that's eligibility to participate within the Nationwide Health Information Network, the policies, business, and legal requirements, particularly an emphasis on privacy, and national level interoperability and technical requirements, which are part of the strategic interoperability and I forget what else we call this framework – standards and interoperability framework. Then to establish the needs and requirements for validation processes, which we're going to discuss in a little bit more detail later on.

We also are at the point of identifying that it would be the federal role to oversee the overall Nationwide Health Information Network governance process to look at ways to coordinate the alignment with the incentives, whether they be the current incentives under HITECH or future incentives and actively participate in coordination process for applying conditions for participation. So we're talking about a role for the federal governance, identifying what those conditions are for participation within the Nationwide Health Information Network. We would also believe that federal entities that would wish to exchange ... Nationwide Health Information Network should meet the same conditions for participation as any other participant. Let me note here that we understand or should understand that in looking at doing these processes that the conditions, particularly for coordination and for validation, may have one or more processes for which this is achieved and that, at this particular point, we're not precluding that there may be alternative processes that would be part of this governance process.

Now I'm on to slide nine, and I think I went through that, so let's go on to the next slide, which would be the attributes for this federal role, that it would be accountable for assuring the public trust, for assuring privacy and security of the data, and encouraging interoperability. That the federal role should have the ability to coordinate across the federal government, and that authority and ability to oversee and assure that there is appropriate coordination across the various governance roles, whether they be government or nongovernmental.

Having put that as background, on the next slide, what we have is the considerations. So what we would want to do under the federal role is, as a group, reach some agreement on which existing federal authorities could be used, what changes would have to be made so that they're consistent with established government principles and objectives. How best do we align the federal and state roles? The last question particularly attains to some of the information we received about the work that's being done in a number of states where there, in fact, actively engaged, as in the case of Minnesota with legislation and identifying the overarching governance of exchange within their state.

These are the questions we have. Do we have comments or questions from the workgroup on the federal role?

**Michael Matthews – MedVirginia – CEO**

Nice overview. I have a few points, and I'm not sure whether they belong here or whether or not you want to finish out the rest of the piece first before we engage in the dialog.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

I think this is the point, recognizing that we're going to talk about coordination and validation process later. Let's get everything out, and if we need to defer them to the later sections, we can, but better to get them out now.

**Michael Matthews – MedVirginia – CEO**

I think this is a time for us to make sure that we have our language as precise as possible because this thing is going to be communicated widely to people who are not as deeply involved or have had as much time to discuss and think through some of these things. There are probably three points I want to emphasize that we should have total clarity on. The first and, to me, the most important is always making sure that we are clear whether or not we're talking about exchange or whether we're talking about overarching NW-HIN. I know we've set our workgroup's work is around that overarching NW-HIN work, but it seems like we often gravitate in our language and conversation to things that seem to relate mostly to exchange.

So, again, I want us to be clear, as we move forward, and perhaps getting more specific than as we move forward at this point in our development process if exchange is what's under discussion that we clearly label it so, that we acknowledge the entities that are currently involved in exchange, including the coordinating committee and ONC in the process. Then if enhancements need to be made to the current structures and processes, that those are identified. But that's still within the context then of the governing authority related to this new thing that we're talking about, the NW-HIN. So we've got the overarching what's NW-HIN, how does that relate to exchange, and then what else is to be governed, if anything, outside of exchange under NW-HIN. Let me stop on that point to see if, first of all, it's clear, and then I want to tie that back to a couple other pieces.

**Mary Jo Deering – ONC – Senior Policy Advisor**

Perhaps for those who are listening to us who might not have heard some of the earlier discussions, I would put on the record that as ONC set up this workgroup, our charge to the workgroup was to be agnostic as to both technology and models of exchange, and that it would be comprehensive, so that was ONC's thinking when we went to you for guidance.

**Michael Matthews – MedVirginia – CEO**

Yes. I certainly am in concurrence with that, Mary Jo. I just think, as we're in the middle of these discussions, a lot of the examples, a lot of the issues and so forth that we talk about have to illustrate whatever the opportunity is or challenge is of whatever it is. We seem to gravitate toward exchange as examples, and so all I'm trying to do is to draw a fine point on if it's an issue around exchange, I think, because of the history of exchange, that there might be certain approaches in governance related to exchange that are different than NW-HIN and some of the issues there because, by definition, we're talking about the creation of something new. What's required of the something new, to me, is to be coordinated with what exists today related to exchange, and we're not talking about a replacement of the existing structures with exchange. There's no particular punch line to that other encouraging us to be clear which one we're talking about during the course of the conversation.

**Laura Adams – Rhode Island Quality Institute – President & CEO**

Just in line with that clarification component, I just want to be sure I understand what you're saying. When you're referencing exchange, you're referencing it as a verb, not the NHIN or NW-HIN Exchange with a capital E, right?

**Michael Matthews – MedVirginia – CEO**

No, it's not. When we first started out, our nomenclature has evolved. We started out calling Nationwide Health Information Network the Nationwide Health Information Network, and then NHIN Direct came along, and so we then clarified that an exchange formally known as NHIN needed to have a new term to be able to differentiate it from NHIN Direct, and so we started calling it NHIN Exchange. So now there's the third possible name of NW-HIN as a placeholder, which would then presumably be over or have some kind of authority, responsibility role of coordination or oversight for both the NHIN Exchange, which was formally known as NHIN, and Direct and, as Mary Jo said, other things that might not be so specifically named.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Other comments?

**Michael Matthews – MedVirginia – CEO**

John, if I may then.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Go ahead.

**Michael Matthews – MedVirginia – CEO**

I'm going to tie it to two other pieces. One is we've also drawn a distinction between the role of governance versus the role of operations. I think that's one that we need to continue to be careful with our language on as well, just like on slide eight, establish the NW-HIN validation needs and processes. Again, I think we're all, the ones who have been involved in this are clear about the distinction between operations and governance. The governance needs to make sure these processes are in place, but not to do the processes. I think, as we start moving this forward through larger and larger audiences, that we need to be very precise in what a governing authority's role is related to operations and the operator itself.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

I think that comment on the validation process, we need to come back when we get to that, just to make sure that as we're developing that recommendation, we make it really clear that we're talking about the governance of that process.

**Michael Matthews – MedVirginia – CEO**

Great.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

I thought you had another point.

**Michael Matthews – MedVirginia – CEO**

I do.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Are there any other comments on that point before we move on? Okay. Hearing none, go ahead.

