# Interoperability Standards Priorities (ISP) Task Force

Transcript November 13, 2018 Virtual Meeting

# **SPEAKERS**

Name	Organization	
Kensaku Kawamoto (Co-Chair)	University of Utah	Co-Chair
Steven Lane (Co-Chair)	Sutter Health	Co-Chair
Andrew Truscott	Accenture	ISP Task Force Member
Anil Jain	IBM Watson Health	ISP Task Force Member
Arien Malec	Change Healthcare	ISP Task Force Member
Clement McDonald	National Library of Medicine	ISP Task Force Member
Cynthia Fisher	WaterRev, LLC	ISP Task Force Member
David McCallie	Cerner	ISP Task Force Member
Edward Juhn	Blue Shield of California	ISP Task Force Member
Leslie Lenert	Medical University of South Carolina	ISP Task Force Member
Ming Jack Po	Google	ISP Task Force Member
Raj Ratwani	MedStar Health	ISP Task Force Member
Ram Sriram	NIST	ISP Task Force Member
Ricky Bloomfield	Apple	ISP Task Force Member
Sasha TerMaat	EPIC	ISP Task Force Member
Scott Weingarten	Cedars-Sinai and Stanson Health	ISP Task Force Member
Tamer Fakhouri	One Medical	ISP Task Force Member
Terrence O'Malley	Massachusetts General Hospital	ISP Task Force Member
Tina Esposito	Advocate Health Care	ISP Task Force Member
Valerie Grey	New York eHealth Collaborative	ISP Task Force Member
Victor Lee	Clinical Architecture	ISP Task Force Member
Lauren Richie	Office of the National Coordinator	Designated Federal Officer

#### <u>Lauren Richie – Office of the National Coordinator for Health Information Technology -</u> <u>Designated Federal Officer</u>

Good morning, everyone and welcome to the ISP Task Force November 13<sup>th</sup>. We will call the meeting to order starting with roll call. Ken Kawamoto?

#### Kensaku Kawamoto – University of Utah – Co-Chair

Here.

## <u>Lauren Richie – Office of the National Coordinator for Health Information Technology -</u> <u>Designated Federal Officer</u>

Steven Lane?

## Steven Lane – Sutter Health – Co-Chair

Good morning.

### Lauren Richie – Office of the National Coordinator for Health Information Technology -Designated Federal Officer

Anil Jain?

#### Anil Jain – IBM Watson Health – ISP Task Force Member

I'm here. Good morning.

#### <u>Lauren Richie – Office of the National Coordinator for Health Information Technology -</u> <u>Designated Federal Officer</u>

Arien Malec? Okay. Not yet. Andy Truscott? Not yet. Clem McDonald?

#### Female Speaker

He's on his way from another meeting, but he should be here in the next couple of minutes.

#### <u>Lauren Richie – Office of the National Coordinator for Health Information Technology -</u> <u>Designated Federal Officer</u>

Thank you. Cynthia Fisher? I believe she dialed in. David McCallie?

#### David McCallie – Cerner – ISP Task Force Member Here.

#### <u>Lauren Richie – Office of the National Coordinator for Health Information Technology -</u> <u>Designated Federal Officer</u>

Edward Juhn?

Edward Juhn – Blue Shield of California – ISP Task Force Member Here.

#### <u>Lauren Richie – Office of the National Coordinator for Health Information Technology -</u> <u>Designated Federal Officer</u>

Terry O'Malley?

#### Terrence O'Malley – Massachusetts General Hospital – ISP Task Force Here.

#### <u>Lauren Richie – Office of the National Coordinator for Health Information Technology -</u> <u>Designated Federal Officer</u>

Les Lenert? Not yet? Jack Po? Not yet? Raj Ratwani?

#### Raj Ratwani – MedStar Health – ISP Task Force Member Here.

#### <u>Lauren Richie – Office of the National Coordinator for Health Information Technology -</u> <u>Designated Federal Officer</u>

Ram Sriram? Ricky Bloomfield? Sasha TerMaat?

## <u>Sasha TerMaat – EPIC – ISP Task Force Member</u>

Here.

#### <u>Lauren Richie – Office of the National Coordinator for Health Information Technology -</u> <u>Designated Federal Officer</u>

Scott Weingarten? Cheryl Turney? Tamer Fakhouri?

#### Tamer Fakhouri – One Medical – ISP Task Force Member

Here.

#### <u>Lauren Richie – Office of the National Coordinator for Health Information Technology -</u> <u>Designated Federal Officer</u>

Tina Esposito? Not yet. Valerie Grey did indicate she was going to be absent. And Victor Lee? Okay. Did I miss anyone from the top of the roll call? Okay. Great. So, we'll circle back and check back later for those that may have joined late. At this point, before we turn it over to our guest presenter, I will hand it over to Steven and Ken for any opening remarks.

#### Kensaku Kawamoto – University of Utah – Co-Chair

If Steven can lead us up on this, that'd be great.

#### <u>Lauren Richie – Office of the National Coordinator for Health Information Technology -</u> <u>Designated Federal Officer</u>

Sorry, I didn't quite catch that. Was that Ken?

#### Kensaku Kawamoto – University of Utah – Co-Chair

Yeah. Steven, if you want to lead us off. I think you're muted probably, Steven.

#### Steven Lane – Sutter Health – Co-Chair

Yeah, sure. Sorry about that. Good morning. Welcome, everybody. We wanted to welcome you back to our next meeting. We continue presently in our journey of exploration regarding referrals and care coordination. You'll recall that at our last meeting we spent a lot of time thinking about the 360X standard, which is work that's been going on under the auspices of HL7 for a number of years now to look at what are the basic components of closed-loop referrals between a referring provider and a consulting provider and looking at how to leverage standards to support that workflow. We have said that as part of the scope of this inquiry, we also want to talk about the care coordination which goes on subsequent to and sometimes in parallel with referrals that really involves the need to communicate bi-directionally between different members of a patient's care team.

So, what we've done today is we've invited Dr. Luis Maas to join us to make a presentation on the Direct protocol and where it came from. This of course, the Direct protocol relies on the 360X work. Though I think we're going to discuss later the fact that the actual functionality of messaging and referrals doesn't necessarily have to be built on top of direct. But within 360X, it has been built on top of direct. And we want to understand Direct as really the current state to support our messaging between members of a care team, including potentially with the patients and their caregivers as well as with clinicians and others who are involved. So, we're trying to kind of lay a foundation to understand the various standards that exist that are used to support this very important use of Health IT. And then we will build upon that to develop some recommendations similar to the work that we did around orders and results.

There has been some discussion in the background about the fact that in some sense, orders and results are almost a special case of this kind of messaging – the idea of a message going from one actor to another either requesting a test to be done, a procedure to be performed, a referral to be performed. So, there's some sense in which we're kind of thinking about this holistically, but we're also trying to keep it in bite-size pieces around these specific uses that we identified early on. So, Luis, I see you're on the line. I don't think I heard you, but I do want to welcome you. But first, Ken, do you have anything you want to add to that by way of background?

