# Health IT for the Care Continuum Task Force (HITCC)

Transcript
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Virtual Meeting

## Speakers

| Name | Organization | Role |
|---|---|---|
| Carolyn Petersen | Individual | Co-Chair |
| Chris Lehmann | Vanderbilt University Medical Center | Co-Chair |
| Aaron Miri | The University of Texas at Austin | Member |
| Steve Waldren | American Academy of Family Physicians | Public Member |
| Susan Kressly | Kressly Pediatrics | Public Member |
| Chip Hart | PCC | Public Member |
| Lauren Richie | Office of the National Coordinator | Designated Federal Officer |
| Cassandra Hadley | Office of the National Coordinator | HITAC Back Up/Support |
| Beth Myers | Office of the National Coordinator | SME |
| Hannah K. Galvin, MD | Lahey Health | Guest Speaker |
| Stephen Patrick, MD | Vanderbilt Center for Child Health Policy | Guest Speaker |

**Operator**
All lines are now bridged.

**Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer**
Okay. Good morning, everyone and welcome to the Health IT for Care Continuum Task force. We have all of our members accounted for. So, I don't have to go through roll call individually. I also want to think Dr. Galvin and Dr. Patrick for joining us today. Before we get started, I will turn it over to our Co-Chairs, Carolyn Petersen and Chris Lehmann to get us started for a few welcome remarks before we dive into the discussion on privacy considerations.

**Carolyn Petersen – Individual – Co-Chair**
Thanks, and good morning. Welcome, everyone. It's great to see everyone at the meeting this morning as we start to wind down our work and think about the future. We have a really solid agenda this morning. We will start with a discussion of some privacy considerations presented by Dr. Hannah K. Galvin – Lahey Health – Guest Speaker. We will then move to a presentation and discussion about neonatal abstinence syndrome from Dr. Stephen Patrick – Vanderbilt Center for Child Health Policy – Guest Speaker.

Then we will revisit some of the discussion around opioid use disorder, request for information, and again, talk about some feedback from the HITAC meeting on April 10th. I will now pass the mic to Chris.

**Chris Lehmann – Vanderbilt University Medical Center – Co-Chair**
Thank you, Carolyn and good morning, everybody. I echo Carolyn's sentiment. I'm very glad to see this large group assembled this morning. I think we have some very important topics. I am very grateful to Dr. Galvin and Dr. Patrick for joining us and providing their expertise. We are tasked with the EHR format and in that task, we have thrown in to consider issues related to privacy, especially adolescent privacy and to think about opioid use disorder and the effect on infants who are born to mothers on opioids.

I wanted to make a comment up front. Last week – that's why I'm so excited about the privacy discussion – last week, I received an email from Aetna that showed an encounter that one of my grown children that are both adults but they're still on my health insurance as an effect of the Affordable Care Act. I received a statement that indicated a certain provider, which allowed me to deduce the services this child of mine had received in the previous month.

By now, I know not to look at these because I know they lead to privacy violations. But as we think about the privacy of EHRs of children and adolescents, I think we also need to think about what happens outside the EHR in the billing and revenue cycle and how this could be a detriment to the privacy consideration that we would like to include. So, without further ado, I'll turn this back over to ONC.

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

Sure. I think we can go ahead and start with Dr. Galvin's presentation. Are you ready, Dr. Galvin?

**Dr. Hannah K. Galvin – Lahey Health – Guest Speaker**

I am. Thank you. Can everyone see my screen?

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

Yes.

**Dr. Hannah K. Galvin – Lahey Health – Guest Speaker**

Excellent. So, I'm Hannah Galvin. I'm the Medical Director of Informatics for Lahey Health. By way of disclosures, I've been doing some work with the American Academy of Pediatrics Council on Clinical Information Technology to develop a multi-disciplinary national workgroup to address some of these challenges. I have no financial conflicts.

So, I have been asked to talk about the proposed rule and give some thoughts on the proposed rule, including some thoughts on the DS4P send and receive criteria as well as the consent to share resource and give some thoughts around implementation considerations for both the pediatric use cases and the opioid use disorder cases as well.

So, starting with some thoughts on the proposed rule – so, I certainly applaud ONC's response to the community and industry request for more granular tagging standards to meet clinical use cases. This is a very busy slide, but the upside is as you know, previously, the previous standard allowed tagging at the document level and now, there will be tagging available at the section level and the entry level. So, just for your reference, those are the sections and entries of the CDA.

I do think and want to highlight to this group what I have experienced in terms of the challenges with vendor adoption. I previously worked for a vendor, a large national vendor and about four years ago, championed the implementation of DS4P for that vendor even though the ONC had not adopted the new DS4P standards at that time, we knew the DS4P standards for more granular tagging were available, that you could tag at the section and at the entry level at that time.

I had a really tough time getting that vendor to prioritize DS4P on to their roadmap. There just wasn't a good business case for it, even though the head of product understood the value for patient care for promoting interoperability, but because there was not a regulatory mandate and because there was not a business case, a financial impact, getting this on to their roadmap was not a priority.

So, I think the pediatric certification is a really good first step. I think the major vendors will

want to achieve this pediatric certification. But I say this with a few caveats. The first is that in the proposed rule, there's a relatively broad definition and it requires DS4P and my understanding is this task force so far in the working documents, the recommendation has been just to sort of adopt DS4P or make it available. I think those recommendations or those definitions make this really open to vendor interpretation and somewhat difficult to measure success.

So, I would advise this group to really think about how to encourage vendor adoption and in what direction you want the vendors to take this. In order to promote interoperability, some degree of standardization of vendor adoption is going to be needed. Then the other caveat which I'll go over and actually, Chris, you just emphasized as well is that the CCDA is not the only data exchange standard.

So, this partially addresses the use cases but will not fully address some of the use cases. I think it's a great first step, but there needs to be an understanding there is a first step to addressing this issue.

So, as a high-level recommendation, I would encourage this task force to consider including a broader requirement to help the vendors to encourage prioritization and within that, to potentially consider some discreet metrics for certification to sort of standardize that. Then again, with my conflict of interest noted, encourage the ONC to consider sponsoring a workgroup to develop a broader implementation framework understanding that this is a very complex issue that won't be solved by just one standard or a combination of two standards. Those are some high-level recommendations that I'll circle back to for DS4P.

Regarding consent to share, again, I really applaud the ONC's efforts to proposing a consent management standard. Consent to share is compatible with DS4P. It allows for consent initiation, consent management, and redaction. I linked in this slide deck here, if you want to go back to it, to a great YouTube video by SAMHSA that really goes through the workflow there. I took these screenshots from there.

The only caveat here is that the vendor or the organization really needs to evaluate their value set in terms of defining what is sensitive data. This is how someone would create a consent using consent to share and they can say, "I want to share all my medical data," or, "I want to share medical records except for sensitive information, except for this specific information."

So, either the vendor or that specific organization needs to define what does sensitive data mean and that requires some alignment with whatever is going to be tagged by DS4P. So, just an understanding of that, that significant work needs to go on the back end, either at the vendor level or at the organization level to do that. I think it's a great addition to the certification proposal even though it's not a required criterion.

So, going on to the pediatric use cases, from the proposed rule, the specific use cases that were mentioned are as follows regarding sexual health, disclosing an emancipated minor's sensitive health information while permitting a guardian to consent for treatment and

segmenting child abuse information. So, I wanted to talk through each one of those.