**Michael Matthews – MedVirginia – CEO**

Thank you for the opportunity to weigh in on some of these things. The third one was captured from our last meeting, and I appreciate the piece around the federal engagement. I just think we need to put it in bold. Put an exclamation point behind the federal agency engagement that I know that's not something that ONC is in a position to lever in the sense of having VA, DoD, SSA, IHS, CMS, etc. But we're talking about the federal role and not ONC role. From the federal role, having the Feds show up with active, enthusiastic, not just engagement, but participation and commitment. I keep saying it, and I'll keep saying it. I think the Feds in this space are the kingmaker with our NHIN Exchange, not just Exchange, but our NW-HIN, all of the activities that we've been talking about here. I don't want to see anything less than very aggressive and active participation on their side. I think anything less than that is going to compromise our success. With that, I've exhausted my points. Thank you, John.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

On that last point, then it would seem to me that we ought to make it clear in our recommendations when we talk about the federal role that there needs to be a clear entity that has the responsibility to make sure that there is that coordination. By assumption, also has the authority to do that. Is that fair? Hello?

**Mary Jo Deering – ONC – Senior Policy Advisor**

I'm sorry, John. Were you addressing me? I thought you were talking to John.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

No, to Mike.

**Mary Jo Deering – ONC – Senior Policy Advisor**

I meant to Michael Matthews, right?

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Yes. Did we lose Michael?

**Mary Jo Deering – ONC – Senior Policy Advisor**

Michael, if you're trying to answer that question, let me say that you're on mute. While you jump up, I think that what we were—and I want to clarify, John, what you just asked. Michael was getting at the point of having the federal agencies participate. I heard you talk about an entity that would have the authority to be able to make sure there was federal coordination. I wanted to clarify both your response to, Michael, and make sure that we were synched up here.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Yes, and I was asking the question of Michael whether or not that was – what would satisfy the need, whether it's to insure participation versus having authority to coordinate.

**Michael Matthews – MedVirginia – CEO**

John, my apologies. Don't let it reflect on my technological prowess, but I thought I was going on mute, and I hit disconnect, so I missed your question.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

I would have some judgment about that if I hadn't done that myself a number of times. The question was, you had talked about having this federal coordinating entity, having the ability to get the federal agencies to participate. I was raising the issue in asking you if, by that, did you mean also that this entity that we were talking about have some authority to assure the coordination at the federal level, or are we looking at basically them having a role getting these agencies to participate because they're different?

**Michael Matthews – MedVirginia – CEO**

They are different, John. When I said those comments, I was thinking more of federal role more generally, not the federal role as embodied in with the authority inside our new governance structure or governance authority here. I think that's a fascinating question how that authority could actually be created and granted, but just to clarify where I was coming from, I think that's a necessary ingredient for success, and that if that occurred, however that occurs, even if it's just voluntary, but all the federal agency participate, then the NW-HIN governing authority would have an enormous coordinating role to coordinate the activities of the federal agencies who are participating, and then are connecting that to the private sector and to the states as well. Anyway, I'll stop with that as to where I was coming from.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Any other questions or comments? That brings us to our, if there are no other general comments, back to the specifics of the question, which is, which federal authorities could be used. I'll just point out the 800-pound gorilla that's in the room is the Office of the National Coordinator with certain authorities under HITECH, and particularly in relationship to governance. Do we believe that that would be the existing federal authority, or are there other federal authorities that we should identify as being used to play the role that we talked about, which is basically setting the national rules of the road for this new mode of exchange through the Nationwide Health Information Network?

**Mary Jo Deering – ONC – Senior Policy Advisor**

Because I don't like a vacuum, this is Mary Jo, and one of the things I wanted to say is that several of our commentators and also Carol Diamond, who is coming late to the call, have really done a lot of good work in laying out an array of existing federal authorities and, I will say, in excruciating detail because, as anyone knows who works in this space, there are indeed many. So I did want to point out that while we didn't share it for the purposes of these slides because it's quite detailed, we've had a lot of very robust input on that question. I don't know if those on the phone can make any higher-level recommendations on that that we'd really value.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Mary Jo, it doesn't sound like we have any takers.

**Mary Jo Deering – ONC – Senior Policy Advisor**

Either that or they all disconnected, right?

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

What we'll do then, I'm going to run.

**Mary Jo Deering – ONC – Senior Policy Advisor**

But you know, John, what might be useful, and maybe we'd get some uptake on this third bullet is specifically federal and state roles. Again, New York State, Minnesota, as you've mentioned, there's actually a patchwork across the states of different approaches to their governance and regulatory responsibilities. While in our NPRM, of course, we'll have to look in close detail at that, why I think we would really value the workgroup's general input and suggestions on processes or approaches to align those roles and any essential guidance. There's the issue of variation across states in certain areas. Are there any particular issues or aspects to that question that you'd like to give us guidance on? Are there particular areas where variation is to where certain common standards or common approaches need to be established? Input on questions like that would be very helpful.

**Michael Matthews – MedVirginia – CEO**

With the cooperative agreements out to the states for the creation of the HIEs, there'll be contractual responsibilities embedded in that for the states that will have to be compliant with a number of things, and the overall strategic and operations plans of the states have to be approved by ONC. How ... time bound do you see ONC's relationship to the state HIEs? Do you see anything surviving beyond the four-year cooperative agreement, and whether or not there are other structures outside of that, at least as far as that goes, you'd be able to contractually obligate the states to achieve some degree of compliance with the overall direction that we were talking about today in this particular workgroup? Can you comment on that?

**Mary Jo Deering – ONC – Senior Policy Advisor**

I cannot really give you a definitive answer on that. I can make some, what I think are factual statements. I wish that Claudia Williams or someone from our state HIE program were here. I'd observe that the purpose of the HIE grants was to support the states to address those areas where governance was needed for those states to both remove barriers from the negative sense and proactively promote exchange in the positive sense, not only within their jurisdictions, but across jurisdictions, and presumably, again, this is not a policy statement. Presumably, if those structures have value to the states, and they serve their purposes, they would survive. They would be perceived to be something that was of continuing need to the states. I would also note that that's part of what we will need to establish through this governance process is exactly how do we relate to what exists in the next ... years and what we might be able to project going forward. So I can't give you any more precision than that, but we're certainly very conscious of it as an issue.

**Michael Matthews – MedVirginia – CEO**

I'd just suggest that we have this window here where there is going to be this contractual relationship that does achieve some degree of alignment of the states' role and the federal's role related to health information exchange. So perhaps we can also think about how to think through the use of those contractual relationships and then what succeeds those contractual relationships once those have come and gone, or what survives after that that would insure the ongoing alignment of interest, and if there's anything we can do contractually during this time period, now would be the time to be very specific and clear on that so that we have something to show after ... have gone away.

