

**Governance Workgroup – Group #1
Transcript
May 18, 2012**

Roll Call

Operator

All lines are now bridged.

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

Thank you very much operator. Good afternoon, this is Mary Jo Deering in the Office of the National Coordinator for Health IT. This is a meeting of the Health IT Policy Committee's Governance Workgroup and it's a subgroup #1. It is a public call and there will be an opportunity for the public to make comments at the end, and I'll begin by taking roll. Arien Malec?

Arien Malec – RelayHealth Clinical Solutions

I'm here.

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

Judy Warren?

Judy Warren – University of Kansas Nursing School

I'm here.

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

Are there any other members of the Governance Workgroup on the call? Would staff please identify themselves.

MacKenzie Robertson – Office of the National Coordinator

MacKenzie Robertson, ONC.

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

Adam are you on? I think he's on mute only. And Mary Jo. All right Arien, I'll turn it back to you.

Arien Malec – RelayHealth Clinical Solutions

Excellent. Are we presenting or are we doing this offline? Is there a web conference. Hello?

Judy Warren – University of Kansas Nursing School

There's an Adobe connect, it's seen in the email, I just sent mine a few minutes ago.

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

Alan, are you going to be projecting the slides?

Alan Merritt – Altarum Institute

Yes, we have the slides that were sent earlier.

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

Good.

Arien Malec – RelayHealth Clinical Solutions

Excellent. So, let me make sure I've got that up and running. We... I framed up a set of slides last night, using Jonah's template which I really liked, and we framed up the ten questions that we have to consider, none of them very trivial questions. They're all deep and weighty questions. We got all the really fun, big ones. And so what I'd like to do is first of all just frame up what those ten questions are and then walk through the questions one by one. What I did was kind of pull out the relevant material from the RFI and then pull out the questions. I took the questions for the first group somewhat out of order so we could cluster related questions together, and I started with what was question #3, which was really the, should we be doing this at all, what's the justification for doing this at all question. Then clustered the set of questions that relate to the frame or the type of governance approach, the relationship of governance to the states and then the lifecycle of CTEs. So, if we can go to the first slide, or the second slide I guess.

These are the ten questions that we have to consider. So first is the questions relating to establishing the governance mechanism and the second set are relating to the CTE lifecycle. And, we'll go one by one through the questions, so I won't read all these questions here. So, if we go to the next slide. The first question is the fun one, which is "How urgent is the need for a nationwide governance approach for electronic health information exchange? And conversely, please indicate if you believe that it is untimely for a nationwide approach to be developed and why." So, I'm going to pause there and Judy, ask for your reaction to that question. I've got my own thoughts there, but...

Judy Warren – University of Kansas Nursing School

I was going to say, make me go first. You know, this is one of those that I could probably argue both sides of the question. But when I take a look at the work that we've done on NCVHS with the implementation of standards and having been working towards this for probably the last 6 or 7 years, one of the things that I have seen in there is some guidance as to appropriate structure for anything that goes national. So, it's almost like the Interstate Commerce situation; you have to be sensitive what goes on in each state and certainly they have laws and regulation that govern some of the exchange of health data. On the other hand, if every state goes about inventing their own wheel, we probably are not going to get to a national infrastructure. So, I think for us, it's probably pretty... I don't want to say it's urgent, because Meaningful Use has kind of gotten in everybody's way about urgent, but I think it's incredibly important that some guidance be provided on what the governance structure should look like, both at the national level, with implications for each state to consider at their own levels. .. (indiscernible) my background.

Arien Malec – RelayHealth Clinical Solutions

So at least one of the rationales for governance is that without a governance framework at the nationwide level, we'll get inconsistent governance at the state level.

Judy Warren – University of Kansas Nursing School

Yeah.

Arien Malec – RelayHealth Clinical Solutions

And that will impede the growth of the market?

Judy Warren – University of Kansas Nursing School

Well, it will impede the growth of the market and my feeling is, we're asking very busy people with limited resources to do a lot of work that may or may not lead anywhere.

Arien Malec – RelayHealth Clinical Solutions

Right. The other... so, let me play the other... so I actually find that argument incredibly compelling. I want to play the other... the devil's advocate to this and say, what would happen if there... has the lack of nationwide governance, except with respect to NwHIN exchange, has the lack of nationwide governance been material. So, I think we can safely say that the speed of change and speed of deployment of

information exchange has been slower than anybody wanted and the question that I would ask is, has the lack of nationwide governance impeded the speed of exchange. So, is there a compelling market failure or a lack of nationwide efficiency due to the lack of governance. My reflection is that most of the drivers for the lack of speed have been business model related, although it is a classic pattern that any time a regional or statewide organization spins up, they tend to spend a year of time establishing governance and in effect, rehashing all of the same rules in a repeated way.

Judy Warren – University of Kansas Nursing School

Well, I'll agree with that. Given my own state where I work, which is the state of Kansas, one of the things that started propelling us forward down this path was we received a grant when we were doing the HISPC work, so looking at privacy and confidentiality, and that grant facilitated us bring the right stakeholders together, which were a very committed lot and even after funding ceased, continued to meet to try to answer some of these issues. And, you're right on target, one of the first veins of discussion was business model of who pays for what, who owns what, how do we become trusted entities so that the providers and the people of Kansas will trust what we do, and where does that fit. And of course, right in the middle of all that was when all of the state budgetary things started heading south a little bit, like every other state.

Arien Malec – RelayHealth Clinical Solutions

Every other state.

Judy Warren – University of Kansas Nursing School

Yeah. And, so I agree with you that a lot of dialogue trying to come up with that, but one of the advantages we had was several people not only work at the state level, but also have paid attention to what's happening at the national level, so really monitoring a lot of what's going on at ONC, certainly I've been giving reports on where NCBHS is going and they've been trying to anticipate where some of that dialogue is. So, they've tried to get as much guidance as possible from those initiatives and I guess that's why I'm coming out with at least what we need to do is start coming out with a framework and the framework may only be these are the questions you have to have, you have to have agreements here. I think one of our later questions has to do with certification. In our area, once EHRs started being certified, it really speeded up the adoption that we had in small hospitals and in physician clinics, because they finally had the bandwidth to go and select from ones that they knew would work instead of having to spend time going through tens to hundreds of vendors.

Arien Malec – RelayHealth Clinical Solutions

So, let me see if I can replay what I think we've just said, because we've just said, we've just noted three areas for governance provides... where the main function of governance is to provide a framework that facilitates a more efficient market. And those three areas are consistency across state lines, which allows for a national market for health information exchange services. Second is, the lead time and cost associated with individual governance discussions that often repeat and rehash the same materials locally that could be discussed nationally; so a framework would help reduce the overall time and cost of those efforts. And the third is the effect that certification has on creating a more efficient market by at least establishing a baseline set of common characteristics so that you can... then market actors can choose from among the remaining market characteristics without having to worry that the products or services they're selecting won't work together.

Judy Warren – University of Kansas Nursing School

I think that's a fair summary.

Arien Malec – RelayHealth Clinical Solutions

In the work that I did in the direct project, one of the conclusions that we came to is that... so I think there's two exercises that I think are illustrative. One is the exercise that NwHIN exchange did where, and Mary Jo, if she's allowed to comment, can I think provide really helpful comment here, but, that NwHIN exchange found itself in a position where until the participants came into common agreement on the rules of the road, which were established in the DURSA, it was really hard to go to the next step, which is to actually exchange data, because they found themselves in the position of independently

hashing out their rule and that has an n-squared complexity; as the number of participants grows, the number of dialogues that you need to establish also grows. And at least the NwHIN exchange found itself in the position where establishing a common governance framework was the only way to get exchange flowing.

In the direct project by contrast, we tried to establish a mechanism that works without requiring central coordination and one of the conclusions that we had is that at least with respect to identity and common rules for identity, you could establish local exchanges, but you couldn't establish local exchanges that would then mutually talk to each other, without some common, ideally nationwide, trust fabric, particularly because transitions of care and transitions to the patient occurred on a nationwide basis. So, as I said, at least one of our conclusions was at least with respect to common policy for identity, you couldn't get to the objective, which was nationwide liquidity of movement.

I think the NwHIN exchange and the direct project came to similar conclusions, slightly different frameworks. NwHIN exchange said in order to get robust kinds of exchange, you've got to have a single common, centralized trust fabric and trust framework. Direct project said, you can decentralize some of it, but at least if you really want entity to entity conversations, you need to have some things that are common on a nationwide basis. So, there's some... at least there's some evidence that for entity to entity or ACO to ACO, RHIO to RHIO, HISP to HISP kinds of exchange, you need at least some common trust framework in order to have those kinds of exchange. Otherwise entities have to mutually and bilaterally create agreements.