Reproductive and sexual health is really the use case that many of us think of and it is one of the use cases that we have been working through in the workgroup and the Council on Clinical Information Technology. When we think about sharing reproductive and sexual health data, we think of all of the places that could go. It can go within your system.

So, if a patient shared that with their primary care doctor and maybe they didn't want that shared with their physical therapist, that's consideration. It can go system to system. So, a patient shares it with one system and they don't want it to go outside to an HIE or to another organization.

It can go to the various integrated clinical systems so the patient gets a lab done and the diagnosis is attached to the lab. The patient is prescribed birth control pills and that's sent to the pharmacy. The patient gets an ultrasound for a possible ectopic pregnancy and that goes to the radiology information systems. It can go to all of those different systems. Then information goes to the patient portal and that's a concern. That's a big concern for adolescents. It goes to the payer and that's a big concern for adolescents as Chris mentioned with the EOB.

So, wanting to go through each of those – so, interorganizational, within an organization, generally a CCDA is not used there. That's a vendor-specific privacy functionality, generally not very granular. But a CCDA is not utilized. So, DS4P wouldn't be active in that case. It's really between organizations where the CCDA is most commonly utilized and the biggest use case for DS4P. That's going to be very helpful in those situations.

The Integrated System for Clinical Care, often used in HL7 and CPDP or DICOM – I'm not super concerned about those data transfers, usually for that particular care situation and its knowledge and data that needs to be transferred for that particular purpose, but there can be some concern there, particularly around the diagnosis that goes to the lab and then the lab system submits a bill. That takes us to billing.

So, this becomes a big concern. The payers generally get their data through this EDI-1550 feed and that becomes a concern for adolescents. So, again, DS4P is not utilized there. Printed materials become a concern for adolescents. So, the summary of care record is CCDA. School notes have been concerns and talked about at length. They tend to be separate and again, it's a vendor-specific privacy functionality there for those printed materials.

So, the patient portal – I wanted to highlight this just to note that any screenshots here, I got off of Google. We are an Epic shop and did not take any screenshots from our EHR, but these all came from Google. So, in the patient portal, the summary of care record is pulled in through CCDA.

In general, in many cases, structured data is pulled into the portal that is generally a type of view into the EHR and not a CCDA. So, here, the allergies, the vaccine, the problems are not transmitted over by CCDA, at least in many vendors. So, DS4P would only partially be helpful

here with the portal. Open notes as well is not CCDA. So, organizations that have open notes set up.

Blue Button and the next generation personal health records, they're FHIR. Some of them can parse CCDA. So, DS4P would be helpful in some of these situations and not others. So, all of this is to say that DS4P is going to be helpful in many of the data transmissions that we are concerned about, but not in all for reproductive and sexual health data.

Regarding disclosure of an emancipated minor's sensitive health information while permitting consent for treatment, I think that this was meant to be a mature minor's sensitive health information so that the parent could still provide consent for treatment. Now, generally, this is done either in person at the institution, in which case the sensitive health information would be redacted from the consent via whatever the vendor's specific functionality is. Again, if it's sent via the portal, then the information is, as I just said, not completely limited to the CCDA.

The consent to share right now has consent for sharing, but not, as far as I know, consent for treatment. That would potentially an enhancement for consent to share and then some requirement for a role designation or role-based security within consent to share. But happy to discuss this potential use case further.

And then child abuse information – again, data sharing modalities as I discuss. Additionally, really role definitions and security are needed because one parent may need to have access to the data and another parent may need to be excluded from access to the data. So, really considering role definitions there as part of a second step as well.

In terms of the opioid use cases, this is from the proposed rule, thinking about ways that sharing data and having regular privacy tagging could contribute to patient safety and enhancing care coordination, thinking about this in terms of the adult population and sharing data, DS4P, again, is going to be most useful, sharing data between organizations. It's less useful inter-organization.

So, this also speaks to the sharing of a prenatal record with the child. If mom has an opiate use disorder and the child is now of age and has access to that data, within an organization, that is going to be a vendor-specific functionality. DS4P, again, is mostly useful if that data is shared outside of the organization and sent to another organization.

Some common practices we see now with adults are that data sharing may be limited for patients with sensitive conditions. So, we'll make an agreement to share rules of the road and share data across organizations without additional consent for all patients except if you have certain conditions, in which case that data won't be shared and may be flagged that additional consent is needed, but that can potentially create disparities if that data isn't shared in a timely manner. So, DS4P certainly would be helpful in those situations.

Additionally, more and more organizations have gone toward a segregated behavioral health EHR, which can be limiting. That data can be only shared sometimes in a limited fashion. So, a

patient can be prescribed a behavioral health organization and not make its way back to the general EHR. So, there can be concerns there. So, that's what's going on in today's ecosystem without DS4P.

So, again, the limitations are, as the previous slide, that it doesn't hit every use case, but it's a really good start. There are several, as you probably know, opiate-related patient-level documents that have become commonly used, the opiate agreement and a voluntary non-opioid directive, which is often used for patients to declare that they do not want to receive opiates, particularly if they have opiate use disorder or have had an issue in the past. Those are not CCDA documents.

I know the interoperability framework, CommonWell and Carequality have been working on ways to share advanced directives as patient-level documents, potentially using that framework. The opiate-related patient-level documents could be shared as well. I think that would be important to further explore and then explore ways to potentially tag those as sensitive.

The group has asked around best practices on usable display for opiate use disorder. I think this is generalizable to the other use cases as well. I would suggest that some guidance is needed from the ONC or an industry consensus would be helpful here. In an ideal state – this is a screenshot from Google, but I've modified it. It's the EHR from Dr. Hoff.

**Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer**
Dr. Galvin, I think we've lost your screen.

**Dr. Hannah K. Galvin – Lahey Health – Guest Speaker**
Oh, you lost my screen?

**Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer**
Yeah. Is there any way you can share it again?

**Dr. Hannah K. Galvin – Lahey Health – Guest Speaker**
Yeah. Let's try that again. How's that?

**Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer**
There it is. Thank you.

**Chris Lehmann – Vanderbilt University Medical Center – Co-Chair**
We see it. It's very small.

**Dr. Hannah K. Galvin – Lahey Health – Guest Speaker**

It's small.

**Chris Lehmann – Vanderbilt University Medical Center – Co-Chair**
I got it now.

**Dr. Hannah K. Galvin – Lahey Health – Guest Speaker**
Okay. Great. My recommendation of an ideal state is there would be some type of dynamic interaction with the C2S application so that there would be some visualization that the data had been redacted. In this case, the patient had a problem that was tagged as sensitive. You would see the problem list. It would say the data is redacted. Click here to download the patient consent. Some organizations may feel that they need emergency access.

So, those are considerations to consider as part of an implementation recommendation to the vendors as well, but I think that a usable display at the point of care really involves the provider being able to see that there has been some data redacted, that there is data there that's been redacted.

Finally, thinking about data availability for clinical decision support – so, clinical decision support logic has not necessarily been built with regard for potentially sensitive data. As you see here again, I pulled off the internet – this is an alert that is firing and indicates that the patient is on chronic opiate therapy. Ideally, clinical decision support fires to the right user and the right workflow at the right time.

So, it should not be firing to users who don't need the information for clinical care. The algorithms may pull from areas that don't include CCDA elements. So, it may be difficult to apply DS4P. I'm not sure that DS4P should be applied. There may be patient safety concerns. I think that this would be of concern to the industry and I think guidance from the ONC, again, and industry consensus around some implementation guidelines around clinical decision support.