#### Kensaku Kawamoto – University of Utah – Co-Chair

I think that's right. And I think what we've heard so far is there's a lot of great work starting in this area like the 360X project. But there's still probably a decent amount of piloting work that needs to happen. So, probably not as good of a parallel to what we experienced in the orders and observations topic that we covered earlier where the work was already fairly mature and it was basically just to encourage that direction. So, I think what we want to continue doing is hearing about what's being done. But I think the next step in this area might be less saying, "Hey, this is a standard we should really advocate for," and more, "We should advocate for more pilots that meet the functional needs that we've been discussing."

#### Steven Lane – Sutter Health – Co-Chair

And I'll just respond to that by saying – and I think Luis will set us up for a good discussion here – that really, a lot of tremendous piloting and use case implementation has been done, built on top of direct. I think the 360X that we heard about last time is really but one of those. There have been a lot of success stories of people using Direct for all sorts of purposes. And I think Luis will give us a preview of that. And then we can discuss that with him subsequently. So, Dr. Moss, would you like to perhaps introduce yourself and your background before you get us into the presentation?

#### Luis Maas – EMR Direct – Guest Presenter

Sure. Thanks very much. Can you hear me okay?

### <u> Steven Lane – Sutter Health – Co-Chair</u>

Yes.

#### <u>Lauren Richie – Office of the National Coordinator for Health Information Technology -</u> <u>Designated Federal Officer</u>

Yes.

#### Luis Maas – EMR Direct – Guest Presenter

Okay, great. My name is Luis Maas. I am currently the Direct project coordinator. I'm also the Chief Technology Officer for EMR Direct, which is a Health IT vendor that works in the Direct Project space as well as with a few other interoperability standards. I am both a physician and a scientist. I was a practicing radiologist in San Diego for over ten years and I did scientific work in the design of medical equipment and signal and systems processing back in those days. I've now moved entirely into the Health IT space. So, I'm trying to bring all of those experiences together to improve the delivery of care here in the United States and anywhere else that's interested in using our standards that we're putting together.

So, within EMR Direct, we joined the Direct Project a long time ago – about five years ago, right as the first standard was being published. And since that time, we've continued to work with that community to improve that standard and build upon the related standards that are promoting communication between different vendors. So, essentially, what my company does is produce software that lets various Health IT vendors basically plug direct messaging and other standards right into their products without a lot of work so that they can then communicate across to different vendor platforms following these standards.

To your comments about pointing at various standards and such, I think the Direct Project and the Direct protocols and their associated standards for notification and transmission of information – especially transitions of care – are pretty well established. This has been in certified health technology since the 2014 edition of ONC's certification program. And the first products with Direct functionality were rolling out into the real world – certified products – back five years ago almost – four years ago. So, this has been around and the networks built on this protocol have grown. And primarily pushed initially by the regulatory influences that required this particular use case to be implemented by folks. But after that network reach a critical mass of sorts, lots of other people began thinking about, "Well, what else can we do now that this network exists?" So, I did send some slides to your team. I don't know if – you can review them later if they weren't there in time for today. But it's basically a little general background of Direct and then a little more focused background on some of the more recent work that we've been doing in expanding it to general use cases, not just the initial transitions of care use case that was formulated out in the ONC procedure. I don't know if you want me to focus more generally on Direct Project or more on how it refer – or how we are looking at using it in things like closed-loop referrals and other use cases.

#### Kensaku Kawamoto – University of Utah – Co-Chair

This is Ken. Sorry. Who did you send the slides to on our team?

#### <u>Sarah</u>

Hi, this is Sarah. I'm just sending the slides to the folks to be able to present them right now.

#### Kensaku Kawamoto – University of Utah – Co-Chair

Perfect. So, we'll have that up in a second. And I think in terms of the context, it would be really useful to get your thoughts on where are the gaps in what we can do? And clearly, from the end user perspective, this is still seen as an important issue. So, what is it about the current technical infrastructure and the way we are using it that is leading to this still being perceived as an important issue?

#### Luis Maas – EMR Direct – Guest Presenter

Sure. I think that lots of you are – I see some names here who I think would be intimately familiar with the Direct Project. But just in a general overview to start simple there, a need was perceived some time ago that a standard space-secure mechanism to electronically push health data from one location to another was needed that was vendor independent, reusable – sort of much like the fax network that it was hoping to replace that existed at the time. Just something that you'd plug into the network, and you could then communicate with the folks that were already on the network. So, from that and the original work, a couple of different technical implementations were discussed. But the ultimate decision was to base the mechanism on a combination of essentially conventional Internet email coupled with the security, confidentiality, and integrity that was provided by public key cryptography.

So, this is slide two if you want to catch up there on the – essentially, by giving everyone a Direct address, they would be able to – much like they do with a regular email – communicate with one another with arbitrary payloads. Pretty much like what you can do with a regular email, but covered with the security of an S/MIME and X.509 certificates so that this would be compliant with the different regulations that protect the privacy and security of health information. And then with some additional potential to include some assurances about identity. What is the sending endpoint? What is the receiving endpoint? Basically to create messages that can only go to a certain location, can't be read by anybody else, and with the ability to be certain about where it came from.

All right. So, next slide, please. So, this came out - as I mentioned, out of the original

meaningful use incentive program, and the ONC Certification Program, and the technology list required in health IT, one of the Catch-22's of that – the double-edged sword, if you will – is that essentially only one use case was really defined. And that is the transitions to care. So, one of the limitations – to get your point on that – is that many of the implementers that built this out essentially built it out in a very limited way that covered exactly that use case and was not intrinsically extendable in the way that was envisioned initially when the protocol was built. Although the network has grown substantially – and this 1.4 is an estimate based on numbers from one of the big networks – the connected users in this network have been sending these transitions to care fairly effectively.

Some systems more than others. Some localities more than others. But hospital discharges are a very common use case. Automated push of discharge information to primary care physicians for transitions to skilled nursing facilities, and other post-acute care facilities, and things like that. And even referrals between physicians on the ambulatory side or transfers back to hospitals. That type of data was fairly well defined in the original use case that was laid out in the regulation. But nonetheless, people want to do more. Right? Once you have this ability and you can see that you can push this data out of your system and push data into a system – because the regulation also required the ability to receive, display, and incorporate data that came from other places – it wasn't long before folks realized you could do a lot more. Especially in the areas of care ordination, keeping records complete. Much better than faxing data. If you get the data electronically, you can incorporate it right into your longitudinal record. And then more things started coming out.

The original view was this might have more human interaction. But ultimately, people started designing automated workflows and leveraging that environment. Essentially, you have built this network that can transfer data to go beyond what you can do with the original payload, which was the CCDA XML structure document. Essentially, a slight variation on the continuity of care document in most cases. People wanted to do different workflows and different payloads because ultimately, Direct is primarily a secure transport to get data securely from point A to point B in a healthcare – in a way that complies with healthcare regulations. There are a few notes here about some of the ideas people were interested in putting in, but we can go on to the next slide.

