



**HIT Standards Committee
Data Provenance Task Force
Final Transcript
January 23, 2015**

Presentation

Operator

All lines are bridged.

Michelle Consolazio, MPH – FACA Lead/Policy Analyst – Office of the National Coordinator for Health Information Technology

Thank you. Good morning everyone, this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the HIT Standards Committee's Data Provenance Task Force. This is a public call and there will be time for public comment at the end of the call. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. I'll now take role. Lisa Gallagher?

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Lisa.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Good morning.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Aaron Seib?

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Present.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Aaron. Floyd Eisenberg? John Moehrke?

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

I am here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, John. Mike Davis? And Becky Kush?

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hey, Becky. And from ONC, do we have Julie Chua?

Julie Anne Chua, PMP, CAP, CISSP - Information Security Specialist, Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

Yes, I'm here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Julie. And I think Johnathan Coleman's on as well?

Johnathan Coleman, CISSP, CISM, CBRM, CRIS – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.

I'm here. Good morning.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Good morning, John. And with that, I'll turn it over to you, Lisa.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Thank you, Michelle.

Mike Davis, MS – Security Architect – Veterans Health Administration, Department of Veterans Affairs

Mike Davis joined.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Hi Mike, welcome.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Okay, who just joined? Oh, Mike, thank you.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Good morning everyone and welcome to what is the final meeting of the Data Provenance Task Force. I want to start out this morning by thanking everyone, all the members of the task force. I know this was a quick turnaround task, we've had three meetings in three weeks and I appreciate everyone's participation during the meetings and in between when we've worked via email and other mechanisms, even while folks were on travel. We really appreciate everyone's participation. I also want to thank the folks that have been supporting us at ONC, Julie Chua, Michelle Consolazio, the entire ONC team as well as Johnathan Coleman, who has provided yeoman support as well. So thank you to everyone.

Today our sole purpose is to review a draft set of recommendations. Those were created by myself, the ONC folks and Johnathan from what we had in our notes from the meetings that we've had as well as input from task force members. So our goal today will be to review those draft recommendations, discuss them, make sure that our message, our scope is clear, that we've stayed within the scope of the questions that were asked to us by ONC and come up with a final set of recommendations that we all approve. After that, the next step will be for the recommendations to be presented at the Standards Committee next Tuesday. Finally, we will have public comment where we'll hear from members of the public on our final recommendations as stated.

Okay, can we go to the next slide, please? Next slide...yes. I wanted to start out with just a reminder of the scope of our questions from ONC. This has to do with the ongoing work of an S&I Initiative, Data Provenance Initiative. The Data Provenance Initiative has created and proposed a use case on which we were asked to analyze and comment; a specific question, and then three sub-questions. I'm just going to restate those quickly. Given the use case developed, S&I Data Provenance use case, what first step in the area of data provenance standardization would be the most broadly applicable and immediately useful to the industry? Next slide, please.

And this next slide reflects the three specific questions. You'll see, as we go through our slides today that we have provided some draft recommendations linked to each of these supporting questions. First, do the three scenarios in the use case and the use case's identified scope address key data provenance areas or is something missing? The second question, the use case is broad and spans a lot of challenges. Where in the use case should the initiative start, in terms of evaluation of standards to meet the requirement? And the third question, are there any architecture or technology specific issues for the community to consider? For each of these areas, ONC has given us some sample answers; in most cases we've directly addressed those answers and in some cases, added some additional information. Okay, so let's move on to the next slide and the following slide.

Here we're going to review the draft recommendations. We are starting with question number 1 and we'll follow that format. I think Julie and Michelle, I probably should go through the entire set or do you want comments on them as we go through one at a time? Well let's start out...

Julie Anne Chua, PMP, CAP, CISSP - Information Security Specialist, Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

Yes.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

...with question number 1; do the scenarios in the use case and the use case's identified scope address key provenance areas or is something missing? We were asked that question sample responses yes or no. I tried to characterize our highest level response in a way that would give some scope for the subsequent specific comments and added an item "c," the use case may be over specified. The task force recommends the following focus areas and then the focus areas will continue to be addressed on the subsequent slides.

We also wanted to sort of provide an overarching theme for our recommendations focused on where does the data come from? Has it been changed? And can I trust it? I want to stop for discussion on this slide; I want to make sure that we are all agreed that we'd like to communicate that the use case may be over specified and also whether we would want to stress the theme of our recommendations in the beginning or if that's not necessary; just comments or thoughts on this slide?

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Lisa, this is Aaron. I would just say that I think that this is a very good characterization of at least my themes here. I think the last bullet, can I trust it is kind of a...maybe we need to be more specific on that, but otherwise I think its spot on.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

I like the way you've addressed this, Lisa. I haven't seen the rest of the slides, but I think it may be over specified in that we need to, at some point, recommend that they go back to a set of requirements as opposed to all of the different scenarios that have been proposed.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Yeah Becky, I think you did provide that comment via email and I didn't explicitly state that, so I think as we go through, if we could find the place to say, we recommend that you specify a set of requirements for the initial use case as scoped, as we recommend it be scoped and see where we could put that, okay?

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Okay. Yeah, I haven't seen the rest of the slides so I'll wait and we can look at it afterwards.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay, thank you. As far as can I trust it, I think we are considering a recommendation later on that has to do with whether there can be defined levels of trust and trust-related metadata in any form or fashion. So..

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

I...

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

Lisa?

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

...I don't...rephrase it?

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

(Indiscernible)

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

I think I understand...

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

But, can...maybe we could go on and see the whole thing and then come back because for a high level I think this is right.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

So Lisa, this is John Moehrke.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

(Indiscernible)

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

I absolutely agree that these three questions; where did it come from; has it changed and can I trust it are needs. I would though observe that the normal realm of provenance focuses mostly on the first one, it certainly has some overlap with the confidence that it hasn't changed, which is related to the trust. But the integrity controls and the trust, the authenticity of the data are also characteristics that are enforced by other mechanisms, such as, for example, the transport mechanism that was used to convey the data or the persistence layer that was used to store the data. And those wouldn't classically be considered provenance, but they certainly support these needs.

So, I would just observe that, and although these are needs and from some people's perspective when they think of these needs, their mind heads towards provenance. But, these are overlapping concern domains as well.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Yeah.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

That's true.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

So...

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

I think when you talk about it in those terms, there's actually a distinction that is made between accuracy and integrity because if it's not accurate in the beginning but you take it through the system and it doesn't change at all, then you've maintained the integrity but it may not have been accurate at the start.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

Correct.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

This is Aaron. I think what we might be able to do to improve it is the use of the word "it;" when we say, can we trust it, can we trust the fact that the mechanism that's ensuring it hasn't been changed follows the appropriate standard. I think we've got to keep it transport agnostic at this point.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Well that's interesting because the data could be "it" or the source could be "it..."