**Laura Adams – Rhode Island Quality Institute – President & CEO**

I would send that idea that this is a nice window of opportunity with that alignment, as it exists under the cooperative agreement, knowing that approximately 30% of every one of those state HIEs funding was to go to regional or national connectivity or exchange. So it feels to me like there are—and I don't know that

we've received a tremendous amount of guidance from ONC as yet on the use of that one-third of those HIE funds for those purposes. I think there's a lot of opportunity there.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

I think it's probably worth making a comment here that state action on these will, in many ways, depend whether or not there's the appearance of a void in federal action. So, to the extent that the governance process works, that there's accountability of the entities that are exchanging data that the validation process works, states would seem to have less incentive to continue to pass legislation to fill that gap. I think the other piece on this one is that the issue of federal/state roles are going to be very critical, particularly for major metropolitan areas. Having been state health director in Illinois, there's the interaction between and flow of patients between Gary, Indiana, and Chicago, Illinois, between East St. Louis, Bellville, and St. Louis, a number of states, individuals from downstate Illinois go into Indiana so that it's a cross-state migration, which occurs in Kansas City, and just name it, not to mention the whole Northeast means it's very critical that the safe, but unimpeded flow of information occurs across state boundaries in ways that are in the best interest of patient care.

I think what we have here in relationship to the federal role is that we have some material that we can incorporate in our report from Carol, and that we'll get a little more granular on that. We, I think, have had a little bit of high level discussion about state and federal roles. So at this point, and again, reminding us that we will have a meeting again next week on the— Sorry, Mary Jo. Do you have the date?

**Mary Jo Deering – ONC – Senior Policy Advisor**

Next week is on the 12<sup>th</sup>.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

On the 12<sup>th</sup> where we will hope to finalize that, so between now and then, we're going to be having at least a significant straw person document developed that at that point we can come back and revisit and make sure that we're comfortable with the answers that we seem to have arrived at.

**Mary Jo Deering – ONC – Senior Policy Advisor**

John, we will be sharing with the workgroup a slightly more, actually, a significantly more detailed analysis from the matrix that we got our input in as to exactly where the existing entities do exist, and that's what will certainly guide the drafting of the recommendations, I'm sure. I am apologizing that we didn't share this with the workgroup. It was in advance of this call. I think it probably would have given them a higher level starting point, and they would have seen the level of detail that has come in. So we will share that with them, and we will share the specific feedback from the blog and from the e-mail comments. Again, everybody knows we're on a fast train here, and we'll get you all this information so that you will have access to all that staff has, as we help you help us.

**Christine Bechtel – National Partnership for Women & Families – VP**

I think, having that document that Mary Jo has described would be very helpful because I know at least I'm struggling, as I think about what the entities at the federal level could be, of what the basic options even are. But I do want to say before we leave this topic that the one thing that also occurs to me is when I think about federal interaction with the states, I think it's both a coordinating function to insure that states have the right policies and governance mechanisms in place, but it's also, I think, important to have a channel where the states can also inform the federal government, as technology evolves, as new policy questions arise, as things come in that need to be addressed. We have sort of a good sense now, but I think those things will evolve. So I think having that bidirectional nature of a process would be helpful. I don't know what the answer is, but I want to flag that as something we ought to think about.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Why don't we move on then to coordination role, if everybody is agreeing with that? Next slide. So that there's a need for a new structure or structures that are responsible for coordinating and facilitating the harmonization, interpretation, and application of the federally determined conditions that we just talked about before that would be identified through the federal governance process. That the governance function of coordination would coordinate across the broad range of NW-HIN stakeholders to engage and

solicit input to develop applied and implementable eligibility criteria. For those entities that are eligible to participate, the policies and technical requirements, the conditions for participation, including input and feedback from the Office of the National Coordinator. That the second kind of input would be to identify obstacles to and opportunities for nationwide exchange and to promote that exchange. Third to provide input to verify that validation criteria are implementable and align with the implied conditions for participation, and to provide input to the various federal advisory committees.

The attributes, the next slide, of this coordination role would be to meet the requirements of OMB circular A1-19 for federal participation. Mary Jo, if you could jump in here and say what that is.

#### **Mary Jo Deering – ONC – Senior Policy Advisor**

This is a document, which particularly addresses development of standards and federal participation in outside organizations. It enables federal agencies to actively participate in the activities of an outside organization, which follows certain principles of openness and transparency and participation, etc. As I say, it was drawn up in particular with regard to the development of standards and standards development organizations, but it's been used as a guideline for the conditions under which federal agencies can participate.

#### **John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Okay. We'll come back to that particular component when we talk a little bit about the considerations in just a minute. We would want this coordination role to be focused in on the results that we're trying to obtain in engendering trust and promoting interoperability. That a critical component of the work of this coordination entity and role would be that it needs to be open and transparent so that all stakeholders can understand exactly what's going on, how decisions are made, and that that means that there needs to be broad stakeholder representation. As we have continued to do throughout our process with a comma, particularly consumers, that balances the various interests, and is engaged in a consensus and quality improvement process, which was one of the areas that we felt were critical to assure that the governance process and particularly this coordination role is able to change over time, as we see changes within the field and how exchange is happening through the Nationwide Health Information Network, and the provisions, to coordinate the provisions for accountability.

So that leads us to some critical questions, which gets down to what this would look like. First, what is the scope of this coordination role? It raises the issue of how does that relate to the federal role, so would this be a public/private entity? Would it be a committee? What would it look like? How would this coordination role interact with existing governance mechanisms? What type of structure would be appropriate? Are we talking about a public/private collaborative, a committee or a FACA committee, or some other kind of entity? We heard at our hearing from the National Quality Forum, which began as a public/private collaborative, as an example of what something like this could look like.

Should there be more than one subgroups working under a single coordinating body? If we determine that there may be work, there may be existing entities that are playing this coordination role within a certain component of what we would envision as being the activities of the Nationwide Health Information Network, and so we don't want to preclude the fact that it would only be more than one, but if so, if it seems like there needs to be more than one, then why would that be the case? Then, finally, how would coordination be handled across multiple entities? What would be that coordinated activity? Those are the questions that need to be answered for our report, and I'm going to toss it open for members of the workgroup to jump in, or not.

Let me jump into, so as we think about the various entities that are existing out there and, Mike, I think you have a certain perspective heading up the coordinating committee. Do you see the character of this kind of entity as being a public/private collaborative, or would you think that a committee similar to the one that you're engaged with as being the best entity to play this coordination role?

#### **Michael Matthews – MedVirginia – CEO**

Well, a few thoughts on this, John. One is, certainly the authority of the coordinating committee is derived from the DURSA and everybody has come together to ... coordinating committee. I guess, by its name, it

does have a coordination function in it, not just coordination amongst the participants, but also with the technical committee, with ONC, with the onboarding process, and that sort of thing. I think there are processes that we play a coordinating role that is part of our overall governance requirement.