Just covering some of the limitations of what was in the original regulations, some of which has been addressed by the 2015 edition where some of the early complaints were, "Well, this system only gets CCDA's, and I can't send anything else." Well, the later certification program expanded this to include text, and PDFs, and XDM messages. But one thing that the implementing community and folks that are on the supporting side of the technology realized is that a lot of this data didn't really have a good way to include patient context. You get an image attached to an email, and have to kind of figure out who does that patient belong to. And how can you do that in a reliable and automated way? For a CCDA, that data's encoded right in the CCDA. And for a PDF, maybe you can scrape it out of the data or not. But for other types of data, it's even more difficult.

XDM clearly has a lot of context integral into it. It's clinically focused, and it does have a very robust vocabulary for expressing many of the same concepts. And so, one of the things that the Direct Project community considered was emphasizing XDM more. But we realized there

was some use cases that XDM didn't really work effectively for. Some use cases that included a large amount of data that was small in individual message size such as MHL7 ADT message, things like that. There's a lot of overhead in an XDM package to carry something that's a few hundred bytes long. Also, some of the workflows that we were interested in reusing this secure network for just didn't really fit the XDM model at all, such as encapsulation of API calls where the Direct messaging was used. For all of the security related items that I mentioned, a secure way for Hospital A to talk to Post Acute Facility B without having to build a VPN every time or exchange secure credentials manually.

That same transport tunnel can basically be used to carry API transactions. And that was not something very well carried in XDM. And a lot of the vendors just never really built out the stack to support the XD metadata. So, it was considered, but we decided we would try to make something simpler and more universal that could carry additional workflows and payload types that weren't necessarily available with XDM. And then we also recognize CCDAs are not always for transitions of care. And if you just received a CCDA via Direct, how would you know? Well, is this the standard ONC 2015 edition transition of care use case, or is this supposed to be something else? So, these were the limitations that were recognized and discussed by the community maybe two years ago. Three years ago, this conversation started. The output was this context idea I'll share briefly with you. There is information in these slides that you are free to review with lots of links at the end to some of the supporting documents as well.

If we could go to the next slide, please. This is basically summarizing what I've said – the things that we wanted to do with Direct – so we can skip over this. Essentially, what the work group decided – and we wrote an implementation guide you may recognize. *The Implementation Guide for Expressing Context in Direct Messaging* is the title. It's in the ISA as version 1.0. Version 1.1 was completed earlier this year and is a minor update to version 1.0. Essentially, the idea for the technical folks in there is that some of the metadata is expressed in the human readable plaintext attachment that goes along with the direct messaging or in the direct message along with some header metadata so that automated processes can find it. The idea here is that when you extend the standard, it may take a while before everyone adopts the extension, or maybe they never do.

So, we wanted something that, even if you didn't adopt it, wouldn't break the existing implementation and it would potentially even be useful by someone who didn't support the newer extension. So, by making it human readable, at least it's there. If necessary, it can be viewed on screen even to help people match things up with the patient manually or with a workflow manually. But the key idea is that it identifies the workflow right in the metadata. These are the initial set of categories and actions that were defined. In 1.1, we added this area category, which I could talk about for a long time. But I think it is a little bit of a tangent. So, I'll just leave that. Anyone who is interested in that can let me know and I can share more information about that. But essentially, broad categories of data workflow types and broad actions that essentially follow in a relative sequence.

So, for example, the initiator who wanted to order a radiology study might include the CCDA but with the metadata tags of radiology/order. And potentially, in that CCDA, there would be the information to determine what the order is or it might be expressed in an attached PDF

of assigned order or something like that. But whatever it is, the idea is that the receiving system can put this into the queue for the folks that handle radiology orders or the automated system that handles radiology orders. When the result is returned – the report returned by the radiologist – it could be sent back as radiology/report.

On the next slide, there is a transaction ID that is used to tie these things together, which I'll show you in the final example. But there are also patient identifiers. Where each party in the transaction as the message goes back and forth can be attaching their own patient IDs to this list, so that as the circle grows, each party can find itself in its own local reference. Or if it recognizes the IDs of other parties in the communication, it can use that for cross-referencing.

Many of these fields are optional, because not every communication will be about a specific patient. But many, if not most, are. Next slide, please. If you don't know the patient ID at the other facility, you can include various patient matching attributes. This list was extended in version 1.1. It's essentially based on LDAP names with a few additional elements added by the group that were felt to be especially useful for patient matching. You supply what you know. And the receiving party can use from that list what it wants or what it can. If we can move on, please. Information for the ability to express purpose of use was felt important. And basic purposes were put there that we anticipated would be used in early iterations of this implementation.

Obviously, all of these list are extendable. The ID has made the list official as far as if you view wanted to extend the list, it would require a new version of the ID, which would be a version bump. And the version is expressed in the metadata, so people would be able to build a system that can know what to expect rather than just have a bunch of arbitrary tags.

Next slide, please. Here is an example of what it looks like. Again, that's a complete metadata attachment. Generally, I say it is human readable. It's more or less human readable. If you had to look at this, you would at least see type radiology report and the patient name, John Jacob Doe. I think you probably would be able to figure that out. The patient ID after the colon, maybe you'd figure it out or not. But obviously, this was intended for a machine to read in an automated manner but with something that could fall back potentially to a human reader. So, five lines to look at compared to some of the other metadata options we had that were pages of XML. This was felt like maybe it would work even in a limited – somebody who just has, say, a webmail interface to access Direct may still be able to make use of this.

Next page, please. The actual email, if you're familiar with direct messaging, it basically looks just like regular email. One extra header tag added there in blue just to signal to the receiving system there's context attachment with the CID or content ID tag to help them find it. The rest of the direct message looks the same as any other direct message, except on the next page, you'll see the metadata attachment just gets stuck in there as another MIME part, another attachment, if you will. If you can go on. And then the rest of the data. There is a PDF encoded in the message. And then that metadata refers to all of the other attachments. So, if you have to talk about multiple patients, you'd still have to send multiple messages. But you could send multiple attachments with one piece of metadata. Next slide, please.

We have done some implementations. There are several prototypes of this that are already in the field. This data is – this slide is a couple of months old already, so we have tried this out in a few connective situations. And based on the feedback from those scenarios and those test cases, we did make the revisions to version 1.0 – which was a draft for trial use – and released 1.1 earlier this year, which is the actual normative version – first normative version. Obviously, Direct Project Implementers' workgroup continues to talk about this from time to time. We continue to get feedback. There are a couple of different ideas floating around about how to continue to improve this, but this is where we're at. I think that's the end. I may have one more slide. This is more of a word map of different things that we've heard people wanting to do with context or different use cases and workflows that could be supported by context.

So, obviously a wide range of things. A lot of people very interested in care coordination in particular. And I will leave it at that. So, that's the end. The next slide is just some references. You can find the PDFs for this standard and some of the standards it relies on at the end as well as my email address. If you have any questions or any ideas that you have about how we can continue to improve this context IG and the Direct standard, please feel free to let me know. So, I'll stop there.

#### Kensaku Kawamoto – University of Utah – Co-Chair

Great. There's a hand up from Arien. If – oh, yeah. Arien, do you want to comment or ask your question?

#### Steven Lane – Sutter Health – Co-Chair

We don't hear you, Arien.