My personal opinion is that all patient data should be available for clinical decision support but that these tools continue to be implemented according to the rights of 5 Rights of CDS with some awareness around patient privacy concerns.

So, overall, just a summary of my recommendations are that this task force really understand that vendors are not going to prioritize privacy in their roadmaps, either DS4P or consent to share without some type of business case or regulatory requirement.

I think the voluntary pediatric certification is a great first step, but considering potentially a broader requirement, perhaps to support opiate use disorder, prevention and treatment as well, to really try to encourage that vendor prioritization and along with that, recommending a discreet metric to try to focus it on the vendors in a single direction, perhaps focusing on an entry level so that it's not as open to as broad interpretation.

Just the recognition that data exchange is complex and that these two standards alone won't

fully address the proposed use cases but are a great start. Then again, my conflict of interest statement here, but considering ONC's sponsorship of a multidisciplinary workgroup such as the one we're already forming to develop this broader implementation framework because this is such a complex issue, including consensus recommendations around the adoption of these and potentially additional standards to protective privacy while promoting interoperability as well as data visualization at the point of care and the availability for clinical decision support systems.

So, open it up for discussion.

**Chris Lehmann – Vanderbilt University Medical Center – Co-Chair**

Thank you very much, Dr. Galvin. I think you raised some very, very important topics. I especially liked your thought about decision support. I'm part of a group that builds decision support and privacy considerations really have never been much of a concern when building this.

Now, I was racking my brain trying to figure out if we ever did anything that required data that could potentially be considered significant. Yes, clearly, when it's about managing pregnant patients, that is certainly the case. We have never considered that in the billing process. I think that's – I think we're not particularly different from anybody else. So, this is an important layer to pay attention to.

Now, I have a question for you. By omitting things from a chart, I can actually deduce relatively quickly certain information about a patient. So, how do you propose to handle this? Is there a need for certain information that you really want to make sure that it is kept private, that you have a **[inaudible] [00:26:57]**? How would you suggest that we handle the fact that by absence of data, data can be predicted or guessed by clinicians?

**Dr. Hannah K. Galvin – Lahey Health – Guest Speaker**

That's a great question. So, I think this is one of the reasons why we need a multidisciplinary workgroup with stakeholders from all of the specialty societies to speak to this from all of the different perspectives as well as the vendors and the interoperability frameworks as well. My personal opinion is that we can go as far as we can, but not – there's not necessarily going to be a way to fully remove the data.

For instance, in this screenshot here, if this was under a heading of infectious disease, someone would know that there was an infectious diagnosis there. Do you actually remove medications from the medication list? There are huge potential patient safety implications to that. You know if the patient is on ECT that they have HIV. Any provider can deduce that.

So, I think this is one of the reasons that this has not been addressed so far, because it's such a complex issue and it's one of the reasons that we are gathering the group that we are to try to at least start with some limited use cases and trace the data transfer and address some of these issues and try to get some consensus around it.

That's the real challenge. I don't think that we're ever going to be able to fully remove a clinician's ability to deduce or guess some of these sensitive diagnoses, but we can really do the best we can.

**Chris Lehmann – Vanderbilt University Medical Center – Co-Chair**

Thank you. This group that you're talking about that the AP is forming, is the output of that work, is that going to be in the public domain so that ONC and others could digest it?

**Dr. Hannah K. Galvin – Lahey Health – Guest Speaker**

So, our hope – we are just forming the group and hoping to have many specialty societies involved. Our hope would be to have ONC as a stakeholder as well and yes, to have the output in the public domain as well.

**Chris Lehmann – Vanderbilt University Medical Center – Co-Chair**

Thank you for a fantastic presentation.

**Dr. Hannah K. Galvin – Lahey Health – Guest Speaker**

Thank you.

**Chip Hart – PCC – Public Member**

I have a couple of comments, if that's okay. I realize that nothing I say here is going to move the needle on anything. I want to just get these comments out there so we can start thinking about them. First of all, I think your presentation was excellent. It was nice to see a privacy discussion that actually had some understanding of the pediatric needs because they are a little bit different most of the time.

Most of the time, everyone zooms in on that HIV diagnosis or pregnancy. One of the things that we know from our work with pediatricians is that almost any element of a chart is and should be considered potentially private. We have a lot of experience dealing with just hiding demographics from guardians who share a patient. The mom does not want the ex-husband to know where she lives, even though they still share custody of a patient.

One of the things that I want to remind us all of is that any element of a chart is considered potentially private, especially in pediatrics. We also have a lot of experience indicating that almost any diagnosis can be considered private. I'm going somewhere with this.

We ran into this when we were working on the Michelle Obama obesity program and they wanted every pediatric chart now to indicate whether the child is obese or underweight and we had a lot of pushback from our physicians saying, "We do not want this clinical indication even appearing to the patients." So, suddenly, we have the doctors fighting with their own chart notes about what they want to share with the patient in question.

That all leads to the biggest concern I have with the implementation of any of these privacy things. This is not an objection to any of it. This is just my concern with how we implement it. If you take a look at your slide deck and you go to slide 18, there was actually a really good

example there.

I'm not exaggerating, but I'm extending a little bit for the purpose of my point. It's a patient's problem list and there's a scrollbar that makes it look clearly that this page is filled with a problem list. It clearly goes down two more pages. For each item on that problem list, the physician or the clinician has to indicate some level of access.

It is absolutely conceivable on any individual patient that you could have something where the diagnosis, A, is allowed to be sent to clinical study A, but not to the HIE or to the lab. However, Guardian B and see it, but not Guardian E, the Care Coordinator F can see it, but the Care Coordinator G cannot.

So, even with all the permission grouping and everything like that, you have exploded an exponential number of privacy clicks that are possible. I really fear the impact of that privacy clicking on a) the wellbeing of the physicians who have to do this stuff every day, and b) the punitive result to the clinicians who fail to click exactly right.

So, these are surmountable problems, but any opportunity I have to talk about patient privacy, I'm going to always raise the flag to say this is really, really hard and it's not going to be solved by technology. The really great example you gave, which I've never seen anyone bring up before, which is how do you blend the need for effective clinical decision support with patient privacy – I don't think that is solved with technology.

That's solved with a little bit of legislation and some understanding of the medical community. Then the vendors and the physicians say, "Okay, now that we know it's appropriate, this is how we're going to develop for it." We do not want vendors making this stuff up or figuring it out because that will be a disaster. I say that as a vendor. That's my soapbox for today. I'll shut up now.

**Susan Kressly – Kressly Pediatrics – Public Member**

This is Sue. I just want to add on this, that unless there's universal adoption, it's a problem because if I can fix this and Chip can fix this, but we can't send it anywhere and be fully confident it can be handled on the other side, it doesn't matter. We can solve our own problems for our own patients and our own application and our own portals, but we can't send anything anywhere unless there's 100 percent adoption and we can feel confident we can send things.

**Chip Hart – PCC – Public Member**

Amen, Sue.

**Steve Waldren – American Academy of Family Physicians – Public Member**

This is Steve Waldren. I think it's more than just 100 percent adoption. Two of my challenges – one Dr. Galvin elucidated extremely well that focusing your tagging on a particular standard like CDA limits you. Until we say that we take this tagging all the way back to the source of the data, we're always going to have problems about being able to have data leakage where

we won't want it to leak.

