Health IT for the Care Continuum Task Force (HITCC)

Transcript

April 12, 2019

Virtual Meeting

Members/Speakers

Name	Organization	Role
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Christoph Lehmann	Vanderbilt School of Medicine	Co-Chair
Ken Kawamoto	University of Utah Health	HITAC Member
Steve Waldren	American Academy of Family Physicians	Public Member
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Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Good morning everyone, happy Friday, welcome to the Continuum task force, we have Carolyn Peterson, one of our co-chairs, Chris Lehmann could not be with us today. We hope that the other members will join us soon, with that, I will turn it over to Carolyn and Sam, Sam Meklir, from ONC to get us started.

Carolyn Peterson – Individual – Co-Chair
Thank you, I'm glad we have a good group this morning, small but intimate, and we have a couple of really interesting presentations this morning, related to the clinical decisions functionality, and the data segmentation for privacy and consent management for API certification criteria. And then we will have a discussion about the request information related to the fourth quarter. At this point, I will hand the mic off to Ken Kawamoto to get us started on the PDF presentation.

Ken Kawamoto – University of Utah Health – HITAC Member
Great, thank you very much. I'm going to get my screen share going. Okay, it should work. I'm sorry, the share my screen for some reason is not working. Give me one second. I'll provide a – I'm not quite sure what is going on with the screen share. Okay, so I'm going to be providing background on the ONC and CDC sponsored project, that I think was referenced last by the PDF connect project folks. And, this one is around the CDC and ONC's efforts, to take the CDC guidelines for opioid prescribing for chronic pain management, and to put them into standard form for better integration into EHRs. The issue here is that, let's see – oh. Now it's working. So, I learned that FHIRfox does not work on this desktop for sharing, but Chrome does. So, let me see if I can share that. Okay, I think you can see it now.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
We can, thank you

Ken Kawamoto – University of Utah Health – HITAC Member
Awesome. Okay, so I will be presenting on that. This is again the standards-based opioid ONC-CDC decision-support resources for the CDC prescribing guideline, and I will talk a little bit about the development use and lessons learned.

Okay, so disclosures. In the past year, I have served as a consultant researcher or invited speaker with honorarium at ONC, SRS, and also ASAC. Also Hitachi, McKesson, Premier, Claysish, the University of Washington, UC San Francisco. And of particular relevance to this one, I am currently serving as a consultant to ONC on this project.

Again, the goal for this project is to provide standard space decision-support for the CDC prescribing guideline. This is an ONC and CDC-sponsored effort. There are a lot of contributors of course, CDC, ONC, AHRQ, Yale, SRS, ISAC, and many others. The approach, and I think this is where some of the relevance comes in to work with HITCC, this is using HL7 standards. So, in particular, CDS hooks. Also leverages **[inaudible] [00:04:29]** FHIR. And a knowledge and coding standard CQL, for clinical quality

language. We do make use of an open source framework for the decision support called open CDS. That's something I started a while back through some NIH funding. And we've gotten so far a pilot implementation at the University of Utah with the Epic EHR, using CDS hooks and Smart On FHIR. This is currently being scaled to other institutions on other vendor platforms, including at Yale with another Epic implementation, and at Indiana University with Cerner.

So, there are 12 recommendations. The initial batch that were targeted are these. These include using immediate release opioids when starting therapy, a pretty complex one I will talk about in a bit is really looking at morphine milligram-equivalents of the opioids being prescribed. Basically, normalizing and standardizing the overall opioid dosage, and being careful about going past certain thresholds where there is data that indicates an increased risk of overdose. Another one is to evaluate benefits and harms with patients periodically. Another is to consider offering a naloxone as a reversal agent for opioid affect, when there is an increased risk of opioid overdose. Using urine drug testing to make sure things that should be taken are being taken and not diverted. And avoiding prescribing benzodiazepines concurrently with opioids because that increases overdose risk.