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Right.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

...or maintaining integrity could be "it."

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

So, using the word it is what we've got to kind of focus in on and put a different word there that is more specific to the fact that, can we trust that whatever mechanism was used to ensure that it hadn't changed is a trustworthy mechanism.

Mike Davis, MS – Security Architect – Veterans Health Administration, Department of Veterans Affairs

So this is Mike Davis, just my comment is, I like it, I like the three bullets as they are, I think they express the problem and we can all consider areas that we'd like to put in that, but our brevity and terseness and getting the point across in a poignant way I think it's great.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay. I mean, one thing I can do is when I'm speaking about this, I can say these are high level, we will give more specificity in subsequent slides, but this is sort of just the overarching theme and just leave it at that.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Yup.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Yup.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay. And at the end, if anyone wants to propose an alternate wording, we can come back to that. Okay? So let's go into the recommendations. Next slide, please.

The fir...so there are, let's see, one, two, three recommendations; there are three slides that are coming up that have to do with question number one. So the first one, begin focus from the perspective of an EHR. Provenance of the intermediaries is the only important if the source data is changed. So, begin focus on the EHR including provenance for information created in the EHR and when it's exchanged between two parties. The notion of who touched it along the way is not important for provenance as long as the information was not changed.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

This is John, I agree.

Mike Davis, MS – Security Architect – Veterans Health Administration, Department of Veterans Affairs

I agree as well; this is Mike. I just note that the use cases presented in provenance include this, they have...all their use cases are relevant. We saw the...Gary Dickinson's use case, which is the first use case, the simplest one and the assembler, composer use case, which this refers to, is in there as well. So, I think we're trying to handle them all simultaneously but...

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

I think...

Mike Davis, MS – Security Architect – Veterans Health Administration, Department of Veterans Affairs

...there's nothing wrong with this.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Well Mike, I think that there's...the subsequent recommendations will help narrow the focus a little.

Mike Davis, MS – Security Architect – Veterans Health Administration, Department of Veterans Affairs

Okay.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

So maybe, we can look at the set of the three and maybe, if we need to clarify this first one, you know, as presented it does seem like its encompassing the whole use case and then we proceed to narrowly scope it in the subsequent ones. So, let's look at...if there are no specific comments on this, let's look at the next two and the look at the set of them.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Yeah, it would help me to see all three.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay, so let's go to the next slide. And here we spend some time talking about differentiating between the communications requirements and a system requirement, which we mean to be agnostic of transport technologies; so both are important. Start with the assumption that at the point of information exchange the source provenance is good, complete and trusted. And then we recommend that they address communication and information exchange requirements and address the system requirements, including consideration of the work on the FDA project and the definition of the term source. So I'll let you all read this briefly. There's a lot of text here and maybe we can pare that down if you think...wanted to get the message across.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

While people are thinking to comment, I just want to remind folks, there's a heavy breather on the phone, so if you are just listening in and breathing heavy, if you could mute your line that would be wonderful. But, we do want you to participate, so thank you.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

So this is John, it reads good to me.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

This is a...but it is...I think it's one requirement we're talking about in the second bullet as a basic requirement, singular or are we trying to make more than one here?

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Oh yeah, you're right, okay. As a basic requirement, okay. Do we...

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

We're just saying one requirement in that, right?

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Right, right. Yeah, delete the "s." In that item, is it clear what we mean in terms of using the terminology "lossless?"

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

It is to me.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

We're saying if we change transport modes, the content itself is identical regardless of the new transport mode.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

I mean, that's another way of, isn't it, of saying that you have to maintain the integrity of the data?

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

(Indiscernible)

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay, yeah.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

Yeah, and I think this is saying not just the data but the provenance, too. So, your transport mechanism can't lose the provenance data.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Right, that's true. That's true.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay, so when I'm presenting this, I can give some explanatory information to clarify that term, but I think we like the term.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Yup.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

It is a term of technical...so that's why I'm comfortable with it, so I agree; you may want to judge your audience.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

So the audience...

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Lisa, I think I'm seeing a place where I can fit in the requirements piece, but I'd like to see the third one before I speak.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay. Okay, well let's move to the third...well, the third, fourth and fifth recommendations on the next slide. Then has it been changed; we're clearly asking for a focus on that concept and what the implications are for provenance. Any help on wording here is appreciated. Also, Becky I think this was your discussion, we are...we have a comment about the security aspect and finally a comment on if there are any policy considerations, recommending that they identify them and turn them to the...refer them to the Policy Committee. So those were three other areas that folks had addressed. Any help on wording is appreciated.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

So this is Aaron, I have a question in the form of an example that might help discuss this.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

And just using OpenNotes as an example or a similar paradigm, we have a data standard content that comes out that has been accepted by the native EMR. It's passed to an EMR that doesn't know how to handle the annotations of the patients or something to that effect, but it maintains the C-CDA standard content. If it loses the annotations from the OpenNotes process, is it sufficient or is that an issue?

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

This is John; in your use case the provenance...the critical provenance is in the CDA, correct?

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Yes.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

So the annotations are data annotations not provenance annotations.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Good. Is it...

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

So I think if we focus purely on provenance, the CDA header will maintain the provenance. But, I would be more concerned about, are you losing clinical data than provenance? That was just my...

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

So in the example of what...I'm sorry, are we still discussing that question? I was moving to another topic. I agree with what the comment was.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Okay.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

So, in the, has it been changed, and we're talking about the data being changed here, in the FDA example you would retain the original data and you would put what the change is too, so you would retain that information. Because sometimes it's a simple change of somebody misspelled a drug name or something like that and they want to change it to the correct name and then you can trace that change and when it was made and why.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Yes.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

So, would it be worthwhile to reference the FDA work here as well?

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Umm, no, I'm just saying you were looking for some wording and I think amend, update, correct, whatever, I think that's fine. I could go back to 1 and 2 now and make one suggestion on how to include that, but...if we're ready to leave this slide I could go back two.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay, let's hold that thought for a minute and see if there are any other comments on this slide.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Yup.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

I do have one question about the content standard, and I must admit that I have some confusion and it may be my fault...

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Is this Aaron speaking?

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

This is Aaron, yeah.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

I think you're example Becky is great, there's a drug; somebody has misspelled it. The originator of it has misspelled it. It goes through an exchange to a subsequent provider who notices the misspelling and

changes the spelling and then shares that forward. Will the third person who receives that data be able to see the history?