The other issue, though, is with these types of standards, they kind of de facto require a business agreement between the two entities. If I don't redact it out of the CDA but I just tag it as sensitive and then I send it to you, I have to assume that you're going to abide by those rules. Even if you've implemented it 100 percent correctly, you may not.

If HIPAA still allows you to view that information, although it's been asked not to be viewed, you have to have that business agreement to be able to require that other entity to maintain that confidentiality. We need almost a national policy. That's where you start to get to these trusted exchanges. Otherwise, we're going back to HL7 V2, where it's really point-to-point instead of more of a network-based exchange.

**Susan Kressly – Kressly Pediatrics – Public Member**

And I just want to add that's really important, but just because this is hard, we can't say it's not critically important to move forward. This is problem one of the most difficult things to tackle, but it's got the most implications. Every time we defer and kick this down the road, there is an opportunity lost cost of patients potentially getting inappropriate or incomplete care because we can't share complete information in a safe way.

**Dr. Hannah K. Galvin – Lahey Health – Guest Speaker**

I agree with Steve on that. This is Hannah.

**Chris Lehmann – Vanderbilt University Medical Center – Co-Chair**

Being the practical person that I hope I can be, I'm going to ask this group – what are the next steps? How do you proceed? Is there a need for a minimal privacy data set description that could be used as a consensus around what is considered private without them having to do what Chip described, the death by 1,000 clicks for determining which items are private and which aren't?

**Susan Kressly – Kressly Pediatrics – Public Member**

So, I think it's yes-and. Yes and we have to give users the ability to tag anything at the user level, not that they have to maintain it, but it's not just the systems level or a functionality of the software. There is a human and a software component to it. I think the only way you solve this is to put a lot of stakeholders in a room and hammer it out.

**Dr. Hannah K. Galvin – Lahey Health – Guest Speaker**

I agree.

**Chip Hart – PCC – Public Member**

I also would love to see maybe a document from the AAP talking about patient privacy best practices in general. Actually, everyone here as already pointed out the issue of data leak. This isn't simply a matter of technical specs and exchanging data between two vendors. This does cover the entire world of communicating in general. It's phone calls. It's faxes. We run smack into he conflict of first do no harm.

Which is less harmful? Keeping some clinical information out so you get an imperfect clinical understanding of the patient or exposing all the clinical information perhaps to another detriment. I think that has to be solved fundamentally in order for the computers to do their little part in this process. I'm just extending the comment that if the computers do everything properly, it depends on so much proper human intervention to work properly that we have to get that part down.

The other thing I'll add really quickly – we touched on it lightly, but I think the issue with – I'm sure there's an expression for it and I don't know what it is – of redaction leakage as we all read the Mueller Report this week. It's clear that redactions can tell you as much or more sometimes what's going on with someone.

I don't think medicine has yet to really understand how to manage those things. If you have a patient chart note, the section that says whatever, fill it in, sexual history, and it's redacted and it's four pages long, that's just as much as having nothing there. I realize that all the vendors are clever enough to avoid that, but I think there are some real subtleties and unintended consequences that are going to result as we march down this road. We just have to be really, really careful.

**Dr. Hannah K. Galvin – Lahey Health – Guest Speaker**

I agree. This is Hannah again. But I think that as folks have started discussing this, all of these concerns come up and that has historically, as you said, kicked this can down the road and no one has addressed this because of that. What we have started talking about in this workgroup is how we can start addressing these in a strategic way.

How can we start looking at all the data elements or looking at all of the modes of data transmission and then pulling some use cases and starting one step at a time, understanding that we're not going to hit all of these use cases at once, but actually taking an active approach there.

I would advocate for that. I would advocate that ONC continue to promote privacy standards like DS4P and consent to share just with an awareness that it is only the first step and that a larger work group of stakeholders really is needed to flesh this out and to address some of these larger concerns and that it's not going to be a short process. This is a very complex process that needs to be addressed piece by piece.

**Chip Hart – PCC – Public Member**

Excellent. I'm glad to hear that. This is one of those things where we have many examples on the vendor side of the world where legislation comes along and says, "Okay, this is how you're now going to have to do this. This can be anything from sending claims to exchanging IMS records. The pathway to there is littered with the dead bodies of bad design. That's how we end up where we are today, where physicians literally do not like going to work because of all the clicks in their EHR and the danger of clicking wrong. We don't want to add to that.

**Dr. Hannah K. Galvin – Lahey Health – Guest Speaker**

Agreed. Certainly, we don't want to increase administrative burden or clinic overhead and physician burnout. That all needs to be taken into account as well.

**Chris Lehmann – Vanderbilt University Medical Center – Co-Chair**

This has been a really great and robust discussion. What it shows to me is something that I have been thinking about for quite a while is that this task force is really the beginning of the work in the pediatric EHR and it's the beginning of the work around privacy as it relates to the pediatric EHR. I think it's becoming very apparent from the suggestions that we hear that there is a need to further work on this, elaborate on this, come up with best approaches and recommendations going forward.

So, as I look at our work and the charge that we have, I think it's very apparent that the process of EHR certification for pediatrics is just starting. To me, it's just the beginning, just like certification for EHR in general started out in one place and got changed and improved and modified over time, I think there will be a need to continue to do the same thing for pediatrics.

Looking at the large amount of recommendations that were included in the original pediatric EHR format, many pertaining to privacy as well, I think with the recommendation that we looked at here, it's a fraction of the original 650. Also, it's only 10 percent of the high-value item that was identified by AHRQ in 2017, which were like 47 items total. So, to summarize something long very succinctly, I think this is beginning of the work and I hope that ONC will recognize that and will understand that there's need to continue to improve and fine-tune whatever comes out of this task force.

**Carolyn Petersen – Individual – Co-Chair**

Thank you so much for the excellent presentation and all of the really rich discussion that has followed on. I know this will be really valuable for us as we review the transcript and start putting together the transmittal letter thinking about recommendations and possible discussion and support for this when we bring it forward to the full HITAC. Thank you so much, Dr. Galvin, for coming and sharing this with us today.

**Dr. Hannah K. Galvin – Lahey Health – Guest Speaker**

Thank you.

**Carolyn Petersen – Individual – Co-Chair**

With that, I will introduce Dr. Stephen Patrick, who will talk to us today about neonatal abstinence syndrome. Dr. Patrick?

**Dr. Stephen Patrick – Vanderbilt Center for Child Health Policy – Guest Speaker**

Hi. It's such an honor to be here with you all today. Most of my conversation is going to really focus on some of the clinical aspects and potential gaps that I think may be amenable to some EHR solutions. Let's make sure I can get my screen to advance. There we go.

First, I have no conflicts of interest to disclose. I want to first provide a little bit of context about neonatal abstinence syndrome and the broader context of Mom. I think it has some relevance to some of the OUD work you all are doing as well.

First, substance use in pregnancy is not that uncommon. We know that young women age 18-25, about 7.5 percent of them use some elicit substance, according to SAMHSA reports. About 5 percent overall of pregnant women use some elicit substance. Importantly, that's still far less than the general population at around 12.5 percent. We know that pregnancy is a time when women seek changes. They try to access treatment, cut down on use. It's an optimal time to engage in new care patterns.

Legal substances in pregnancy are also harmful as well and merit some mention as we focus a lot on opioids these days. About 14 percent of women still smoke cigarettes in pregnancy and one and ten use alcohol. That's important because we know that alcohol is the number one preventable cause of developmental delay in children. Oftentimes, I think it's missed by the conversation.