Then again, I looked at so then we would also be coordinating with the overarching NW-HIN governing authority, so looking at it from the perspective of a NW-HIN authority, what is their coordination role. One of them would be to coordinate with the coordinating committee of the exchange. Another would be to coordinate with the agencies that are participating. Another would be to coordinate with the standard setting bodies that there's some rhyme and reason for not just how standards are developed, because there are a lot of people doing that work, but then how do those get vetted nationally and become policy, and what transcends then exchange and ... in other types of exchange situations. Let me stop there for a minute and see if there's any reaction to that.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

It doesn't sound like it, so keep going.

**Michael Matthews – MedVirginia – CEO**

That's .... Where we've got a process structure or public/private collaborative, I would say it needs to be broadly reflective of the things that it is coordinating. If you've got one or more subgroups, if it's a subgroup of just federal agencies who are participating in NW-HIN, then perhaps not, but again, if we're overarching, and we're looking at all those who want to participate, are participating, have a role, or are impacted by health information network exchange, then by all means it needs to be broadly representative of those who are impacted by its work and have a stake in that work.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Do we—?

**Mary Jo Deering – ONC – Senior Policy Advisor**

John?

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Go ahead. Yes.

**Mary Jo Deering – ONC – Senior Policy Advisor**

Again, staff are feeling extremely apologetic here for not having provided more detail to the workgroup. Part of the problem was there were blog comments, and that we knew were coming in. We only really got them this morning. Most of them came in after we had prepared the slides and the materials for the meeting today. With that apology, I'm going to ask Mariann to at least verbally share with you on this point of coordination some of those issues of the gaps and the types of existing entities and approaches just in real time right now that we've had. Again, Michael, the fact that we only saw most of the most substantive blog comments in the last 24 hours, and e-mail comments that really also would be very helpful to this discussion. So I'm going to put Mariann on now.

**Mariann Yeager – NHIN – Policy and Governance Lead**

Good afternoon. There were a couple different areas where, in looking at the feedback, that there appeared to be sort of a theme emerging that there were specific areas where coordination would be of benefit. The feedback, based on the input we got, really seemed to point to this. There was a need for a strong federal rule to adopt policies for the NW-HIN and oversee policy development, etc., at least at a national level. But there would be some minimum or some baseline set of national level policies. National level conditions for participation was sort of the term that was coined that would include eligibility requirements, policies for privacy, security, interoperability, and that there would be similarly a process to establish at a national level the technical requirements for the NW-HIN.

Beyond that, there was also a recognition that there would need to be some coordination process, whether it be a public/private collaborative or a community structure or some other mechanism that could really bring stakeholders together with a strong consumer presence that could really go through and apply

those national level policies to certain domains, but that there would need to be some way to make sure that there was a way to harmonize how these policies were applied in a way that was workable across states, for instance, or that was workable. Maybe there was essential ... to make sure that even between certain domains that there was some compatibility and consistency.

In looking at the analysis and the feedback we got, I wasn't clear that that was necessarily that coordination role and that harmonization role was necessarily a federal rule. But the question came forward, if not the federal government, then who would do that. And it wasn't clear that from this analysis, this assessment of what existing governance mechanisms there that could be leveraged. It wasn't clear that there was any really one body or bodies that could do that, currently do that today, but rather, there may be pockets or groups of entities that may need to come together and really participate in this facilitated coordination function, and there needed to be somebody, some entity or maybe a group of entities that really were on point for that. So that was really the gist of the feedback that we received thus far, and it will be interesting to see how the e-mail comments and the blog comments feed into that.

**Elliot Maxwell – ONC – Expert Contractor for Health IT**

Let me make one other point, which is tied to the later discussion of validation. In the discussion of validation, we talked about finding those things, which are most critical for overcoming barriers and promoting exchange, and they would have the strongest need for validation. Similarly, one could think about coordination having some of the same characteristics that those elements that are really necessary for nationwide exchange are candidates for a kind of stronger coordination or for focus by the coordinating body, and those that are less important for that, the couplings can be looser. So one keeps coming back to those things that are most critical for overcoming the barriers, most critical for facilitating exchange and saying there there's a stronger role both for coordination and, later on when we get to the question of validation, for validation or stronger and ... validation provide you a higher level of assurance.

**Mary Jo Deering – ONC – Senior Policy Advisor**

Was that at all helpful? Have we lost everybody on the call? John, are you there? Judy Sparrow, are you there?

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Yes, I'm here. Allen, can you tell if the individuals are still engaged?

**Allen Traylor – HHS/ONC**

Let me check with the operator.

**Christine Bechtel – National Partnership for Women & Families – VP**

I'm sorry. I'm still here.

**Laura Adams – Rhode Island Quality Institute – President & CEO**

Laura Adams is still here.

**Michael Matthews – MedVirginia – CEO**

Michael is here.

**Mary Jo Deering – ONC – Senior Policy Advisor**

John, did we lose you?

**Judy Sparrow – Office of the National Coordinator – Executive Director**

We may have. I don't know whether he was traveling or not.

**Mary Jo Deering – ONC – Senior Policy Advisor**

He may be on mute, or he may have done exactly what Michael did.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Allen, can you tell if Dr. Lumpkin is trying to reengage?

**Allen Traylor – HHS/ONC**

We'll check with the operator.

**Mary Jo Deering – ONC – Senior Policy Advisor**

Laura and Christine, let me just step in here for a minute because you both have experience with national level coordinating activities, and you probably have the scars and arrows in your back to prove it. Coordination, to put a little levity in here, we used to say in an office where I came from that coordination is an unnatural act that you have to do every day, and so it is difficult, and especially when you are trying to bring the private sector together with the public sector. I guess I would ask you because you are knowledgeable, both about this domain and what's going on and the needs of various stakeholders that you're closest to, and you have the experience of coordination, and you have the experience of dealing with the Feds. So we would really welcome your perspective, even if it's only at a higher level right now, about how you might envision this coordination working.

**Christine Bechtel – National Partnership for Women & Families – VP**

My experience in larger national bodies has been focused, like something like the policy committee, and I think the key mechanisms have been some of the attributes that you outlined where there is transparency. There is open governance. In other words, it all comes down to there is an opportunity for a stakeholder to shape the direction of a particular initiative and the meetings have value, and it's not an endless series for nothing. So if we think about the policy committee as a model where it multi-stakeholder, and there's some attempt at proportionate representation, so you have more than one consumer, for example, and there's clearly sort of something in it for everybody because it impacts their work and their lives and the lives of their constituents, that's been, I think, some of the most important attributes.

Where I think the challenges happen is particularly around the kind of work, Mary Jo, and I think you're flagging it, that it takes to actually coordinate across the various entities that comprise the group, as well as the other external entities that the group needs to be working with, so in our case the standards committee, all of the individual workgroups of the policy committee, the federal government, ONC, CMS, and that takes a lot of work to really figure out the right processes and systems that are in place for that. I don't know if that helps. I can probably talk for a day about what I learned in terms of the process for coordination, but I'm not sure that's exactly what you're getting at here.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

I'm back in. I don't know what happened. I could hear you, but you couldn't hear me.