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

They should be.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

And does the existing standard support that?

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Yes.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

A C-CDA standard?

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

I don't think the C-CDA, frankly, I'm not sure it has all of that provenance information which is why we're doing this work. The ODM standard does, which is the standard that takes the data out...

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

This is John Moehrke...

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

...and then the structured data capture proposal is...supports that.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

This is John Moehrke, I can speak for CDA. It does have that capability.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Okay.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

It would have the...what generally is a problem is it is not always utilized, but it certainly does have the capability to either at the simple level, to indicate these are predicate re...these are predicate documentations or even at an element level, which we showed in the DS4P project, you could do it all the way down at the element level...

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

And what I'm trying to be mindful of is...

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

That's good.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

...for this to be useful in the first year or in the coming years, we have to assume that the deployed EMRs, that this will work within their framework.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Yup.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

We're not going to be able to retool all the EMRs that are out there to support it so the question is, for those that don't support the storage of those changes, do we have guidance or what is our recommendation?

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

You know, that's an interesting thing that goes along with what's under 5 because if you store the change, then the person receiving it can make their judgment as to whether it's a...what level of trust they have. Otherwise you have to attach another whole set of definitions and meanings around these trust related metadata. If you retain the original, like the verbatim and then you'd retain the change, then you don't have to go attaching decisions around it.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Agree with you.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

The recipient can make their own decision.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

Yeah, this is John Moehrke; totally agree and I think that is considered a best practice it's just not often practiced with CDA...

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Well it would be the easiest way to implement...

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

...that it is...

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

...it if CDA already supports that because then you won't have to get into all the policy around this decision making around trust.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

Yeah, I think though your...so there are two things. One is, when you create a CDA does it include the provenance of any source materials used to create this CDA, right? So that's a practice guidance that would drive a use of an existing structure. The other one that you brought up quite nicely is, when you import a CDA from somewhere else, oftentimes you will want to extract out all of the various

components of the CDA into your data set, but you should retain the original CDA for backwards traceability so that you can always prove at any point that this medication came from that CDA which is authenticatable and contains the provenance of where the data came before it. So, the example given here where a medication was misspelled two steps ago...

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Um hmm.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

...be discovered. If you not maintain that information and the originator didn't put the information in, then you cannot discover...so I think there are two recommendations there, right?

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

There are and then you would kind of eliminate a couple of these sentences at the bottom about turning this over to policy because you wouldn't...I mean, you could consider that later but it wouldn't be necessary in the first implementation.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Right, I think the policy should be that we recommend to the policymakers that all consumers, all applications that would consume data would be able to store and maintain the changes of that drug spelling through time and know who made those changes.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Right.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

But the immediate scope, you know, my question about the immediate scope is, when provider "B" sends it to provider "C," we're expecting provider "C" to trust that the corrected spelling is the latest version in his system, not necessarily in the originator's system. Or are we...

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

Yeah, you...

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

...or are we telling them that we want you to send along what it was originally from the originator? That's kind of my...

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

This is John. I hope we don't because that could...I mean, in this example, its valid information because there's a correction along the way, but oftentimes as you improve upon prior art, prior documents, you are really not modifying the prior so a reference is sufficient rather than inclusion of all of the original information. So I think...oftentimes it's referred to as an "n-1 problem" which essentially means, the current documentation has to include all without fail of prior documentation which for a long term care use case or a chronic condition could produce huge documentation of very little value.

So I would like to say that it just needs to repre...the current needs to represent the singular past and the expectation is, if there is a need to discover the minus beyond that, you can discover it by way of the linkage, but it's not included.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

And that's the traceability that you have the right data at the end, but if you have to trace it back that you can do that.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

So it's that traceability that links from provider "B" when he sends it to provider "C" with the correction, provider "C" can also discover that there's linkage to provider "A's" version, but we don't need to carry forward all of the provider "A" data.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

Right.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

That sounds right.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

So that is the recommendation that I would be very, very comfortable with. I think that that's the next iteration that the industry and this space could support.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

So you're saying the C-CDA can support that and I'm saying that the structured data capture initiative which points to other forms that might carry data from EHRs like ODM could also support that, which is good.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

Excellent. And I'll also indicate that FHIR can support that, too. I mean, it's being developed to fully support that...

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

That's good.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

...and more. But, this is a basic functionality, I think, of all of these mechanisms.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

So maybe we don't need the last sentence on this slide, you could...levels of trust if necessary would be a policy issue, but we're not saying that it's essential to the implementation.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Yeah, that was just meant as an example so, we can remove it, we can edit it. We just...

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

I think that just ending with that little sentence that says defining levels of trust would be a policy issue is enough.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay. So going back to item 3, is there any proposed wording, based on the discussion. This is pretty high level, just saying consider definition that implications of change, but is there anything we want to add to reflect the discussion?

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

This is John again; I think the...what we've discussed could be added there, if it's a level of detail you want.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

That's my question.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

Yeah, I think we kind of cover this on some of the next couple of slides, but essentially a shortened version is somehow to indicate that at any step of chan...at any time data is created or changed, it needs to indicate at least the source material, needs to reference its sources.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

So this is Aaron; I would...

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

And then I think the other task was, when consuming data, you must maintain the provenance that you are given.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

I think it's worthwhile, Lisa, to include some description there so that you don't lose the audience as you're...at this early stage; something that describes what that traceability and linkage is on this slide is useful.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

I can say that because I read this last night and I wasn't sure, so I want to make sure your readers and your audiences are clear...

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Right.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

...talking about.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

We could put it in as a sub-bullet and say we recommend that this is how you approach it, and I'll just need some wording. I've jotted down current data should store and maintain provenance of related changes to data, but, I need some wording there.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Linkage to the prior origin is...

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay. So we can work on some wording and send it out to everyone for a sub-bullet to number 3.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Yeah.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Let's take a look at 4 and 5. Becky recommended we delete the very last sentence on the slide, so I have that crossed out.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Yeah, I...so, just for my own edification we're saying, we're not making some judgment call about whether it's highly trustworthy, trustworthy or somewhat trustworthy.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Right.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Leave that up to some mighty Gods that can figure that out because I don't know how to.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Yeah, that's the Policy Committee.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Yeah.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

So Lisa, this is John Moehrke. I think it may...this is good around trust, but back, on our original question we also had the “has it been changed,” which is what the security is intended to protect, is that it...

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Right.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

...it no...it has not changed. So I think we may just want to add, not just can you trust it but has it changed to this particular aspect, to kind of then indicate that you’re security layer is the prime place where trust and integrity come from and it is related to provenance.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay. Gotcha. Okay, so Becky, going back to your point, did you want to go back to the previous slide and offer an edit?