#### Arien Malec – Change Healthcare – Task Force Member

Darn it. That's my mute button. This is a great overview. Really fantastic, particularly for somebody who knows nothing about Direct. That was a joke. Anyway, the idea of universal context is incredibly useful. One of my observations has been that the Direct protocol was by design transport only and was content neutral, but that the content experience is what defines the user experience and the clinical experience. So, most physicians' frustration is they have an experience with Direct – I'll just – I'll say their experience, if they have an experience with Direct – I'll point A to point B, but is heavily formed by what's going on at the content layer. And in particular, about how their EHR renders the consolidated CDA.

And in particular, whether or not they receive what they're expecting to receive, which is a human formatted clinical narrative – a human readable textual narrative written by another clinician that contains the essentials of the case – or whether they receive instead the classic 45 pages of garbage facts that is the typical rendering mode that many EHRs provide when a consolidated CDA comes through. So, the idea of additive context is incredibly useful to address the problem of message content that comes in without a context. But has the Direct

community or the transitions of care community addressed some of the content layer issues that actually are more defining of the user experience that physicians have when they receive Direct messages?

#### Luis Maas – EMR Direct – Guest Presenter

I think that question is for me.

#### Arien Malec – Change Healthcare – Task Force Member

Yes, please. Thank you.

#### Luis Maas – EMR Direct – Guest Presenter

In part, the CCDA requirements, unfortunately, are pretty specific as to what is needed to be considered compliant with the certification program. Right? So, by its nature, it's going to include sections that may or may not be relevant to a specific workflow. It's really more of a summary record. I think the point that you're making and that I agree with is that the standard transitions of care, the CCDA, isn't really the appropriate payload for every workflow. And that's definitely true, you know. And in some limited use cases that are not supported by all vendors – and there are 400-some vendors that have implemented this in one way or another – there are new ways to present and carry payloads that are more workflow appropriate for other workflows.

As far as where to put that narrative or how to express it, if you start from the position of, "Well, here is what I have to carry to have a certification program compliant CCDA XML file," well, then you're going to be of course limited by what that CCDA file can carry. If you take the view that that CCDA file is intended for a very specific use case and if you are doing a different use case, you don't necessarily have to carry that payload or that specific payload, well then you could run into issues of a system that is only expecting that kind of payload. It's going to probably not be very workable if it receives a CCDA that is structured differently, or has different elements, or if it gets some other type of payload.

So, it is – I think there is a catch up period that is going to be needed as implementers and Health IT vendors kind of move from the 2014 very one use case workflow specific implementation into the 2015 edition, which at least allows for more payload types without crashing, if you will. That they have to be able to accept a wider variety of payload types, which is more toward the long view of payload neutrality diagnostic, really. And I think in building out that type of system, the next logical step is to start thinking more like to be able to handle even more types of payload as opposed to just a subset of payloads. But how long will that take? I can't really tell you that. People are thinking about that. Some of the vendors out there already have a more payload neutral interface. It doesn't necessarily entirely address your question, but it's a step along the way to that type of flexibility.

#### Arien Malec – Change Healthcare – Task Force Member

Got it. Thank you. And one follow-up question, if you would. You used email headers as the context metadata. Did you contemplate using a FHIR attachment to hold the context metadata? And maybe the answer is embedded in what you just said, which is you're looking for complete payload neutrality and went with the email header approach. But I'm just

curious as to why or what the trade-offs were between an email header and a mandatory FHIR-based attachment.

#### Luis Maas – EMR Direct – Guest Presenter

Right. So, the idea in the metadata was actually structured after other email report types like the disposition notifications and status notifications in the email standards, which are essentially header colon value lists. So, the idea was that this would be something that would be renderable in an email client that didn't understand anything, and still give the opportunity to be human readable. Because obviously, the email headers were designed to be human readable and machine readable back in the '60s and '70s. And so, the idea is essentially the same. A couple of different things – standards were considered to carry that metadata. But ultimately, in the interest of simplicity and consistency with email and hope that it would be somewhat readable to a dumb client, if you will – not the person, but the application – that we would follow a presentation format similar to other email related standards. But obviously FHIR is one of the payloads that we talk about a lot.

There's a lot of excitement about how context helps direct the transport for FHIR. In fact, you can – and I didn't talk about this in the presentation. But you can actually use Direct as a conduit for query response using the FHIR restful API. Instead of HCPPS, you can use Direct as the backbone now. That obviously would make sense if you had larger queries or you didn't need an immediate synchronous response. But in fact, any arbitrary API call can be carried using Direct for security and transport so that it – you know, basically, you can effectively carry HL7, V2 transactions, FHIR restful APIs or any other HTTP-based API that you can think of.

#### Arien Malec – Change Healthcare – Task Force Member

Thank you.

#### Steven Lane – Sutter Health – Co-Chair

David, you had your hand up?

#### David McCallie – Cerner – ISP Task Force Member

Yeah, thanks. Thank you for the good presentation. I too know something about direct, at least in the early days when we first got it launched. And it's really nice to see the progress that's been made. I would however caution – well, let me just back to the history a little bit. We had many debates in the early days about whether Direct would become essentially a general purpose API mechanism between systems given that it did in fact create a secure channel, which is no small accomplishment. But I think the dominant feeling back then was that Direct was intended to be human mediated like email – on which it was not only based, but actually implemented – and that attempts to try to make it an automated way for systems to interact with each other might get us into trouble. That there might be better ways to do that than trying to essentially piggyback complex automation on top of what was fundamentally a human mediated email channel.

So, I like the context headers. To me, that makes good sense because they are human readable and they are friendly for humans deciding what to do next. They are not intended

to automate processes in the background. And I would urge the Direct community to resist that temptation to try to do too much automation using Direct as the channel. With that said, it might well be that the Direct security context that can be established between two systems could be used to establish other kinds of channels reusing some of the security infrastructure but not necessarily trying to force transactional activity on top of S/MIME containers, which just aren't really well-suited for that. And I think the 360X is right on the hairy edge of whether it's crossed over into trying to do too much automation.

I think the consensus of the implementers so far is that it is okay. I would defer to those folks with direct experience using 360X pilots as to whether it works well enough for us to endorse it. But it's right on the edge of getting to be too complicated for a simple email interface.

#### Steven Lane – Sutter Health – Co-Chair

You know, David – this is Steven Lane. I think you raise some really interesting points. And I think that this is really one of the challenges for our task force. We have people on the task force with a broad range of backgrounds. Some of you are very technical. We've got people on the call who were involved in the birth of Direct. And then we have people who are really here kind of representing a much more patient-centric, layperson type perspective, though it's hard to categorize any of us really as complete laypeople. But I think that our challenge here is really to determine or to try to understand what the state of these standards is and what is needed. And what we have heard in Luis' very nice explanation of what's been baked into Direct version 1.1 is that a lot of work has gone into acknowledging the limitations of the first iteration of Direct that, as we have heard, we've all been party to over the past few years. And trying to figure out what is needed to go forward.

