HTI-1 PROPOSED RULE TASK FORCE 2023 MEETING

June 6, 2023 10:30 AM – 12 PM ET

VIRTUAL

Speakers

Name	Organization	Role
Steven Eichner	**Texas Department of State Health Services**	**Co-Chair**
Steven Lane	**Health Gorilla**	**Co-Chair**
Medell Briggs-Malonson	UCLA Health	Member
Hans Buitendijk	Oracle Health	Member
Hannah Galvin	Cambridge Health Alliance	Member
Rajesh Godavarthi	MCG Health, part of the Hearst Health network	Member
Adi V. Gundlapalli	Centers for Disease Control and Prevention	Member
Jim Jirjis	HCA Healthcare	Member
Hung S. Luu	Children's Health	Member
Anna McCollister	Individual	Member
Clem McDonald	National Library of Medicine	Member
Deven McGraw	Invitae Corporation	Member
Aaron Miri	Baptist Health	Member
Eliel Oliveira	Dell Medical School, University of Texas at Austin	Member
Kikelomo Adedayo Oshunkentan	Pegasystems	Member
Naresh Sundar Rajan	CyncHealth	Member
Fillipe Southerland	Yardi Systems, Inc.	Member
Sheryl Turney	Elevance Health	Member
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Daniel Healy	Office of the National Coordinator for Health Information Technology	ONC Program Lead
Sara McGhee	Office of the National Coordinator for Health Information Technology	ONC Program Lead
Dustin Charles	Office of the National Coordinator for Health Information Technology	ONC Program Co-Lead
Michael Wittie	Office of the National Coordinator for Health Information Technology	ONC Program Co-Lead
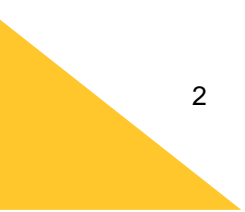
Call to Order/Roll Call (00:00:00)

Michael Berry
Good morning, everyone, and welcome to the HTI-1 Proposed Rule Task Force meeting. I am Mike Berry with ONC, and I would like to thank you for joining us today. On behalf of ONC, I would like to thank the cochairs and Task Force members for your dedicated work over the past six weeks. Today's meeting is of the full Task Force, but the focus will be primarily on Group 1 recommendations. When developing your final recommendations, I encourage you to consider how they will move the needle forward for the healthcare industry and how patients will benefit, even if they are difficult to implement. We only have a limited time to spend on each topic area so that we complete Group 1 recommendations today. All of our Task Force meetings are open to the public, and your feedback is always welcomed, which can be typed in the Zoom chat feature throughout the meeting or can be made verbally during the public comment period that is scheduled toward the end of the meeting. I would like to begin rollcall of our Task Force members, so when I call your name, please indicate if you are here. I will start with our cochairs. Steven Lane?

Steven Lane
Good morning. Welcome, everyone.

Michael Berry
Steve Eichner?

Steven Eichner
Good morning, all.

Michael Berry
Medell Briggs-Malonson? Hans Buitendijk?

Hans Buitendijk
Good morning.

Michael Berry
Hannah Galvin? Adi Gundlapalli?

Adi Gundlapalli
Present.

Michael Berry
Jim Jirjis? Hung Luu?

Hung S. Luu
Good morning.

Michael Berry
Anna McCollister?

Anna McCollister
Good morning.

Michael Berry
Clem McDonald? Deven McGraw?

Deven McGraw
Good morning.

Michael Berry
Aaron Miri?

Aaron Miri
Good morning.

Michael Berry
Eliel Oliveira? Kikelomo Oshunkentan? Naresh Sundar Rajan is unable to join us today. Fil Southerland?

Fillipe Southerland
Good morning.

Michael Berry
Sheryl Turney is also on vacation, so she will not be able to join us. Thank you, everyone, and now, please join me in welcoming Steven Lane and Steve Eichner for their opening remarks.

HTI-1 Proposed Rule Task Force Charge (00:02:03)

Steven Lane
Thank you, everyone, for showing up today. We really appreciate it. We are in the final push to get over the finish line. As Mike said, we do not have time to dilly-dally and get too deep into implementation challenges and whatnot. Our goal here really is to make meaningful recommendations to move the ball forward on nationwide interoperability, and I know that we are going to do that. We actually did a lot of the work on our Group 1 recommendations last time, with plenty of do over the next 86 minutes. We are really excited that we have members of the public joining us today, a top group of folks, many of whom have been here for most, if not all, of our meetings. Thank you all for your participation. As always, do take advantage of the public chat during the course of the meeting, and please be ready to join us in public comment at 10 minutes before noon Eastern Time. Ike, do you want to add to that?

Steven Eichner
No, I just want to appreciate the work of all Task Force members up until this point, and I am excited to be heading towards the home stretch.

Steven Lane
So, we are going to zoom through our formalities here. This is our agenda, focusing on our recommendations. Next slide. I think we still have the slides for our charges, which are here. These are the same slides you have seen before; we will not belabor them. On the next slide, I think there are highlights.

No? Well, we had a slide about what we were responsible for in Group 1, but that is okay. It will become immediately clear. So, let's hop over to the spreadsheet. We want to be on Tab 1, and we completed Row 2 and turned it green, so we are not going to belabor or revisit it. The same is true with Row 3, so we are going to come down to Row 4, and Deven made some very specific recommendations. Ike, can I count on you to monitor the chat?

Steven Eichner
Absolutely.

Steven Lane
Okay, great, chat and hands. You do that, and I will be flying along in the spreadsheet.

Steven Eichner
As always.