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

I’d like to go back to the first two, just briefly.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay, then let’s go back...yeah, one more, back one more. Okay. That’s the first one.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Yeah, which is fine and I don’t know if there...if it goes at the bottom of this slide or if we just slightly modify the next slide because what I would say is that if we look at all those different places where we’re supposed to start this effort and we’ve picked, begin folks with the EHR that’s fine, but when we talked about whether we’re going from a patient reported outcome or an e-Diary or something to an EHR and an EHR to other places, the provenance requirements should sup...be such that they would support all of those scenarios.

So rather than look at a whole host of scenarios, look at the basic requirements that are needed for all of those so that you don’t have to change what you’re doing about provenance depending on the use case, I think that’s dangerous. And that we should have a common set of requirements and what we’ve been talking about would work for any of those different scenarios or use cases. So when you go to the next slide and you talk about using the FDA case as an example, it’s...they don’t...they have use cases but there’s also a set of requirements and there are 12 requirements and they may or may not totally pertain to this environment, but I think a number of them would because when you read investigator, you read clinician or whoever is taking care of the patient. And you start looking at what the requirements are and there are 12 of them that helped build the provenance into that transport mechanism, which we discussed could be supported by C-CDA or ODM.

So, I think it’s important to say consider the FDA project, there are requirements based on use cases. And then somewhere put in that we recommend, I think it’s up here maybe in the bullet above it, about

the requirements, that we need to address a basic set of requirements to support all of the potential use cases.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

Yeah, this is John. I kind of read that that's what this page was saying, because it's talking about a system, it's not talking about only the EHR. And maybe that's...

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Yeah and so I think that just needs to be made clear...

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

...needs to be made more clear.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

...and maybe that comes after number 1 that we're saying start here, but a basic set of requirements that supports all these use cases is needed before we move forward.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

Yeah. Because I'm reading number 2 here as being across any system that's used, whether it's a PHR, you know, patient generated or even transport, a health information exchange that might add value; those are all systems. Do we need to make that more clear?

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Well I think in number 1, if we're just picking one of the many things they asked us to talk about, we should say, we can begin here but a set of requirements needs to be developed that supports all of those use cases and is common to those.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

I think I would suggest...this is Aaron, after we had that italicized text, we add that the requirements developed for EHRs as the starting point, should be future ready for other scenarios.

Mike Davis, MS – Security Architect – Veterans Health Administration, Department of Veterans Affairs

So this is Mike, I just have a question about the one that says; who touched it along the way is not important. I'm not sure that I understand that and general in provenance it is important who touched it along the way or who held it. If you think about during the Second World War, the Germans who absconded with a lot of paintings and stuff like that, after the war returning it to the original owners and reparations and stuff like that is important. So if in healthcare someone along the way grabs the data, doesn't actually transfer it until later and causes delay in providing information or incomplete information, knowing that who touched it along the way might, in fact, have some relevance.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Right and I think what...I think maybe clarification that would help...this is Aaron, is where we say is not important, we should probably make it clearer that should be derived from linkages to the prior provenance. That way, Mike, you could determine if you were the folks who were trying to figure out which Jewish family had the rights to the property that...

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

This is John Moehrke; I think Mike, I think the bluntness of the text is potentially causing the wrong interpretation.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Exactly.

Mike Davis, MS – Security Architect – Veterans Health Administration, Department of Veterans Affairs

Great.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

This is trying, I think, to say that everybody, all of the Wi-Fi routers and servers that carried the data do not add value to the provenance record. So the point was to say, it is when the data are modified or created is what is the most important to record and almost to say that it shall be recorded whenever you modify and so maybe it's just the bluntness that's the problem. Because I think this was trying to drive away from having to have the current documentation include the audit trail of all of the pathway by which this data got to me, even though 90% of those touches did not modify it and can be proven that they did not modify it.

Johnathan Coleman, CISSP, CISM, CBRM, CRIS – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.

Lisa, this is Johnathan, can I ask a quick question, please?

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Sure.

Johnathan Coleman, CISSP, CISM, CBRM, CRIS – Initiative Coordinator, Data Segmentation for Privacy Principal - Security Risk Solutions, Inc.

Thank you. So John and Mike and Task Force members, would the where it's been question, could that be more, I guess, readily addressed by the provenance of the containers that would house that information so that the system events and the security events as the stores that held the data along the way would presumably have information about where it's been rather than...or, what information they have rather than it being associated with the information itself as it made its way through?

I guess what I'm asking is, would this comment be more a question about the provenance of the container rather than the information, you know, the container being the system that maybe held it but didn't change it at all?

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

Maybe that's wor...you know, it's certainly worthy to say.

Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC

This is Floyd Eisenberg; is there a time I can make a comment?

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Please Floyd, go ahead.

Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC

So I was...I'm sorry I joined late. I just heard John Moehrke's comment and Johnathan's. Question, so I...just to clarify, I think my concern would be that the value for reliability of the data is from its original source and if it has been modified, whoever modified it, perhaps could be the new original source because it's modified. As far as where it came from, I think the information might be important where it last came from, but not all the places it traversed. And as far as Johnathan's question, I think it makes sense that the container may contain that, where it's been.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

I still think it's important...

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

This is Aaron; I think Floyd put that very well.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

...though to be able to trace back to the original source if necessary.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Right so, this is what I would understand what Floyd said; provider "C" would have a way to link back to provider "B" as the original for him, provider "B" would be able to link back to provider "A" as the original source for his version.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

I'll just tell you if FDA is provider "C" at some point along the chain at all, they're going to want to be able to figure out how to get to "A."

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Yup.

Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC

And I don't...this is Floyd, I don't disagree with that, my concern is if it's been modified along the way, in a sense it's been remanufactured so we might need to know...we would need to know who modify...where it was modified.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Correct.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

I think one of the other things that is potentially being conflated here is the provenance requirements for traceability, which is being represented here as provenance needs to be able to show traceability of

changes and creations being conflated with the topic of security audit log, which is who has viewed and/or created or modified.

So both are needed but they are potentially independent mechanisms and I would certainly say that the security audit log is often an independent mechanism from a provenance statement. And if maybe we add to this item here the, those who have viewed the data without modification are not added to a provenance statement, but of course would be added to a security audit log. Maybe that helps dispel the concern, because I think that is potentially being conflated.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Yes and I think we talked about that at a previous meeting, it's a fine line between provenance and security and that we need to be...to pay attention to that. Is there a proposed wording change for this italicized sentence here that would be helpful? Is it something...maybe we should delete it here and deal with it la...on a subsequent slide so that it's not actually directly related to number 1, but maybe we move it to slide 2 somewhere?