And my understanding is that there is some controversy. And I think you called it out, David. Is Direct the appropriate standard to move forward to automate more of these processes? With the closed-loop referrals in 360X being one example of that. But we heard about a whole host of other opportunities that Luis mentioned – orders, results, conversational messaging, and other use cases that people are trying to put Direct to. And then at the same time, we have the ongoing evolution of FHIR.

And I think for our group, the struggle is to really understand what we – if we are going to be able to suggest one standard or another or some combination of standards that the ONC and others should support to help move this forward. And I for one find this whole area very confusing. Because there are experts who really have opinions sometimes that vary with each other, and I know are trying to work things out. So, I'm really curious – from the perspective of the other members of the task force – how we move forward and how we add value given the state of this discussion.

#### David McCallie – Cerner – ISP Task Force Member

Just one comment to that neck. I agree with that perspective. I think one of the things that worked in the orders and results phase of the work that this task force did and the cadence that we got to that I thought was incredibly helpful is this taskforce has clinicians who are in daily practice dealing with the problem of treating patients, and the problems of the existing mechanisms of interoperability. And it was incredibly helpful to hear the real world of orders

and results and then compare and contrast that with the level of standards development. And I think in that case, we concluded that there was a standards adoption gap relative to what was available in the standards community.

But I generally think that framework of let's describe the clinical experience, describe the high-target gaps in the clinician experience and the clinical care experience, and value-based care experience, et cetera and then backtrack that to what the standards gaps are and then backtrack that to what the standards gaps are and then backtrack that to what the appropriate mitigant is.

And in this case, it may not be everything's there and we need to go do something, which needs to spur adoption. It may be that pieces are here and pieces are there and we need to have a more coordinated approach, or we may need to change tracks, or what have you. But I think that separation of here is the clinical experience, and it's broken, or here is where it's broken – here are the standards that exist, and here is what's done. And then maybe piece together at the end what gaps exist and what we can do to fill the gaps. That framework seemed to work really well in the orders and results case.

#### Holly Miller

Steve, this is Holly Miller. May I say something?

#### Steven Lane – Sutter Health – Co-Chair

Hold on, Holly. We're trying to clarify here. We have a precedent of having task force members speak first. So, I want to be true to that until we have clarification from our ONC team how we're going to manage this. David, you have your hand back up again?

#### David McCallie – Cerner – ISP Task Force Member

Yes, Steven. I just wanted to echo. I think that you raised the fundamental tension nicely. And with respect to Direct, my comments maybe were a little bit abstract. I'll just get a little bit more concrete. I fully support the notion of expanding the range of content that can be moved back and forth with Direct, but using human mediation as the gateway. In other words, think of it as just exactly like what you use email for on your desktop. You can send Word documents, Excel spreadsheets, PDF files. You can send all sorts of complicated material back and forth with your colleagues, but you don't let your email take over your computer and do things in the background when you're not paying attention.

And I don't think Direct – I think Direct should be just like email. Target the things that get sent with faxes. Eliminate the fax. Make all those things flow over Direct channels where humans can dispatch them appropriately. And then leave deep API automation to a different space. So, that's where I would draw the line. And 360X, I think, is – I think we can make it work as sending referrals back and forth. I would just be leery of trying to automate too much of it.

#### <u>Steven Lane – Sutter Health – Co-Chair</u>

Thanks, David. That's really helpful. And Holly, sorry. I didn't mean to be rude at all, but I just wanted to seek clarification on our protocol here. So, why don't you go ahead and share your

thoughts.

#### Holly Miller

David, I appreciate what you are saying. But I can tell you in the field that one of the beautiful things about Direct is that there is discrete data that is being exchanged and that it's possible to integrate that discrete data HER to HER, which facilitates decreased duplicate testing. It facilitates avoiding adverse drug events because there are not transcription errors. And in fact, there's much demand in the field when clinicians use this for increased automaticity that is enabled by context. Then it allows for appropriate routing. And so, if what we want to achieve is to decrease provider burden of documentation and of managing and caring for patients safely, I think there's enormous possibility. And I think that it is quite different from email.

#### Steven Lane – Sutter Health – Co-Chair

So, I think that this is one of the key challenges within our task force. Again, as people who on the whole are not deep in this space, to determine how we want to comment, what we want to recommend to ONC. I think listening to Luis' discussion of version 1.1 and what it's attempting to accomplish, it sounds to me, as a clinician, very exciting. Like Holly, I am well aware of the challenges that we have experienced attempting to use Direct for even the most simple email-like exchanges between providers and other clinical members of the clinical care team. There is a whole community of folks who think that Direct would be appropriate to support conversational messaging between patients, and providers, and other members of their care team. And I think there's just a lot of open questions.

I mean, obviously a tremendous amount of work has gone into Direct and continues to be done. There are great opportunities and some tremendous successes. I just don't know – I really don't – whether this committee or this task force is in a position to say. "Yes, we think Direct is great, and the OMC should continue to push it forward. And it has all of these opportunities to accomplish more in the field," kind of in the way that Luis was appropriately laying it out, or whether — or not. And I'm really interested in people's thoughts on that. Les, I see you've got your hand up, and Sasha. And you had weighed in on the chats, and maybe it would be great to hear from both of you.

#### Kensaku Kawamoto – University of Utah – Co-Chair

Les, please go ahead. If you're talking, you're muted.

#### Sasha TerMaat – EPIC – Task Force Member

Les said in the chat that he has to dial in, but this is Sasha. I think we – you know, my perspective was that I was really resonating with Arien's suggestion a moment ago that one of the things that was helpful to our previous approach in sort of knowing what technical standard would make the most sense would be clarifying first what are the exact gaps that we would suggest that ONC prioritize solving. Because if we mapped out and said in the Direct messaging workflow, the primary challenge is actually knowing the address of who you are going to message versus being able to associate the messages with the appropriate other metadata from the order that it would be related to, for example. Obviously, those would lend themselves to very different technical next steps. And I think that might help give us

some nice context to – even if we aren't able to recommend a particular standard, at least recommend priority areas of focus.

#### Kensaku Kawamoto – University of Utah – Co-Chair

That sounds great. Let's see if – Les, are you back on?

#### Leslie Lenert – Medical University of South Carolina – Task Force Member

Yes, I am. Thank you. I just wanted to comment that it seems really exciting how much a small amount of stated information can really enhance the Direct protocol. And I think that having a small number of categories like that is a good start. Obviously, it should probably be linked to some kind of oncology of doctor-patient communications or doctor-to-doctor communications to try to strengthen what those categories are. Recognizing version 1.1, very early in the process here. But I also want to make the comment that Direct is – as a route to send messages, is just – what it was supposed to do is that we're kind of taking a protocol that was supposed to parallel a fax machine, and continue to extend that. That there is only so far we can push this. And one really wonders how much having a fax machine on steroids is really going to be the solution to interoperability.

#### Kensaku Kawamoto – University of Utah – Co-Chair

Thanks, Les. David?