Update and Revise Draft Recommendations (00:04:27)

Steven Lane
So, in Row 4, Tab 1, we had drafted some recommendations, and I took to heart Deven's recommendation to make it more clear that we really have two layers of recommendation, one recommendation that really points ONC in a new direction, and a second recommendation that says, "But if you do not listen to us, we would like you to at least do this." So, the first of those recommendations is "We recommend that, in lieu of the manner proposal as presented, ONC work with OIG to establish a general safe harbor for TEFCA participation," and it goes on to include a lot of detail, which I am sure you can all read. On the display, why don't you guys zoom in a bit so that that fills much of the screen? I would zoom in even one more level. I want to make sure everybody can see this. Aaron, thank you for joining us today. I know you have been a very busy beaver down there in Florida. Obviously, we look to you to help provide any guidance from a HITAC leadership perspective on how best to craft these sorts of recommendations.

This one in particular is a little unusual in that we rarely say, "No, you guys really got it wrong, you should really go in this other direction," but I think the ONC can take that into consideration. The point here, Aaron, since you missed a lot of the discussion, is that a number of us, perhaps all of us, really felt that the way that the manner proposal was constructed really ran the risk of disincentivizing TEFCA participation by essentially making it such that those who chose to engage in TEFCA exchange would have a real potential downside when it came to the manner proposal and the inability to defend their desire to use alternative manners, but more importantly, we felt that it saddled people with the requirement to utilize SOPs and purposes of use that had not been fully defined, so that was one thing, and the other is it excused them from the fees exception and the licensing exception in a way that, again, we thought would put people off, frankly.

So, again, the first proposal is another way of crafting a supportive encouragement and incentive for the use of TEFCA that we thought would be appealing to users and participants who might be standing on the sidelines, making their decisions, but again, if they did not want to throw the bathwater out entirely, we thought that there were ways to limit the scope of the manner proposal and present it. So, we worked through this at some length last week, and Deven made good on her promise to point us in a slightly different

direction, and Deven, I would like to hear how you feel about the red font text I popped in there. Do you think I did the job?

Deven McGraw
Yes, absolutely. Thank you.

Steven Lane
Terrific. Does anyone have any concerns about this? Oh my God, I love it when you talk like that. So, why don't we turn the screen, if that works for everybody? Any concerns about that? Going once, going twice… Aaron, do you feel like we are on relatively solid ground?

Aaron Miri
Yes, it makes sense to me, Steve, and I do think there needs to be some discussion about reconciling this at the full HITAC, but I think it is a good proposal.

Steven Lane
Great, excellent. All right, thank you. As you can see in Row 5, which was the item where they said, "Are there any other TEFCA reasonable and necessary activities that we should be thinking about?", they did not make any specific proposals, and I did not come up with any. I happen to work with an organization that is looking at this from a QHIN perspective, and they did not come up with any. We have not heard any proposed here, so I think we will leave this one blank, or we could add some text that just says that we looked at it and could not think of anything, which seems kind of silly, so I would just leave it blank. Does anyone object to that? Hans, you have obviously been close to Commonwell.

Hans Buitendijk
I think the second one is fine. I have been fairly quiet, but the first one is one that can go both ways, so I am curious how it is going to fall out because TEFCA has advantages where everybody does it the same way and helps reduce cost. At the same point in time, I understand the concern that Deven raises, and I do not have an alternative to the proposal, but I am not sure that this is the one that really balances the interests sufficiently. I have no real clear alternative because this really depends on which side of the equation we sit.

Steven Lane
Thanks, Hans. I had actually moved onto Row 5, the question, but it is all good.

Hans Buitendijk
I was still wrapped around.

Steven Lane
That is because somebody is in the field. In fact, whoever is in there… Oh, Anna, you are in there. Could all of you please get out of the fields in Column J? I would like to be able to make edits. If you are in there before me… It looks like Dan is in there. Anyway, stay out of Column J, if you can, for participants. Anyway, my question, Hans, had to do with Row 5. Are there any additional TEFCA reasonable and necessary activities? We have not really come up with any. Okay, we will leave that. We went through Row 6, and Aaron, this will be of interest to you. There were a number of things that started as recommendations that

we thought were valid to send to HITAC, but they were really outside the scope of the Task Force. You are familiar with this concept. The great catcher's mitt for those is the Annual Report Workgroup, so we have one here that we are going to be handing off to them. So, we finalized that one, and we also finalized Row 7. Deven, again, thank you very much.

Aaron Miri
Sorry, one second, Steven. I was just reading that quickly. Why is this going to the AR WG, and not the main HITAC?

Steven Lane
Well, because it is not really a recommendation about what is in HTI-1. Our review of HTI-1 led to a sidetracked discussion, and our feedback related to it really is not feedback about HTI-1, it is something else that we think ONC should be considering, so the ONC team guided us, as they have in the past, to figure out some other way to route those, and now that the Annual Report Workgroup has a nice, mature process of catching things working them up, and then transmitting them with the annual report, we felt that was the place to put it.

Aaron Miri
Got it. At the Annual Report Workgroup meeting, we may need to talk about this to make sure we bubble up to our Annual Report Workgroup update at the HITAC so that everybody has clarity that this was bubbled up from this workgroup to that one, just so everybody is aware of this.

Steven Lane
Oh, I like that.

Aaron Miri
So, I like the process, I just want to make sure everybody is aware.

Steven Lane
Please, take it and run with it. There are a couple more, as you will see.

Steven Eichner
From a functional standpoint, I would think it is the workgroup recommending to HITAC that HITAC refer the topic to the Annual Report.