In all, when we think about substance-exposed infants in the US, about 440,000 infants are exposed to elicit drugs and alcohol per year according to SAMHSA estimates. We only detect 5 percent at the time of birth. That's when we step back, I think, and look at a holistic approach to how we can begin to detect these problems. It's not just focused on the birth hospitalization.

Before we start talking about neonatal abstinence syndrome, it's worth talking about treatment for opioid use disorder and pregnancy. The medications that are primarily recommended for use are buprenorphine and methadone. They've been shown repeatedly to improve outcomes for pregnant women. For moms, they decrease risk of overdose death, relapse, hepatitis C and HIV. For the infant, the infant is more likely to go to term and have higher birth weights, but this does come with some tradeoff in terms of drug withdrawal.

In a sense, we are trading the risk of having a very pre-term infant at 25 weeks or something like that, with a larger infant at term who has drug withdrawal. In general, that's a pretty good tradeoff. The thing about access to these medications that problematic is that we know that even among pregnant women who are able to get into treatment, less than half receive these medications even though they work.

That's with people who get into treatment. There are multiple barriers in terms of actually accessing treatment. We're talking about privacy barriers too – addiction care oftentimes in the US is pretty separate from the rest of how we deliver care and we see that too clinically in terms of some siloes in care that we see pregnant women have to deal with.

When talking about neonatal abstinence syndrome, it is a drug withdrawal syndrome and we see some federal agencies including FDA and CDC calling it neonatal opioid withdrawal syndrome. In general, these terms are somewhat synonymous. It generally follows an opioid exposure. Though, if you look in the older literature, there have been some other medications and substances that have been implicated, including alcohol, benzodiazepines

and barbiturates.

The literature suggests that around 40 percent to 80 percent of methadone or heroin-exposed infants develop neonatal abstinence syndrome. From some of our work, it appears to be a smaller number. About 5 percent of those were exposed to opioid pain relievers, medications like Vicodin and Norco.

How we treat neonatal abstinence syndrome is to first control the withdrawal, minimizing its complications including some of the more severe complications like seizure. This first begins by controlling the environment, promoting grooming in with mom and baby, breastfeeding when it's appropriate, but for severe withdrawal, it includes using an opioid like morphine or methadone or increasingly buprenorphine these days too. The infant is captured and slowly tapered to control their clinical signs.

We've seen a pretty rapid increase in the number of infants diagnosed with neonatal abstinence syndrome in the United States. This is from some of our team's work. On the Y-axis here is rate of neonatal abstinence syndrome per 1,000 hospital births and on the X-axis is year.

What you can see is about a sevenfold increase in the number of infants diagnosed with neonatal abstinence syndrome, rising in parallel to what our country has experienced with many other opioid-related complications. By 2016, about one infant every 15 minutes was born in the United States on average having drug withdrawal, a pretty stark increase from just a few years ago and accounting for about $500 million in hospital costs just for the birth hospitalizations per year.

Some of the issues we have in caring for infants with drug withdrawal, including those challenges that I mentioned earlier for mom is substantial variability of what we do in the hospital. We know from some recent studies that even among children's hospitals, they only do the same thing including the medications they use to treat drug withdrawal about 80 percent of the time. Those variations in care practices lead to substantial differences in hospital length of stay. So, we know from that study hospitals vary twofold in the risk-adjusted length of stay, again, I think highlighting some of the effects that variable practices can have on outcomes.

The large quality improvement collaborative happened in the United States and in Canada from 2013 to 2015, led by a group called the Vermont Oxford Network. At the beginning of that, some of the core elements of what you would do to care for an infant, they surveyed hospitals. Only about 45 percent had a policy to standardize scoring, "This is how you diagnose an infant with neonatal abstinence syndrome."

Less than half had a policy on breastfeeding a substance-exposed infant. We know that this alone can reduce clinical signs of drug withdrawal and shorten length of stay. Only about less than 70 percent had a policy on pharmacologic treatment of neonatal abstinence syndrome. In many cases, what we see in some hospital settings is that we're winging it when we're thinking about how we're treating drug withdrawal.

We also see substantial variation in the medications that are chosen for drug withdrawal. This is from a large group of about 300 neonatal ICUs in the United States from a large private group called Pediatrics. We still see in the United States morphine is the most commonly used medication, but we still see a bunch of other drugs that are still used, including phenobarbital, which should not be a primary drug of choice for neonatal abstinence syndrome.

So, what can we do in the context of this variable care? Well, first, we know that standardization works. Protocol-driven weans work. The Ohio State Perinatal Collaborative sought to look at what medication works better, methadone or morphine. What they found was no effect by the medication choice, but a substantial effect in using a standardized protocol, about half the length of stay. Similarly, the Vermont Oxford Network found that standardized care shortened length of treatment and length of stay.

For this group too, thinking about some of the threats immediately post-discharge and how we can begin to perhaps use information technology to better coordinate the care and identify risks that these high-risk infants have. There's been an increased focus on reducing length of hospital stay and for good reason. When we see some reports of length of stay for neonatal abstinence syndrome, it can be in the triple digits sometimes. We know that drug withdrawal in other populations certainly doesn't last that long.

Still, we know that shorter length of stay in the birth hospitalization is associated with higher risks of being readmitted within 30 days of discharge. We're also seeing emerging threats for infants too, the rise of hepatitis C. Over the last five years or so, we've seen a doubling in the number of hepatitis C-exposed infants in the US with some state-to-state variation. West Virginia, for example, 1 in 50 infants are exposed to hepatitis C or were in 2014.

And our systems of care to ensure that these infants are followed to see if they seroconvert are pretty poor. Even though the vertical transmission rate is 6 percent, infants have to be followed post-discharge to see if they convert. A recent study from Philadelphia found only 16 percent of infants were tested within two years to see if they seroconvert. Another study from Wisconsin a similar rate of 34 percent.

The other thing that we see frequently is in outpatient treatment, infants being discharged home on medications. In some ways, this can be problematic. In a recent study that we did here in Tennessee, we found that of infants treated in the state of Tennessee in the state Medicaid program for a three-year period, about half were treated with a medication as an outpatient. They were started with a medication on an inpatient and then discharged home on a medication wean.

Outpatient therapy was three times longer than inpatient therapy, 19 versus 60 days in newborns and we saw one infant that was an outlier had treatment with phenobarbital for 200 days as an outpatient. ED utilization for outpatient treatment was higher. One of the most alarming things we found was about 90 percent of these infants were treated as outpatients with phenobarbital.

This has been associated in some studies, particularly febrile seizures with some poor neurologic outcomes. I think sometimes what happens is a bit of inertia. We, as hospitals, are trying to discharge infants home quickly. So, do we that with phenobarbital and then we don't give great guidance on what to do in the outpatient setting and infants stay on for a long period of time.

So, focusing on the discharge process – again, another place where I think there could be better standardization, perhaps using information technology – what does an optimal discharge look like? I think first, it starts with improving the care we deliver inpatient, engaging families, breastfeeding, doing appropriate assessments of family needs and follow-up needs.

It also considers the post-discharge needs. Are we appropriately connecting to groups like Home Visitation, to MIECHV, to the child welfare system – how can we promote positive interactions with the child welfare system? IDA Part C, this is early intervention services – infants who are substance exposed should be referred. We don't great data on how many actually are. Perhaps more frequent pediatrician follow-up as a safety net to ensure that infants are doing well and maybe we can do a better job with coordinating with maternal follow-up as well to keep moms engaged.