 This shows you what this looks like in the knowledge representation. This uses CQL, clinical quality language. It is also starting to be used by CMS and others for quality measurement purposes. So, you can see here, it is saying, you can see here, it is defining what a total morphine milligram mix is, and giving some text depending on what that is, whether it is over 50, etc. As you can see, it is pretty human-readable. The intent of CQL is to express clinical logic in a manner that is not tied to specific implementations and computer programming languages but can be parsed into that.

 One of the key parts that we developed in this project is a terminology knowledge based on the National Library of Medicine's knowledge resources. This, for example, takes the content in NLM's resources and uses these APIs to create relationships between the medicines and all their content. This is important, for example, if you have medications that include oxycodone, even if it is a combination drug, finding all of the semantic. clinical drug components and all of their dosages so that we can appropriately calculate opioid dosages. So, this is something that is used a decent amount in this project.

Another part , something that I personally spent a decent amount of time on is free-text SIG parsing. Like with a lot of medications, free-text SIGs are pretty prevalent in prescriptions and are something that just has to be accounted for at this point. Assuming that you don't lock down the system to say clinicians simply cannot prescribe using free-text SIG's. So, at our institution, University of Utah, we identified in one year close to 20% of opioid prescriptions year were free-texted in the SIGs or instructions. That ended up being over 10,000 unique patterns that we saw. For example, somebody might say, one to two tablets every three hours for pain as needed, up to the max of 12 per day, not valid without seal, refill three days before use date, and use dates are this and this. The challenge with this is traditional analytic tools cannot evaluate these free text SIGs.

So, for example, in our EHR system, if you have a free-text SIG, the system basically bypasses it and says, "We can't really do anything with this." That is pretty substantial because it is about 20% of our prescriptions. At the same time, I looked to see if there was something that was available, thinking we

can't be the first ones to encounter this, right? This is a well-known problem. But I couldn't find anything that was available to deal with this. So, I developed something to deal with this. And this allows computation of about 80% of the SIGs with confidence. Things that we cannot process with confidence we will mark and just leave alone. It does reduce the amount of opioid prescriptions that can't be processed from the 20% range to more like a 5% range.

This shows how this works in the EPIC system. And to make this work for our purposes, what we did was – this is a fake patient, of course – Test Patient Opioid. What we did was, in this initial version, there was no CDS hooks availabilities support in the EHR, so we build some middle-ware that takes an EPIC-specific web-service-based decision support mechanism and created some middle-ware to convert. EPIC now supports native CDS hooks for when you open a patient chart, although not in the ordering process. That is what we are piloting now. When the ordering-based hooks become available natively from the EHR vendors, we should be able to move on to those.

You can see here the patient is on a number of opioids. Opioids are about to be prescribed; this shows recommendation number five, around opioid **[inaudible][00:11:14]**. When you sign the order, it goes out and pulls back content from the CDS hooks. So, this one is identifying that the patient's average morphine equivalents, that's what we call MMEs at our institution, is 87 milligrams per day and just be careful due to the dosage being high.

Some of the key things I want to point out here are, one, we have distinguished the notion of average and maximum OMEs per day. This is because our providers told us that everyone seems to use the notion of maximum morphine milligram equivalents, but in outpatient settings, a lot of times it is not relevant because you often times prescribed a month's supply. They say 1 to 2 tabs 4 to 6 hours as needed. But there is a clear expectation that you are not going to take that much, because if you do, you will run out and you're not going to get another script 10 days in. So, we preferentially use the average.

We can also do things like getting additional content for details. You can see here for example; we are doing free text SIG calculations where we can see in this daily dose max we say there is four daily max per SIG. It says in the SIG, maximum four per day. That has been parsed and picked up. Whereas if you just look at the first part, it says every two hours as needed which would calculate to 12 times per day rather than four per day. This would significantly change the calculations.

Those are the kinds of things that are enabled here. A fair amount of complexity went into allowing opening and closing things because they are not allowed a script in the CDS hook standards. So, this is all using CSS style sheets to make all of this dynamic stuff work. This was the UI that I created, I thought it was good but that is where it was. This is showing how this works in Cerner and some initial implementation at **[inaudible][00:13:38]**.