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Well I think...Lisa, this is Aaron, I think what might be helpful is to...I think we have to say something here.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

And I think we have to have consensus on the workgroup here that what we're trying to say is along the lines of what I think Floyd eloquently put into words. We don't need to know that when provider "C" receives data from provider "B," he doesn't need to be able to immediately discover what the value was with provider "A," but be able to find that if he needed to.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

I think that's a little different than this sentence.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Okay.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

So that's an additional, perhaps, sentence.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

So this sentence...is this sentence getting to John's point about the hops along the way where it didn't change at all?

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Um hmm.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

Yeah, I am...if that's a consensus, I'm willing to work offline; I'm just not really good at being eloquent on...

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Yeah, me either.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay, so we will...so basically saying that information about where the data went does not add to the provenance data if there is no change to the data. So we can retain that notion and then maybe perhaps another sentence that addresses what Floyd said and Floyd, maybe we can work offline on that?

Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC

Absolutely. I don't know if it works for you, but for some reason it makes me think back to the issue of reusable or non-reusable devices in hospitals. When I dealt with that in the past and once you reuse something that wasn't supposed to be remanufactured it and so that's why I've been kind of thinking it as a remanufacture of the data. I don't know if that wording works for you or not.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

It's the right notion...

Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC

It may not be the right words though, right.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Yeah, I think we ought to capture...be more generic for the, I don't know how many people are on the Standards Committee, but.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay, so I think we have the concept and we'll need to look at the wording. Becky, I don't know if there's any wording in the FDA guidance on, you know, when you modify data the concept of that new data, what it's called or what that process is called.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Ohh, let me think about that and I do think we kind of went back to looking at that italics section and I maybe could come up with just a simple sentence about where we were going before that about making sure that we...that there be a set of requirements that supports that particular use case and all of the other use cases.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay. All right, so I'll take suggestions via email separately for comments number 1 and comment number 2, if there are any.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Yeah and I need to go back and look at exactly how they word that in the FDA documents.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay, perfect. Thank you. So...

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Lisa, do you have to present this on Monday?

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Tuesday, Tuesday.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

You better....

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Yeah the wording Lisa is probably not in either of those two links I sent you, it would be in the regulation, it would be in 21 CFR 11, which is around electronic record keeping and that was the 1997 document.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

I'll look at that.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

Lisa, a potential surgical text change is we may want to change the word "touched" to...

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Yeah.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

...viewed or conveyed without modification.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

Because “touch,” when you touch something in the physical environment you leave a fingerprint behind, which is obviously a modification, but was it an important or not. The word “touch” just kind of brings out potentially emotions that we don’t really intend to bring out. We’re speaking more about who viewed or used or conveyed, without modification.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay, that makes sense, John. Thank you. Okay, with that I’d like to ask the task force if we can move along to questions number 2 and 3, just in the interest of time. We do have two more of the sub-questions to go over, as far as our responses. Is that okay with everyone?

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

Yes.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Yes.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay, so if we could go to slide 10, please. Okay. So first of all, what we did in these, there are let’s see, one, two, three slides for question number 2; the first one addresses the question we were asked, what is the order...the priority order in terms of the use case and addressing of the specific standards? Here we have proposed the order which we think we heard from the discussion. We did get some comments via email about this slide. One had to do, it was from Aaron and maybe I’ll let you speak to that, but it had to do with actually adding some text to item “A” to clarify exactly what we mean, even though that wasn’t in the text suggested by ONC. But I think that’s perfectly fine so, Aaron, why don’t you give them your input on that item.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Sure. And I think the conversation we’ve had today kind of echoes what I was trying to convey is that “A” is very specific when it says between EHRs, you know, it’s saying between this particular category of systems...

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Um hmm.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

...focus there and what I think we want to s...I think that that’s too limiting. So it would be whenever there’s an exchange between systems is where...

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

And your wording...

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

(Indiscernible)

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

And I...

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Your wording was, changing it to, with the exchange of data between an EHR and an external consuming system such as another EHR, HIE or PHR.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Yup. And just suggested...

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Yeah, but this is what we're saying is that we shouldn't have to order these; we should have to come up with a set of requirements and a set of provenance standards that address all of these.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Right, and Becky, I agree with you, I think you're talking about the solution and I think for this...what they're asking us for is for some prioritization, because they've got to figure out how to...

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Well, yeah, but...

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

...like...

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

So Becky, I think I understand your point. So I think it's okay for us to answer this question, but again, perhaps I add a bullet at the bottom that says...

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Yeah.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

...that they should develop a basic set of requirements for provenance data that applies to all use cases.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Right, because...

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

We'll get...basics that could be?

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Yeah.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

I'd like...

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

And we don't have to follow that, I think that's our suggestion to the initiative.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Right. Okay, I'm good with that.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Thank you, that sounds like a good suggestion.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

That's a good...

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

I'll add a bullet there and I'll make sure that I clarify that in my spoken words.

Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC

And this is Floyd; I think that those comments resolve my concern as well.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay, so let's go to the next slide. The next two slides were comments that I picked up from my notes and put on slides, so we're going to need to look at them and see if we want to include them and if

there are any edits. So one bullet here is, determine if origination of patient care event record entry is in scope. And I think Floyd, this was from discussion you had, if I recall correctly. So...

Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC

Yeah, actually I've been...over the past week I've been talking to some quality measure developers and people who are involved in decision support and part of the concern is in creating electronic quality measures or decision support, they sometimes have had to relax what they really would like to know about the reliability of the data elements because they don't feel they can get it through electronic means. And they feel that decreases the value of the measure and the decision support capabilities.

In other words, if something came from a device or as opposed to manually entered, there's a difference in reliability and they at the moment feel that they can't specify well enough because of that. So that was...that's been some of the concern. And I think it's similar to what the researchers are seeing and worried about.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

So, I got lost there. Floyd, this is Aaron, are you talking about the first sub-bullet?

Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC

Well, I can't see the bullets in front of me because I'm only on the phone, so, I'm sorry.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

No, no, okay.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Oh, okay, so yeah, we're...this is...these bullets were my creation and I think I'm going to need you to review it, Floyd, to make sure that I captured what you were trying to say.

Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC

Okay.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

I don't know how...I think, Julie, I guess we have to do that offline; Floyd can't see the slides, today.