The group we've started, we've worked to improve the care delivery we are providing for infants with neonatal abstinence syndrome. Over the last 18 months or so, we've had about 200 opioid-exposed infants that are greater than 35 weeks come through our hospital. It's been a group that we've really focused on improving our care delivery.

One of the things we focused in on has been discharge. So, we thought – we wanted to look back at our group and see how good of a job are we doing on making sure we had a good handoff. We've defined a good discharge as we've scheduled a primary care doctor appointment for the infant post-discharge. If they were exposed to hepatitis C, that we schedule them with a follow-up for hepatitis C, that we referred them to early intervention services and that we referred them to a developmental pediatrician if they were diagnosed with neonatal abstinence syndrome.

Here, you can see last summer, we were doing this about 1 percent of the time. This is in the context of us looking and trying to improve care for this population. I think discharge is a place where we often times don't look.

We did some pretty simple interventions. First, we just audited to see what we were doing and discussing that improved our outcomes. Then we did some EHR and paper checklists and education of the residents and we saw a pretty big bump in improving our discharge processes until we had a social work transition, where we lost the social worker.

One other thing I hear often times, I know there are various groups looking at the potential of using EHR as a way to measure long-term outcomes. This can be complex. Much of the studies that we have and many of the things that we think about in terms of long-term

outcomes for infants can be confounded by additional substances like alcohol, social stressors. We're learning more about the effects of adverse child experiences, trauma, environment, even maternal health.

So, I think there is something to be a little bit cautious about how we utilize these data for thinking about long-term outcomes. But I do think there are a ton of possibilities – first, to begin to standardize what we do, our processes, our definitions, beginning with inpatient treatment for neonatal abstinence syndrome.

How can we work to improve and standardize our treatments for diagnosis and treatment inpatient, to begin to standardize the discharge process and fill in the gaps for appropriate developmental follow-up, early intervention, and other common comorbidities for both mom and baby, including mental health and hepatitis C?

Early identification of potential developmental risks that may appear in EHR that sometimes may get missed and, in some instances, the developmental science for infants is pretty subtle early and may become more problematic later. The connection with providers, resources, schools, and perhaps data harmonization to break some of the siloes that we see.

So, in summary, pregnant women and infants have been affected by opioids and they face a system that does have substantial gaps. I think there is room for both standardization, coordination, perhaps using data and health IT technology.

I'm happy to take questions and talk a little bit more.

**Susan Kressly – Kressly Pediatrics – Public Member**

This is Sue Kressly. I have a question about the developmental issue that you just brought up. And thanks for a great presentation. There are some states now that are automatically qualifying any children who fall in this risk category to be tracked by early intervention. Has anyone tried to pull data sets together and look at that? That would seem like a very valuable piece of information.

**Dr. Stephen Patrick – Vanderbilt Center for Child Health Policy – Guest Speaker**

Agreed. Those data are difficult to get ahold of. I've actually looked and tried to make requests as part of education before – very difficult. At the state level, we're partnering with state's Education Department to gather those data in the process of that. It is one of those things where I completely agree this is a clear safety net in every community and it should be something we are looking at more deeply.

**Chris Lehmann – Vanderbilt University Medical Center – Co-Chair**

Thank you. Stephen, excellent presentation. Quick question for you – one of the most effective ways of standardizing care is creating order fit. It reduces the amount of time that a physician has to take to create orders for a particular patient. You don't have to hunt and seek the order items. They're all there in one document and you can just sign it off and be done with it. Would you think that the management of the inpatient infant with neonatal

abstinence syndrome would lend itself to a national effort that would standardize care through recommendation on how to create an order set for these infants?

**Dr. Stephen Patrick – Vanderbilt Center for Child Health Policy – Guest Speaker**

I do. I think there are a lot of gaps there. Even though I can't say that there's one specific weaning protocol that is superior, I think beginning to standardize that. We see that time and time and time again in the literature consistency improves outcomes. So, I do think that has a lot of possibility for the medical treatment for sure, even though there's a little bit of ambiguity there, but certainly for the connection to other things like post-discharge resources. I think there's a lot to be gained there.

**Chris Lehmann – Vanderbilt University Medical Center – Co-Chair**

Do you think it's realistic to expect that an expert group could come up with a consensus that could be shared nationwide?

**Dr. Stephen Patrick – Vanderbilt Center for Child Health Policy – Guest Speaker**

Sure. It's easy for me to tell you that I think you guys can do work that I don't have to do, but I do think if not this group, then who else? I think what I've seen in this space is these things always feel daunting. I would love to see a broader conversation at the federal level about how we can begin to standardize definitions, what we do, and perhaps this group is one of the venues for a piece of that.

**Carolyn Petersen – Individual – Co-Chair**

Thank you so much for the wonderful information and the very nuanced perspective that comes from experience. I think in terms of informing what we put into our transmittal letter to ONC, this is tremendously helpful. I also appreciate the encouragement and the support for the work that we are trying to do going forward as well.

Of course, ONC is looking for feedback and thoughts about very specific topics within those in charge of this task force, but its work is ongoing and it's really great to see support from the folks who are outside the task force to move the needle on some of these issues. Certainly, NAS is not going away. As we try to come up with a cogent and applicable and useful strategy for dealing with the opioid use disorder. I think there's certainly a role for the work that you're doing and for this task force moving forward. So, thank you so much. I hope if we have need of your assistance we can call on you in the future.

**Dr. Stephen Patrick – Vanderbilt Center for Child Health Policy – Guest Speaker**

Most definitely.

**Carolyn Petersen – Individual – Co-Chair**

Thank you so much.

**Dr. Stephen Patrick – Vanderbilt Center for Child Health Policy – Guest Speaker**

Of course.

**Carolyn Petersen – Individual – Co-Chair**

Other thoughts from task force members or other questions for Dr. Patrick? I know we're running a little bit behind schedule, but this is really important information and valuable ideas we can bring forward to ONC just within the discussion, aside from what we do in the transmittal letter.

**Steve Waldren – American Academy of Family Physicians – Public Member**

This is Steve Waldren. I agree with Chris's consideration of the order set as a very practical, very quick way to start to address. I think there's also this opportunity to think of this as a specific use case in a larger issue of how we get standardized care into these EHRs. And then I think we can also even think about it a little bit larger in thinking about how we create that standardized knowledge in a way that is able to be disseminated.

I know the folks at Netherlands have a project called the Magic Project. Some in the medical specialty societies have had some conversations about how we can use that process of creating standardized knowledge and guidelines and put those in a way that can implementable across multiple EHRs. So, I think this is a great example that can be used to set the stage for how we would make this more of a standardized process for anything that we want to standardize in clinical care.

**Chip Hart – PCC – Public Member**

If I can just insert one little comment there – you and I have been on our share, as has Dr. Lehmann, of committees where we get presented with what looks like a really reasonable, interesting, and helpful clinical guideline but at the end of the day, what we wall want is something given to us that's computable. That is, I'm identifying very specific language that says, "If this happens, this is what should happen next."

When we have that computable protocol in place, it's very easy for the EHRs to implement these kinds of guidelines and implement them correctly. Whenever you have vendors translating guidelines without a computable process, you end up with problems. That's my experience. If you need more guidance about what that means, you might not totally understand what I mean. You can tell me to shut up, but if you need guidance on what computable means, I know that everyone here would be glad to help in that regard.