One of the things we did, that our colleagues at EPIC looked at and said, "That doesn't look quite right, you can do better." So, their designers helped us come up with a cleaner look. This is the same content; this is what is running production in our system right now. Basically, it cleans up the user interface quite a bit, but it has all the same content. It can still get all the details which are all the

same. We also built the smart on FHIR of this. This is on-demand access for this information. Of course, all the other content in the guidelines can be made available. Fight now there are efforts to get the remaining six guideline recommendations implemented as well. That is currently in process.
Some lessons learned. Whereas Smart on FHIR is fairly mature, CDS hooks is still bleeding-edge work. One of the things that we touched on is ordering-based CDS hooks are not yet standardized, so obviously it is not yet available in a standard form. We are working through. NHL-7 issues, such as do we separate out the medication versus procedure hooks. We did have to use some middle-ware at this point. As we depend more on CDS hooks' capabilities, we'll need to track the speed at which these go into product for EHRs.

Another thing we learned is that complex CDS hooks visual displays are handled differently EHR vendors. If you want to use just simple text, it is a no-brainer to make this work. When you try to do complex visuals, we found that harder and more challenging. Just as one example, j getting that section to open and close took a lot of work. One thing we learned, some EHR vendors said they established the CDS hooks framework, so when you put in the stylesheet, you can change the look and feel of the hooks outside the actual CDS hooks in the space pop-up. So, we were changing how the rest of the EHR looks when we invoke the CDS hooks service. Obviously, that is unintentional and whatnot. These are the kinds of things that need to be worked out and further standardized.

Also, when you look at the ultimate end-user functionality, we found it requires a hybrid of CDS hooks services and mobile EHR CDS capabilities. For example, whether you allow snoozing of the system. That is not currently supported in CDS hooks. For example, if the patient is in palliative care, you can say don't show me this again. Or the patient is undergoing active cancer treatment, don't remind me again for six months. These are things that currently CDS hooks doesn't support, so we have to do that within the EHR.

Things like enabling one-click order placement and cancellation, that is also not directly supported currently in the CDS hooks standard, so we have to do that in the surrounding rules framework. So, we do this, for example, naloxone placement. In the inpatient setting, when we discharge patients who are on high levels of opioids, which has had some significant impact. But we have to use some EHR-specific mechanisms. Also, restricting service is a relative context. As you can imagine, you don't want to call this kind of a CDS hook for non-opioids, but the hook itself may invoke it on any medication order, not just opioids, or perhaps even any order. You can imagine the computational intensity if you are about to order a CBC and you are invoking this, the amount of overhead that's involved. Obviously, you would put in things like "only implement this in outpatient settings" and only for prescribers, and only when an order is being placed. Or one of these types of medications, but those are all done outside of CDS hooks at this point. Those are called trigger guards in this context. It is something that is not currently efficiently supported in the CDS hooks standard, other than perhaps in the description.

At the same time, despite these challenges, evidence-based care support by standards-based decision support finally appears to be within reach. This is in production use. Through this and other efforts we've found our opioid prescribing rates have certainly come down quite a bit. I'm sure there are a lot of factors, including greater awareness. I think, it might be once you get things into production, in

clinical use, and in clinical acceptance, I think it passes a level, a bar that is hard to demonstrate with this type of work.

Some future directions were standards-based encoding of remaining six CDC prescribing guidelines, recommendations on CDS hook services, working on pilot deployments, working on some impact evaluation. Hopefully that is going to continue. Working on facilitating the enhancement and adoption of underlying standards, so a key for this for this, for example, is how to get the order-based hooks in place, standardized and adopted. We at the University of Utah are probably a little bit unique in that we can make all these sorts of enhancements and we have seven people who have been trained and certified to build new FIHR interfaces inside our EPIC system. I think for sustainability this really needs to be adopted at the EHR level, of course.

We are using Smart on FHIR in addition to CDS hooks for workflow integration ultimately we are aiming for widespread dissemination impact.

This is a partial list of acknowledgments, for folks who have been engaged in this project. I think that is all I have here, so if you do have time, I'm happy to answer any questions.