#### David McCallie – Cerner – ISP Task Force Member

Yes. Just to respond to Holly's thoughtful comments, I fully agree, Holly, with the notion that we should support automated routing using these context headers. If a vendor wants to build an inbox that understands inbound referrals get routed a certain way and can do that by parsing the headers, that makes great sense to me and would be consistent with uses of email. But if the request is landing in somebody's inbox, my assumption is that we probably – and that request might have embedded in it sufficient context encapsulated as a FHIR bundle or a V2 bundle to be determined sufficient context to determine whether it's appropriate to accept the referral or not. That makes good sense. But I'm not sure we would want to make the requirement be that Direct is sufficient to actually transact the acceptance of that referral in an automated fashion. Because my guess is – my bet is that the edge cases are so numerous that you'd have stuck systems.

So, there's some fine line there that makes good use of the appropriate technologies and of the human skills that offices deploy to do this kind of stuff all day long. And I'm open to being convinced of the exact right place to draw that line, but I think we need to be respectful – that we shouldn't push Direct too far. How far that goes, I don't know. But let's go figure it out. Somebody – I know you guys are working hard on it, and I think that's great.

#### Kensaku Kawamoto – University of Utah – Co-Chair

Great.

#### Arien Malec – Change Healthcare – Task Force Member

David, by the way, I like the framework of let's look at the sources of faxes and see what we

can do to kill 95 percent to 99 percent of the sources of faxes in a typical clinical workflow.

#### Steven Lane – Sutter Health – Co-Chair

I also like that, Arien. I think that when we – clearly, there has been a challenge laid out by some of them and others to try to drive the fax out of healthcare where it's not serving a purpose and where we have opportunities to improve efficiency, and the security, and the reliability of that data transmission. It certainly does seem that Direct, as a protocol, has the opportunity to do that. Though, as we've seen in real life, it has not been implemented with sufficient consistency, either by providers or by their vendors, to really be able to do that. And I wonder whether we, as a task force, are in a position to support that.

Not – as David said not expecting Direct to be all things to all people or to be able to accomplish the kind of deep automation and integration that we also desire, but looking at an opportunity for the task force to see Direct for what it is and what it can be with some modest advances and continued support in order to help us accomplish that goal. So, I'll just – I'll leave that there. But Vassil has his hand up. Vassil, also we've invited as a subject matter expert. You'll recall that Viseal helped give the presentation last time about 360X, so has a lot of experience here. Viseal, what can you add to this?

#### Vassil Peytchev

Hi. I want to agree again with Arien and with David about the need to focus on the experiences, the gaps, and what we want to improve and where to draw a line. And when we talk about faxes, if you look at the fax-based workflow, there's a lot of manual work that happens with faxes. And just saying that we'll exchange the communication of the fax with Direct message and then continuing doing the manual work after that, just doesn't seem that this is a good enough target for this group. A lot of work currently happens now within an EHR system or within an automated system. And so, we need to have – we need the ways to combine both the communications and the work that is being done. And that has been the goal of 360X from the very beginning is to enable the work that a nurse, or a physician, or even a clerk at the stopgap provider site does. It is similar whether they do, for example, internal referrals or they do a referral across the country.

And given that goal, the experiences that we've had through building 360X and now starting to test it – we tested it last year at the IHE Connectathon. We have seven vendors that are going to test it at this year's Connectathon and so on. And we're looking forward to those pilots – is that there is possibility and value in discrete context being transferred using the existing metadata. For those who are looking forward in the future for API-based interoperability and multiple apps being able to hook into different parts of a workflow and enhancing the user experience that way, I wanted to just point out that the API – the resources in FHIR called document reference and document manifest – are directly modeled based on the existing meta data from IHE. They were meant to be interchangeable, and interoperable.

And so, that is one other advantage of having 360X as a base starting point is that it will open up future applications and future uses of automated workflow based on other technology. And finally, my final point is that when you talk about closed-loop referral and continuation of care, a lot of the work that needs to be done in order to automate these processes is within the applications themselves, within the endpoint. And so, again, 360X is trying to guide these implementations to what is absolutely necessary to be there in order to be able to take advantage of automated closed-loop referral management. And that base, once created and expanded and being available, again will continue to be useful in the future with new technologies, with new applications if you want—if you wish, towards the goal of getting both the provider and the patient in a better place when it comes to the care, and continuation, and the ubiquity of information for their care.

#### Kensaku Kawamoto – University of Utah – Co-Chair

Okay. I see Les' hand up and I think, Steven, you wanted your consensus statement on Direct functionality available. Maybe if you can upload that. And Les – maybe we can take a quick comment from Les. And then Steven has some things he wants to lead our discussion through.

#### Leslie Lenert – Medical University of South Carolina – Task Force Member

My comment is this: it's only so many types of communication that can deal with variable latency on both sides of a communications process – push, wait, process, maybe return later – without confirmation of receipt of the message or of the action within a realistic timeframe. Pushing the Direct protocol so that – without regard to the issues in latency that are inherent in it is a mistake. And that we really – it cannot do everything. And that we need to move beyond this protocol to something that really understands the issues of latency in communication and makes this more of a live, interactive process.

#### Steven Lane – Sutter Health – Co-Chair

Thanks, Les. That's a really, I think, important observation. Sasha earlier made the comment that it would be helpful to know what the gaps are with regard to Direct and how it has been implemented, and how it is being used, and how those gaps should be prioritized for solving on the part of the vendors and the users of Direct. It just so happens that Holly Miller and I led a group that did exactly that work. And this was presented at the ONC. The ONC had a couple of meetings focusing on Direct interoperability. So, we will post this document, I think, to the website if we can. At the very least, we can put it up in the share drive.

But this is exactly what Sasha was identifying as a need. I mean, again, it was developed by a bunch of clinicians, so it may not completely – you know, it was specifically meant to identify challenges from the clinician's perspective as opposed to the patient's or other stakeholders'. But I think it goes a long way in doing what Sasha was suggesting that we do. I just wanted to bring this to people's attention.

#### <u>Clement McDonald – National Library of Medicine – Task Force Member</u>

This is Clem. I'm not at a terminal, so I can't put my hand up. But let me know when I can ask or when I can comment.

#### <u>Steven Lane – Sutter Health – Co-Chair</u>

Go ahead. Go ahead, Clem.

#### Clement McDonald – National Library of Medicine – Task Force Member

Okay. Well, you know, this discussion of Direct and the latency and all, I think we need to separate. The biggest demand – at least I felt when I was in practice – is to get stuff that has gotten done at another site when it got done. And for that, push is the very best mechanism. Now, that doesn't take away from the fact that if you are really doing a dialogue that you need something else. But man, if everything could get pushed to you – all the results. And especially when they're updated and all that stuff, there's no better way than push. So, I'd like to at least keep that in mind when people are thinking about Direct.

#### Cynthia Fisher – WaterRev, LLC – Task Force Member

This is Cynthia. May I weigh in as well?

#### Steven Lane – Sutter Health – Co-Chair

Please do. We've been waiting for you.

#### Cynthia Fisher – WaterRev, LLC – Task Force Member

I concur with that, and I support the need for push. And that makes it much more real-time to the patient.

#### Kensaku Kawamoto – University of Utah – Co-Chair

Thanks, Cynthia. We see Sasha's hand up.