**Susan Kressly – Kressly Pediatrics – Public Member**

I agree with Chip. It's interesting. We can take immunizations and the work the CDC has moved to as an example that if we need to tell other people – when we first did in the immunization forecasting and we were told that the vaccines should be separated by a month, a month is meaningless to a computer. Is it 28 days? Is it 30 days? Is it 31 days? Is it the next calendar day in the next month?

That sort of granularity is what everybody ends up doing differently and that's why you don't end up with harmonization of appropriate clinical decision support. So, if we ever are talking to people who don't really et that hook, that's a great example.

**Chris Lehmann – Vanderbilt University Medical Center – Co-Chair**

Yeah. I just want to put a plug in. The American Academy of Pediatrics has had now for ten years a group called Partnership for Policy Implementation. They have been working on this particular issue, making sure that guidelines are decidable, that no fencepost issues are left out, that they also are actionable and that they can be interpreted for computer implementation.

Switching topics, however, Stephen, I heard that you also are thinking about long-term follow-up and the potential to use this data for interventions and programs that might improve the outcomes of these children. My question here to you is is there a defined data set that already exists that is a recommendation of data elements that should be followed up in these children or is this future work that needs to be done?

**Dr. Stephen Patrick – Vanderbilt Center for Child Health Policy – Guest Speaker**

I think that's future work that needs to be done. I think it's important work and I think it's patient-centric. I think I worry a little bit about the accumulation of data for – back to the initial part of this conversation – the accumulation of data for vulnerable populations and how that's used, but in terms of tracking, research, and how things could be utilized. But I think for the purposes of ensuring children who fall behind or at-risk populations, ensuring they're connecting to appropriate services, I think there's a lot of room to grow there.

**Chris Lehmann – Vanderbilt University Medical Center – Co-Chair**

Following up on that, is there a need to make a recommendation downstream if we recommend that such a data set should be created that it cannot be allowed to be used for punitive measures like Child Protective Services actions, prosecution, these kinds of things? Is there a need to make this data set protected?

**Dr. Stephen Patrick – Vanderbilt Center for Child Health Policy – Guest Speaker**

I think so. I think being really clear that both from the criminal justice and child welfare system, it should be separate. We know those are things that drive women away from treatment and sort of what potentially impede things. I also think if these data ever have the potential to be used for research, there should be guidance and caution about that.

We see lots of retrospective secondary analyses in this space – I'm a guy who does a lot of retrospective secondary analyses – that it's well-controlled for, that have big conclusions about adverse effects that infants with neonatal abstinence syndrome have. Oftentimes, I think some of it has to do with unmeasured compounding. Both of those things are potential important.

I also failed to say one thing in the talk that may be relevant too – the American Academy of Pediatrics, some of our committees, we're working on a new statement and guidelines on neonatal abstinence syndrome that hopefully will be out within the year.

**Chris Lehmann – Vanderbilt University Medical Center – Co-Chair**

And if you don't have a PPI involved in that, I'm sure after what I said earlier, you will now, right?

**Dr. Stephen Patrick – Vanderbilt Center for Child Health Policy – Guest Speaker**

A proton pump inhibitor?

**Chris Lehmann – Vanderbilt University Medical Center – Co-Chair**

A partnership for policy implementation.

**Dr. Stephen Patrick – Vanderbilt Center for Child Health Policy – Guest Speaker**

Yes, great. I knew you didn't mean that kind of PPI. Yeah. That sounds great. It was a bad dad joke.

**Steve Waldren – American Academy of Family Physicians – Public Member**

There's no such thing as a bad dad joke.

**Carolyn Petersen – Individual – Co-Chair**

Thank you so much for the excellent presentation and all the wonderful follow-up discussion. I think this has really taken the task force a great leap forward in terms of thinking about what we need to recommend to ONC. So, at that point, I will ask Lauren are we able to do public comment now and then have our follow-up discussion on opioid use disorder as one thing or do we need to break it up with the public comment?

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

We're a little bit ahead of schedule, but why don't we go ahead and pull the phone number up and then open the lines. If we don't have any comments, we can circle back just before we adjourn. Operator, can you open the public line?

**Operator**

Yes. Thank you. If you'd like to make a public comment, please press star-one on your telephone keypad and a confirmation tone will indicate your line is in the queue. You may press star-two if you would like to remove your comment from the queue. Participants using speaker equipment, it may be necessary to pick up your handset before pressing the star key.

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

Okay. And do we have any comments in the queue?

**Operator**

No comments at this time.

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

We can leave it up and then maybe in another five or ten minutes, we can see if we have any other comments. Carolyn and Chris, I'll hand it back to you.

**Carolyn Petersen – Individual – Co-Chair**

Okay. If we could bring up the slides that take us back to some of the recap discussion we wanted to loop back to today – we can start with the opioid use disorder discussion since we were just talking about NAS. Last week, we had a limited number of members on the call. So, Chris and I thought it would be good to kind of recap this and bring out any further discussion or any other thoughts we have for ONC, give them a chance to ask us for any clarifications or other areas that they think would be helpful for them in terms of thinking through what they're doing that we didn't get into a discussion last week.

So, here's kind of a recap – in general, health IT can further clinical priorities and public health goals, give us more systematic and coordinated approaches for OUD prevention and treatment and support clinicians' ability to access and use community research information and make referrals. Medication history and PDMPs should be available at the single point of entry for clinicians to access without having to use a whole lot of portals. I think that's obviously something that everyone would support – and then some more details.

But I'm interested in looping back and getting a sense if there is anything else we need to think about with regard to PDMPs.

**Chris Lehmann – Vanderbilt University Medical Center – Co-Chair**

So, if I may jump in there, Carolyn, I think this is a great recommendation, but the reality is that when it comes to PDMPs, we're dealing with state interfaces and we're dealing with a variety of ways that it has been implemented. With it, we run into a challenge for EHR vendors just like immunization information systems that vary from state to state. So, that's actually a big mandate on vendors. I'm wondering how Chip and Sue think about this.

**Chip Hart – PCC – Public Member**

I'm laughing because I was just sitting here going, "I want to get one of our e-prescribing experts to look at this so I don't say something stupid." So, if you can allow me to get some expert insight here locally, I would like to respond to this.

There is some trickiness relating, in particular, to the fact that we all, to some extent – this ends up being a bit of a third-party mess no matter what. Whether we are dealing with specific state issues, which we are dealing with, but you're also dealing with the third-party layers of everyone from Surescripts to whomever you might be using for your front end or not.

So, I think there's still – I want to say something that isn't vague – but I think there are still requirements here that we want to leverage on the EHR vendors, but it just has some layers of complexity. That's all. I can get you a much more detailed and helpful response with a little bit of thought.

**Susan Kressly – Kressly Pediatrics – Public Member**

So, I will tell you that I think, again, a lot of the biggest issues are not technology. It is really hard as a vendor to support multiple states, different ways of accessing and recording, looking up things in PDMPs, etc. and it even goes beyond that. There are now states that are looking at – they're putting medications that need EPCS that are not Schedule III drugs.

So, there are some states that are actually putting things like Bromfed, which is a cough medicine, and they want that to have to have pre-checks in it because it's being over-utilized. So, we're getting a little into the wild, wild west of scope creep of all of this, which is making it technically more difficult.

**Carolyn Petersen – Individual – Co-Chair**

Are there other thoughts around that? Chip, I really appreciate your offer to get a more detailed, nuanced answer. I'm hoping that's something we can look at discussing next week.