Julie Anne Chua, PMP, CAP, CISSP - Information Security Specialist, Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

Okay.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

But any other comments from other task force members are welcome at this point.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

So...this is John, I'm...whenever the words "origination" or "creator" come up, I get back worried about that infinite, n-1 recursion problem where the current record has to include all of the data from all of

the references and everything that they referenced and everything that they referenced and I just want to re-emphasize, I think a minimum bar, and potentially the only bar necessary is to refer to your sources, because you can always discover what their sources were.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

So, I think this is saying that for an EHR, what are the origination events that we would need to record and I think the listed ones here, import, create, maintain, and export. So if it was imported from a device, you could record that as a provenance event that would be distinct from manual entry into their EHR.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

Right. So I think I'm agreeing in spirit...

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

...I'm just worried about the interpretation of origination can bring up this turtles all the way down discussion.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay, so maybe...we'll look at the wording there and I think what we're saying to the initiative is to take a look at this and see how it could be implemented in a way that could at least distinguish if it was manually entered or came from some other source, from the perspective of an EHR data.

Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC

And this is Floyd; I was able to see it on my iPhone. I had looked at it before; I just didn't know which four things you're looking at. And I would tend to agree with John's comment, maybe the word origination might be a problem, but the sub-bullets looked okay.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay. All right.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

And maybe what you do is just speak to it, Lisa...

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

Because I think people are used to seeing the word origination and as long as they understand that, hey, we really mean on the first hop to record the origination as opposed to the end hop ori...have it record the origination.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay, got it. All right, so let's go to the next slide, please.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Just...Lisa, I'm sorry, just before you jump I want to make sure I understand so that I can...

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Back one slide, please. Go ahead, Aaron.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Umm, we have a payload, a piece of content created by a cardiologist. Some of that content includes data captured from an EKG machine; it also includes data that he entered about his interpretation. And what we're saying here is that it's important for that content to capture the source?

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

For the provenance that the EHR records. So where...what's the source from the perspective of the EHR; so in the case of the device data would be an import and from the perspective of the cardiologist, it would be a create, something like that.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Would it be worth just putting that definition from FDA here and attributing it...

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Sure.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

...versus kind of referencing it, because I don't think it's long.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Yeah, it's actually in one of the backup slides so we could certainly move it forward.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Oh, okay.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

It's on slide 18 in red, so we could definitely move that forward.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

So this is the confusion I have, are we talking about a content standard at that point or are we talking about a provenance standard at that, that's part of my confusion?

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Oh, I was just talking about the definition of the word source.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Yeah.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

But we are talking about provenance data.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Yes.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay, I'm going to need to go to the next two slides, let's go forward. Here we just have a bullet on adding the CDISC ODM to this, and I didn't have the link, but we will add that in there.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Yeah, it's worth noting that this also supports the Structured Data Capture Initiative work, so it's not just coming out of thin air.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

I don't know if you want to put it on the slide, but I think if people say where did that come from, it's definitely...it's a standard that supports that profile.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay. All right, and then the next one is jus...I tried to capture the notion that we would like the initiative to consider that there may be some requirements they need to go look for in terms of regulation and program specific requirements and we gave some examples here. I think, Becky, this goes back to your idea of creation of a basic set of requirements. These might be some sources of tho...or some considerations in creating those. Does that make sense?

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Yes.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay. Any comments on this slide? Okay, I ask also that you all consider if there are any comments on question number 2 that I didn't capture in the three slides here and if you think of anything in the next day or so, please forward it to us.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

So the 21 CFR 11 is the 1997 federal regulation called Electronic Records, Electronic Signature Scope and Application. So, I can send you that link as well.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay. Perfect. Thank you. Okay, can we go to the next slide, please?

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

That's actually in your reference pages already, Lisa.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Yeah, I think, umm, I'm going to pull it forward to the slide, I just didn't do it in time for the meeting today, but I want to be specific and put it right in the slide. Thank you. Okay, are there any architectural or technology specific issues for the community to consider? And these were the options that they gave us, a, b and c; the bullets...the sub-bullets are what I've put in there as our response.

So, for content, refining provenance capabilities for CDA/C-CDA while supporting FHIR; we listed some HL7 projects that are relevant and just said, consider these. I don't know if you're okay with that or if there's anything else you want to say with regard to provenance for C-CDA.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

I mean, you could reference the structured data capture work there. My...the experts I talked to about this tell me this is premature until you've developed your requirements.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay. Do you want to add that as a comment?

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Or maybe we shouldn't say premature, maybe we should say we can better answer this question once we've got the requirements; that would be a more positive statement.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Yeah, okay.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

So, I think these are just statements of consider works, they're not select these works.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Yes.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

So, of course requirements would have to be defined and I think that's what the S&I Framework is doing...

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Yeah, the S&I Framework...

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

...so, I think they're just asking, again, for a recommendation to help them get complete information for the evaluation, not to override they're evaluation.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

So John, this is Lisa; I think for Becky's point, what I'm getting from that is that she wants to be clear that in addition to creating a use case or identifying a use case and its scope, that there needs to be a step taken to develop a basic set of requirements. And we haven't seen that so, we are recommending they consider that; and that's a theme...

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

Yeah, I don't...yeah, I certainly do not mind us emphasizing that...

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Yeah, that's...I was going to...

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

...but, that is the fundamental governance of the S&I process is to...so, anyways, I...

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

The question to me is kind of what I call in project management a shotgun approach is that we can't really answer it until we see the requirements. And I can list a whole set of others that are down here that could go on for another two slides, but I don't think that's valuable.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay, so I will make the point verbally that again we stress the development of a set of basic requirements is important and with that set of requirements, we can consider related works such as these, and if you want to suggest any others, Becky, I can add them. But I think the point can be made by me verbally, and I think it's right that we need to consider that in the context of work on a basic set of requirements.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

It doesn't have to be a long set of requirements, I think that's important to state and maybe I can write a sentence that goes on that slide because when we did this work, we have a 120-page document and we looked at a whole ton of stuff that was going on around the world and we came up with a set of 12 requirements. And that drove the standard and the guidance and everything else that came out of that.

So I think that that's what we're missing here, you know, when we heard the presentations at the HIT Standards Committee, they were all over the place and we said, go back to a more simple approach and I think that means we need the requirements.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

So Becky, can we just add a slide that says, we recommend that you strongly consider these requirements in answering this question number 3?

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Well, they need to de...we need to develop the requirements and then we can say that, yeah, sure.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Oh, I thought you just said you had 12 from...

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Well we do from the FDA case, but somebody needs to look at those and see, are these the...I mean, I'm not sure they're the same 12 requirements. They may...we may need to have...we may need to subtract a couple and add a couple...

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Right, so that could be the response is to take a look at the 12...

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

The requirements were for a use case of different things like using e-Diaries and EHRs and any kind of e-Source for the research community. But we need to support public health, we need to support the exchange between different EHRs and those things and I don't know if those requirements, if we can just use them or if we need to look at them and say, do these apply here?