Aaron Miri
You read my mind. That is exactly how I was thinking of it too.

Steven Lane
Perfect, all right. So, for Row 7, which is the item regarding manner exception exhausted, Deven made her additional input in the Google doc. There you are. Let's just blow it up a little bit so that people can read it. I think what we are interested in is the longer entry. The edits above are really just wordsmithing, which I really appreciate, Deven, but we are down on Page 6 of 9, top of Page 6, the rationale. That was it right there. Just blow that up so people can read it. I will read it, as it is short enough. "ONC should be careful

that these provisions are not interpreted to allow actors covered by the information-blocking rules remain…"
"To remain," right, Deven?

Deven McGraw
Yes.

Steven Lane
"…to allow actors to remain in their current historical exchange patterns," that word that we captured here, "and practices, as the information-blocking rules were intended to expand interoperability across a range of requesters and use cases." So, just that caution that we do not make it easy for people to be stuck in their old ways.

Deven McGraw
Yes. We had the recommendation already, but I thought it would be important to layer in a rationale here to provide some context that would help explain why we made the recommendation we did.

Steven Lane
We have excellent precedent for including rationales behind our recommendations. We are keeping them brief. None of these are going on for pages and pages, as we have tried to do in the past with some other recommendations. Anyway, while we are here, any thoughts on that?

Steven Eichner
This is Steve Eichner. I have a quick question. There may be some circumstances where an actor may not need to change their behavior unless they are asked to, if that makes sense. So, just thinking about language in there, just acknowledging that as well.

Deven McGraw
Well, keep in mind that information blocking is a facts-and-circumstances test. In some circumstances, it may be completely reasonable, or there may be an applicable exception associated with not responding to a particular request, but I just worried that the… Again, ONC's language could be read in a way to kind of ossify current exchange patterns. What does it mean to be similarly situated? Well, I have only been historically responding to treatment requests, so for me, "similarly situated" means another treating provider for treatment requests, and everything else is… I do not necessarily have to get out of the pattern that I have been in, and the whole recommendation is aimed at making sure that as ONC continues to put out guidance and lay out additional circumstances and fact patterns that they be mindful of not having "similarly situated" be defined in a way that allows people to ossify existing patterns that are not necessarily reasonable. I am happy to add more language, but I am just trying to avoid us going into a rabbit hole. Yes, sometimes it might be completely acceptable. It is a facts-and-circumstances rule.

Steven Eichner
The language you just suggested might be a helpful little addition because again, either way, I do not want to force entities into sharing in two different ways just because the rule says they have to. If there is no demand for information sharing, there is no demand.

Deven McGraw
Oh, in terms that it is based on a response to a request? I am happy to work that in.

Steven Eichner
Right, yes.

Steven Lane
Great. We do not want to spend too much time on that level of wordsmithing, but definitely, if you understand Ike's concern and want to suggest a couple words, I will give you the field.

Deven McGraw
Got it.

Steven Lane
Play on that field as long as you want. So, that was manner exception exhausted, which brings us to Row 8, which is our work for the day, and I am glad to say we have an hour to do this. You will recall that we made it almost halfway through this field. At the end of our work last week, there was one that we thought both belonged here and warranted referral to the Annual Report Workgroup, so, Aaron, maybe you can look through that one with the red text under it and think about it, and we can come back to that, but we have managed those first four recommendations, and we wanted to move on to the last four recommendations. Hans, as I recall, you were going to give some particular thought to some of these. Did that happen?

Hans Buitendijk
Not totally. I will have that later today.

Steven Lane
Okay. We will do our best with that. You do that, but let's see what we can accomplish here, okay? So, this is a set of recommendations, and I am glad Hannah is here in particular because of her interest in this area of consent and privacy and how we can best respect patients' wishes in a complex world where the recipients of those requests for restrictions are not beholden to respect them, and yet, the patient wanted a restriction, and sometimes they did not get it when they first put it in. And then, of course, the issue of whole different types of restrictions, some driven by federal law, some driven by state law, some driven by patient requests, some driven by provide perception related to exceptions under the information-blocking rules, so there are a lot of exceptions out there, and I think we do a pretty lousy job as an industry in respecting patients' and providers' wishes, etc., so these recommendations as crafted are my personal feeling about how we can raise the bar, so I want to go through them one by one and see what you guys think about them.

The first one was actually not my idea, but came out of some work that was funded by ONC under the LEAP grant by Mohammad Jafari, who I do not think is with us today. Mohammad, are you out there as a member of the public? No? Okay, that is too bad. We had hoped Mohammad would join us today, but be that as it may, Mohammad did a whole study. I did not personally read it, but my understanding of it is that it goes like this. "Recommend that ONC support further development and pilots of a patient-centric 'hub-and-spoke' model of capturing, storing, updating, and exchanging individuals' restrictions in a centralized,

patient-selected application, allowing other health IT systems to access and utilize a single source of truth regarding patient-requested restrictions." Actually, it is not just patient-requested… No, I guess it is just patient-requested, but it could be extended to include other sorts of restrictions, but most of those should be evident to users. Thoughts on that recommendation? Do you like it or hate it? Do you want to change it or turn it green?

Hans Buitendijk
I am green on that one.

Steven Lane
It is really just saying, "Keep looking into this. You did good work."

Hans Buitendijk
It is critical to move forward with that and explore it further.

Deven McGraw
I have doubts it works, but there is no reason not to keep trying.

Steven Eichner
Steven, this also relates to a recommendation in Group 2 regarding patient privacy recommendations.