**Christine Bechtel – National Partnership for Women & Families – VP**

Welcome back. We can hear you now.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Good, good.

**Laura Adams – Rhode Island Quality Institute – President & CEO**

Mary Jo, in response to your question, I do think that some of the—this can be done. It isn't easy, and I do think it requires a tremendous amount of high level and effective communication that has to do with constantly describing level setting where we are right now, what's got to be done next, what the principles guiding whatever it is that we're going to be doing next, who is involved, and just enormous opportunities for input. I think, with all the capabilities we have electronically now, the ability to receive text and Twitter and voice messages and all types of input, there is just a tremendous opportunity to get input like we never have before, draw out the scene. But I think a couple things that I just found incredibly important in the work that I've done, both public/private partnership at the national level with the National eHealth Collaborative, is that it does take a special skill set among the leaders to do this. You really have to have had some experience and understand what it takes to listen to what ... voices, but understand that there are always elements of that that can be brought together in a way forward.

Also, I think, it takes an organization that kind of understands that idea that when we get polarized on something, if there are two seemingly diametrically opposed, there's almost always a third way forward if we can really deeply understand and continue the dialog to the point that we can get at the real issues. I would say that that public/private partnerships for me are critical in all of this because that's the group that's involved. It's any one entity taking extraordinary control over it, notwithstanding that we understand that the federal government has an incredibly important role alone, set aside from this collaborating entity, this coordinating entity, but at the same time trying to balance even those interests in the coordinating entity are critically important in engaging the private sector. As we know, the private sector can be just a phenomenal force in driving a lot of things forward. It feels to me that that's a big lessons learned there where the public/private partnerships are incredibly important, and they work, that the communication skill sets have got to be top notch, and you have to take advantage of all the elements of communication available to us.

Third, that notion of representation, I have to say that gets sticky in that it's almost impossible to represent every interest, as you start to get into this particular, well, now it's the diabetes group of the patient centered medical home group that has an interest and so forth. There's a way. There has to be a way of structuring and appropriately using communities of interest, which I think can be very, very helpful, and some of those committees form and go away. Some are scanned for a long period of time. I get really excited when I think about this coordinating function because, both in my state of Rhode Island, and at the national level, I know it can work. When it does, it's a beautiful thing.

#### **Christine Bechtel – National Partnership for Women & Families – VP**

I think, in looking at the questions on the slide when you're asking what type of structure would be appropriate, I'm not sure I understand the difference between a public/private collaborative, a committee, or other, only in the sense that I think we have all agreed that this has to be multi-stakeholder. It's not just the federal government that's calling the shots, and that's something we've already agreed on. So there has to be public partners and private partners at the table.

I will say that I think it's important to think about the scope and the authority of the entity and let that actually drive the structure because we've seen examples of public/private partnerships that were effective and ineffective, and we've seen examples of like federal committees that were effective and ineffective. One of the things that I think makes the policy and the standards committee effective and people interested in participating in the, no offense, but endless series of meetings and phone calls is that it does have a direct line to the federal government. In other words, it can be influential and thinking. I think that's going to be a key attribute, regardless of how you structure it. I think there are pros and cons to a public/private collaborative in that regard because when the federal government is sort of one of many players at the table, but there isn't a real direct line of authority or influence, not authority, but influence. That's when I think folks will start to question the long-term utility of it.

With respect to the other questions that you have about one or more subgroups, I'm not sure we need to answer that. It's hard to imagine how a single coordinating entity could not have subgroups underneath it just given the scope of the issues that this coordinating body will need to consider and, as Laura pointed out, the real diversity in stakeholders that would need to sit at this table. I'm not sure we would really get worried about that, although I don't see how it could not do that. I think, as we come to more of an understanding and see the public comments that you've received, it will help us think through how this coordinating function might interact with other governance mechanisms when we know and are able to do the mapping of the governance mechanisms that exist that need to be coordinated with. I think, having representatives from those mechanisms in sort of positions of influence in the coordinating body will be important, not just because they have a vested interest in the stake in the deliberations of that entity, but also because that entity needs to know what else is happening in the environment, and that's the bigger challenge is there's just so much going on that if you don't have representatives who are plugged into those other activities, you will end up reinventing the wheel and doing the same thing over, and over again. So I hope that's helpful.

#### **John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Yes, it is. If I can perhaps suggest that when we think about these terms, I think you outline pretty well the choices. The first would be a committee like the HIT Policy Committee, so it would be a FACA committee that would make recommendations to the federal government. A public/private collaborative and, I think, for those to work well, not only does there need to be federal participation, but there also needs to be some delegation of authority.

**Christine Bechtel – National Partnership for Women & Families – VP**

Right.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

By the federal governance structure to this public/private collaborative, otherwise it can depend so much on then individuals in the particular chairs in the federal government whether or not this is an integral part of the governance mechanism or a thorn in their side.

**Christine Bechtel – National Partnership for Women & Families – VP**

John, can I jump in and just share a little bit? I think there are major politics in that decision and discussion. There were lots of politics around AHIC previously, and should it be a FACA or not, and how should it splinter, and should it be bifurcated. So I just want to raise the point that you are absolutely right that there needs to be some delegation of authority because it is a public/private entity. But the value in the way that the policy committee was structured in the law was that some of the politics were taken out of the process by having GAO be the appointing body for the vast majority of the seats. But, of course, congress wants to have a role, and so several representatives are appointed by the leadership of the House and the Senate as well. But I think, when you think about the structure of the entity, public, private, FACA or whatever, there has to be a consideration of politics that will come into play because, over time, if what we really believe, and I think we do, is that this entity and this coordinating function has to engender trust and promote value, then there has to be some objectivity, transparency, and independence in the way that this entity is formed and continues to operate.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

I agree. Other comments?

**Michael Matthews – MedVirginia – CEO**

I think getting more of today's real world examples in the conversation might be helpful. Again, I keep coming back to Exchange, but let's look at Exchange vis-à-vis Direct and think about a coordinating role there and just some very practical questions around is Direct to be governed, and who had governing authority? Is it ungoverned? Regardless of whether it is governed or ungoverned, how does Exchange coordinate with it? I think everyone would readily acknowledge there could have been better coordination and communication on the front end where the intersection is between Exchange and Direct.