Carolyn Peterson – Individual – Co-Chair
Thank you, Ken, we are doing very well on time, so I think we have plenty of time for a good discussion. Any questions anybody has?

Al Taylor – Office of the National Coordinator for Health Information Technology – SME
Ken, this is Al Taylor, thank you for the presentation, it was great to see it again. I did have a question for you, is it possible to measure if the provider accepted the advice, and avoided or monitored a prescription based on the results?

Ken Kawamoto – University of Utah Health – HITAC Member
Yes, definitely. In the EPIC system, that is pretty easy to do. I also chair our Enterprise Clinical Distance Work committee, so we routinely check that information. I think the only tricky part is that it is a pretty well-known behavior for a lot of these kinds of things where people will cancel the alert or reminder, click out of it, and make the changes outside of the interaction with the alert. So, that can be a little bit tricky, right? To deal with that, you have to put in logic to say things like within so many minutes of somebody seeing something, showed that they made the desired change, or did they make the change. And moreover, in certain settings like inpatient, you want to make sure it was on a discontinuation in the context of a discharge. So, there are nuances like that, that absolutely, at least in our system, which is EPIC, that is very trackable, and we do track those kinds of things.

There has been a lot of discussion in CDS hooks standard on how we want to be able to track at least the changes that are made directly in response to the CDS hooks prompt. To say, did they click on this or click on that, or follow this order or did they cancel the order. To make that data available through a standards-based mechanism. That is not yet in the 1.0 release of the standard that's currently in place. More issues need to be worked out with that, but it should be coming to the CDS hooks standard in the future.

Al Taylor – Office of the National Coordinator for Health Information Technology – SME
And that would apply to all CDS hooks, not just opioids?

Ken Kawamoto – University of Utah Health – HITAC Member
That's right, that is the idea, and a lot of other things I mentioned, too, that we are trying to put into the CDS hook standards. I think the effort has been to get a minimum base that's been well-tested and go from there.

Al Taylor – Office of the National Coordinator for Health Information Technology – SME
Thanks for that, thank you. I appreciate you going through that.

Steve Waldren – American Academy of Family Physicians – Member
This is Steve Waldren, I appreciate the work. I think there is a strong need to be able to have these types of solutions moving forward. One of the challenges is the administrative burden and the usability challenges of the technology. Have you got any end-user feedback on usability, satisfaction, those types of metrics?

Ken Kawamoto – University of Utah Health – HITAC Member
We haven't specifically measured for this one, just by the nature that it is a pop up. I assume that people generally would prefer not to see pop-ups. What we found generally is pop-ups, people don't like, but they tend to respond better than to non-pop-ups. We did take a lot of user input into consideration when developing this. I had a number of primary care and pain medicine specialists, etc.. helping to design this. I went through a fairly extensive round of redesign. For example, the opening and closing content, that was a pain technically to implement. It took a lot of work. I tried to ask them, "Can I just not do this because it is going to take a lot of work?" They said, "No, I really don't want to see all that content **[inaudible] [00:25:11].**

So, I mean, in that sense, we did try to do that. I haven't heard too many complaints, which when something is bad, really bad, we will definitely hear complaints about, so that is good. For this one, we haven't specifically asked. We have developed other types of apps. We have a neo-natal bilirubin management app that uses this type of technology where we did specifically ask those things, and we found excellent usability and documented time savings and read text comments that really praise the app, but we have not done the same for this.

Al Taylor – Office of the National Coordinator for Health Information Technology – SME
This is Al Taylor again. Regarding for the activation of the Smart on FHIR app, can you talk about the automatic nature of that, or what triggers the Smart on FHIR app running, for a particular use or in general?

Ken Kawamoto – University of Utah Health – HITAC Member
For this one, it's just a tab in the EHR. The default is to select it in your activities, or it might be deeper down in your menu that you have to favor it, or just click from within the menu. So basically, you click it, it loads, and then of course for all of these, the timing and latency is the big issue. One thing I didn't

mention, but was a key production issues, was the profiles. EPIC's implementation did not require a search for a past medication with the time filter. So, what that meant was that for a lot of these guidelines, we looked for how continuously the patient has been taking opioids over the past three months, and the alert would never FHIR in each of the past in each of the past 39 days, or three time-periods, the patient hasn't been on opioids for at least 21 days of those, just to try to reduce the fatigue.