#### Sasha TerMaat – EPIC – Task Force Member

This is Sasha. So, I was thinking of some of the work that's been done. And I'm glad, Steven, that you brought up the consensus statement that was put together. I think that could be a really valuable source. Are there – like, should we agree as a group to pick the top priorities from that document, review them, and then focus on our recommendations around those? Do we need to incorporate some patient-centered priorities into the same topic? I guess I'm kind of envisioning in my head a chart that says our -- we've identified as the priorities since, of course, identifying priorities for work is kind of our thing in our name.

If our priorities are for these three things and then sort of the corresponding recommendations related to those – and I feel like as we have this conversation, I'm still not clear in my head what the three sort of priorities we are identifying related to this are. We've learned a lot about various standards. We haven't really sort of come to consensus on – I guess aside from today's conversation about context – exactly what the priorities we're making recommendations about are.

#### Kensaku Kawamoto – University of Utah – Co-Chair

I think that's a great focus for the next steps, right? Let's look at where those gaps are and prioritize them. I think maybe right after David's comments, Steven has another document he's ready to – he has as well. It's sort of walking through the steps and the functionality of the referral process. And maybe, Steven, along with this paper, we can use that as a framework to identify where we see the biggest gaps and what we want to recommend to

address them. David, do you want to comment? And then maybe we can move on to that approach.

#### David McCallie – Cerner – ISP Task Force Member

Sure. I think – so, one thing we've got on the table is kind of how far you can push Direct in terms of increasing the breadth of the content that gets communicated and the degree to which that content can be automatically processed. That's kind of one topic. I think an important one that we haven't talked much about – and I'll just raise it so we track it – is what about secure messaging to patients? From the very beginning, Direct wrestled with how to get patients on the network or not. And we haven't touched on that one. I think that's still an open and important question.

And then the third one – which I suspect we won't talk about at all, but I'll just register it again – is in much the same way that text messaging has replaced much of email, secure text messaging in care settings is on the rise. And I think it's an open question as to whether Direct could be or should be extended to cover interoperability around secure text messaging, given the importance that it plays in many of our institutions. So, those are three broad topics I think quite related to the Direct question.

#### [Crosstalk]

#### Kensaku Kawamoto – University of Utah – Co-Chair

Go ahead.

#### Steven Lane – Sutter Health – Co-Chair

Yeah. Actually, Ken, I think rather than going to the process flow document – let's get that ready if we wanted. But I think, given that our time is short, I wanted to raise one other question. And I hope that Ricky is fully with us. After our last meeting, Ricky and others engaged in an email dialogue about the fact that of course Direct is one protocol for messaging, as we've heard, built on email standards, built on kind of things that we all know about. But as we're all aware, the technology around us is constantly evolving. And we talk regularly about the evolving functionality and potential use of FHIR. And one of the things that FHIR promises to do or aspires to do is also to support messaging in some ways similar to and in some ways different from what is being supported by Direct.

And Ricky and others have recommended that we educate ourselves additionally about the capabilities of FHIR in this regard. Again, thinking again about this domain of referrals, closed-loop referrals, and care coordination. Clearly, as we've heard, messaging is a key piece of this. And I think we want to understand what the available standards to support that are. So, we've actually reached out to some members of the FHIR community to try to bring – kind of in the same way that Dr. Maas brought us really the big picture regarding Direct and as we heard about from the leaders of the 360X effort, we're attempting to bring people who are real domain experts in FHIR to help us understand what its capabilities in this regard are as we're looking at the different standards that are available to support this use.

So, we haven't nailed that down yet. We've reached out to Graham Grieve whose timing in so far as he lives in Australia, is not great for presenting to this group. As he said, this is 2:00 in the morning for him. But we're working on that. Ricky, I don't know if you want to comment on that or flesh out anything from that discussion?

#### <u>Ricky Bloomfield – Apple – Task Force Member</u>

I think that's a good overview. And I think it – at this point, there are a couple of things I'm thinking of. Number one, we do want to certainly get the perspective of the experts. I think Graham would be good. If he can't participate due to timing, perhaps we could find another representative. I think the other thing that's relative here will be discussion of push. And this came up earlier in our conversation here. And I know there's general interest in exploring the FHIR subscription resource and push as it relates to clinical health data. But once that basic infrastructure is built out within the FHIR community and the FHIR endpoint, that could also be repurposed for the purposes of messaging. Whether it's indirect consumer messaging or a more technical definition of messaging that Isaac better discussed at AMIA last week, which is – I'm not going to get into it here.

But there is the idea of using FHIR for other kind of backend type of messaging. But in this case, I think we'd be talking about the consumer patient messaging, closed-loop referrals, and things like that which you already mentioned. So, I think that the FHIR subscription resource is relevant here. And I think also in getting more information on how FHIR might be used for this type of messaging. So, I think you described it well.

#### Steven Lane – Sutter Health – Co-Chair

Thanks, Ricky. So, I think rather than go to the process flow diagram – which again, we have posted and is available for people to review – I think what I'd like to do is perhaps plan to assign as homework a review by task force members of both the process flow diagram and this consensus statement document. But what I'm hearing is that we are interested in supporting a number of uses, again, of Health IT. This was our charge. And that we talked about closed-loop referrals as a key use. We've talked about real-time messaging sensitive to latency issues between members of the clinical care team. We've talked now about a secure messaging with patients as an important use. And then what was raised was secure text messaging. So, sort of hyper real-time, if you will. Even more real-time than the email protocol that we've been discussing.

Those seem to be large areas that clearly support care coordination as we've identified it as a domain. And it sounds like there are kind of competing standards that are still duking it out a little bit in the marketplace, both of products and ideas. And I don't have the feeling that this area is sufficiently mature that our task force could "pick a winner" or even necessarily define how far one would go say with Direct versus FHIR, et cetera. But I think that we can identify that there are these key functionalities that we believe need to be supported. There are perhaps competing or complementary standards that will do that. I think there's a lot that we can say about the content that needs to be moved to support referrals and care coordination, including message context as we was discussing. And there's probably a lot that can be said about governments and what the expectations are around how this will be managed.

So, there are additional pieces of this discussion. We don't want to, I think, spend more time in this priority use of Health IT than is necessary. But I think there's still a lot here to unpack. So, as I said, we're looking to have a deeper discussion about FHIR. We've also reached out to a number of folks to have a deeper discussion about the content in particular that is needed to really support efficient referrals. That is to say an area that we discussed last time of what would be expected by a consultant for them to be able to efficiently manage a referral of a patient for a given condition. And we've reached out to the AMA and others to try to see if there are evolving standards or standards that we can support the evolution of in those areas. Those are all things that we're thinking of bringing back to this group over the next one or two additional sessions that we're going to work on this domain. And I'm interested in people's feedback regarding that approach as we plan for the future work.