Judy Warren – University of Kansas Nursing School

Right.

Arien Malec – RelayHealth Clinical Solutions

So I note this last item that we just discussed as lack of a nationwide framework creates a model for entity to entity business arrangements which, in computer science terms, is a big ON squared, that is, that it scales... the policy scales exponentially and the policy challenges scale exponentially because you're requiring coordination. Now the alternative... so, that means that some kind of governance mechanism is required. Then the next question is, if you want nationwide exchange. And then the next question is, is the government the only entity that can provide that service. And we have seen some private or public private organizations that have formed; there is Direct Trust, there is the CCC that has formed and then I think the direction that ONC is moving in is to move the NwHIN exchange to an entity that would work under an overall governance framework. Although that, at least presumes the governance framework to work, yet the first two did not presume a governance framework to work. And so the question then is, given that you need some kind of... given that I think we've said we need some kind of central policy agreement to establish nationwide exchange, is the existence of public/private organizations... can nationwide governance occur in the absence of federal action or can public/private entities create self-governance mechanisms without a common framework? And I just pose that as a question to you. I honestly don't know, I can go both ways.

Judy Warren – University of Kansas Nursing School

I guess my question is, what would be the motivation that would bring people together to do that kind of work, without some sort of federal leadership or business... not business model, but, and I don't want to say oversight either, that's not it, it's something in between, without some sort of work that's being done federally to take a look at all of the laws and regulations that have come out of those laws, because one of the things that I see happening is, there are so many regulations and requirements coming out right now that people are kind of lost.

Arien Malec – RelayHealth Clinical Solutions

Yup.

Judy Warren – University of Kansas Nursing School

And to ask them to think about coming together in a voluntary fashion to work at this, I think would place the priority towards the bottom of the pile. And yet, a lot of the work that they need to do in these other

areas, whether it's for Meaningful Use, reimbursement, etcetera, could greatly be facilitated by a nationwide exchange. So, I don't know how to answer your question, I guess is what I'm fumbling with. I would like for that to happen, but I'm not sure it will.

Arien Malec – RelayHealth Clinical Solutions

Let me describe at least three areas that I know about, and I think the CCC, the NwHIN exchange and the direct trust framework at least give three indications of how a public/private framework could go. And I'm going to spin NwHIN exchange in a slightly different direction. So, let me start there and say, it's possible that NwHIN exchange becomes, rather than... so, I think the clear policy direction that ONC has established is to say that, and that Congress established, is to say that ONCs responsible for governance, ONC is defined the Nationwide Health Information Network as the policies, Mary Jo help me...

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

Standard services and policies...

Arien Malec – RelayHealth Clinical Solutions

Standard services and policies for Nationwide Health Information exchange. The preamble to the RFI notes the connection between the Nationwide Health Information Network, which is so defined, and the other mandate for ONC, which is the Nationwide Health Information infrastructure and the broad role that Congress gave to ONC to oversee the development of a Nationwide Health Information infrastructure. So, there's at least a legislative mandate, Congressional mandate, to do this work, but, absent that, you can look at NwHIN exchange as, in effect, the federal partners saying in a particular VA, the Department of Veteran's Affairs, Department of Defense, Department of Health and Human Services broadly, including CMS, SSA, IHS, a number of organizations effectively said look, we're not going to recreate the rules over and over again, we're going to band together and say look, there's one policy framework that you need to agree too and one standards framework that you need to agree to if you connect with the Federal partners. And that's a perfectly legitimate role of government, if you want to talk to us, this is how you do it.

Judy Warren – University of Kansas Nursing School

Right.

Arien Malec – RelayHealth Clinical Solutions

And there was no need for an overall governance framework for the Federal partners to do that. DOD and the VA have substantial business reasons to do that. The CCC, as another example...

Judy Warren – University of Kansas Nursing School

Can I just jump in a minute? So, your example about the Federal thing, the part that bothers me with that is, what it does for the private sector is, you have no input in developing this governance or these standards or anything else...

Arien Malec – RelayHealth Clinical Solutions

Great point.

Judy Warren – University of Kansas Nursing School

... and if you want to play with you, you have to do what we say.

Arien Malec – RelayHealth Clinical Solutions

That's a great point...

Judy Warren – University of Kansas Nursing School

I think that would be a very negative statement.

Arien Malec – RelayHealth Clinical Solutions

So, that's a great point. In the absence of a governance framework that has broad public participation, the Federal Government is in the position of creating policy that has the effect of constraining the broader commercial market, without the commercial market's input.

Judy Warren – University of Kansas Nursing School

Right. Okay, so now go on with your next example of CCC...

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

This is Mary Jo, if I could just say a matter of course, I don't think as the exchange is evolving or even in the past that it has the intention to create its own standards. Obviously these are national players and it is evolving toward a membership structure, where obviously as a membership structure, there would be representative forms of governance, so, I think that the concern about the Feds per se identifying and imposing a set of standards in a vacuum is really... it's certainly not their intention.

Arien Malec – RelayHealth Clinical Solutions

It's not their intention Mary Jo, but, I would argue that in the absence... so I think what we're saying is in the absence of a national broad governance conversation, that at the end of the day the Federal partners, particularly DOD, VA, CMS and SSA, and you could also look at the work that the CDC has done and yeah, they've participated in NWHIN exchange, but they've also established policies, procedures... they've also established standards, services and policy for Public Health that occurred outside of that framework.

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

Right. No, you're absolutely correct and I think that they're all on the record as saying they can hardly wait for governance.

Arien Malec – RelayHealth Clinical Solutions

Right. So, I think you could play out a without governance world in which, in particular those actors who have a substantial business or mission interest in exchange, would be forced to go it alone if there weren't a governance framework. And they might choose to go it alone in a nice way, or they might choose to go it alone in a not nice way...

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

Right...

Arien Malec – RelayHealth Clinical Solutions

... but, they have to create that framework themselves if there isn't a national framework. The CCC is an example of an organization that I would say has a mix of mission. I think the organizations that are part of the CCC have a strong mission orientation and, at least all of the founding members of the CCC all still have a business interest in being broad, national providers of health care. The founding members of the CCC, for the edification of at least the public record are Kaiser, Cleveland Clinic, Mayo, Geisinger and Group Health. So, CCC provides an example where the mission, the broad public mission of those organizations combined with their need to be nationwide, and they're already providing nationwide services for healthcare, caused them to band together to create a private exchange, I guess, but with broad governance and at least a stated intention to expand the five members to create a broader framework.

And then direct trust is an example of a public/private governance framework founded around the direct project where the commercial providers of direct services, and the state oversight for directed exchange, led everyone to conclude that without some kind of rules, that you'd get chaos, you'd get local exchanges that wouldn't be able to talk to each other, which would undermine the policy interest in direct; but would also undermine the ability of states to meet their mission and the ability of commercial entities to market

their services broadly. And so there again you had a reason for organizations to band together to create governance, even in the absence of a governance framework and I argue that the governance process has actually made that process in fact more difficult because that process needed to form in the absence of an established governance framework, but knowing that there was a governance framework; but knowing that there was a governance framework that was going to happen.

So, it's an argument either for, if the government just got out of the way, the governance would already get done, or, you can cut that argument both ways. So, let me see if I can try out a position. I can, from the conversation we've just had, and we're spending a lot of time on this question because it is the existential question. From the conversation we just had, we can I think safely say that in the absence of a national governance conversation, you're going to end up repeating the conversation in multiple places, in multiple ways across the country; that there are forcing functions that would lead organizations to join that conversation by themselves and I think that argues for... so, if I'm going to turn this into a conclusion, I think that argues for a framework oriented governance mechanism that serves as the... that kind of leverages the convening role of government, but it argues at least in the short term, for a lighter weight governance mechanism that facilitates conversations, convenes and allows a place... creates a space for the conversation to develop, but doesn't overly constrain the development of the national conversation on governance. And I want to throw that out as a position.

Judy Warren – University of Kansas Nursing School

So, I think I agree with you, I would like to see it in writing before I do a final thing, but, let me just try to paraphrase what I think I heard you say. There does need to be a national discussion about framework, but we don't want that framework at the current time to be overly... to have too many constraints that would impede opportunity in the marketplace to come up with new products, opportunities, by providers themselves or provider organizations to try out new approaches to sharing data. Am I in the right ballpark?