But moving forward, how we have one leverage the other, and certainly within the federal agency, the VA has expressed their interest in seeing does Direct have any opportunities and implications for the way Exchange is done. Certainly there's been a big investment in VLER leveraging the Exchange. I think, to the extent we can talk about that as representative of the types of issues that are raised around coordination might shed some light then on our overall charge.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Other comments? I think we have a little bit of a challenge here in that we're going to need at least for our straw person for our next meeting to come up with a recommendation because, when I go representing you in front of the policy committee, they're going to expect to have an answer for what we see this coordination looking like. I think what I've heard is we've sort of broken this down. Most of the comments have been either what a public/private collaborative might look like versus a committee like the policy committee playing this role. And so what I'd like to do, so we can have an idea, well, there are two ways we can take this approach. One is that we can try to flush out both of them and then take the vote next week, or we can at least do a straw poll here and seeing which way people think that we ought to go, and then see what it looks like when it's flushed out.

**Christine Bechtel – National Partnership for Women & Families – VP**

John, do you mean what's the specific entity, like is it FACA, it is NHIC, is it what, or what do you mean?

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

I think not the specific entity, but what the entity should be.

**Mary Jo Deering – ONC – Senior Policy Advisor**

I think what I would put on the table is that, by definition, a federal advisory committee advises an agency. It doesn't have operational responsibilities and authorities, and so I think, strictly speaking, as we would prepare an NPRM, we would not consider a FACA committee to be an active, implementing, coordinating body. It can provide advice to the government, and its advice could in fact guide some other entity, some other entity if there were a separate entity existing. This other entity could be one of the many ways that the FACA itself obtains input, so there could be a circular, a bidirectional relationship between a FACA. But again, legally speaking, a FACA advises.

**Christine Bechtel – National Partnership for Women & Families – VP**

From my perspective, I'm not personally ready to do a straw poll now, but I think it would be helpful to lay out some quick options. Mary Jo, you just rattled off some that I hadn't thought of that might be very interesting. But I think there are some parameters around this that you just described that are not necessarily top of mind for me. Based on the public comments that you've received and if they might relate and some of the thinking that you just outlined, it would be helpful to have a one or two-pager on here are some options and pros and cons so that we could weigh them.

**Mary Jo Deering – ONC – Senior Policy Advisor**

We'd be happy to do that.

**Christine Bechtel – National Partnership for Women & Families – VP**

It ought to start with a reminder, so everybody is just level set at the right place on scope.

**Mary Jo Deering – ONC – Senior Policy Advisor**

Right. We'd be happy to do that. Again apologies. We're all moving so fast, and input ... so late in the game that we can't provide you with what you need to be as thoughtful as you could be, so we will do that for you.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Right. I think we've set the parameters then for our decision making process next week. Any other things that we need to cover under coordination? Having covered the easy stuff, we're going to move on to the validation role.

**Christine Bechtel – National Partnership for Women & Families – VP**

Just so you know, John, I have to hang up. I'm sorry. I have another conflict, but good luck on the hard stuff. I'll look forward to resolution next week.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Thank you.

**Christine Bechtel – National Partnership for Women & Families – VP**

Bye.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

The third area that we want to talk about is validation. This is the area that we, I think, most recently developed in our deliberations and the one that began to come to light, as we toyed around with the issues of accreditation, certification, and all the other -cation words that we would use validation as a way to describe this sort of process, and that we recognize that it could occur through a variety set of mechanisms. A number of these ways, so we've talked about earlier on about establishing, by the federal governance entity, would establish the conditions of participation. That, based upon these conditions of

participation and reflecting input from the coordinating bodies, apply these rules, these criteria to determine eligibility for the participation in the Nationwide Health Information Network. This validation process and mechanism, which again could be one or multiple, would then verify that the technical requirements are satisfied and also verify that entities, practices are consistent with the applicable Nationwide Health Information Network policies, so it is that first, that validation role based upon first validating the eligibility and then the actual implementation.

The attributes of this would be, of course, would be expertise and the domains would be validated. We wouldn't want somebody new to this field coming in. Leverage, where appropriate, existing mechanisms. Strong coordination with the federal agencies and the coordinating entity, I think we've pretty much decided right now that whatever we were talking about, it sounded like no one suggested a plural, but recognizing that this coordinating entity may have some sub-sectors that would be the equivalent of subcommittees or subgroups, that this validation role would be achieved through an objective repeatable process ... effective, but also able to scale at the national level, and that there is evidence of appropriate management and operation of the validation activities.

The questions that are before us, should there be one or more validation bodies, and should there be alternative pathways to achieve the same validation? I'm going to use an example here that hopefully won't get people too worried, but when I was state health director in Illinois, one of the programs that we ran was the certification program for hospitals to participate in Medicare. There were basically three pathways to get that certification to participate. The one pathway was through a state survey, a survey by the state agency that had delegated authority from the Centers for Medicare and Medicaid Services to conduct that. A second pathway was through the Joint Commission, which is a private entity that has deemed status to determine that an entity does meet those conditions of participation. Then a third was a direct federal survey.

The question for us is, do we see alternative pathways to achieve the same validation? Then if we see multiple validation bodies, and we see multiple pathways, should there be an oversight body? What and who should that oversight body be? Finally, who should oversee the validation activities? Should it be the federal government? Should it be this oversight body we just talked about? Or should it be the coordinating entity that we discussed earlier? Those are our questions, and I'm going to open up for workgroup members to weigh in.

#### **Michael Matthews – MedVirginia – CEO**

I'll start it off by getting back up on the same issue I was speaking to early on, and that is whether or not validation itself is ... of the governance authority. I would argue that the governance authority needs to make sure that the conditions of participation are met through some kind of process, but that it does not have to do that work itself. It has to insure that that work has been accomplished. I think there's a policy framework for that. The conditions and so forth can be established by the governance authority. I just don't see the activity itself having the requisite experience doing it into the means that we were talking about. I think the bullet point was expertise in the domain set would be validated. I just don't see that that needs to be embodied in the governance authority, but again, can be done by it.

As far as the rest of the questions, I think ... functions, should there be alternative pathways to achieve the same validation is dependent upon what the scope is, the ... function on that to say maybe for some elements of things that are being governed, alternative pathways may make some sense. Meaningful use, for example, has multiple pathways for doing something like that versus other things may not be appropriate to have alternative pathways. That one, to me, is a big, it depends. The overarching point I think needs to be discussed is the degree to which validation itself ought to be a function of the governance authority.

#### **John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Mike, you raise some points that reminded me that I had another slide of questions, so if we could go to slide 18, let me toss those into the mix because I think they get to the issues that you raise.

#### **Mary Jo Deering – ONC – Senior Policy Advisor**

Judy, would you advance the slides, please?

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Yes. Actually, Caitlin, can you do that?

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

We got it. I think that refers to the questions that Mike was just asking. Who should be subject to validation, and what sort of levels of assurance are needed? If you look at the graph that's on there that not every type of criteria or not every aspect of the validation needs the same level of validation. So, we need to think about ways that we would construct a validation process that would be consistent with the actual needs, the form following function mantra that we've been using. Then the last question of what validation methods should be used and who should do the validation. In other words, as we've talked about, they can range from anywhere from entirely voluntary with no audit or compliance to certification and accreditation through site visits, review of documents, and all those kinds of activities.