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

And what I'm suggesting...

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

I do think that a number of them are relevant, but I don't want to just say, use these, because we haven't done that analysis.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

So I guess my recommendation is to bootstrap that analysis by looking at the 12 that you guys developed.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

Agree.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Well I think that would make it easier, yes, bootstrap's a good word.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

You don't have to start from scratch; this is all work that the federal agencies have done globally over the last what, 1997, that's almost 20 years. So we might as well use it.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Yeah, rather than us...

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

I'm going to...

Julie Anne Chua, PMP, CAP, CISSP - Information Security Specialist, Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

Hi Lisa, this is...

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Yeah, Julie.

Julie Anne Chua, PMP, CAP, CISSP - Information Security Specialist, Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

...Julie. Can I just add something real quick?

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Please.

Julie Anne Chua, PMP, CAP, CISSP - Information Security Specialist, Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

I just want to...I heard everyone's comment on the setting the basic requirements and I just wanted to emphasize what John had just said and that is really what the S&I initiative is moving forward to do so I do agree that we should verbally state it and emphasize that, but at the same time I would try to caution being a little too prescriptive and doing..."doing the work" that the initiative would be doing as a community. I like the idea of what Becky and Aaron are saying where this task force can present like a set of basic requirements that have been worked on and vetted and pretty much put forth from FDA. However, it should be worded such as, these are requirements that we have solved in these use cases. Initiative look at these and then see what you all come up with based on the use case that you have.

Multiple speakers

(Indiscernible)

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Yeah, I don't think we're saying that we should put forth those requirements, we're just saying; go look at these as a reference...

Julie Anne Chua, PMP, CAP, CISSP - Information Security Specialist, Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

Right.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

...but we need a set of requirements before we can answer question number 3 appropriately.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay, so I am comfortable with that and I will speak to that across the set of slides. I think I will address it on the very first slide. I think we all are in agreement that the initiative should address the task of a basic set of requirements. Becky's point is that in some cases, the question they're asking would be better informed by having that set of basic requirements.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Right.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

Yeah and I think...

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

I think we're all in agreement.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

I think it might be good to do exactly what's been described. I mean, we can answer the question, but then we can say, but fundamental requirements must first be derived and here are some sources of some fundamental provenance requirements and then we can list the FDA, we can list the Health Information Management Society, we can list security...

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Right.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

...standards that Mike and I can offer. There are plenty of places for which requirements come from, so...

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Yeah, I heard yesterday that AHIMA has a set and it's not technical, but it's a framework so it's worth looking at.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

Correct.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay, okay, so we'll gather all those sources. In the interest of time, I want to look at the last...bullet number b...letter b, in particular relating to exchange. What we did here was just pull forward the concept of the provenance of content should be lossless in information exchange. Were there...is that okay and were there any other comments with regard to b?

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

I just looked at that 21 CFR 11 and they talk about audit trails; they also call it traceability. I think it's worth putting a couple of words like that or another bullet. There ne...it needs to carry the provenance data with it.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

So I'm confused...

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

What...

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay, Becky is...go ahead.

Aaron Seib – Chief Executive Office- National Association for Trusted Exchange (NATE)

So the audit trail of the transport is a se...to me, as a user of the data, I'm not investigating did your certificate get properly applied and then interrogated by the HISP that received it and forwarded it to Healthway; I'm assuming, as a user, that that's there and that there are other mechanisms in place for those security audits to take place. I don't know that I consider that in scope for this provenance...

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

So is that a bullet you would add?

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Just...

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

I think it's worthy for us to explain that again, security is the system that is enforcing the protection of confidentiality, integrity and availability and part of that is an audit log. Those are supportive of the health information management, but they are...it's a separate vector; it is not the same thing as what we're trying to address under provenance. So, again, all of that is absolutely necessary and we shouldn't have to say it over.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

I think that's why this question is confusing and it's not a very good place to spend our time on answering this question right now.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

But I think it's worthwhile just to capture that things related to the security audit logs and so forth for transport...

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Sure.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

...are outside of the scope of this provenance task or should be left outside of the scope of a provenance task.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Oh, okay. Yup.

Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC

Yes.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

Yes.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Yup, I understand now, sorry.

Mike Davis, MS – Security Architect – Veterans Health Administration, Department of Veterans Affairs

Yeah, this is Mike. I agree with everything said there. The problem of the main function of the security audit log is to record security relevant events, which may or may not intersect with provenance relevant events.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Yeah.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Correct.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

You can't trust a provenance if the security stuff isn't already there.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Right.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

So we're assuming this...

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay. I think we're set on that one and I want to move to one more slide and then we have a few minutes to discuss and then public comment. So, Johnathan and I discussed bringing everyone back to the focus...the more narrow focus of the use case that we're recommending they think about. And this was my visual depiction of that. So, using Johnathan's...one of Johnathan's original diagrams, that we're really talking about scenario one and we're differentiating system and information exchange requirements. Is this helpful or should we leave it out? Should we move it up to the beginning? I don't know.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Oh, I don't understand this is again, why if we did this right it wouldn't support all of those scenarios?

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

But I think...

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

The slide is useful without the red circle and saying this is what we're talking about because we should be talking about all of these things.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

I agree with you from a requirements definition perspective, from a practical execution perspective within the S&I Framework to build something that will be used for the next 10 years, I think we need to help them constrain the scenario.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

But I thought we talked about how some of these things are already available. I mean, ODM can do scenario one, two and three right now, today.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

That's great and if they pick the right spec, they'll have that. But for right now, I think focusing on this particular scenario, to me, adds value in that we get something practical that's doable and we get done before 2020.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

Yeah, this is John. I want to address that other comment Becky made is that all of the standards can support all of these, the problem is, there's not policy that drives consistent behavior and the policy to drive consistent behavior across all of these is a large body of work so they've asked us to focus on...if we can focus on driving some policies that'll...some best practice policies that will drive the use of the technology that already exists and has existed for years, where should we focus our efforts? What is the biggest bang for the buck?

I think given that, Lisa, I would actually...the diagram with the circle kind of implies that the input to the EHR under 2 and 3 is unimportant and I think when you do number 1, you're including those far right side of the 2 and 3 scenarios, you're just saying that the left side of the 2 and 3 scenario is priority two and three, because an EHR, the import capability is the same.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

That's why I would almost not even show this then because I think we could get...open a can of worms. But I understand what you're saying, we have to start somewhere.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

Yeah.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay, so...

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

That's all I was trying to support was from the ONCs, with the authority they have, they have more success focusing on this from a policy perspective.