Arien Malec – RelayHealth Clinical Solutions

I think that's exactly right and that the government has a unique role to create a space for the conversation to occur.

Judy Warren – University of Kansas Nursing School

Right. Yeah, I agree with that. I think that, I mean from the successes that we've had at NCVHS, it's when we've been able to bring the players together, convene and facilitate the dialogue and when that happens well, then it takes off and the private side begins to own the solution. And, I think that's a really strong strategy. But, the dialogue would never have begun if the government hadn't provided the space and the facilitation to start the discussion.

Arien Malec – RelayHealth Clinical Solutions

So Mary Jo, I'm going to turn it over to you to say, look we've said a lot of things, do we have... do you have enough material to be able to... I've tried to repeat what I think our conclusions are...

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

Yes, and I'd be happy... what I will do at the end of this, it'll take me just a few minutes, but I will pull together what I think I've heard as draft summary comments, because that, at the end of the day, is all you need to put forward is your final draft summary comments. So, I'll do a straw man based on what I've heard.

Arien Malec – RelayHealth Clinical Solutions

That would be excellent. And then I'd suggest that we move forward to the next set of questions. So, just to frame up the next set of questions, the RFI notes that there are three areas for what it calls CTEs, which I guess are no longer cooties. The domains for those conditions are safeguards that focus on protection of individually identifiable health information, which is a term that's defined... Mary Jo, is there a... is that a term that was defined in the context of the Governance RFI or is that term defined in other places?

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

I'm sorry, which term?

Arien Malec – RelayHealth Clinical Solutions

IIHI; I know that...

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

That's a HIPAA term.

Arien Malec – RelayHealth Clinical Solutions

So, it's broader than PHI.

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

Well, it's different from, and Judy, I'll let you jump in there, but it is a separate category. PHI... Judy, do you want give the...

Judy Warren – University of Kansas Nursing School

No, I was going to ask the same question, in terms of HIPAA, I'm familiar with PHI.

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

IIHI, I believe, is just the more general term, that is not explicitly linked to HIPAA. Because HIPAA...

Judy Warren – University of Kansas Nursing School

Right.

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

... exactly describes what it means by PHI.

Judy Warren – University of Kansas Nursing School

Right, okay.

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

So this term means exactly and only what it says, it's not really a term of art, I don't believe, but I could be wrong there and I'd double check it.

Judy Warren – University of Kansas Nursing School

... would double check legislative, but I think I agree with Mary Jo. This... in some of the discussions that have come out under some of the privacy and confidentiality issues that arise from PHI and protecting it, there are other kinds of identifiable data that's not covered under HIPAA and in fact, some of that was extended through ARCA, so, I'm assuming this is a more generic frame.

Arien Malec – RelayHealth Clinical Solutions

So, I know why this term was chosen, I think. So, I'm reading page 13, that notes the HIPAA privacy rule that the standards and implementation specifications for use in disclosure of individually identifiable health information held by these covered entities is called protected health information or PHI. And the issue is, that PHI is a legal term that only has meaning in HIPAA with respect to covered entities.

Judy Warren – University of Kansas Nursing School

Right.

Arien Malec – RelayHealth Clinical Solutions

And so I believe that the intent here is to broaden the definition and not limit it to covered entities, which is why the rule, for example, that's noted is, an NVE must apply as if it were the covered entity is material.

Judy Warren – University of Kansas Nursing School

And this would probably cover some of the issues that we're beginning to look at in Workman's Comp and some of those other areas that are not covered under HIPAA.

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

And Adam has forwarded me to the record that this is a term that actually comes out of the privacy rule, the original HIPAA rules. So, it is a term that's in the privacy rule.

Arien Malec – RelayHealth Clinical Solutions

Am I right in thinking that the intent of using that term as opposed to PHI is because PHI is confined or constrained to covered entities definitions.

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

I can't answer that, but I will certainly check it out and I think, for the moment...

Arien Malec – RelayHealth Clinical Solutions

That's fine. So the second category of CTEs are related to interoperability and the third category are related to business practices outside of those otherwise covered by safeguards. So we can go to the next slide. And so the question is, "Would these categories comprehensibly reflect the type of CTEs needed to govern the Nationwide Health Information Network, if not, what other categories should we consider? And, I want to read back a conclusion that I think the NwHIN Power Team tentatively came to when we discussed some of the interoperability categories in our work. And one of our conclusions was that there is a missing layer in the governance rule; and let me see if I can explain what I mean. So the governance rule implies that interoperability CTEs would be read into or written into the regulatory framework and would be so done every two years, and we'll get at this in the lifecycle issues.

And, what the Power Team noted is that there didn't seem to be a governance mechanism for establishing certification criteria. The lifecycle discussion actually does raise the topic of, is there a need for a governance mechanism related to certification criteria. And we got very confused and I think resolved our confusion when we were discussing very specific certification criteria, because we were dealing with things that were at vastly different levels; one related to a governance mechanism and the other related to very specific certification criteria. And at least our conclusion was, in the context of that discussion, was that the governance rule needed to have a mechanism for creating certification criteria and have a mechanism for choosing the business purposes for that certification criteria and then establish the actual certification criteria themselves; in the same way that the EHR certification process has a policy driven framework for creating Meaningful Use criteria, tying those Meaningful Use criteria to standards that should exist, a process for choosing the appropriate standard and then a subsequent process for developing the actual certification criteria. So, let me pause and see if what I just said was comprehensible, because there was a lot of it, and I'm not sure I expressed myself succinctly.

Judy Warren – University of Kansas Nursing School

So, you went in a different direction than where I thought you were going. So, talk to me more about what you mean by policy driven.

Arien Malec – RelayHealth Clinical Solutions

So what I mean by that is that the EHR certification policy framework has a mechanism for, a FACA in this case, to define policy-oriented criteria for what a provider should be doing with EHR technology in order to meaningfully advance the state of care.

Judy Warren – University of Kansas Nursing School

Okay, okay.

Arien Malec – RelayHealth Clinical Solutions

And so, those are the Meaningful Use criteria. Those Meaningful Use criteria often rely on the existence of standards, in this case... I'm using the analogy of the EHR certification process to describe what I think would be analogous for the information exchange or the Nationwide Health Information Network process. There's a policy process to vet out things that want to happen from a policy perspective to provide better care. Some of those things that want to happen are entirely under the control of the provider; some of them are dependent on standards and implementation specifications. In the cases where they're dependent on standards and implementation specifications, the Standards Committee has a role to point to standards and implementation specifications and ONC has a role in the standards and interoperability framework to convene industry in areas where those standards don't exist. But at the end of the day, the Standards Committee has a unique role to point to standards and implementation specifications, make recommendations to ONC, which then makes the determination that those standards and implementation specifications are appropriate for the EHR certification program and when that action is taken; then the actual certification criteria themselves are developed.

And so, that process of policy goal to standard to certification process is, in my read of the Governance RFI, not explained or not described. The Governance RFI presumes there might be such a process, I think, but the interoperability CTEs seem to me at least, to be at the level of certification criteria and not at the level of this Policy Committee, the Standards Committee recommendation process that exists for EHRs, and I think that's a gap.

Judy Warren – University of Kansas Nursing School

Okay, and that helps. Because when I was reading through the RFI, these materials, I guess I saw the certification policy framework you're talking about as something that's threaded through all three of these categories. But when explain it that way, I think we need to pull it out. However, I think we need to be very careful that we don't confuse people that may read this the same way I did, of seeing certification policy as a thread and what would the other three look like, or would they even change, if we pulled that out?

Arien Malec – RelayHealth Clinical Solutions

And I also want to point out in this context, footnote 26 on page 23, which notes that the RFI uses the term validation throughout the RFI, but defines it in a way that is inclusive of accreditation and certification. And, I actually think that definition confuses... I think it becomes very confusing in the same way that I think you interpreted this discussion, because accreditation to, for example, business practices, safeguards, policies, has a very different feel from certification to a specific set of standards and implementation specifications.

Judy Warren – University of Kansas Nursing School

So I would say, having just come to this idea, that I think I agree with you that the gap is there and that we need to add that in there. And you're talking about the gap of developing the policy framework that then allows us to use the term in the footnote, to validate.

Arien Malec – RelayHealth Clinical Solutions

Right. So, I would state it this way, I would say there needs to be process for establishing the information exchange policy goals, clinically oriented or efficiency oriented policy goals, tying those goals to standards and implementation specifications that are needed to achieve those goals, and then choosing and establishing specific certification criteria that are tied to those standards and implementation specifications.

Judy Warren – University of Kansas Nursing School

Okay. I've got to do some more thinking, but it sounds logical and yeah, because I'm not picking that up from the other read that I have, so I agree this is a gap and we probably need to add that as a fourth piece here, a fourth category.

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

Arien, this is Mary Jo. As a point of clarification, and harking back to the analogy that you did use, of Meaningful Use, it might be helpful if you would discuss whether you thought that there was an opportunity to simply utilize existing mechanisms or are you calling for a duplicate mechanism that would mirror this.

Arien Malec – RelayHealth Clinical Solutions

So Mary Jo, I think we get into this in the last three questions relative to the lifecycle, and that question is explicitly posed. So, I think we'll get to that question.

Stefaan Verhulst – Chief of Research, Markle Foundation

This is Stefaan Verhulst from the Markle Foundation. I'm getting a little bit confused with regards to the answer to the question. If the question is just the kinds of categories, or are you interpreting the questions on how you will establish those categories? S

Arien Malec – RelayHealth Clinical Solutions

So, the term... let me see if I can... I think it's a great question in terms of clarification. And by the way, thanks for joining us.

Stefaan Verhulst – Chief of Research, Markle Foundation

Yes, sorry, I was listening and I was unsure how to... whether I could just speak up, but, here I am.

Arien Malec – RelayHealth Clinical Solutions

Let me pause and just ask if anybody else has joined the call; this is your chance to speak. Excellent. Okay, so, the... and this is related to, as I said, a conversation that we had in the NwHIN Power Team, where we noted that as described in the Governance RFI, there were vastly different kinds of CTEs that were discussed, all under the name of a CTE. There are CTEs relating to privacy safeguards, business practices and the like, that would normally be considered under the framework... under an accreditation framework that deals with accrediting an organization to a specific set of business practices and policies, and then, what would normally be considered a set of certification criteria, that establish conformance to a very specific set of standards and implementation specifications, and that on reading the Governance RFI and discussing specific topics related to those certification criteria, it became clear to us that those criteria exist at vastly different levels. And so it came to us that there was a missing level in the Governance RFI, related to what you might consider the business or mission CTEs that said that it was important. So again, the analogy for the EHR certification criteria notes that there is a determination that to provide effective clinical care, it is important for physicians to receive clinical laboratory results in discrete format because it can be used for care of the patient, it can be used for longitudinal management, it can be used for decision support, it can be used for transitions of care, it can be used for quality reporting.

Stefaan Verhulst – Chief of Research, Markle Foundation

Um hmm.

Arien Malec – RelayHealth Clinical Solutions

Given that policy determination, and I would consider that a condition of trusted exchange, or I would consider that a policy, I don't know if you'd say if exactly falls under the name CTE, but it is a policy thing that wants to happen relative to EHRs. An example in the Nationwide Health Information Network space might be, and again with reference to, for example, the Markle framework, that it is important for there to be a record locator service to identify patients and where their data might be found, and that there is a strong policy with a slightly different kind of policy, so this is a things that want to happen in the real world to improve the quality and efficiency of care. There is a policy reason that wants to happen. Now, having made that determination, there is a subsequent determination of, what's the appropriate standard implementation specification that ties back to that policy and then, having chosen a standard implementation specification, there is a subsequent selection of certification criteria. And what we found

when we read the document was that the certification criteria were actually imbedded as CTEs, and we were missing that whole piece of establishing the policy...

Stefaan Verhulst – Chief of Research, Markle Foundation

Right.

Arien Malec – RelayHealth Clinical Solutions

... and then the associated standard certification criteria.

Stefaan Verhulst – Chief of Research, Markle Foundation

Right, get that. I get that. But then, how does that relate with the question 1 here that we focus on, with regards to, because you can have the same challenge, right, and with regards to specificity, for safeguards, interoperability and business practices. So, you can have a governance with regard to setting the policy for safeguards, and then having detailed criteria on how you're going to implement that policy and achieve, for instance, a trusted environment. And the same thing applies for interoperability and the same thing applies for business practices. So, the question I have is, in order to answer question #1, with regards to the categories, do we need to also, and I think it's a valid concern, because I had the concern as well that you have identified, do we also need to embed that in the answer here, or is that an issue that we should embed in a previous... or in another answer.

Arien Malec – RelayHealth Clinical Solutions

So, I think that's a great question as well, which is, is it the governance... so, if I'm hearing you correctly, you're saying that with respect to the first and third category, with respect to safeguards and with respect to business practices, there is a need for a policy oriented mechanism for setting the policy outcomes...

Stefaan Verhulst – Chief of Research, Markle Foundation

Right.

Arien Malec – RelayHealth Clinical Solutions

... and establishing conditions. And I would agree with that. I would also propose that there is a... that the analogy to... that the right analogy to safeguard CTEs and business practice CTEs is, in effect, the Meaningful Use criteria. That is, that the right statements, that the right level that is analogous to, for example, protecting IIHI, is at the level of there needs to be a record locator service, and that it is several rules down, or two layers down where the actual mechanism by which the record locator service works, is described. So, I'm pointing out a missing level in the framework.

Stefaan Verhulst – Chief of Research, Markle Foundation

Right. I think that's correct and I think it's important to highlight that.

Arien Malec – RelayHealth Clinical Solutions

And I'm also agreeing with your other point that there also needs to be a process for... policy driven process for establishing the other two types of CTEs.

Stefaan Verhulst – Chief of Research, Markle Foundation

Right, and so I think an additional comment I would make here, with regards to answering this question and then also with regards to answering how you go about achieving those objectives is that, my view to answer question #1 here is to pose the additional question, what do we want to achieve? And I think if the objective or the goal of governance in this context is to achieve trust and interoperability around nationwide information exchange, as envisaged, then obviously those categories, which are safeguards and interoperability are valid CTEs to have. So, that's one way to answer them directly the question. The business practices is an element that then regards to the objective of governance I guess, in the manner of effectiveness and probably the kind of outcomes you want to have as a result of the exchange. And I think that's probably another goal that you have with regards to the governance mechanisms that you propose here. So, I would keep those two separate; "A" which is the objectives and then as a result of that, what kind of categories of CTEs will you have to focus upon in order to achieve those objectives.

And then the other element which we've been focusing on as well and I think it's valid to do so, is of course, what are the kinds of mechanisms and to what extent will they be more or less specific and more or less policy; I think I would separate that in our answer here.

Arien Malec – RelayHealth Clinical Solutions

That's right, and so, I agree with you, that the categories are valid. I would also say that the interoperability category should be at the level of describing the policy goals for a record locator service, not at the level of establishing the associated certification criteria for the selected standard and implementation specification, and that there should be a process described in governance, given the interoperability CTEs, there should be a process for selecting the certification criteria and certifying entities. So I'm agreeing with you and adding that additional comment.

Stefaan Verhulst – Chief of Research, Markle Foundation

Okay, do it.

Arien Malec – RelayHealth Clinical Solutions

Mary Jo, do you have a succinct enough take of our position.

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

I don't have it succinct yet, but I think I got what I needed and then I'll work on making it succinct.

Arien Malec – RelayHealth Clinical Solutions

Okay, awesome. Thank you. Let's go on to the next set. I'm hoping that we're going to go a little faster, although, we've been dealing with really weighty topics. So, the next couple of slides describe, or I guess the next slide, describes the approach that the RFI is proposing for a voluntary framework and, I can summarize the words here by saying: A) that the intent is to support a voluntary mechanism; B) to support a set of validation actors who would validate an entity as an NVE and would validate an NVE with respect to types of services. If you go on to the next slide. And note again that the process that's envisioned is voluntary, but that ONC is effectively stating that despite it being a voluntary process, it still has teeth in the sense that the expectation is that if it's a good process, the CTEs will be established as our fee criteria or other kinds of criteria that will lead actors to become NVEs.

And so, if we go to the next slide, we've got a set of questions, question #2 which is also one of these very meaty questions, what kind of governance approach would best produce trusted, secure and interoperable electronic exchange? I'm sorry, my computer just locked out on me. Would a voluntary validation approach achieve the goal and are other approaches required? And, just to remind everybody what we discussed for question #3, so we pulled question #3 out and discussed it separately because it was the big existential question of should there be a governance framework, and we noted that there are a number of forces that are currently existing to create voluntary, consensus based approaches, there were at least three that we pointed to, NwHIN exchange, the CCC and the direct trust organization. There are also a number of other accrediting organizations that have established certification criteria or accreditation criteria.

I would propose that we treat questions #2, #4 and #7 as a whole, because I think that they all are asking the same question in slightly different ways, which is, given the answer to question #3, given that there is a justification for a governance framework, at least to the extent of establishing a common... using the convenient role of government in establishing a common space for having the conversation in ways that increased uniformity across the nation and decreases the cost of exchange, both by reducing the number of conversations that are required for a given exchange, as well as reducing the number of conversations that are required across exchanges. So, given those are the justifications for having a federally defined national process, what kind of approach would best suit that goal? And so again, I propose that we answer questions #2, #4 and #7 kind of as a whole, unless there is objection or reasons to separately consider them. No objection or have I confused everybody.

Judy Warren – University of Kansas Nursing School

I'm probably in a state of confusion right now. Taking a look at what do we really mean by governance approach, because I think we talked about that when we talked about question #3.

Arien Malec – RelayHealth Clinical Solutions

I agree, and we might just want to repeat our answer to question #3 here.

Judy Warren – University of Kansas Nursing School

I was trying to think, is there anything different here for question #2, and then the whole voluntary validation that was in the RFP that may be voluntary, however, various eligibility criteria for grants and other programs would hinge on validation. And so, is that sufficient to achieve. Actually, I think tying money to it probably is sufficient to achieve. I have been amazed at how many people have jumped in to Meaningful Use and some of the other programs that are coming out of HITECH, because that's where the money is.

Arien Malec – RelayHealth Clinical Solutions

Yeah, in fact, I think relative to our answer to question #3, you almost want the governance mechanism to be... take a soft touch, because that power is actually rather substantial.

Judy Warren – University of Kansas Nursing School

Yeah. I think about the... you know, I'm a faculty member and I think about the impact that HITECH has had on Universities as far as our training programs in Informatics and Healthcare in general. I mean, it's been profound having that money available and influencing what we do in those venues. As I work with our University Hospital, a lot of the changes they've made probably they would not have gotten there without Meaningful Use and now that they're on the path, they see the need for that and they're improving their standards of care and things like that. So, I think I would agree that voluntary validation is sufficient.

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

Judy, just for one point of clarification, the element of having other incentives potentially tied to it is totally separate. ONC itself does not have authority to establish any financial incentives, that's not part of our... as we have currently been told, so, it would be whether or not these other, like on the previous slide, it is possible that other government programs might choose to leverage this.

Judy Warren – University of Kansas Nursing School

So, do we consider that? So, Mary Jo, help me understand what you just told me. When we consider answering the question then, we shouldn't assume that those incentives would be around.

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

Not ipso facto.

Arien Malec – RelayHealth Clinical Solutions

The way I would look at the situation is to say, so I'm representing both the policy interest, but also the experience of being a commercial provider of health information exchange services that contracts with health systems and also contracts with the Department of Defense to supply various services. And, I can't imagine that unless the governance program itself was horribly flawed, which means that we didn't do our jobs, I can't imagine that given a well-designed governance program, that the Federal Government, or that DOD rather, wouldn't make achieving accreditation or certification a condition of future business in any of its contractual mechanisms. That is, I have a presumption that if it's a good governance mechanism, then one of the measures of it being good and effective is indeed that Federal partners will embed the criteria in the certification criteria.

Judy Warren – University of Kansas Nursing School

And that was the assumption I was coming from, of participating in various things. So, again, our University has one of the big Center for Translational Science Award, which required that we adhere to a lot of standards that the other 59 organizations adhere to, and just locally it's improved what we do on campus tremendously...

Arien Malec – RelayHealth Clinical Solutions

Right.

Judy Warren – University of Kansas Nursing School

... because it's helped us come to a common understanding, instead of each department doing their own thing.

Arien Malec – RelayHealth Clinical Solutions

And then likewise, I can't imagine in the commercial sphere that a successful governance program wouldn't drive RFP and contractual awards to be contingent on achieving certification.

Judy Warren – University of Kansas Nursing School

Yeah, because if you've got a good governance, then you've built in the quality and the efficiency and those are, I think, strong enough drivers, even if overt money is never attached, just the ability to collaborate with others on a level playing field I think is enormous.

Stefaan Verhulst – Chief of Research, Markle Foundation

This is Stefaan. I agree with everything that has been said and I think a way to answer the questions is that a voluntary approach would probably be superior, depending upon achieving certain success factors of governance, and we may want to just state what those success factors would be, which would be, for instance, success with regard to inclusion of all those that are affected by the CTEs, would also be... that actually is a more cost effective way of establishing interoperable and trusted electronic exchange nationwide, that there is also a certain level of flexibility embedded in the governance approach, so that it can allow for dynamic response to changes in the market and technologies. And so, we could say these are some success factors that will determine the success of a voluntary approach and that a key task of governance will be to develop the value proposition behind governance so that actually there are incentives in place to join and to have a voluntary system.

Arien Malec – RelayHealth Clinical Solutions

Stefaan, that was so brilliantly stated. At least from my perspective.

Judy Warren – University of Kansas Nursing School

Yeah, I like the whole idea of success factors.

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

Got it.

Arien Malec – RelayHealth Clinical Solutions

So, I think we've answered this bundle of questions successfully, #2, #4 and #7. Without objection, I'm going to move on to the next bundle of questions. So, I clustered #5 and #6 together because they both relate to the burden on the States and alignment between the states and, it occurs to me, having just listened to Stefaan's description of success factors, that the answers for these questions would indeed be one of those additional success factors. That is, that a useful and effective governance program would in fact reduce the burden of States and would, in fact, increase alignment between the governance mechanism and the State governance.

Judy Warren – University of Kansas Nursing School

This also speaks to the issue that I started talking about in question #3 of when you look at the burden on States, their burden is, each State is doing their own thing and then when they collaborate, they have to do it all over again.

Arien Malec – RelayHealth Clinical Solutions

Right.

Judy Warren – University of Kansas Nursing School

If we provide the right framework, then what they have to do is match themselves to the framework, which is significantly easier than matching themselves to multiple frameworks.

Arien Malec – RelayHealth Clinical Solutions

And through the various State grants, and existing grants that the Federal Government has with the States, there are voluntary mechanisms for alignment and then there are additional policy levers the Federal Government has to encourage alignment at the State level. But I would go back to Stefaan's point that, it should be a success factor the fact that States are eager to embrace the governance mechanism because it does make their job easier and reduces the number of conversations that they need internally as well as the conversations they need between the other States for which exchange happens.

Judy Warren – University of Kansas Nursing School

Agreed.

Stefaan Verhulst – Chief of Research, Markle Foundation

Right. And one way to approach question #5 might also be to approach within a slightly different perspective, because I think States might have a burden, but they also have a responsibility. And that's the reason why they take on the governance efforts that they are taking on, which is, there is a public responsibility for Stage 2, as we address the concerns that the citizens might have. And so a way to answer question #5 in a more positive way is that a successful voluntary scheme would actually help States provide for responsible ways to address concerns that they might have, and hence, there is no need for actually States to develop, and hence no burden, to develop actually alternative schemes of governance with regards to health information exchange.

Arien Malec – RelayHealth Clinical Solutions

Yeah, that's exactly right, in my opinion. Okay, so are we done with this set of questions?

Judy Warren – University of Kansas Nursing School

Yes.

Arien Malec – RelayHealth Clinical Solutions

All right. Let's move on to the next step, which relates to the CTE lifecycle. And we discussed at least some aspects of this earlier in our response to question #3 and then then bundle of questions #1, I forget what it was, #1, #4 and #6. So, the RFI notes that, I think there's a subtext to the RFI that notes that the rulemaking process is clumsy at best in some cases. Also notes, and I can provide a little bit of the background here, that standards themselves evolve, that the NwHIN was a... the NwHIN Exchange was a pilot, and that one of the goals of a pilot is to learn from it, and address the success and address the challenges that occur to the pilot.

So, for example, the NwHIN Power Team is looking at the criteria under which one would judge standards and certification criteria relative to the policy goals that were established by the standards and certification criteria; and, there's a need to learn from experience and ask the question, does the chosen standard implementation specification or implementation guidance, address the policy need or is there a need to change the standard and implementation guide. And that requires some kind of process to do that evaluation, to review the certification criteria, relative to the policy goals and we also noted that there

needs to be a process to review the policy goals themselves, to ensure that they are still appropriate, to see if there are additional policy goals that real-world experience hasn't covered and a well-functioning governance mechanism should address those aspects of the evolution of CTEs.

If we go to the next slide, the proposal is to note that there are emerging CTEs which are then established as pilot CTEs and then established as national CTEs or candidate national CTEs which are then established as national CTEs. And the notion here is that there should be some kind of process for moving CTEs through the maturity lifecycle and I think there's a missing... we'll get to, are these the appropriate levels. There is potentially also a process to retire CTEs, particularly those related to certification criteria. And again, this is a good reason to separate out the policy... the outcome CTEs from the actual certification criteria, because certification criteria will change more rapidly than the policy will. To give the example that I gave earlier, it would be hard to imagine that the need for some kind of record locator service would ever go away; but it would be easy to imagine that the standard against which we certified needed to be evolved and changed over time. So, there's a... I would propose, given our earlier discussion, there's a greater need to establish flexibility in versioning relating to certification criteria, than there is to imagine changing the actual policy requirements.

So, if we go on to the next slide, there are three questions that are provided, what's the process we should use? And then, two questions relating to Mary Jo's question earlier, which is, is the advisory... are the existing mechanisms that ONC has access to sufficient or is there a need for additional mechanisms and they pose the general question and then pose a very specific question in question #61. So, I kind of did a comment in my explanation of the RFI content, that I think informs one of my answers to question #60; and I think we also discussed it earlier in response to Stefaan's notes; there is a need to review and establish the policy criteria for CTEs, I think we've already said that. And then I also noted that the evolution of certification criteria tied to the policy outcomes for interoperability will evolve much faster than the policy outcomes for interoperability will evolve. That is to say, that if there's a requirement for directed exchange, you can imagine that the specification criteria for directed exchange will change much faster than the business need or the clinical need for directed exchange; likewise for record locator service. So, I would note that there should be one process for updating the policy objectives and a different process for updating interoperability certification criteria or accreditation criteria, because the details there will change faster than the policy objectives. So, I apologize, I talk too much and I will look for feedback from the two of you.

Stefaan Verhulst – Chief of Research, Markle Foundation

Can I pose one question, in order to understand here what we try to answer; and the question is one that I had throughout reading the RFI, which is, who is going to develop the first CTEs?

Arien Malec – RelayHealth Clinical Solutions

Right, and, so if you don't mind, I would actually like to pose that question within the framework of question #61 and #62, which is related to... which I think are relating to the who questions. But, I think you can address the lifecycle questions; what's the natural lifecycle, separately from the who question.

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

This is Mary Jo, if I could just as a point of clarification, respond to the very precise question about the very first CTEs. It is our assumption that they will be established through the very first rule. So, in other words, when the rule comes out, it will have the initial set of CTEs and if you would like to ask what... by what process they're going to be established, then that certainly you can ask as a point of information. I think it's probably sort of embedded in here, but, certainly the first CTEs will come out in the first rule.

Arien Malec – RelayHealth Clinical Solutions

And Mary Jo, if I'm not mistaken, all of the material that I see discussed in the Governance RFI, has been previously discussed for example, by the Privacy and Security Tiger Team of the Policy Committee or by previous work of the Governance Workgroup of the Policy Committee.

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

That's right. That's a very good point, Arien, in that we don't believe that there is anything in what is currently, even in this preliminary RFI presentation, that is dramatically different than... that does not reflect input that has been received through our FACAs and other appropriate channels.

Arien Malec – RelayHealth Clinical Solutions

That's right. And another example is the lifecycle discussion came directly out of recommendations from the Standards Committee that came through the NwHIN Power Team or through the relevant Privacy and Security Workgroup of the Policy Committee and the Standards Committee. So, I would say that the answer to Mary Jo's question is that the Policy Committee and Standards Committee and NCVHS have provided policy framework for the Governance RFI, which would then, as Mary Jo notes, be enabled in a rulemaking process subsequent to the RFI process and a presumed NPRM.

Judy Warren – University of Kansas Nursing School

So the process that we're referring to here is one where the FACAs are directed by Congress to look at certain issues, they do that and then they make recommendations and then rulemaking comes off of those recommendations. And so what we're trying to do is to take that one step further and say, once these CTEs have been identified and put into place, how do we ensure their currency, is that what #60 is telling us?

Arien Malec – RelayHealth Clinical Solutions

That's exactly right. And I noted, or at least I expressed a position on #60 that the policy criteria will change much more slowly than the actual certification criteria, there should be a process for each, that acknowledges the differences in life flow.

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

And Judy, also as a point of clarification, I believe, and I can't point to it right now, you have indeed, both you and Arien, have just laid out the current process of using the FACAs as the input. I think the spirit of this RFI and asking this group, is that sufficient, should there be other channels, other processes over and above what has been used to date, namely, using the FACAs as pretty much the primary source of input and the primary... an leaning on them, and then ONC taking that and making the determinations.

Arien Malec – RelayHealth Clinical Solutions

If I can provide an example, which is the work of the direct project, or the work of the standards and interoperability framework, my highly biased opinion is that that process worked really well and that it was most effective when it actually had oversight with the Policy Committee and the Standards Committee, that the process allowed for rapid evolution and piloting, or emergence, to use the terms that are defined in the RFI, but that it was highly effective to do so under what I would sometimes refer to as the fan-box and other times refer to as adult supervision of the FACA process; because it gave an aspect of legitimacy and an aspect of good oversight of the process that was nonetheless lightweight enough to actually get the work done on the ground, to evolve, for example, a sort of new policy framework which is, how do you do directed exchange in the real world, and then more... with more evolution in the actual certification criteria.

Or as another example, the work that Rich Elmore has been doing in query health, that again posed a somewhat new policy question which is, under what conditions should somebody be allowed to ask population questions of a covered entity and then, what are the standards that are applied to that question. So, I think that's been a relatively useful framework, but I'd also note that there are lots of private organizations, public/private organizations that have been evolving the art of information exchange without policy oversight or adult supervision, and I'd argue that they've been doing it reasonably effectively.

Stefaan Verhulst – Chief of Research, Markle Foundation

Right. Right. One way to... again, I agree with everything that has been said and I think one way to answer question #60 is to perhaps deconstruct the kinds of updates that we may anticipate and one with regard to the lifecycle. I think there is one bucket of issues, which we may call new issues that may lead to new CTUs or new concerns and challenges or even new opportunities that arise, and I think under that, you need to have a process to take stock of, are there new issues that require updates of the CTUs or require new CTUs. And I think there, there are again, three kinds of new issues, I guess. One kind are real new challenges, whether they are related with tentacle challenges or whether they are related with privacy and security or whether they are related with new business practices.

Arien Malec – RelayHealth Clinical Solutions

That's right.

Stefaan Verhulst – Chief of Research, Markle Foundation

So, that's one bucket. The second... and here you need to have a process to solicit those new concerns that there might be, or new opportunities that there might be. Then the second bucket are then developments in the policy and legal framework in which the CTEs operate, because obviously the CTEs have to adhere to the existing policy and legal framework that are out there. And if they change, then the CTEs might have to change. And so, that's a second bucket that might inform the lifecycle. And then a third issue under the rubric of new issues, a third one is are there, for instance, new requirements that those who might provide additional incentives to the voluntary condition here, have posed that could lead to actually new CTOs. For instance, is there a new Meaningful Use criteria, well that might actually... and they may inform, or maybe a way to actually increase the incentive to join the voluntary process, they may actually guide the creation of new CTOs.

I don't know whether that's clearly stated, but... so, these seem to be three kinds of new issues that require possibly different kind of processes. The first one in new concerns might be more of a public process, and here you can have a variety of means, including the FACA, but also, anyway, we are in a digital era, so, you could think in terms of how you actually adopt some new technology to establish a more public participation. But the issue here is then, you need also a process then to decide which one you're going to take on and which one you won't take on, right, because then anyway the agenda setting can become really challenging.

With regards to the second one, you need of course, some kind of legal guidance to determine whether you need additional CTEs or not, and that's almost like the role of a General Counsel kind of function. And then with regards to the third one, there you almost need like stakeholder relationship management, right, to really know what kind of criteria would actually help those who also depend and actually compliant with those criteria. So, these are the kinds of processes, I guess, that you may want to think about and would improve governance with regards to the lifecycle as it applies to the first bucket, which are the new issues that come along. Then the second bucket, from my perception, or the second kind of process, relates within the evaluation process, so this is not... an evaluation might lead to new CTUs, but it's evaluation of those that are already in place. And here you need to develop a set of metrics, there needs to be a process that can inform that evaluation with regards to how the CTEs are doing and, especially you need to have a cost-benefit analysis of whether the CTE is still achieving what it wants to achieve in the most cost effective manner.

Arien Malec – RelayHealth Clinical Solutions

Can I interrupt you for a second...

Stefaan Verhulst – Chief of Research, Markle Foundation

Yeah, and here I'm going to stop, because I've been talking too much, but that seems to be a way to actually deconstruct that question in a meaningful way, probably.

Arien Malec – RelayHealth Clinical Solutions

I actually completely agree with you and I put an additional point out, which is to say that a good policy... good CTEs, at least as I would see them, would be highly unlikely to change...

Stefaan Verhulst – Chief of Research, Markle Foundation

Yeah, exactly.

Arien Malec – RelayHealth Clinical Solutions

... unless there are radical changes in environment.

Stefaan Verhulst – Chief of Research, Markle Foundation

Right.

Arien Malec – RelayHealth Clinical Solutions

Interoperability CTEs might change a little more rapidly because the state of the world of what's feasible might change...

Stefaan Verhulst – Chief of Research, Markle Foundation

Right, right.

Arien Malec – RelayHealth Clinical Solutions

... but the need for a record locator service is unlikely to change radically over time. The associated accreditation, and especially the certification criteria, will change quite rapidly and so, what I was... Stefaan to your point, what I would say is your first three criteria of changes, would be changes to the CTE, the policies themselves...

Stefaan Verhulst – Chief of Research, Markle Foundation

Um hmm.

Arien Malec – RelayHealth Clinical Solutions

And the second criteria that you proposed, or the second process you proposed, would be changes to the associated accreditation and certification criteria that are tied back to the policy goals. And so, you'd expect that the policy goals would change only slowly, or with regard to significant changes in the environment, but, that the accreditation criteria might change a little more rapidly as practice is established and firmed up, but very slowly subsequent to that, again, except in environmental changes, and the certification criteria's themselves will also change rapidly at first, then more slowly, and then will need to get phased out and Wes on this... Wes Rishel on Standards Committee has pointed out that the phase-out and replacement process is incredibly important to think through, because you need multiple versions of standards and certification criteria in existence in the real world as you actually evolve and upgrade the system. But, the policy criteria to which those certification criteria are mapped, likely won't change very much.

Stefaan Verhulst – Chief of Research, Markle Foundation

Right.

Arien Malec – RelayHealth Clinical Solutions

And I like the frame that you gave of thinking through the kinds of changes that are likely to change the CTEs themselves and then thinking through the kinds of changes that are likely to change the accreditation criteria and the certification criteria. Judy, we've been talking a lot so...

Judy Warren – University of Kansas Nursing School

Well, I was down at the more pragmatic layer. It seems to me that when I look at this, one of the processes that we need to be sure is in place is a way for the private sector to surface issues with the FACAs. At NCVHS we do this by trying to stay very close to the private sector that is interested in us, so we cultivate friends and keep them close. We also identify people who have really great ideas, but don't always see eye-to-eye and try to keep them close as well, because they help us surface the issues that are coming up that we need to address in recommendations. So, it would seem to me that that be an important process to add to the current one. There is a place whereas people are working with these CTEs and see needs for changes or see problems in them, that they can bring that to our attention.

The other thing is there, kind of in #62, should we consider a process outside the advisory committee. And I... in just thinking about how people go about getting information on how to do work every day, there really is a significant benefit for having a lot of this stuff coordinated through the FACAs because it means they have one place to go look and see what's being required, to get their education, to participate in the process, etcetera, and we've been doing... trying to do a lot of work to educate the private sector in how they can participate and, I think that we probably should keep our process within the FACAs, because of that. Just keep them there as a coordinating thing. We've got to assume that we've got a good process for people to bring their issues to and participate with.

Arien Malec – RelayHealth Clinical Solutions

And Stefaan noted a success criterion that is near and dear to my heart, which is that a good governance process should in fact allow lots of innovation in the real world. And sorry, this is related to something that I've been meaning to bring forward from the NwHIN Power Team; we noted that the safeguard in business practice CTEs will be broadly applicable to many forms of information exchange, but the interoperability CTEs and the associated certification criteria may be applicable only to certain forms of information exchange and it should be, where I think you need a lot of innovation is in new ways of doing things that aren't either yet tied to an interoperability CTE of the kind of, there needs to be a record locator service and it should work roughly this way, from a policy outcome perspective; or, given that need, there needs to be a way of creating new mechanisms, and it would be a bad governance process if the only way to evolve the state of the art was to go through a formal FACA process, at least with regards to the emergence side of the work. It would be a bad...

Judy Warren – University of Kansas Nursing School

Yeah, I hope I didn't give the impression that I felt that FACAs were the only ones that could drive this. What I really want to see is the innovation occurring; what I'm concerned about is where do we... how to we know what innovation's occurring, how do we make that innovation available to the private sector so that they know what's happening. And as innovation occurs, how can we harvest the really good pieces that happen and bring them back in to, whether it's into a CTE or whether it's into some other part of this sharing of health data. How do we let people know what's going on? It's that whole problem of communication. You know, you can never communicate enough and even if you do, it's never to the right people at the right time. Or, they're not ready to hear it, and that's a concern that I have.

Arien Malec – RelayHealth Clinical Solutions

Let me see if I can restate what I think we've just been saying. We've been saying, A) that in the emergence phase of evolving new accreditation or particularly certification criteria and potentially new interoperability CTEs, that we desire a governance process that is explicitly open to and allows innovation to occur in the public and private sector, outside of a formal process. That we desire a good process for learning from the work that's been done in the real world, both from an innovation perspective and from a how are these CTEs and the associated accreditation and certification criteria practically playing out.

Judy Warren – University of Kansas Nursing School

Yes.

Arien Malec – RelayHealth Clinical Solutions

And that that needs... that we also then are... we also agree that the FACAs are the appropriate place for taking that information forward to what's referred to as the pilot and National phase of the lifecycle.

Judy Warren – University of Kansas Nursing School

Right. And when we talk about pilots, to me there are two kinds of pilots. I see a lot of the innovation work being pilot work that would occur outside of what the FACAs are doing, but the FACAs can also recommend that pilot work be done.

Arien Malec – RelayHealth Clinical Solutions

Right, so sorry, I think the interpretation that I have of the RFI is that that work is called emergent in the context of the RFI, that work that's being done in the real world that's in response to innovative new ways of doing things, would be in the emergence phase and that the pilot phase would get triggered when, for

some reason, somebody believes that that work should be considered for a nationwide standard, and that in that context, the pilot work would be overseen by the FACAs. And so, I think what you're calling pilot, I'm calling... I think the RFI is calling emergence.

Judy Warren – University of Kansas Nursing School

Okay. I just want to be clear on that, because you know, pilot is one of those words that can be misinterpreted. I know from NCVHS' perspective, we have been able to do our best work when we were able to partner with CMS to fund pilots, before regulation was written, so that we knew that we had the process right.

Arien Malec – RelayHealth Clinical Solutions

That's right. Beth Noveck referred to this once to me as practice before policy.

Judy Warren – University of Kansas Nursing School

Yeah.

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

...This is Mary Jo and again, just a question for clarification. I've certainly heard and I understand that the policy CTEs will evolve much more slowly, but in the event that there is, for one of the reasons that Stefaan has identified, the need for change in the, not in the accreditation or certification criteria, or the interoperability CTE, but in a business practice or in a safeguard CTE, would you like to articulate what kind of a process you think would be helpful there, or is it just the FACA; I'm not sure that I've captured that part of your thinking.

Arien Malec – RelayHealth Clinical Solutions

So Mary Jo, just as a point of clarification, I would look at accreditation criteria as being tied to the safeguard and business practice CTEs and the certification criteria as tied to the interoperability CTEs

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

Okay, no, I do understand that, but you're still talking about at the level of the criteria as opposed to the CTE itself.

Arien Malec – RelayHealth Clinical Solutions

That's right, and I think we're proposing the same process for evolving the CTEs themselves, that is, there needs to be some mechanism to learn from what's going on in the real world, but that the FACAs are the appropriate mechanism for evolving the CTEs. And I apologize if I'm misstating what I heard the other two of you say.

Judy Warren – University of Kansas Nursing School

No, I agree with the way you stated it.

Arien Malec – RelayHealth Clinical Solutions

And I believe we just got through all ten questions.

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

Have you answered #61 specifically?

Arien Malec – RelayHealth Clinical Solutions

I think we answered #61 generally.