**John Mattison – Kaiser Permanente – Chief Medical Information Officer**

Sorry. I've been on for most of the call, but they had me on hard mute, so I couldn't participate.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

That had to be frustrating.

**John Mattison – Kaiser Permanente – Chief Medical Information Officer**

Yes, but a quick question. Are other people seeing the slide that John is referring to because I'm still on the slide that says workgroup considerations coordination?

**Mary Jo Deering – ONC – Senior Policy Advisor**

I'm on workgroup consideration validation too.

**John Mattison – Kaiser Permanente – Chief Medical Information Officer**

My screen didn't refresh for some reason. All right. Let me come back to one of the earlier questions ... related to this current set of questions.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Sure. Go ahead.

**John Mattison – Kaiser Permanente – Chief Medical Information Officer**

It has to do with the question of what should the structure of the committee look like in order to serve this coordination function. First of all, I agree with essentially everything that's been put out on the call today. It seems like there's a lot of coherence. The one thing I would like to add is that there's a fairly high risk, and I mentioned this on last Friday's call that the vendor community is going to race ahead of what we're doing and obsolete and make irrelevant this work if we're not careful, and so it takes us right back to the initial set of questions that we started this whole thread out with of what are the levers we have to pull. What we've talked about on the call today so far is how do we get authority? How does the federal government grant authority? If it's a policy advisory committee, it's simply advisory and has no authority. I think the authority question is important, but equally important is what are the levers that can be exerted. To the extent that the structure and organization and population of this coordination committee is legally entitled to pull whatever levers are available, but potentially, I think, should be a significant input to who and what and how we structure that coordination function.

**Mary Jo Deering – ONC – Senior Policy Advisor**

I just want to say I'm sorry that you've been on mute so long. We appreciate your input. I think that points to one of the specific questions on slide 17, back on 17, which is who should do the validation. Would it be this coordinating entity? I must say that one of our actual vendor comments did suggest the kind of oversight or coordination of the technical and validation activities and of the various standards setting activities as well. So while certainly one voice doesn't speak for an entire industry, why at least it indicates that there might be some support for more coordinated approach at least.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Other comments? One thing that might be useful for the working group to make a recommendation about is a preference for competition and heterogeneity versus uniformity. That would speak to some of the considerations about coordination, as well as validation, and also speaks to some of the questions that John just raised about essentially some form of capture or actions that preclude the setting of standards or participation or the like. We haven't talked much about that in the discussions so far, but a preference for competition in heterogeneity would have some impact on how you think about validation, multiple payouts, how you think about coordination and the like.

**John Mattison – Kaiser Permanente – Chief Medical Information Officer**

I agree that we would need to do that. I would frame the issue a little bit differently. Instead of favoring competition and diversity, the way I would frame it is to have a very deliberate strategy about understanding where solutions require innovation and, in those spaces, encouraging some deliberate competition, innovation, experimentation, diversity, and so forth. But I think, particularly in the interoperability content space, we've been trying to solve the problem of innovation and diversity rather than use it as a solution set for many years. I'd be very careful to use that as a blanket truism as opposed to one vehicle for innovation and targeting the solution. I don't know if that resonates with anybody, but it's a pretty significant concern I have that if we innovate everywhere, we'll end up with no standards on anything.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

That's a major component of the validation process is assuring that the mechanisms for maintaining privacy and security are going to be in place and consistent across the network to create an environment of trust. And so the balance, as we discussed in our initial discussion about the balance between risk versus benefit, I think, is also appropriate to think about the risk and benefits associated with innovation.

**Mary Jo Deering – ONC – Senior Policy Advisor**

John, I'd like to ask another question back on slide 17 about the oversight, and just ask in principle whether, based on the experience of the workgroup members, they would imagine that having a separate validation oversight body from some other coordinating entity would be optimal or suboptimal. Is it good to have two different authorities with separately delegated authorities? Then they just coordinate it, and you just establish some coordination between them? Should there be some stronger relationships between them that, e.g. does the coordinating entity directly oversee or coordinate the validation activities? Again, based on your experience, do you have thoughts in those directions?

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Or not? Any other thoughts on this? I think those are good questions, Mary Jo. It seems to me that we're tossing around a few ideas related to this validation process and its interaction with the coordinating entity that we discussed earlier. At some point there needs to be a mechanism to review what in fact the exchanging entities are doing and how they are doing it in a way that provides the level of accountability that we had talked about in our principles and in our prior recommendations about the what. I think that, and I'm just going to toss this out for discussion, do we feel comfortable that that kind of technical attention to detail, in other words, actually going out and looking at what each individual exchanging entity is doing, is compatible with the high level responsibilities that one would see in a coordinating kind of environment.

**John Mattison – Kaiser Permanente – Chief Medical Information Officer**

Could I kind of toss out a straw dog that answers all these questions just for us to all take a shot at and use as a potential exemplar?

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Please do.

**John Mattison – Kaiser Permanente – Chief Medical Information Officer**

It just occurs to me that it needs to be monolithic validation is the set of outcomes that are to be validated. If we have multiple bodies, so long as they have sufficient process to insure that those targeted outcomes are indeed validated, then there's no problem having more than one validation or oversight body. From a managed competition standpoint of a particular entity is not performing well, what are your options? If they're the only entity, your options are very restrained. It would probably make sense to deliberately have more than one validation body, so if one body is under-performing, you shift work to the other one until the first one cleans up their act, or you replace them with somebody else so that there's continuity of services without the discontinuity of slopping out a monolithic vendor for another vendor while preserving the monolithic outcomes that you are validating. I would argue strongly that there should be no innovation around what the outcomes are by these validation bodies, but that having more than one would help preserve some continuity of contracting over that service. Does that make sense to others?

**Elliot Maxwell – ONC – Expert Contractor for Health IT**

I think that you're right to be concerned about innovation and where it takes place and under what circumstances. I suggest that the answer probably is it depends. It depends on how critical the activity is that you want to validate or accomplishment of your goals, and that will tell you where you want or can allow variability and where you are clear that you want absolute alignment in the results. So the more we can understand where variability is acceptable and where it's not, taking into account the issue that you raised about innovation, the better off that we'll be in terms of the recommendations.

**John Mattison – Kaiser Permanente – Chief Medical Information Officer**

I agree. I totally agree.

**Mary Jo Deering – ONC – Senior Policy Advisor**

I think one of the things we'll need to do is to tee up for the workgroup a better framework for them to help identify those areas where variability is optimal and should be supported and where it is not, and help you identify those areas for us.