What we found was, because the profile didn't include it, and EPIC didn't implement a way to filter past medications, when we needed to pull the past medications on a typical patient, it might take five or 10 seconds to pull the past medications through FHIR in production. So, obviously that was unacceptable . You were trying to place an order and you are waiting for 10 seconds. You can just imagine, that is just not a good thing. So, we built a new profile and updated the interface so that you could specify the time window of the prescription that we care about, and then it became snappy. But, anyway, that is a key issue.

In terms of activation beyond the provider remembering to use and to access, you can recommend something to be used in CDS hooks, or one of these alerts. We haven't really gone there yet because, what our experience is, the only things people tend to really respond to are pop-ups and we try to minimize those. And when we put in passive reminders, we find people often times ignore them anyway, so we are trying to use education. It is a challenge, but from this perspective I think it is almost a good challenge because when you are allowed to pop something up in front of a provider, you can do that even if the design is poor or if people don't want to see it.

When it is something people actively go to, it forces you to build things that people want to go to and will save them time. I would just be a little bit careful about the notion of having a lot of pop-up alerts to remind people to use smart apps. I think that is generally not the ideal approach. But, it is a challenge. We have a bilirubin app that is used in 93% of our births, about 25,000 times a year, and that saves about 400 hours of provider time. But, it is the kind of thing where not everything saves that much time. Sometimes it is a challenge.

Steve Waldren – American Academy of Family Physicians – Member
One other question on the informatics side of things. One of my concerns is the scalability of building out these recommendations and how they start to interrelate. It seems like the standard is not really built to support that, there is not another set of standards to manage libraries of these you talked about, the trigger guards and the interdependencies can be an issue. I guess, from your experience, is there anything from a policy perspective, or from this committee would say, "I wish you guys would think about this or recommend that?" Is there anything to help support you in those regards?

Ken Kawamoto – University of Utah Health – HITAC Member
I think CDS hooks actually makes it a little bit easier because right now, combining different content is kind of a pain, and when you have overlapping content, we run into this. For example, there are a lot of things people want to do when they are being initiated on new opioids. Opioid-naïve patients are getting started on opioids and at some point, we literally have four different initiatives going on. The typical ways of integrating that is hard. I think it would be easier if all of those were CDS hooks services,

because hopefully they will be a little bit more granular and you can have almost like a uber-meta service that looks at all the content of the other services and merges them in. I don't think that's something that should necessarily be standardized. I think it is something folks are certainly aware of. I think probably from the standards perspective, probably the biggest things are the adoption of CDS hooks is it is still pretty early. As far as I know EPIC is the only one that has supported any CDS hooks capabilities in production yet. And all vendors doing it currently are only doing the patient view hook and missing a lot of these other, more sophisticated capabilities. we are discussing. That's still moving forward, but I think that would be something that would be good to support, especially as the use case becomes more important.

I do think, like anything else, having access to the underlying data is probably the biggest. If you don't, you are going to make erroneous recommendations or you are just going to have users spending more time entering data. I think supporting the needs of different initiatives through, in particular, the USCDI, and having the USCDI as a mechanism moving forward is very important. Even query parameters, one of the challenges here is that in a test environment, things may look beautiful, but if it takes five seconds or even three seconds extra, that is going to really add up, and it is just going to frustrate people.

Carolyn Peterson – Individual – Co-Chair
Thank you, Ken. Do we have any other questions? Okay, thank you for coming and giving us this presentation. It'll be really helpful for us as we think about how to address the opioid use disorder RFI in the NPRM and also formulate better recommendations for the broader HITCC.

Ken Kawamoto – University of Utah Health – HITAC Member
Great, thank you for the invitation.

Carolyn Peterson – Individual – Co-Chair
We will now go into the data segmentation for privacy and consent management for application programming interfaces certification criteria. With us today we have Alex Kontur, