

Governance Workgroup Subgroup #3
Draft Transcript
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Roll Call

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

Good afternoon. This is Mary Jo Deering from the Office of the National Coordinator for Health IT and this is a meeting of the HIT Policy Committee's Governance Workgroup and the subgroup #3. It is a public call. There will be a chance for public comments at the end. So, I will begin by taking the roll. Jan Root?

Jan Root – Utah Health Information Network

Yes. Thank you.

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

Michael Matthews?

Michael Matthews – CEO, MedVA

I'm here.

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

John Blair are you on yet?

John Blair – Taconic IPA

Yes, I'm here.

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

Oh good, excellent. Leslie Harris? Are there any other members of the Governance Workgroup on the call? Okay, would staff identify themselves?

MacKenzie Robertson – Office of the National Coordinator

MacKenzie Robertson, ONC.

Adam Aten – Office of the National Coordinator

Adam Aten, ONC.

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

Okay, over to you Jan.

Jan Root – Utah Health Information Network

Okay, great. Thanks so much for setting this up Mary Jo, and I really appreciate all the work you've done to get this going. So, this is group 3 and we had a specific list of questions that we needed to review and at least start the conversation on. So, I thought I'd be logical and just start at the beginning and work through them. They are an interesting sort of potpourri of issues. I'm going to assume that people have read the RFI and so, I hope that's a good assumption, but if you haven't, I'm going to raise a couple of points that I brought to these questions as we move ahead. So, I thought we would start with question 18 which, Mary Jo always let me know if I've missed a question, because this was such a scattering of questions, I hope I caught them all. So, question 18 is about appropriate monitoring and oversight

methods to include as part of the governance mechanism for the National Health Information Network. In the paragraph before, they've mentioned a couple of things, and for those of you that were on the call yesterday, there's a little bit of overlap here, but, the idea of... one of the oversights was essentially sort of no oversights, in a sense of voluntary industry self-policing. We had a long discussion yesterday about voluntary validation framework, what's that. But I think, and Mary Jo, tell me if you think this is right, this is really about, I think this was about, what do you do if somebody did something wrong. Is that a correct sort of layman's read to it?

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

I think that is absolutely squarely within this section, that is one of the critical items, obviously, but I think it goes beyond the negative to the affirmative as well. We also interested in how we might just be monitoring the system, from a positive way as well as a negative way. So, definitely, checking for breaches and other things, but is the process working well, you know, monitoring the governance mechanisms overall is another way to also think of it.

Jan Root – Utah Health Information Network

Yeah. So, I just wanted to throw it open to people that are on the call for discussion. So, we're on question 18, appropriate monitoring and oversight methods. Oh, I should add one tag, from an IT perspective, and Mary Jo, again let me know if this is correct, ONC doesn't really have any direct IT control. For example, in my network, if somebody gets outrageous for whatever reason, I can turn them off, because I control the exchange, from a technical perspective, as well as from a business perspective. But, that, my understanding Mary Jo, is that capacity does not exist here.

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

That's correct. The ONC will not have direct control over any network, and its sole... its direct authority in that regard would be to rescind recognition as a nationwide health information network validated entity or in...

Jan Root – Utah Health Information Network

Right. Yeah, so that would be about the limit of the most punitive, is that a good, is just to rescind their NVE status?

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

For ONC specifically, right.

John Blair – Taconic IPA

Hello, this is John Blair. So, I mean they talk in the section before about FCC and OCR and if these NVEs are considered covered entities, I would assume that the Office for Civil Rights would have the same kind of jurisdiction and oversight as they do with HIPAA.

Jan Root – Utah Health Information Network

Yes, specifically around privacy and security.

John Blair – Taconic IPA

Right. And then they talk about where FCC would play into this. So, as they speak about this earlier, under C monitoring transparent oversight, they do mention the accreditation process as being part of that oversight, so to me, between what would play out with accreditation, as opposed to certification, but what would play out with accreditation along with OCR and FCC, I mean, I'm comfortable with that and I think that that would be enough.

Jan Root – Utah Health Information Network

Yes. I think the OCR has proven that they have teeth and certainly the FCC has, on occasion any way, proven that they have teeth. And so what I hear you saying John is, if the governance for the NwHIN creates some, at least minimally robust, I'd like to be conservative, accreditation and validation processes, and if those happen within a reasonable cycle, 1 year, 2 year, whatever the decision is; that that would be an appropriate monitoring and oversight method. Is that what you're saying?

John Blair – Taconic IPA

Yes, that covered with the fact that the NVEs would be covered entities.

Jan Root – Utah Health Information Network

Right. We did have a little bit yesterday about this term voluntary validation, and I think Mary Jo, remind me and John if I'm correct, is that we kind of came, I think, to the conclusion that that term meant that participation in the NwHIN is voluntary, but if you are going to be part of the NwHIN, you would go through a validation process that would be mandatory. Is that correct?

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

Well, and again, we try not to talk about being part of the NwHINs anymore, what we try to say is, in this context is, you are not required to seek to be validated, to seek to be governed, to seek validation. No one's going to . . . at least in this proposed RFI, we're saying that an entity that exchanges information is free not to seek validation.

Jan Root – Utah Health Information Network

I would have a lot of problems with that.

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

Well, and that's what I think we need to tease out, is that acceptable, but, that was in the other group, so we may go back to that again. But, to the extent that an entity does wish to be recognized as an NVE and both for itself and just to be part of that broader trust, I hate to call it a network, because it's not really a physical network, but, that universe or that environment...

Jan Root – Utah Health Information Network

...name it like a consortium or something, I don't know.

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

...then it would need to be validated.

Jan Root – Utah Health Information Network

Right.

John Blair – Taconic IPA

And I agree with that, and that's how I see it too. I mean, you're going to have data exchange that's not within an NVE and I don't think that they have to... I mean, they don't have to validate anything, yeah, I think if it's an NVE.

W

Right.

Jan Root – Utah Health Information Network

Yes, and I was just re-reading, for example, what the CCC is doing and thinking, okay there's an example of a group that is working to do something similar and I looked at their PowerPoint for example from HIMSS, and there wasn't really any mention at all of any kind of governmental structure or validation of

message type or anything and I'm thinking wow, that's just going to create so many problems. Okay, so in terms of . . . does anybody else have anything else they would like to add on question 18? Okay, so I think what, I think if I'm going to summarize this here, is what we would recommend is that the appropriate monitoring methods and oversight methods to include as part of the governance mechanism, is some kind of, and I'm going to put this word in big quotes "robust accreditation" and "robust validation." I don't know what those mean yet, those haven't been defined, but some kind of accreditation and validation that has some value to it, in addition to the duties that are already performed and the regulatory authority of the OCR and the FCC. Those are appropriate.

And I think in terms of answering the why part of that question, is that it really, as far as we can tell right now, covers the span of what needs to be covered, which is are you basically HIPAA, you know, privacy, security compliant, any operating rules that come out of this will probably be part of the validation, I hope be part of the validation process. So, do you create correct messages, do you have the right encryption, are you following the operating rules and then for actual legal enforcement, that goes on to the OCR and FCC. Is that a good synopsis?

Michael Matthews – CEO, MedVA

This is Michael. Before we tie the bow around that one, let me raise a couple of things. One would be, I don't know what the accreditation and validation process means either, but, one of the things that we've been thinking through at the state level is around attestation on the part of the participants, that they have met the requirements that they've signed on for; their obligations, as part of their participation agreement and, you know, we can't have a police network where, if we do that, we're not authorized to do that nor would we ever have the technical capability of doing that. So, the accreditation process I suppose could incorporate that concept that, are they doing ongoing monthly, annual kinds of monitoring of their own activities.

But, from where we've gone so far, like with the existing, current structures for exchange policies and procedures, it kind of breaks down into, what are the rules of the road and how do you know when the rules of the road have been broken, and then what are your enforcement capabilities once those broken rules have been identified and acted upon. So, it kind of brings some of that into this current conversation, I think that sort of basic framework makes some sense for us to think through as we're going through the various questions that are coming up with 19 and 20 as well. Mary Jo, do you...

Does that make sense to you?

Jan Root – Utah Health Information Network

Yes, absolutely. I mean, in a way that there's an attestation. Right, I say that I do, basically comply with HIPAA, and I totally agree in one like really underlying, what is accreditation, we don't know yet. What is validation, we don't know that yet either. So, I think we're going to run the gamut from potentially, at least as a discussion point, from attestation all the way through to some kind of formal accreditation. I think the validation part, Mary Jo, if I understand correctly, it's yeah you do test with NIST and so you test all that sort of technical stuff that's testable. That is "relatively easy," it's not that it's... relatively easy compared we're saying, what's your security; you know, do you require certain passwords and blah, blah, blah, all that stuff.

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

And I think that when perhaps the full workgroup gets back together, it might be useful for there to be a really robust discussion about what should go into accreditation.

Jan Root – Utah Health Information Network

Yes.

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

What in your mind would constitute “robust accreditation”? And just so that we’re not tripping over language here, remember that we have the overarching accreditation body, which only exists to accredit the other validation bodies and these other validation bodies include entities that will do both accreditation for process and policies and the certification and testing of the technical requirements.

Jan Root – Utah Health Information Network

So if I understand what you just said Mary Jo, I think what you meant is like ONC would have that oversight role, the high level role and then they would either designate or create or whatever the sort of technical validation and the processes accreditation. Is that...

John Blair – Taconic IPA

That’s not my understanding. I mean, what I read in this is, ONC would have the role of assigning that overarching accreditation – would then assign or choose the others that Mary Jo was talking about.

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

I think that is correct, and again I think this will all remain to be seen, but, we would certainly lay out the parameters by which... two sets of parameters. First of all, we would competitively pick the overarching accreditation body. We would set up the parameters by which it needed to function and then different entities could apply to be recognized as that overarching accreditation body. And then, we would have also laid out the parameters by which that chosen accreditation body would, in turn, accredit candidate organizations to do either the accreditation side of validation or the certification side of validation. If you think of the parallel, it’s cleaner and clearer right now in our EHR certification program, in that you’re only going down the certification and testing path; but, I think if you think structurally and process wise, it’s a similar concept, we’re just adding the additional dimension of accreditation of policies and processes.

Jan Root – Utah Health Information Network

Right. And again, just to inject one thought that came from yesterday is one idea around accreditation, not validation, but accreditation, is that like for example, if you are a hospital like Kaiser Permanente, and you’ve gone through Joint Commission, assuming that Joint Commission actually covers all of HIPAA, which I’m pretty sure they do, and you’re accredited through Joint Commission, that might be an acceptable alternative to direct, redirect accreditation, so you don’t have to do the same thing over and over again, because that’s very expensive; anyway, just a thought. So, I think it’s very important though, Mary Jo, to put a big flag by the fact that we don’t know what accreditation and we don’t know what validation means right now and a lot of our answers to these questions might change, maybe even dramatically, depending on how those terms are functionally defined.

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

Okay, I’ll certainly flag that.

Kate Black – Center for Democracy & Technology

Hi everyone, I’d just wanted to interject... this is Kate Black, I’m here on behalf of Leslie Harris, we had a last minute scheduling snafu, so I am a little bit late, but, hello everyone.

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

Thank you Kate.

Jan Root – Utah Health Information Network

Okay, so any other comments on question 18? Okay. Question 19, what other approaches might ONC consider for addressing violations of compliance with CTE? I think the violations question... so, in terms

of enforcement, Michael, I think you mentioned the enforcements issue, because that is a critical question to address.

Michael Matthews – CEO, MedVA

Yes.

Jan Root – Utah Health Information Network

And I think what we've said so far is, if it's a HIPAA covered entity, OCR is definitely in charge of those kinds of violations. They do talk in here about the fact that there might be some non-covered entities, and I have to confess that when I read through one of the CTEs is that you will comply with blah, blah, blah, blah, blah, blah, blah; and I didn't have a chance to go back and read exactly the text of all of those pieces. So, Mary Jo, perhaps you can tell us if any of that includes the HITECH fines? Do you know if, I think it was in S-1? I think we can get to that later if we need to, but anyway. I know, like we deal with non-covered entities like property and casualty insurers, okay. They are not covered entities, they are medical entities, but they're not covered entities, and they have a lot of problems with the HITECH fines, let's put it that way.

So, I don't know what we would do about non-covered entities and how far are they willing to do HIPAA, but I think what we're saying right now, as far as this is... ONC, as far as we can tell right now, will only redress as a sort of a final redress would be to remove that entities NVE status, sort of destatify them. If there was a violation under ORC or FCC, they would handle those violations? So, are there any other ideas, I mean, obviously you might want to have, they mention in here like a process for, as you mentioned again Michael, identifying; you know, what are the rules, how are you going to discover a violation of the rules and then, how do you enforce those. So, ONC, I think would set up a process for: one, stating the rules, probably much more specifically than is currently stated in the CTEs, because those are pretty high level, and then saying, okay, for this kind of violation, that's an OCR violation, for this kind of violation, it's an FCC violation, for this kind of violation, it's an ONC violation and here's our process for bringing those issues forward, making some kind of determination, having an appeal process, all of that sort of due process piece that needs to go into this.

John Blair – Taconic IPA

So this is John, again. So, outside of the covered entity OCR piece, you might have the accreditation body, since they're attesting and potentially doing audits, etcetera, etcetera, but, part of the accreditation might be the ability that if there is a violation to have a remediation period and/or go clear to termination of their NVE status.

Jan Root – Utah Health Information Network

Correct. You know, one thought I just had is, should that whole NVE status concept get worked into the DURSA, in terms of some more formal statement around termination, you know, it says if the member is out of compliance or the NVE is out of compliance, this is the process, because we put language like that in our agreements with our members. I think there is termination language in the DURSA right now, but there isn't... I don't think that NVE concept is in the DURSA.

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

Jan, this is Mary Jo, and one thing that that brings up is, we have in various places, recognized both the existence of the Exchange, but of also just recognizing the fact that there are other activities out there and we have said that once governance is in place, it is quite logical, or possible or probable, depending on which adjective you want to choose, that other organizations would incorporate elements of governance into their own activities. So, I think that we have sort of assumed that and if this workgroup would like to make a recommendation that ONC, I'm not sure ONC can encourage any outside organization to do that, I don't think that's really within our direct authority. But if this group wants to comment that it assumes or would see value in outside organizations incorporating certain governance concepts or processes into their own policies and procedures, that's certainly okay.

Jan Root – Utah Health Information Network

Yeah, I would worry about that a little bit. I should probably confess, I'm a Democrat with sort of Republican leanings, in a sense that I worry about government getting too involved in how businesses are operated and so, maybe that's a pass for the future, but at this point in time, I would suggest that anything like that get incorporated into the DURSA. I know of several HIEs who have taken the DURSA, for example, and used that as their starting point for their own business agreements. And so in that sense, they are adopting those programs. Anyway, maybe we could sort of parking lot that idea as something to consider in the future, would that be a thought?

Okay, so are we okay with question 19? I think what we've said is that the DURSA or some ONC formal process would be put in place for violations of... for setting the rules down, discovering violations, trying to figure out how to enforce those violations as far as anything within the purview of ONC itself; remediation periods, all of that stuff, that that would be put into the DURSA specifically with the concept of the NVE so it's very clear how that applies, and then relying on OCR and the FCC. One other example of a non-health care entity that's increasingly getting involved in healthcare is the financial sector, the banks, are increasingly getting involved in it, so, they're under Oxley Sarbanes, anyway, that way. They have a whole set of privacy and security and guidelines that they have to follow, so we might need to talk a little bit about, at a later date, about what happens if financial institutions start to get involved in this thing. For example, property and casualty companies are actually considered financial institutions.

M

Sarbanes Oxley, but that's a moving target too, as we tend to move towards more deregulation...

Jan Root – Utah Health Information Network

Oh yes.

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

Right.

Jan Root – Utah Health Information Network

I just brought that up as an example of something that might have to be looked at in the future.

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

Jan, let me make one clarification, is that when you said that NVE status should be worked into DURSA, that's not anything that ONC can say, I mean, really we don't have any role in saying that.

Jan Root – Utah Health Information Network

Okay.

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

So I think that it wouldn't be a comment back to ONC to make this happen, because that's really up to the Exchange and the Coordinating Committee and the participants.

Jan Root – Utah Health Information Network

Okay, cool. Yeah. Well, maybe as a side light, maybe Marianne Yeager or somebody we could say, here's a thought for the governance... Governance Committee. Since you're going to have this legislation possibly, you know, if all this ends up as some kind of final rule and this concept of NVE is worked in, it just kind of makes logical sense that the commerce agreement would include the concepts from the legislation, but, that's great, you raise a very valid point Mary Jo.

Okay, so then we are on to question 20, am I correct? So what limits, if any, would need to be in place in order to ensure that services and/or activities performed by the NVEs for which no validation is available, but not misrepresented as being part of an NVEs validation, should NVEs be required to make some type

of public disclosure or associate some type of labeling with the validated services or activities they support. What I was...

Wes Rishel – Gartner, Incorporated

Can we advance the onscreen slides?

Jan Root – Utah Health Information Network

Do I need to move the slides, I'm sorry, I'm just reading from my notes at this point.

Wes Rishel – Gartner, Incorporated

Thank you. Yeah, okay. This is Wes Rishel by the way.

Jan Root – Utah Health Information Network

There we go.

Michael Matthews – CEO, MedVA

Jan, this is Michael. Just to give you a heads up, I'm signing off of this call and reconnecting on another phone.

Jan Root – Utah Health Information Network

Oh, okay, you'll be back right?

Michael Matthews – CEO, MedVA

Yeah, in about 60 seconds. Bye.

Jan Root – Utah Health Information Network

Great. When I was thinking about question 20, again, just to get the conversation started, NwHIN is accredited by EHNAC and we have that little ENHAC sticker on our website, and the ENHAC website is the one that's responsible for saying, this sticker covers these specific issues, of which there are tons, I think there's like 84 of them now, around privacy and security, and working with your customers. So, I'm wondering, if you get the NVE... Mary Jo, is this the idea is to say, okay, if you get an NVE sticker, I'm just going to use that as kind of an irreverent way to say, I'm a validated NVE and you can put that on your website, is that what this is talking about, because...

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

Yes and I think what we're recognizing here is that governance is starting out fairly minimally, it's trying to cover a few specific services that are far from the complete range of activities and services that entities are conducting right now. And, that means that you'll have entity X out there that's conducting services A through M, because those exists in information exchange today. But under governance, we've only chosen to cover services D, E, F, G or something like that.

Jan Root – Utah Health Information Network

Sure. Right.

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

But how do we... and so, while we're giving them a sticker for D, E, F, G, and we'd be pleased for them to say that they were validated for that, and think that that would have a market value, why, how do we address the fact that they've got all these other services that were not validated and so that the public and their stakeholders and their customers have knowledge of where the certification begins and ends.

Jan Root – Utah Health Information Network

Yeah. And again, if it's okay, just drawing back from INAC, they have a number of different stickers that you can get, also the stickers are versions, right? So you can say, I've got the EHNAC version blah, blah,

blah, and so it's not me that says my sticker applies to these services, because it's a moving target, right, over time that will change. But because the sticker is versioned, the entities that are interested in knowing, okay, what is that, what kind of services does that sticker cover; you can go back to the INAC website and you can look up the version and it'll tell you, it covers these things. I mean with that... I'm just throwing that out...

Wes Rishel – Gartner, Incorporated

This is Wes. I came to the call late, but, what I understand... it seems like one of a host of considerations that we have is the bad actor, who might copy and post on a website some artifact that looked like a certification, the EHNAC approach where the specifics of the certification are only available through the EHNAC website is a defense against that, provided that the EHNAC website is well enough protected.

Jan Root – Utah Health Information Network

Yeah. They also list, I should say, who's been accredited and for what dates; so, they are, as far as I know, it is pretty protected, obviously that's their responsibility, but, so, that gives you a version and it gives you, if somebody were to stick an artificial, because it's so easy to do, an artificial version of the NVE sticker on your website or wherever you want to put it. If there was some question about whether that was valid or not, the consumer would need to go back to ONC, presumably, and validate that. It's kind of like when you get an email from somebody you know, but it looks suspicious. I had that happen to me yesterday, so I emailed the person and I said, "did you send me this email," that kind of stuff.

Wes Rishel – Gartner, Incorporated

Yeah. I think that we're dealing with a couple of things. One, if we have a breadth of vocabulary to describe twenty services, very few people accept technicians working for HIEs are going to understand those twenty services; and, there you can imagine a consumer organization creating alerts that say well, there's a potential error if you don't find service #W and something's going on. They tend to serve as advocates for the public rather than direct representatives of the public.

Jan Root – Utah Health Information Network

Sure.

Wes Rishel – Gartner, Incorporated

But, I think we should be limited to saying what we have identified and can assure, and not create categorizations of things we can't assure, because just the process of identifying what we can't assure and creating an ontology for that begins to standardize what those things are and is probably inappropriate.

Jan Root – Utah Health Information Network

Yeah, and again, just pulling in from INAC experience, just because that's the only model I have for this question is, they started with one accreditation that had like 40 things on it, or maybe even less than that, and they've now branched out to all kinds of... they've got like, I don't know, twelve different accreditations, and each of those have a version. So, there's a way to... because I completely agree with you, that you need to be able to say, okay, this kind of accreditation covers these specific services or... yeah, the accreditation might be more around are you... do you comply with HIPAA or do you do the sort of basic processes stuff well and the validation would say, can you send lab results, can you send a CCD 32, can you... you know, what are you getting accredited for or validated for on a technical side, and figure out a way to put that information, make that so that there is, like you just said, a very valid link between whatever sticker or whatever the NVE gets to put on their website and/or their products, and a way to link that back to what they've actually been accredited to do. I mean, CCHIT does that because they have modules, right, that you can get your EHR accredited to and so, first there's the module accreditation approach.

Wes Rishel – Gartner, Incorporated

CCHIT does within the current authorized testing bodies do it with a module. I mean, CCHIT has its own branded certification and it also offers the government branded certification, which is set by a regulation. The modular certification is a point of major confusion for EHR buyers at this point...

Jan Root – Utah Health Information Network

It is, I agree.

Wes Rishel – Gartner, Incorporated

...and, when you mention something like 80, some number like 83 for the INAC, I just thought, that sounds more like the things that are to be grouped into modules as opposed to individual modules.

Jan Root – Utah Health Information Network

Yeah, the difference, let me just explain, the difference between INAC, part of the difference between EHNAC and CCHIT is EHNAC basically says, “are your policies and procedures in place, your logs in place,” it’s really about compliance with privacy and security and being able to, for example, escalate customer problems and those sorts of things; it’s not, “do you do lab reports.”

Wes Rishel – Gartner, Incorporated

I understand that, I’m just thinking in terms of, who would create the clinical decision support algorithm for deciding whether you could do such and such with so and so, who had, depending on which 73 of the 83 they had. I mean, it’s a branding discussion is really what it is and I think that the fewer the brands, the better.

Jan Root – Utah Health Information Network

Yes.

Wes Rishel – Gartner, Incorporated

I think for reasons of supporting the market, ONC has lost a little control over that principle “the fewer the brands are better for certification of EHRs.” But, there’s no reason we shouldn’t start out with a recommendation of relatively low granularity, high level of clumping, and orientation to services that are functionally understood as opposed to arcane measurements that are necessary, in order to think, and those may very well be in the criteria for a module, but not in the naming and structure of the module.

Jan Root – Utah Health Information Network

Right, yeah, I think I’m understanding what you’re saying is that...

Wes Rishel – Gartner, Incorporated

...I’m saying, KISS.

Jan Root – Utah Health Information Network

But, pardon?

Wes Rishel – Gartner, Incorporated

I’m saying, keep it simple stupid.

Jan Root – Utah Health Information Network

Yes, exactly. I couldn’t agree more, but I just need to open the floor up for other people. Other thoughts? The one other thing I would add is that not only is it very important to keep it simple, because you need to remember that your audience are people, as you said, that may not be very technically sophisticated, which is not a sin. But, whatever the accreditation or validation that’s done, I think you or someone said, it needs to start on solid ground, right? What is it we know we can check, do, you know, and not get out into the “oh, we should do this, but we don’t really know how to do it,” and so any discussion around accreditation or validation needs to be very concrete rather than theoretical.

Wes Rishel – Gartner, Incorporated

I would say that that’s an additional and equally important point, which is that if, I’m trying to think of some way to even make it more concrete. We have sort of two levels we’re talking about here; one is, individual criteria and the second is clumps of criteria that get named and branded as a way of comparing

the capabilities of one NVE to another. I would say that the individual criteria must be as objective as possible, but I think you're wanting to go farther, and I'm having trouble trying to restate that.

Jan Root – Utah Health Information Network

Yeah. Well again, I know I should let people know, I am an EHNAC commissioner, so, one of the things we do is we not only set the criteria, but we figure out what has to happen, and CCHIT does the same thing; what has to happen in order for an entity to meet that criteria. And that's not like a secret, for example, if in CCHIT you have to be able to display an x-ray, okay. The criteria is, you have to have some DICOM standard and you have to be able to display an x-ray at such and such pixel resolution. Boom. Then you've got to prove you can do it. So, it's not like a secret question, but it is... yeah, anyway... whatever.

Wes Rishel – Gartner, Incorporated

It's in fact quite the opposite right, all of the scripts, at least for CCHIT, all of the scripts that are used to validate are public and have been through two rounds of public comment before they begin to be used.

Jan Root – Utah Health Information Network

Yes, a lot of public comment needs to go into these sorts of things. Absolutely. I'm writing that down, too. So let's see. The second part of this, should NVEs be required to make some type of public disclosure or associate some type of labeling with the validated services. I don't know about the word required, I know most people that go through the agony of being accredited or validated by somebody are typically very proud to put that up there on their website or their products. So, I don't know about the word required.

Wes Rishel – Gartner, Incorporated

Well, the actual services that we're talking about, for the most part don't have a user interface, right, there may be some exceptional ones, but, for the most part they're things that go in the background, so it's really hard to tie a little label onto that fiber optic cable line.

Jan Root – Utah Health Information Network

(laughter) Yes.

Wes Rishel – Gartner, Incorporated

I would, I haven't got a clear enough picture yet of how this all fits together, but I would argue that an entity should be showing somewhere, it's up to date status with regards to certification and it should be cause for a complaint if that's out of date.

Jan Root – Utah Health Information Network

Yes, that's a good point. Yeah, okay.

Wes Rishel – Gartner, Incorporated

Because that can happen both by accident and on purpose.

Jan Root – Utah Health Information Network

Yeah, absolutely. So, it needs to be that somewhere they should...somewhere typically, in my experience, it goes on the websites of the company...

Wes Rishel – Gartner, Incorporated

Yeah, as part of their signage in the internet world, it would go on the door or on the wall in the waiting room if this was a clinic and it was a clinical certification.

Jan Root – Utah Health Information Network

Correct, yeah. But this whole idea of making sure it's up to date; that's an important, really important.

Wes Rishel – Gartner, Incorporated

But, I think, yes, you're right, and I think that one way to read this question is, could an NVE decline to say what its current level of certification is, or, acceptance is; and if you put it that way, the answer should be absolutely not.

Jan Root – Utah Health Information Network

Okay, so let's look to that that and say it should be required to make some type of disclosure.

Wes Rishel – Gartner, Incorporated

Yeah. Right. The information continuously publicly available I think.

Jan Root – Utah Health Information Network

And it should be current.

Wes Rishel – Gartner, Incorporated

Right. It becomes... I mean, it should be that it is, if nothing else, it is consumer fraud if they...

Jan Root – Utah Health Information Network

So in a way it's kind of like perhaps an analogy is like a business license, you know, it has to be stuck someplace where people can see it, or at least made available, and for at least a new... you have to do this every year, so, it would have to be kept current.

Wes Rishel – Gartner, Incorporated

Yes, and I assume, that is what the CCHIT does, which is they have the year prominently in the emblem, so that if someone goes stale and continues to display the old emblem, that's not a violation. If they update to the new emblem without getting the new certification, that's a violation.

Jan Root – Utah Health Information Network

Right. Okay, do other people have thoughts about question 20? Got about ten minutes here, eight minutes. Okay, question 21, how long should validation status be effective? Mary Jo, my first question here was, they use the word validation, but would that include accreditation or is that question asked someplace else?

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

No, validation remember is the overarching term for both accreditation and certification.

Jan Root – Utah Health Information Network

Oh, okay. Okay. So validation equals both accreditation and the technical side.

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

That's right.

Jan Root – Utah Health Information Network

Okay. So, thoughts? Um, again, just from the EHNAC side, it's good for two years. But that's only the accreditation part. You have your processes, HIPAA compliance, all that stuff, what we're actually doing on our clearinghouse side, which is every single transaction gets validated all the time. That's probably excessive for this project.

Wes Rishel – Gartner, Incorporated

Is validation . . . what does validation mean in this context? Is it... I mean validation has a technical definition for any kind of transaction but certainly HIPAA transactions; you know, does it parse on the current level of the standard, does the data that can be extracted after a parse meet certain business rules? Is that what we mean by validation for NVEs in this context or do we mean something less?

M

I think validation in this context means certification and accreditation, those are the processes.

Wes Rishel – Gartner, Incorporated

Yeah, okay.

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

It means the recognized status, so, it's not referring to any of the individual components of the CTEs and how they're done; but it's the recognition. So, once an NVE is recognized as a valid NVE, and it's gotten the certificate that you mentioned previously, that should be continuously and publically shown to be up-to-date, how long... another way to pose the question is, how often should an entity be required to go back to be recertified? I mean, revalidated.

Wes Rishel – Gartner, Incorporated

I think we need to address that at the level of accreditation and certification.

M

Which is what I think they're doing. I mean, two years sounds appropriate to me. My question... I mean, whether it's two years, three years, I don't know, probably two but, my question is, if CTEs are going to be brought forth, modified and sunsetted, how does that work in this kind of cycling?

Jan Root – Utah Health Information Network

Yeah, again, I can tell you how that works from the EHNAC side, sorry to keep going about that. I can tell you that an every two year cycle is really fast. It doesn't sound fast, but, it is fast and again, that accreditation has a version or a date, whatever you want to... or both, that you want to put on the sticker and so, as you get one and something new comes up, what I've found with INAC is at the beginning, there was a flurry of activity and all sorts of things were added, and then it slowed down and so the changes that happen now, because a fair number of changes had happened as a result of HITECH, but what's happening now are more like business practices, what is a good industry standard for business practice. So, that is, relatively speaking, a slow change. So, again, my experience on the INAC side is that every two years is actually a pretty rapid turnover, like I think Joint Commission is what, every five years, something like that? So, that's my two cents.

M

Well I think that one of the questions, and you've really begun to address that's Jan, right?

Jan Root – Utah Health Information Network

Yes, correct.

Wes Rishel – Gartner, Incorporated

One of the questions is, how rapidly are the criteria changing and I would argue that there will be a time when the criteria are stable and a three year validation, a three year accreditation would be perfectly appropriate, and you could embellish that a little bit to say, unless there are drastic changes in the governance or other things about the company that's being accredited, that would call for notification and a re-examination. So, the company goes into Chapter 11, the company gets acquired, the company... all of those things... there may be a series of... in the tax world we would call life-change situations that would cause accreditation to be more current, I mean more (indiscernible), but otherwise, years. For accreditation...

Jan Root – Utah Health Information Network

INAC's calls those sentinel events, yeah...

Wes Rishel – Gartner, Incorporated

...for certification, I think that it has to be keyed to changes in the standards that the company is being certified to; so, if a new set of standards... right now, for example, with the 2014 edition, we're changing the definition of C-32, we're changing it slightly, but it's a change. It doesn't make sense to carry forward old... certifications of the old C-32 for more than a specific overlap period.

Jan Root – Utah Health Information Network

Right. Yeah. So, I think what we're saying, I don't know if we have a specific number to throw out, and again, what I'm hearing is, some hesitancy because we still don't know exactly what validation, in terms of the technical part of it, and accreditation involve, right. But, I think we're saying it should be probably more than a year, maybe between one and five years, something like that? Is that?

Wes Rishel – Gartner, Incorporated

Well, I think, we have all this conversation, we're going to come back to two years to start, because...

Jan Root – Utah Health Information Network

Two years to start...

Wes Rishel – Gartner, Incorporated

...because I don't think we can assume that the predication criteria will be all that stable.

Jan Root – Utah Health Information Network

Not at the beginning.

Wes Rishel – Gartner, Incorporated

Not at the beginning.

Jan Root – Utah Health Information Network

But, there's also that point that you raised about buyouts, bankruptcies...

Wes Rishel – Gartner, Incorporated

Yeah, and I think...

Jan Root – Utah Health Information Network

...there have to be rules about...

Wes Rishel – Gartner, Incorporated

I think the accreditation contract, or however the rules for accreditation have to identify certain situations where there's a requirement to notify, failure to notify has some consequences and re-examination begins...

Jan Root – Utah Health Information Network

...that they need to re-accredit, even though their term hasn't expired. For example, like NwHIN uses the Axolotl backbone for HIE, if we were to throw those guys out and bring in Medicity, that would be a sentinel event.

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

Folks, we are at the end of the hour...

Jan Root – Utah Health Information Network

Up, we're out of time...

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

...and public comment.

Jan Root – Utah Health Information Network

Sorry.

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

This is fascinating and shows why we did need five hours, or more, and just a reminder, that, we're in the process of rescheduling the next call for this group so that it will be on the 22nd of May, from 2:30 to 3:30, I think that's what I said, right?

M

So, you sent out that invitation?

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

It should be coming up momentarily, I don't know if it's quite yet, but, it should be out shortly. It will be an update, you probably already have on your calendar one for 4 o'clock p.m. on the 21st, and that's the one that we're going to change. And, it should come out this afternoon. So, are we ready to call for public comment?

Jan Root – Utah Health Information Network

That's good, yes.

Public Comment

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

Okay. Operator, would you open the lines please.

Caitlin Collins – Altarum Institute

Yes. If you are on the phone and would like to make a public comment, please press *1 at this time. If you are listening via your computer speakers you may dial 1-877-705-2976 and press *1 to be placed in the comment queue. We do not have any comments at this time.

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

Well thank you everybody. I think that ends it...

Jan Root – Utah Health Information Network

Thank you, Mary Jo. Appreciate you keeping us on track here.

M

Hasta la vista.

Jan Root – Utah Health Information Network

Yes, we'll see you guys at the next meeting.