Johnathan Coleman, CISSP, CISM, CBRM, CRIS – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.

This is John...

Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC

This is Floyd, is it worth splitting the diagram and just showing the part that's in red and nothing else?

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

I don't even...I thought that was already on the other slides in words, but...

Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC

Well, it is, this is just a diagram.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

We don't need to include this at all...

Johnathan Coleman, CISSP, CISM, CBRM, CRIS – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.

Can I just...this is Johnathan, can I just make a very quick comment please. This diagram summarizes the scenarios that are currently in the use case and when an initiative builds out an implementation guide, which is the next step, it covers all of the scenarios that are in the use case. So I think that if the recommendation is to focus on one of those scenarios first and build an implementation guide around that simple scenario, then it can subsequently be used to elaborate the capabilities of scenarios 2 and 3. So I think that...

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Yeah, but...yeah, that's appropriate but the recommendation is to go back and do a set of requirements before we jump into a scenario and an implementation guide.

Johnathan Coleman, CISSP, CISM, CBRM, CRIS – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.

Okay, I...so the use case...

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

These are...

Johnathan Coleman, CISSP, CISM, CBRM, CRIS – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.

...is the requirements document that drives the harmonization...the standards harmonization.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

No but a use case isn't the kind of requirements that we're talking about, the use case is not a set of requirements. I'm sorry. That's not what the recommendation is, it's...the set of requirements is different than a use case.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

So, I don't have any argument with what you're saying, Becky. There...from the SDO perspective what you're saying is very practical and I think what they're asking...

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

No, but this doesn't come from the SDO perspective, this comes from people who do these types of systems and electronic diaries, electronic, you know, exchange of information and they've had to follow the regulations from FDA for 20 years so that's what I'm talking about here. Why are we starting...

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Well, but EHRs have not had to follow FDA except when submitting...

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

I understand that, I understand that...

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

...so this is a new audience...

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

...and that's why it's a different set of requirements.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

I understand but it...so...yeah, I think the problem with the...potentially hearing the discussion with the diagram is that it appears, via the red circle, that we're saying, don't even bother with 2 and 3...

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Yeah.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

..and possibly we should, you know, use a numbered system, say, start here, then go here, then go here. On the other hand, I think I agree with Becky's statement earlier that I think we've already covered this space in text above and the diagram then just potentially opens up misinterpretations of what the diagram is trying to say as opposed to...

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay, so...

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

...saying this diagram is emphasizing the text above.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Yeah, so I think what I'm going to do is recommend that we just delete this. I created it, I don't...if it's...if I'm going to get to the end of our recommendation slides and then throw everyone into confusion, then it's not worth it.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

It's just...yes; it's just hard to visualize it.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Yeah, I'm thinking we'll just delete it and hopefully I can do a good job of explaining it verbally. Is everyone okay with that, deleting this slide?

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Yup.

Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC

Yeah.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay. Okay, well, so we...I think, Julie, I think we're at the end of our slides.

Julie Anne Chua, PMP, CAP, CISSP - Information Security Specialist, Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

Yes.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

So, we will then...our next steps will be to, with everyone's help, finalize the wordings of the slides. We are...there were some folks who were going to suggest wording, suggest links and additional reference documents. We will take those suggestions today and early Monday get a slide...a set of slides out to everyone Monday, hopefully in the morning. Julie, stop me if this doesn't track, but sometime morning of Monday to everyone for approval and then we need to send them out in anticipation of the Standards Committee meeting on Tuesday morning. Julie, did you want to add anything?

Julie Anne Chua, PMP, CAP, CISSP - Information Security Specialist, Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

No, that sounds good. We will await the suggested language and all that and we'll incorporate it and make sure there is something for review for the task force members Monday morning.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay, so if you all could send us what you have today, optimally that would help.

Julie Anne Chua, PMP, CAP, CISSP - Information Security Specialist, Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

Yeah.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay, I want to say thank you to everyone on the task force, this has been a monumental effort and I have felt everyone's support and participation. It's been a great experience, thank you so much and thanks to the ONC staff as well and to Johnathan. I think Michelle; I turn it over to you for public comment.

Public Comment

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Sure. Operator, can you please open the lines?

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

And thank you for your leadership, Lisa.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Thanks.

Lonnie Moore – Meetings Coordinator – Altarum Institute

Okay, 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. If you are on the telephone and would like to make a public comment, please press *1 at this time.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

We do have a public comment from David Tao. David, just as a reminder, you have 3 minutes for your public comment and please go ahead.

David Tao, MS, DSc – Technical Advisor - ICSA Labs

Thanks; David Tao from ICSA Labs, appreciate the opportunity. One concern about data exchange as it may relate to provenance is the potential loss of context. Supposing a provider creates a clinical document and exchanges it with another provider, but it goes through an intermediary such as an organization or a piece of software and so the intermediary doesn't actually change any data elements, it filters and extracts some elements and passes those elements unchanged to the recipient.

So while those data are unchanged, the receiver may not be aware of what was filtered out, which could have provided important context and that's an issue that can occur when someone like an HIE assembles documents by combining data from multiple sources. And it's also a challenge to address when transitioning from whole documents, which provide their own context, to granular, data element queries that don't know what the source would have deemed relevant context.

So, I'm just offering this as a suggestion that the Data Provenance Task Force consider the question of, what, if anything to do when data are unchanged, but they're not in their original context. And this may apply less in scenario 1, but I think it applies more in some of the other scenarios. Thanks.

John Moehrke – Principal Engineer, Interoperability & Security – GE Healthcare

That's a great comment, thank you.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Thank you, David. There are no other comments at this time. But I also do want to thank Lisa for her tremendous leadership; this has not been easy, this has been a really fast turnaround so thank you so much Lisa. We know that we put a lot on you, but we know that everything will go well next week and thank you so much.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

So thank you, Michelle. Thanks everyone.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Thanks and have a great day.

Julie Anne Chua, PMP, CAP, CISSP - Information Security Specialist, Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

Great, thank you.

Public Comment Received During the Meeting

1. One concern about data exchange is the potential loss of context. Suppose a provider created a clinical document and it was exchanged with another provider through an intermediary, either an organization or a piece of software. Suppose that the intermediary "touches it along the way" by filtering and extracting some of the data elements, and passes those elements unchanged to the recipient. While those data are unchanged, would the receiver be aware of what was filtered out, which might have provided important context? It's an issue when someone (like an HIE) assembles

documents by combining data from multiple sources. It's also a challenge to address in transitioning from whole documents (which provide their own context) to granular data element queries that don't know what the source deemed relevant context. I suggest that the DPROV task force consider this question of what, if anything, to do when data are unchanged but not in their original context.