**Susan Kressly – Kressly Pediatrics – Public Member**

I will try to ask our folks that as well.

**Carolyn Petersen – Individual – Co-Chair**

Great. I don't want to beat a dead horse, but I think the more specific and nuanced feedback we can bring out for ONC as well as for ourselves, the closer we can get to something that is useful and feasible and can be supported for the HITAC and supported by the HITAC.

**Chip Hart – PCC – Public Member**

Yeah. I'd be glad to get that feedback. It is going to boil down to exactly what Sue said, which is akin to what we run into the on the IMS red side. Yeah, this is great, but there are 50 different states implementing this 50 different ways.

There's at least one vendor that covers a big chunk of them in terms of interfacing with a bunch, but all that means is as an EHR vendor, you are now dependent on a third-party to do this implementation and add just another layer of complexity. So, any time there is something that is state-level delivery is going to just be a huge problem for the EHR vendors.

**Susan Kressly – Kressly Pediatrics – Public Member**

And not only does it add complexity, it adds cost to the end user. It costs vendors to work with a third-party to incorporate the functionality that has to have a business case, which means it gets passed on to the end users, who are already feeling nickeled and dimed to support a lot of interface and exchange.

**Carolyn Petersen – Individual – Co-Chair**

Good point. Could we move to the next slide, please? This brings us to the other part of the discussion that we had last week that related to CDS and also, a public comment. With regard to CDS, there's a recognition of the value tools, including things like CDS Hooks for the OUD use case. However, there are also some concerns about burden and usability and how the CDS Hooks is triggered from the clinician's perspective in terms of managing workflows.

There was a bit of a question about how the task force can support CDS and for support CDS Hooks identified from the presenter's response, the importance of having some underlying data available in the USCDI, which is work being undertaken by another task force as part of the overall NPRM.

There was a note that the implementation can be made as simple as possible, obviously. We would aim for one click that makes it easier to track and monitor the desired outcome. Are there any other thoughts related to CDS or anything else in this opioid use disorder area?

**Susan Kressly – Kressly Pediatrics – Public Member**

Yes. This is Sue. Two thoughts – a lot of the CDS and hooking support can work well in a hospital or health system organization. That is way harder to get down to where the rubber meets the road, where a lot of people get care in rural America where also sometimes the internet is spotty. So, every time that we have clinical decision support that's a web call, we are leaving behind some people who may be the most in need of the functionality.

So, again, I'm going to plead for yes-and. There has to be a way to make this – not everybody has to reinvent the wheel, but there also has to be functionality at the point of care that's not always a web call somewhere to be enabled and that can be delivered to small practices in rural places in the country, where the opioid use disorder often has the highest impact and the most vulnerable patients.

**Chris Lehmann – Vanderbilt University Medical Center – Co-Chair**

I think Sue's point is an excellent one. Building good decision support is hard even if somebody builds it, integrating it into your EHR because you need to know what items trigger an action on the decision support. So, the integration is difficult and requires resources. That said, I think I want to go back to the comment I made earlier, Carolyn.

I think one of the less sexy but very efficient ways of bringing decision support into the treatment of patients and creating standardization are order sets. I want to emphasize how important it is, whether it's a patient with addictions or whether, as we talked about earlier, neonates that are born with withdrawal symptoms, creating order sets or creating a standard that people can use to create order sets in the EHR, they were relatively easy and quickly built because they don't require a lot of technical expertise, might be a very effective and very quick way of bringing decision support into the treatment of this disorder.

So, I really recommend that we look into this as an actionable item down the road.

**Carolyn Petersen – Individual – Co-Chair**

Thanks, Chris. So, we are coming to the bottom of our meeting. It looks like it's 10:27. I think Beth from ONC had a bit of information she needed to share with us. Beth?

**Beth Myers – Office of the National Coordinator for Health Information Technology – SME**

Yes, thank you. I just wanted to give everyone a quick announcement. Those of you who are

on the SACA list will have already received this in your email from Lauren, but just to give a head's up since hopefully people weren't multitasking and reading email at the same time – ONC and HHS as a whole made several announcements this morning.

The first one that I want to draw to your attention because it impacts the schedule for the task force and some of the work that you all have been and will continue to be doing that we greatly appreciate is that the comment period for both the ONC rule and the CMS rule have been extended. That extension was announced this morning and posted in the federal register. So, an additional 30 days has been added to the public comment period for the ONC-proposed rule and it will now be closing on June 3rd instead of May 4th.

So, we are asking the committee to continue doing the work that they've been doing and have recommendations prepared for the May 13th meeting with transmittal letters to the National Coordinator by the 27th. There are new tentative schedules going around. So, just check your email for that. Lauren has sent that around to everyone already.

The second announcement is that the Trusted Exchange Framework and common agreement second draft – so, that does include a second draft of the Trusted Exchange Framework, a second draft of the minimum required terms and conditions that had previously been released, and then a first draft of a QHIN technical framework – so, that includes some of the technical provisions that are part of the overall package of the Trusted Exchange Framework and Common Agreement or TEFCA, has been publicly released as well for public comment. There is a 60-day public comment on that. That will close on June 17th. So, that has been posted this morning and is available on ONC's website.

In addition to that, the notice of funding opportunity for our recognized coordinating entity, which would be an industry-based nonprofit entity that would be responsible for finalizing the last bits of terms and conditions for the Trusted Exchange Framework and Common Agreement and actually administering the Common Agreement. So, the notice of funding opportunity for that has also posted and that is available for 60 days as well for applications. So, all of that information is available at healthit.gov/tefca. You should also have received an email from Lauren this morning that includes this information as well.

So, that was my announcement. If anyone has questions, please do let us know. I'm trying to get us stopped in time for the cutoff. I can pass that back to Carolyn.

**Carolyn Petersen – Individual – Co-Chair**

Great. Thanks, Beth. I appreciate all the information. I'm going to echo Beth's comment – if anyone has difficulty locating that or you don't get the email for some reason, feel free to reach out and I'll be sure that you get whatever you need.

So, our agenda had initially included a menu item – I'm sorry. I'm not speaking well this morning. It's very early and it's Friday. We had planned to have a discussion about some of the HITAC meeting feedback that we got April 10th. I think that's worth having a discussion with the larger group so we can revisit some of the thoughts that we've had so far and also get a sense of where we are and if we really want to stick with our initial thoughts. We are at

the bottom of the hour now. So, I think we will push this discussion forward to our next meeting, which is next Tuesday.

Before we schedule anything else, working towards that May 13th deadline for presentation of our guidelines, I wanted to check with folks about Friday versus Tuesday in terms of what our best day is for you all to meet, if you can let us know. It seems that this is a good time for everyone to get together. We'd like to keep that so we can continue to work as a group. But we do want to be respectful of your personal calendars and ensure that we put the meetings on days that work best for everyone.

With that, I will pass the mic to Chris for any final comments.

**Chris Lehmann – Vanderbilt University Medical Center – Co-Chair**

Thank you very much, Carolyn. I just wanted to thank our speakers. I wanted to thank the committee for the spirited discussion today and ONC for keeping us on task and on time. Thank you, everybody.

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

Thank you.

**Carolyn Petersen – Individual – Co-Chair**

Yes, thank you.

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

Okay. We are adjourned. Thank you, everyone. Bye, bye.

**Carolyn Petersen – Individual – Co-Chair**

Have a wonderful day and a great weekend.