Steven Lane
Yes, no question. There is definitely some overlap, or at least juxtaposition, between some of the Group 1 items and the Group 2 items, so we will come back to this.

Steven Eichner
Right. I am just bringing that to folks' awareness if they were not familiar with both sets.

Hannah Galvin
This is Hannah. Can you hear me now?

Steven Lane
Yes.

Hannah Galvin
Okay, great. Yes, I support this. I think that there are a number of different business models toward this out there. There are some that are commercializing this, and then there are some that are looking at an open-source model for this, and I would personally encourage an open-source model to this in order to promote equity by design and not limit the access to such an **[inaudible] [00:23:13]** application to only those who can afford it or health systems that can afford it, but I think we are not quite there yet, and I think at this point, just supporting the program pilots and providing further grants to develop this type of model is a fair recommendation, but I would just point out that in lieu of federal funding toward this, the only way that something like this would exist is in small, commercialized companies that could fund such a thing, and that we risk disparities in access if we go down that route.

Steven Lane
Those are really good points.

Steven Eichner
Hans?

Hans Buitendijk
I agree that having encouragement for certain open-source components can help. If we put that in there, I would be concerned if that would be phrased as the only way that can be achieved, as there are aspects of the infrastructure that one should be able to provide those capabilities more tightly related to the software that they provide to actually make it fit in the environment. So, there are elements that can benefit from open-source, and there are elements where open-source is fine, but should not be exclusively used. So, I think it is a good suggestion to include it as a component of, but not an exclusive way of doing it.

Steven Lane
Actually, I do not think we even need the suggestion. I think we should keep this really simple and noncontroversial. Just support more work on this, and I think the rest of that will fall out in time.

Hans Buitendijk
That is fine.

Steven Lane
Ike, did you have something else to say about that?

Steven Eichner
Real fast, a little bit of wordsmithing. It is really the data that should be centralized, not the application. So, it is a centralized resource of preferences that is accessible by providers, and there may be multiple ways of updating those preferences.

Steven Lane
How about I say "individuals, restrictions, and data-sharing preferences." Would you like that?

Steven Eichner
"Restrictions in a centralized database using patient-selected applications."

Steven Lane
Good. All right, we are going to move on because we still have a lot to do, I swear. It does not look long, but it is. I have separated the next one out visually. "Recommend that ONC require certified health IT to manage and respect patient restrictions, insofar as possible, as data is exchanged via messages, including HL7 V.2 and possibility NCPDP, in addition to documents, such as HL7 CDA, and RESTful APIs, such as HL7 FHIR." Hans, this was your recommendation. I think it is a good one, and I think it is pretty clean. Does anybody have any concerns about this?

Hans Buitendijk
I would just say that with this one and the next one, this is somewhere between Group 1 and Group 2.

Steven Lane
Yes.

Hans Buitendijk
I think this is good, but it has dependency on other things that need to happen first before you can require that, and that sits in Cell K next to it, where to do this, we need to have agreement on what is that key starter set of flags or otherwise that we agree to that are particularly the sensitivity flags, to some extent, confidentiality flags, and what they are that we talked with Mohammad about. We need to bring that together because otherwise, if this is read on its own here only, not in the context of the other part, this might jump the gun and start to require data segmentation as you wish to be included, and that is not going to work. So, this is important to be done, but based on an agreed-to implementation guide set of flags that can start to be shared. Otherwise, it would not work.

Steven Lane
So, to be clear, this is a response to the RFI. This is not a response to the draft rule. So, we were asked to provide input regarding IT capabilities for data segmentations and user patient access, so that is why it is here and not in Tab 2, where it is a response to the specifics of the NPRM.

Hans Buitendijk
In this case, I would then suggest that we add to it, not subtract, that once guidance is available. In response to the RFI, we need to get to that requirement, but once that is available, that guidance, because if there is no guidance, then that will not work. In the other part, we can flesh that out.

Hannah Galvin
I agree with Hans that any of this needs to be in a maturity model and a stepwise approach, and there are some dependencies that include a semantic conceptual model. I do not think that we need the entire semantic conceptual model in order to move forward. I think we can do that based on one or two use cases, and then have some required certifications based on those use cases, but I think we do have some dependencies before we can get to certification, the shift comment outline model to get there, and reference also in the RFI some work being done by IHE. There is a draft IHE profile called the Privacy Consent Framework that maybe utilizes a stepwise approach to get where we are going here.

Hans Buitendijk
I completely agree.

Steven Lane
Okay, so I brought over some of your commentary, Hans, from Row K and stuck that in there. Again, I think that is fine. If you want to craft a sentence, Hannah, about maturity models, then we can tag that on there too. Again, I think this is a great opportunity to insert these concepts into the thinking for future rulemaking. Let me know, Hannah, if you want to do that. I am sure we can do that offsite.

Hannah Galvin
Yes, I am happy to.

Steven Lane

Okay. We are going to move down to the next one, which I think was mine. Let me just cordon it off here. Okay, "recommend that ONC require that information regarding restrictions on the access, exchange, and/or use of health information be maintained and exchanged with the restricted information and support the ability of recipients of data for which a restriction has been requested by the patient to honor that request insofar as possible." So, again, this is an RFI response. This is like "In the future, you should really think about this," and the rationale is "Since requested restrictions do not have to be granted, either by the recipient of the request or subsequent recipients of the relevant health information, this gives entities receiving data for which a restriction has been requested an opportunity to review and discuss requested restrictions with the patient representative and to grant or partially grant such restrictions as deemed appropriate, even if the restriction was not granted or respected by the initial recipient of the request." That is a mouthful. What do people think of that one?