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

And the answer I think was yes.

Arien Malec – RelayHealth Clinical Solutions

I think the question to #61 is rather than stating it this way, we would state it desiderata of the governance process that emergence, this is really into pilots... huh.

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

In other words, does validation only start when things have reached what is determined to be national status?

Arien Malec – RelayHealth Clinical Solutions

Oh, I got it. Mary Jo, let me see if I can put this question back, with respect to the direct project. It would have been useful if there was a process for saying that we had kind of a voluntary mechanism for validating direct compliant entities for their pilot work. We had no mechanism for saying, here's a formal process for validating pilots in the context of NwHIN exchange, ONC served as the validation body for pilot activity. And I think stating it that way, and looking at the practical considerations, I think it would be useful to have that role, but I'll turn that over to Judy and Stefaan to see if you agree or disagree with that. So again, just relating... again, I was... terminology clarification issue that Judy was falling into looking at pilot and emergent, not thinking no, but with pilot as the formal step from going on the real world to we want to test this to see if it's appropriate for national adoption, my experience is that it would have been useful if there had been some kind of validation process or certification and accreditation process for that work.

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

Yes, and what they... and again, just to specify, some pilot activities can be fairly robust, but they could be just geographically limited or limited in some other sense and again, they certainly fall short of being truly nationwide in maturity and adoption. But, it wouldn't mean that they might not be fairly extensive, but in some constrained way.

Arien Malec – RelayHealth Clinical Solutions

Yeah, and again, the direct project work is a good example of that, and my...

Judy Warren – University of Kansas Nursing School

So when you say that ONC should be the validating body...

Arien Malec – RelayHealth Clinical Solutions

No, sorry, I'm not saying that. I just want to clarify that. For the purposes of NwHIN Exchange as it currently works, ONC is the validating body. I think it would be useful for the purposes of NwHIN Exchange, if there were a separate accreditation and certification bodies, to get ONC out of the business. I was just stating a matter of my understanding of facts.

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

And it could be that for example, the CCC, I know is going to, one of the things it especially wants to look at is patient matching and patient identity or, it might look at some other population health or someone might... it might expand its population health work and it could be that they go fairly far, but the work that they're doing in the standards that they have chosen are not necessarily at a national level and certainly their exchange experience is amongst themselves and they might, as large and significant as they are, they might still fall under the category of pilot.

Arien Malec – RelayHealth Clinical Solutions

Correct, that's right.

Judy Warren – University of Kansas Nursing School

So let me come back to the question then, maybe I'm not understanding the question. So if CCC becomes one of these validating bodies, is there...

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

No, I didn't say that they would become a validating body, I said they would be a pilot.

Judy Warren – University of Kansas Nursing School

It says here, should we expressly permit validation bodies to provide for validation to pilot CTEs. So tell me what a validation body is.

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

A validation body, that is an umbrella term that covers both bodies that do certification, which is of course of technology and conformance to standards, etcetera, and bodies that do accreditation for policies and practices.

Judy Warren – University of Kansas Nursing School

Okay, so then would ONC, if we had other people besides ONC be the validation body, ONC would be the one that would recognize their authority to be a validation body?

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

Yes, the way it's spelled out in the RFI is parallel to the way it's done with certified EHR technology now; ONC chooses one... first of all it starts with one overarching accreditation body, which in turn is authorized to recognize the sub-bodies. And in the case of EHR certification, they're only recognizing certification bodies, certification and testing bodies. Under governance, this overarching accreditation body would have the authority to recognize both certification bodies and accreditation bodies, but ONC would not be doing any of the validating.

Arien Malec – RelayHealth Clinical Solutions

And that's the work that Team 2 right now is talking through.

Judy Warren – University of Kansas Nursing School

Okay. So, I think I understand that, but, it shows the need for a roadmap and a glossary.

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

Right.

Arien Malec – RelayHealth Clinical Solutions

That's right, particularly the definitional things we were tripping over in terms of the word pilot...

Judy Warren – University of Kansas Nursing School

And the different ways we use the terms between what we do at NCVHS and what ONC is doing. So, just forgive me as I translate between worlds.

Arien Malec – RelayHealth Clinical Solutions

So, just to give you a practical example, and I won't use direct, let me use CCC as Mary Jo you brought it up. Let's say at some point CCC is not satisfied with the way that patient identity currently works, and wishes to explore a new mechanism for patient identity in the context of the record locator service. And

so, in this world, the interoperability CTE, that is the policy desiderata for interoperability, likely wouldn't change; but the certification criteria might well change and it would be... if validation bodies weren't allowed to accredit or certify organizations for a pilot, then CCC would have to do it kind of themselves. If validation bodies were allowed to, or formally authorized to, I guess they would always be allowed to, but formally recognized as responsible parties for the purpose of pilot, then there would be a mechanism for CCC to go to a validation, a certification body or a set of certification bodies, to explicitly certify for the purpose of that pilot. Mary Jo, do I have that right?

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

Yes, I think that is right. But again, I would also use accreditation. Let's say that some small group decides to pilot a patient identifier and approach say a voluntary, you know, unique patient identifier, and within their closed community, they're really able to do it and they're really able to test it out; but that is obviously an area of a safeguard CTE...

Arien Malec – RelayHealth Clinical Solutions

That's right.

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

... and would we want them to be able to be validated. Again, it would still be expressly for a pilot status, it would not be recognized, I think that's in the text that it would be clearly stated that this was a pilot status, not a national status.

Arien Malec – RelayHealth Clinical Solutions

And I think phrased that way, my response would be, absolutely yes. It would have been really useful for direct, it would have been really useful for some of the S&I work we did, I think it would be really useful in the examples that we just gave.

Judy Warren – University of Kansas Nursing School

Agree.

Stefaan Verhulst – Chief of Research, Markle Foundation

Agree.

Arien Malec – RelayHealth Clinical Solutions

By the way, as a general comment, despite the existence of footnote 26, I think for future work it really would be useful to separate accreditation, certification and the policy objectives, I should think it makes... I know that ONC was trying to simplify the discussion, but I think it actually made the discussion more complicated. Mary Jo, do you have what you need in order to write this up?

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

I'm sorry, what I was going to do, I have certainly lengthy notes. But I was actually going to take a stab at drafting what could represent the more succinct statements, you know, answers to these questions...

Arien Malec – RelayHealth Clinical Solutions

Correct.

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

... as best I can. And I can circulate it to all three of you, and hope to do that certainly by the end of the day.

Arien Malec – RelayHealth Clinical Solutions

Awesome.

Judy Warren – University of Kansas Nursing School

Right.

Arien Malec – RelayHealth Clinical Solutions

And then, we'll approve those and then I'll present those to the Governance Workgroup at our next meeting. That's the process.

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

Which is Monday.

Arien Malec – RelayHealth Clinical Solutions

Is Monday.

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

Right. And then you may be done, unless they push back and say, if there's anything they'd like you to reconsider. You don't currently have another meeting scheduled. Most of the other groups do, but they've only been able to squeeze single hours in this week, so, the other two groups are simply not finished their work and so, they definitely need to meet next week. But, unless the full Governance Workgroup meeting on Monday raises a new question for you, you guys might well be done.

Arien Malec – RelayHealth Clinical Solutions

That would be so fabulous.

Judy Warren – University of Kansas Nursing School

That's due to Arien. Keying him up I think with question #3 really facilitated the dialog today.

Arien Malec – RelayHealth Clinical Solutions

Well thank you.

Stefaan Verhulst – Chief of Research, Markle Foundation

Agree.

Arien Malec – RelayHealth Clinical Solutions

Mary Jo, do we need to turn this over to public comment?

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

It is almost precisely time for public comment. Thank you very much. So operator, if you would do that for us please, open the lines.

Public Comment

Alan Merritt – Altarum Institute

If you'd like to make a public comment and you're listening via your computer speakers, please dial 1-877-705-2976 and press *1. Or, if you're listening via your telephone, you may press *1 at this time, to be entered into the queue. We have no comments at this time.

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

Thank you operator.

Arien Malec – RelayHealth Clinical Solutions

Thank you everybody, I think this has been an incredible discussion, I've learned a ton and I'm pretty confident we're going to have some very valuable comments back to the workgroup.

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

Thanks everybody.

Stefaan Verhulst – Chief of Research, Markle Foundation

Thank you.

Arien Malec – RelayHealth Clinical Solutions

Thank you.

Judy Warren – University of Kansas Nursing School

Thank you, bye.