#### Kensaku Kawamoto – University of Utah – Co-Chair

This is Ken. I'll add my two cents. I agree with Steven's assessment that there is still more work that needs to be done in this area. I'll just put in my straw man recommendation in this area. What I think – at this point, what I personally think might be relevant is to identify the probably two tiers of functionality that we want in the space. Let's just say basic referrals and another where there is more structured data that has been identified as needing to be sent for certain referrals and our responses back. Basically, define those functional requirements and identify where there tend to be gaps right now in how those referrals work with the current proposed process and at this point, recommend that more work be done using the Direct-based approaches and also potentially to explore the more API-based approaches. I don't think I've heard anybody basically say, "We've figured the space out, and all we need to do is to promote that approach." I think some of this is getting pretty close to being able to say, "Hey, if we do the pilots and everything looks great, then maybe we can support it." But it just doesn't seem like it's something that's going to happen in the next month.

#### <u>Steven Lane – Sutter Health – Co-Chair</u>

And with that, why don't we transition to public comment? I know there are a number of members of the public that have been listening in with us today. Lauren, do you want to take us through that?

#### <u>Lauren Richie – Office of the National Coordinator for Health Information Technology -</u> <u>Designated Federal Officer</u>

Sure. Hello? Operator, can you please open the public line for comment?

#### **Operator**

Certainly. If you would like to make a public comment, please press \*1 on your telephone keypad. A confirmation tone will indicate your line is in the queue and you may press \*2 if you'd like to remove your comment from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the \* key. Again, that is \*1 if you would like to make a comment at this time.

#### <u>Lauren Richie – Office of the National Coordinator for Health Information Technology -</u> <u>Designated Federal Officer</u>

Thank you. And let me just circle back. Is there anyone that didn't announce themselves on roll call at the top of the call? I know Arien, and Ricky, and a few others joined throughout. Do we have Andy, or Jack, Ram, Scott, Cheryl, Tina, or Victor? Okay. Hearing none, let me just check back. Operator, any public comments in the queue?

#### **Operator**

None at this time.

#### <u>Lauren Richie – Office of the National Coordinator for Health Information Technology -</u> <u>Designated Federal Officer</u>

Okay. We will close public comment, and I will turn it back over to Steven and Ken.

#### <u>Steven Lane – Sutter Health – Co-Chair</u>

Great. Thank you so much, Lauren. I do see, David, that you have your hand back up.

#### David McCallie – Cerner – ISP Task Force Member

Yeah. I just wanted to echo what – I forget which of you two said it just a minute ago, that we should not be tempted too much by the lure of new technologies when, in fact, the really hard problem in this space is governance. You know, we had the code for Direct written long before we figured out how to actually get directory structures in place, and agreement on which kinds of certificates we would trust, and organizations – I mean governance around the decisions around how to extend it. Governance is always much harder. So, just swapping out for a new protocol is tempting because you think it's going to solve a lot of problems. But you still have to figure out governance. So, we should really take that in mind if we make any dramatic recommendations for change. You've got to account for all that governance overhead.

#### Steven Lane – Sutter Health – Co-Chair

Well, and that's a really good point, David, and I think perhaps another area where we may want to consider making a suggestion. I mean, where does the governance for this live? And obviously this – there are a lot of different pieces of this. You know, we've talked about referrals. We've talked about messaging between care team members with patients, texting. But we anticipate a work being done on a trusted exchange framework and common agreement for the country. Is that where governance of these things might reside, or is this something that we are going to expect from the community?

#### David McCallie – Cerner – ISP Task Force Member

Yes. I mean, my thought is that clearly, ONC's vision for the single on-ramp, as they described it in the TEFCA draft one, would in fact encompass some of those things. And I think that makes sense. But I would say that's still a long ways down the road. In the meantime, we have entities that have sprung up to address the governance concerns of some of these various approaches like Direct Trust around Direct and CommonWell and Carequality around distributing query. So, those entities would still, I think, continue to be operative. But creating something brand new to deal with – you know, a new protocol that didn't fit into one of those other groups, it's a lot of work. It takes a lot of time. And it's usually much harder than the technology part.

#### Steven Lane – Sutter Health – Co-Chair

Thank you. I wanted to point out again this document that we prepared, and did a little bit of iteration on, and have posted it on the share drive. And I want to invite task force members to go through and review this. And what I think we can do, Lauren, I believe is to make this available for comments but not editing. That is a technical capability, isn't it?

#### <u>Lauren Richie – Office of the National Coordinator for Health Information Technology -</u> <u>Designated Federal Officer</u>

Yes. For the task force members, you mean?

<u> Steven Lane – Sutter Health – Co-Chair</u>

Right.

#### <u>Lauren Richie – Office of the National Coordinator for Health Information Technology -</u> <u>Designated Federal Officer</u>

Correct.

#### Steven Lane – Sutter Health – Co-Chair

So, I think it would be helpful if we do that, if we make this available with comment opportunities for all the task force members to look at over the next week or so. And as we said also, that consensus document. I want to say that Terry, as a part of the leadership here and as a co-chair of the USCDI task force, and Ken, and I have been trying to put our heads together and figure out how to move from this broad discussion into what might be a framework for some recommendations. And again, as we mentioned, we've thought about parsing this out as looking at recommendations around the functionality itself, the content of these messages that are moving, the exchange standards, and the governance. It sort of seems like there's this natural breakdown into those four dimensions of this work.

So, we're going to continue to work on that and try to put that together into a draft framework to bring back to this group. As we said, we've also reached out to folks to take a deeper dive into the FHIR standard as a complement to the Direct standard, as an exchange standard for some of these transactions. And then we've also reached out to, as I said, the AMA and other to talk about one of the content pieces related to the referrals. So, I think that – I anticipate that our next meeting will be some combination of discussing FHIR standards, discussing content standards supporting referrals, and discussing this framework for putting together our recommendations. But I do hope that when we come back, we will all have had a chance to comment on the process flow.

You know, what are the key pieces there from different perspectives – clinicians, patients, et cetera? What have we perhaps missed in the flow? And then also, a little bit about the prioritization that has been identified for additional usability of Direct. And here, again, I do hope that those who are representing the patient's individual perspective have a chance to think about that. Because again, that document that was prepared is really primarily focused

on the use of Direct between clinicians. Ken, do you want to add to that as we approach our time here?

#### Kensaku Kawamoto – University of Utah – Co-Chair

No. I think this is a pretty complicated topic. But I think hopefully we'll get some concrete recommendations pretty soon.

#### Steven Lane – Sutter Health – Co-Chair

Anyone else in the last couple of minutes remaining? Any ideas about kind of the direction we're going with this? Any thumbs up?

#### Male Speaker

Are you going to make sure we have links to the appropriate file share and send it out to us?

## <u>Steven Lane – Sutter Health – Co-Chair</u>

Yeah. Lauren, your team will take care of that?

#### <u>Lauren Richie – Office of the National Coordinator for Health Information Technology -</u> <u>Designated Federal Officer</u>

Yep. We'll definitely follow up shortly after the call.

#### Male Speaker

Thanks

#### Steven Lane – Sutter Health – Co-Chair

Great. Well, thank you all. And thank you, Luis, if you're still with us, really. And Holly and Viseal, we really appreciate the subject matter expertise that all of you are bringing to these discussions. And we're going to try to do our work as a group and turn this into some meaningful and hopefully useful recommendations.

#### Kensaku Kawamoto – University of Utah – Co-Chair

Thanks, bye.

#### **Duration: 87 minutes**