Steven Eichner

This is Ike with a friendly amendment. It needs to be reconciled with the hub-and-spoke model in the recommendation above. There should not be a requirement to store it separately and exchange it separately in a manner that is not consistent with the hub-and-spoke model, or whatever it is, if adopted.

Steven Lane

Clearly, there are a number of architectural approaches that could be tried for this.

Steven Eichner

I am not saying it needs to be one particular way, it just needs to be compatible so we are not doing it two different ways simultaneously.

Steven Lane

I kind of feel like that goes without saying. Maybe "require" is the wrong action verb here. "Explore processes that would allow," right?

Hans Buitendijk

Or "identify information."

Deven McGraw

I have some thoughts on this with my hand up.

Steven Lane

Great, sorry. I was not tracking.

Deven McGraw

No worries. I read this to refer to the request for restrictions that does not have to be honored, which would not necessarily have anything to do with a consent registry where those consents are presumably required by law and registered globally, particularly where the law requires downstream users to adhere to it. Steven, I read what you put here as an effort to try to say if a patient restricts in one setting, there is a good chance they might ask for that same request downstream. It is not required to be honored, but it is a nice thing where that gets communicated downstream so there is a conversational opportunity. Right to request

restrictions, except in the case where people have paid out of pocket and they have asked for a restriction to their health plan, are not required to be honored, which is the place we are starting. In addition, I am a little uncomfortable with tying this to a set of pilots around a consent registry, which does not create a requirement to use them at all.

Steven Lane
Good point. So, you are saying let this stand on its own.

Deven McGraw
Yes.

Steven Lane
And you nailed it exactly. My thought is if somebody places a request for restriction in a small setting that does not have good IT, or good HIM practices, or whatever it is, and they just cannot deal with it, that does not change the fact that the patient really wants this data to be restricted, and I do not believe you should allow this unrestricted data to fly freely around the ecosystem. If it still matters to the patient, we should take that into account.

Aaron Miri
I would also add not just consent, but asset. For those who are not of age, but almost there, we need to respect their wishes as well. I do think that we need to be inclusive of the entire continuum of care in this situation, so I think some good points have been raised, but not just consent, but assent.

Steven Lane
So, we have restrictions. "Data for which a restriction has been requested by the patient" is the focus here.

Deven McGraw
Right. This is not a consent recommendation. It is related to the right to request restrictions.

Aaron Miri
That is correct, but even if somebody cannot consent to restrict because they are not the legal guardian, they can assent at that age and still have their wishes respected and acknowledged. That is my point. From a pediatric setting, we have to take that into account.

Deven McGraw
Right. I think if it came from an adolescent, I think it would still be framed as a right to request a restriction as opposed to an assent situation where assent is required, for example.

Aaron Miri
I am just simply saying to take it into account. As long as we incorporate that as part of it, I am good with that, whatever the right language is legally, but the reality is that maybe it is not adhered to by law, but we have to respect that, and it should flow downstream.

Steven Lane

That is actually coming, Aaron. Hold that thought. Let's move this above the line, if no one is really uncomfortable with that, and then let's come back to that as we go through this next one.

Steven Eichner

Hannah, do you still have a question?

Hannah Galvin

I think Deven covered it. I am fine with moving on.

Steven Lane

Great. All right, thank you. Last one, four parts: "Recommend that ONC develop future requirements for certified health IT to support the following use cases to respect patient preferences and comport with applicable law. The metadata regarding these restrictions should be maintained with the restricted data when the restricted data is subsequently released, at least until such time that the user or the individual determines that the exception is no longer appropriate." So, we want to come back to that "at least" question because there are clearly going to be challenges in implementing some of this, but again, this is all request for information, future thinking.

So, the first one is when data flagged as self-pay restricted at one institution is exchanged, a recipient at another institution should receive metadata regarding the restriction and have the opportunity and technical capability to respect the restriction. This one seems really straightforward, it is based on federal law, but I do not think we have the capability today to flag self-pay restricted data as it moves down the line. I do not know why the field is gray. Somebody else must be in there. Oh, Hannah, would you get out? Thank you. Any thoughts on that first one? Self-pay restricted seems straightforward. Is everybody good? I love it.

Deven McGraw

Steven, I put a note in the chat. I will check, but I am pretty sure that the self-pay requirement to respect the wishes of a patient not to send stuff to a payer if they have paid in full has to actually be done at each link in the chain because you cannot assume that the patient does not want to pay for… The way that it is framed today, I think at each provider visit, the patient would need to say, "I am going to pay this out of pocket, please do not send to my insurer," as opposed to the restriction only having to say that once and having it be perpetuated downstream. I am not sure the law requires this, and maybe it should.

Steven Lane

I think most of the things we are about to talk about are not yet required by law.

Steven Eichner

Deven, I would agree with your interpretation. That is my understanding as well.

Steven Lane

Mine as well. Again, this is not like "Well now, I am going to get treated for syphilis again." It is like "I got treated for syphilis four years ago, and now I have changed insurance, and I still do not want my insurance to know I got treated for syphilis four years ago."

Deven McGraw
Right, "And I lost my job, and now I need my insurance to pay for it."

Steven Lane
Right, you can imagine all manner of circumstances, but by sending the fact of that restriction downstream, it gives… I could put in that sentence about giving the opportunity to have a discussion, but just sending it downstream is really what I was after. All right, one down. Three to go. No. 2, "When data flagged as exceptional under the information-blocking rules, such as invoking the harm or privacy exceptions, at one institution is exchanged, a recipient at another institution should receive all available metadata regarding what data was restriction, based on what exception, at what date and time, with any available discrete or free-text explanation of why the exception was invoked, as well as the institution and role of the user placing the restriction. The receiving institution should have the technical capability to review and respect the restrictions as applicable." Thoughts?