**John Mattison – Kaiser Permanente – Chief Medical Information Officer**

I think that'll be a foundational piece of work actually to help guide and not only when to use competition and innovation, but how to do it, so there are certain circumstances. You can use the DNA as a model. If you've only got one copy of the critical gene, and you innovate there, you're going to die, or you're not going to survive gestation. Whereas, if you have multiple copies, and you experiment in a redundant copy, you can create a superior solution that overcomes the original source. I think it's a very successful model of innovation that has parallels for what we're doing and, in some cases, we can innovate real time in production with everybody or with a subsegment. In other cases, we need to experiment in a very isolated environment, prove that it works first, and then introduce it subsequently. It's not only knowing where innovation is required or desirable, but it's knowing in what sandbox that innovation can and should occur.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Would there also be, as we're thinking through this, would there also be variability in the validation process based on the type of entity? An individual provider that chooses to exchange from a rural area for which there is no HIE might be validated differently than an HIE or ... entity?

**John Mattison – Kaiser Permanente – Chief Medical Information Officer**

Or another example that I like to question a lot, another question would be validation of a lab entity be kind of a different beast than validating a provider organization, and might that, as a natural result, argue for sort of subspecialization of the validation process.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Right. Perhaps consistent with our principle of our thought in fact that this is going to be a dynamic kind of governance process, it seems to me that when we talk about an approach to validation that we need to leave room for there to be some specialization. That's another component. Maybe that fits within the innovation rubric, but that there may be initially one validation entity and subsequently would leave room for some subspecialization and other entities to come into play. We may see that that initial entity would

then establish itself in such a way. It could be what we've raised as the issue of the oversight body that would more intentionally develop those spin-off subsets that would have more focus and specialization.

**John Mattison – Kaiser Permanente – Chief Medical Information Officer**

Or at least the coordination body would be a forum for debate if a sub-sector of the environment protest the process or if the validating entity wants to specialize or spin-off or whatever. There could be opposing views brought forth to the coordination body.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Mary Jo, do you think you have enough?

**Mary Jo Deering – ONC – Senior Policy Advisor**

Here's what I see happening. First of all, I think we will promise by close of business today to get out to the workgroup the summation of all of the inputs we've received, and we do have a very high level graphic that just sort of shows how these things might relate to each other. At this point, it's entirely just a visual. It's not really a flow chart at this point, although I will tell you, we are also trying to work on flow charts and processes that might show how these work. By close of business today, at least the workgroup members will have more background and more detail and understand where these higher-level questions came from.

Secondly, I've heard, and we will most definitely be teeing up some draft materials for you. We've heard a couple of areas where you'd like some specific options laid out with pros and cons, and we will do that for you. Mindful of the fact how tight this all is, we will do our best to get them to you as early as we can next week, but obviously it's a huge leap from where we are today to where we need to get to still. I can't promise a particular day or date, but we will certainly get it to you.

I think one of the things, John, that you might ask yourself, and I cringe to ask it, so I'd rather you ask it for me, is whether there may need to be another call in the week of the 15<sup>th</sup>. I know that people are very burdened. Obviously it's hard to carve out even a half-hour of time, much less two hours of time, but I would like to say that certainly staff are willing and able to try and do that if we need to or have a series of ad hoc outreach to individual members to accommodate their schedules, if need be, around particular topic areas. We're happy to try and do whatever we can to get the expertise and the diverse expertise of the workgroup members delivered in a timeframe that meets their calendars.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Yes. I'm thinking, my guess is going to be that it's going to be hard to do that with this short notice. I think we can work through some ways, if we can get— I think, if we can find some timeframes, I think Wednesday the 17<sup>th</sup> might be a potential, but that's kind of pushing it. But maybe if we can get some commitment from the members to respond quickly to various drafts and questions, I think that may be the way to do that.

**John Mattison – Kaiser Permanente – Chief Medical Information Officer**

One thing that I found useful in this kind of exercise that you got sort of disbursed collaboration, and you got a death march to a timeline is towards the end, you have frequent, short checkpoints, so people can torque their schedule for 15, 20 minutes in a way that they can't torque their schedule for an hour or two. So that week, what I typically do with my teams in this kind of effort with the kind of timeline we're under on the 19<sup>th</sup> is to propose a 5:00 call every day of the week to last 15 minutes. If there's no business, you check in, and you hang up.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Okay. I like that. I think that I certainly can agree to that and probably fit that into the schedule. I think, at least probably Monday, Tuesday, and Wednesday of the 15<sup>th</sup>, 16<sup>th</sup>, and 17<sup>th</sup>, if we could ask people to hold on just 5:00 to 5:15.

**Mary Jo Deering – ONC – Senior Policy Advisor**

We'll send out a query for that.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Okay. I think we're running short on time, and we do need to have a short period of time for a public comment. Do we have any last statements, concerns, questions from the workgroup?

**Michael Matthews – MedVirginia – CEO**

Let me talk out something that I'd be willing to work on, on behalf of the coordinating committee, and other members of the group can comment whether this would be helpful in pushing this forward. That would be if we published a framework from the coordinating committee perspective related to governance of the exchange related to what the intersection of the exchange to this NW-HIN governing authority might look like, where we see the points of intersection, where we could see coordination being required relative to Direct, and perhaps where the coordinating committee might view its governance authority intersecting with the new and ever expanding member of an HIE, such as the states that will have to go through the whole eligibility determination and the onboarding process, validation testing, and so forth.

Again, I think we've had to deal a lot in abstraction. To me, the most concrete thing on the table today is around Exchange and the coordinating committee. So if we can use the coordinating committee and Exchange as a frame of reference that might help then shed some light on what these other related entities above, beside, and below with no ... adjustment in what's above or below, but relative to the types of exchange being implemented. Reactions?

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Well, I think, from my part, I think, having additional information, we've modeled a fair bit. We've all done—gave out at early part some information on reading through the DURSA. I think it would be helpful to know their thoughts. And I'm just making sure that our FACA experts are saying that that's okay.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

I don't see any reason why it wouldn't be.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Other thoughts or comments? At this point then, I'll just remind everyone, we do have a call next week at 10:00 a.m. At this point, if we can open up for public comment.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Operator, could you see if there's anyone from the public who wishes to make a short comment?

**Coordinator**

We don't have any comments at this time.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Great. Thank you. Thank you, John, and thank you, everybody.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Thank you. We'll talk soon then. Bye.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Bye.

**Mary Jo Deering – ONC – Senior Policy Advisor**

Thank you, everybody.

## **Public Comment Received During the Meeting**

1. Mary Jo, please can you put the flowcharts on the site as well if possible???
  2. The blog and docs aren't easy to find.
  3. We really need a better software that lights up visually the person that is speaking. It's probably too disruptive to their flow for them to remember to announce who they are each time they speak.
17. Is there a document we can access for Senior Policy Advisor for the OMB circular A-119?