Hannah Galvin
My only thought there is infeasibility may still apply here, right?

Steven Lane
Of course, absolutely.

Hannah Galvin
So, all of the exceptions potentially except infeasibility because if the actual data is infeasible, the metadata may also be infeasible.

Steven Lane
Yes, and I intentionally left that as an e.g., though infeasibility is kind of interesting. It is kind of similar to the one above, where it is like I might have placed a restriction at a place that could not manage it because of infeasibility, but then, when that data flows downhill, it would be good to know that. Again, I do not think this would apply to only specific exceptions, I am just saying if it was exceptional under information-blocking rules, the subsequent recipient of that data should know as much about it as the system can send. Again, this is future thinking. This is not like we are going to require this tomorrow.

Steven Eichner
I have a quick interruption for a moment. Can we scroll up a little bit on the screen? The recommendation is a little bit low.

Steven Lane
Maybe we just need to make the column a little wider. There we go.

Steven Eichner
Thank you.

Aaron Miri
Steven, this is Aaron. Could I just talk through it out loud so I understand correctly? So, I like the idea that assuming I am exchanging information with you, I am the one who holds it back because of a delay of

potential patient harm, and you see that Aaron delayed results, should you be able to challenge that, or just simply be able to read the metadata? Should you be able to ping me and say, "Dude, why did you hold this back?", or is it just simply that I should be able to see that and all the information appropriate in metadata?

Steven Lane
I am in the latter camp. Just send the data downstream. I think it is premature to say what all the workflows might be, and similar to the point that Deven made earlier, there is no requirement to respect this when you are a downstream recipient of the data, but damn, it is important to know it. With privacy in particular, this really overlaps with all the patient requests for restriction. There are some privacy exceptions which really are a patient request for restriction. There is an overlap there.

Aaron Miri
Absolutely. So, the workflow I was thinking of specifically is a high-risk pregnancy with a 2:00 a.m. delivery at another location, and you are trying to break the glass to get the records, and even today, before information is put up, the difficulty in getting priors… That is what I am trying to say. Is there a way to break the glass for an emergency situation here? The data was delayed appropriately, but I still need it for emergent treatment. That is where I was going in my head, but I see your point.

Steven Lane
I do not think this gets at that problem. You will notice I use the word "should" in the last half of this. "The receiving institution should have the technical capability to review and respect the restrictions."

Aaron Miri
Fair point.

Steven Lane
It is not a shall…not yet.

Aaron Miri
Right. Well, until our friends in LTPAC and other long-term care get money to do Meaningful Use, it is going to be difficult for everybody to have an EHR, so it makes sense.

Steven Lane
Any other concerns on this one? We are killing it, guys. I am really enjoying this. Okay, No. 3. "When data flagged as restricted from parent/guardian access based on adolescent confidentiality due to applicable state law at one institution is exchanged, a recipient at another institution should receive all applicable metadata regarding what data was restricted and what date and time with any available discrete or free-text explanation of why the restriction was invoked, as well as the institution and role of the user placing the restriction. The receiving institution should have the technical capability to review and respect the restrictions as applicable." So, we did self-pay restricted, we did exceptional under information blocking, and now, this is adolescent confidential. To me, these all deserve to flow downstream, but I separated them out to be clear. Go on, Hannah. This is yours.

Hannah Galvin

I will just say that Shift is convening a group of experts across the industry that include patients, patient advocates, partners, ethicists, and privacy law experts, as well as those in the vendor space, to go through a modified **[inaudible] [00:44:14]** process to give recommendations such as this, what should the intended recipient receive regarding it, and that is specific to granular segmentation, although we are not specifying granular segmentation here per se, but really, what is safe, appropriate, and ethical care. I think this is reasonable, but I would just like to inform the HITAC and this subgroup that there is ongoing work to really get expert opinion on what data should flow and what is reasonable. There is a broad spectrum of opinions on this, all the way from privacy experts who say if even the metadata is shared, that may put confidentiality and privacy at risk in certain situations, to the other side of the spectrum, where some providers say, "If I do not have any of that data at all, I may not be able to provide appropriate care," which is part of the reason that group is convening.

So, I just want to set the context that I think it is fine to give these recommendations, but there is broader work being done with a broad group of stakeholders to provide the specific recommendations, and we may want to word them as we recommend that ONC develop and support ongoing work to develop recommendations around what metadata should or should not be shared as opposed to giving a definitive recommendation from a group that may not have all the appropriate stakeholders at the table.

Aaron Miri
Hannah, that is a really good point. This is Aaron. Is the definition of metadata formally defined anywhere that would list out all the elements? I think that is a great question you are asking. If you can point at that, if that exists, it may also help.

Hans Buitendijk
It does not. I would not know what to put in there. I think the concept is good, but I would not know today what exactly that data set is. There is some that has started to be defined for 72-hour delays on certain lab reports and starts to become a little bit more clear, but I do not think we have settled agreement yet on what it is.

Aaron Miri
Steven, as an idea for consideration, that might be another item to recommend to the Report Workgroup or to the HITAC, to try to suss that out so we get a formal definition of what metadata means to everybody.

Steven Lane
I just added this red text. Whoever is in there, get out of there. You are turning it gray. Also, "recommend that ONC support the advancement of ongoing work to develop guidelines regarding what type of metadata should be shared."

Hannah Galvin
I support that. Thanks, Steven.

Steven Lane
Hannah, as I crafted these, I was really thinking of you a lot and thinking that I want you to take these and run with them because you are in the center of all these discussions.

Hannah Galvin

That is what Shift is trying to do, we just need some funding.

Steven Lane

Take ownership! I just cannot thank you guys enough for working through this. The last one is "patient requests to delay or prevent release of data, such as to a portal API or VDT access, for a period of time or until a specific event, such as review by or with a provider." So, that is to say when this happens, when there is a delay or prevention of release, for whatever reason, and again, there is some overlap here because there could be the privacy exception, but when that occurs, the fact of that should be shared downstream. Sometimes, the need to prevent or delay persists, even after the time of data sharing. Obviously, data sharing happens all the time, so you could be in the midst of whatever event led to the delay or prevention, and people go to a lot of trouble to delay or prevent at Institution A, and then Institution B looks at it, and boom, it is out the door! This has happened with my patients, where I carefully, thoughtfully do a restriction, and then the patient goes across the street into the ER, and boom, the data is out there and information is being shared in a way that was not the patient's or the provider's desire. So, this is No. 4.

Hans Buitendijk

Steven, I have one suggestion on that based on a verbal comment you made. Should we include "patient or provider request," because it can come from both, to suggest a delay?

Steven Lane

I love it. Absolutely. Deven, remind us: On the information-blocking rule, I know there is a lot about that the person placing the restriction has to have a personal relationship with the patient. Is it that they need to have a provider relationship? I have always imagined that the patient should be able to give a back-office person or a front-office person the request as well.

Deven McGraw

Oh, absolutely. It does not have to be communicated to the provider, but the provider is the covered entity that has the right.

Steven Lane

Okay, so it is still a provider, even if it is a non-clinician in the provider **[inaudible – crosstalk] [00:50:08]**.

Deven McGraw

Yes, someone on the workforce could handle this. I am struggling, though, to understand this provision because again, if a patient has said, "Please do not release these lab test results to me until you call me," I do not understand why that has to get persisted downstream once those results in question have been released, and the patient might feel differently at different provider opportunities, and then, substantial risk of harm really needs to be individually determined by that patient's medical provider. That actually does have to be done by the medical provider because there has to be an assessment of whether there is a significant risk of harm. Another provider might have a completely different judgement call.

Steven Lane

Absolutely.

Deven McGraw

So, I am not sure who the person communicating this downstream is.

Steven Lane

This does not include all the fancy language so they have a chance to have a discussion and act on it. Again, there are periods of time, episodes of care, during which a restriction like this should apply, and sometimes they go on for months or even years. Think of the maternal health thing and the paternal access, not to be sexist, but the point is that when you receive data, you should know when it was restricted, by whom, and for what purpose.

Hannah Galvin

Perhaps I can give an example that is one that my and other institutions are having with information-block provisions. So, consider a mammography workflow. A patient goes for a mammogram, either a screening or diagnostic mammogram, and says, "If there is an issue here, I may not want to get the results," and so, you put that in with the specific order for the mammogram, but then the diagnostic mammogram does show something, and it becomes an ultrasound, which is actually another order, and maybe then it goes to a diagnostic biopsy, which happens at another institution, and sometimes there become communication preferences between those different providers who are placing the different subsequent orders saying, "Hey, the patient really did not want to get their ultimate diagnosis of cancer here without a provider calling them because there are subsequent orders downstream."

Those are actually most of the safety issues that I have heard around the information-blocking provisions, where there are some communication concerns with subsequent orders, and I think that would be very helpful in this case, but Deven, I agree with you that just because I want a delay in one situation certainly does not mean I want to delay in every situation or another situation. It is really where there is a reflex lab test or a subsequent order to get to that diagnosis where it may be a helpful provision.

Deven McGraw

Right. I understand your explanation, and I get what I think Steven's intent here is, to just communicate a bunch of metadata so there is awareness as opposed to communicating a downstream restriction that then has to be honored. Hans's comment in the chat suggests that someone who makes a preference at a provider around delay of results could then end up binding my laboratory, but I actually do not think the information-blocking rules would necessarily allow me to rely on a communication of a hold-back of release that was not communicated to me by the patient when the patient goes into her portal and requests her data.

Steven Lane

That makes sense, Deven. Again, I think there is a lot to be worked out by implementing these things in the future, but again, my goal in crafting this set of recommendations is to say there is a bunch of stuff that happens, and it would be really nice to send that metadata downstream with the data, and the details are yet to be worked out, and that could be done **[inaudible – crosstalk] [00:54:27]**.

Steven Eichner

Yes, and laid on top of it, looking at things like laboratory results data, where state legislation may come into play in terms of looking at holds that are releasing the data under state law also come into play.

Deven McGraw

I am fully aware.

Steven Eichner

Yes, as another level of complexity.

Hans Buitendijk

To Clem's comment in that regard, I think there is a distinction in a couple different things where you "restrict" data. The one that I described here is where HL7 was actually approached a year or two ago about the ability that, as part of placing the order from a provider to an external lab, not a lab inside the provider, it needed to be accompanied with a request to delay the results disclosure by the lab because depending on the context, they currently are required to provide it "directly and immediately" to the patient, whatever that means exactly, so that is a restriction that is being put on, and it was actually being asked for by laboratories to be able to properly document that when they did not release that information directly to the patient, it was done under the authority or clear statement that it was being withheld, and therefore could be used to clarify "We are doing this under the prevent harm clause of information blocking so we would not be under an information-blocking claim. It was done properly under that flow." And then, the next variant came across that the patient should be able to do that as well, where they would like to have that preference.

So, I understood No. 4 to look at that more in the short term as you are working on that individual result, but it is a reflex, whether it is the initial test result or not, that you want to have a temporary restriction delay on making that available to the patient. If that is not the intent of No. 4, then I think we need to clarify the other way around to make sure that this is a temporal restriction versus the other kinds of restrictions, which I think ties back to the first sentence of the recommendation. These are classes where you want to have more "permanent" restrictions, though they are all temporal, in that they truly flow down to the next provider and next party, who has to take them into consideration as well. This is an operational "do not make it available." Still, when I get the result back and the patient has received it, then independent of that, I may or may not have a restriction to share it with others, but that is then a separate aspect, and I think we need to keep those two distinct, very temporal operational versus "No, I do not want to have it shared with these stakeholders or these others beyond my current provider."

Steven Lane

Again, I think we are getting into the details of what would be future rulemaking or certification requirements. This is an RFI. They want us to help them understand what needs to be worked on in the future, so I do not think we need that level of detail.

Hans Buitendijk

I think we do need to clarify, if you look at 1 through 3, that they are more generally flagging, and 4 seems to be very specific to that individual report, that initial reporting back to the patient. I think there is a distinction between 1 through 3 and 4. The other part I think we want to make clear is that this

recommendation… Steven, I am not sure what the intent was. Are these the four, or are these four specific ones, in addition to generally restricting and preferring sharing of data?

Steven Lane

Well, the patient-requested restrictions under HIPAA are what is in the proposed rule and what we will be talking about tomorrow. In my mind, these are the things that keep bubbling up, where I want to be able to respect restrictions down the line that were separate from the HIPAA patient-requested restriction, which they included in the rule, so that is how I read the RFI.

Hans Buitendijk

Perhaps in this particular case, it might be helpful just in that first sentence to have "in addition to." Everything might be in that context, but this one might help certain readers to make sure that 1 through 4 are not read to be exclusive across the board. That is just a helpful extra reminder.

Steven Lane

So, I want to capture that. You would recommend that "ONC, in addition to…"

Hans Buitendijk

Something like that.

Steven Lane

Okay, got it.

Hans Buitendijk

This might start to be read as an exclusive list as opposed to a particular subset in the overall picture.

Steven Lane

Do we have any other hands? Okay, that is incredible. It is 8:30, and we got through our work. I do not think, Mike, that it makes sense to try to pivot to another group's recommendations. I think Ike and Hung have a plan for the next two days, and we have Friday to fall back on, so given what a long week we are going to have, I think cutting to public comment early and even ending a few minutes early, if we do not have public comment, is a reasonable approach.

Public Comment (01:00:39)

Michael Berry

That sounds fine to me. Can we pull up the public comment slide, please? We are going to open up our meeting for verbal public comment. If you are on Zoom and would like to make a comment, please use the hand raise function, located on the Zoom toolbar at the bottom of your screen. If you are on the phone only, press *9 to raise your hand, and once called upon, press *6 to mute and unmute your line. Let's pause for a moment to see if any members of the public raise their hand. I am not seeing any hands raised at this time, so I will turn it back to the cochairs.

Steven Lane

Well, let's pop back to the spreadsheet and see whether you are comfortable, Hans. I just quickly threw in here "recommend that ONC, in addition to efforts to support patients' restriction requests under HIPAA,

develop future requirements for certified health IT to support…" Does that capture what you were trying to get at?

Hans Buitendijk
Yes, thank you.

Steven Lane
No, thank you. Did we get through everything that you had captured in Column K, Hans?

Hans Buitendijk
Yes, for this one, and then, in the next step, we can tackle the other one.

Steven Lane
Okay, and did you copy it into Tab 2?

Hans Buitendijk
That could be. If not, I will double check.

Steven Lane
Okay, because I do not want to lose it. Good. I am turning this cell green, very excitedly. Thank you to whoever jumped out of there. All right, we are green on this tab! We are done, Group 1! I cannot thank you all enough. Is there still no public comment? Come on, Corey, Mark. I know you guys. Nothing to say?

Hans Buitendijk
Steven, I just checked. It was already actually in Group 2.

Steven Lane
Awesome, then I am going to delete it from Tab 1, just because I have OCD and that is what I do, so we are good. Tab 1 is clean, and ONC team, you can do the rest of the work to bring all of that over into the text document, and I think all of us, cochairs or group leads, will commit to working on the text document between now and Friday, when we are hoping to finalize. I am going to just accept all of Deven's wordsmithing here because it is just delightful.

Deven McGraw
Thanks!

Michael Berry
Steven, I have noted that Clem just joined us, and I wanted to double-check with Clem to see if he has any last-minute comments before we close out.

Steven Lane
Oh! Good day, Clem. Before we go, Aaron, do you have any other observations about our process and how you see it setting us up for success with our HITAC presentation?

Aaron Miri

No, I think next week will be good. I think the discussion will be robust around the HITAC and it will be good to get some more eyes on it, but I like the defensibility of each of these comments, and the rationale, so I do not think there will be any exceptional comments. I think folks will just opine on it, but I do not see anywhere that folks will point that out as a big, gaping hole, so this is good stuff.

Steven Lane
Great. Well, I hope we come through Workgroups 2 and 3 equally intact and green at the end, so, everybody go enjoy another cup of tea, and we will see you tomorrow.

Adjourn (01:04:38)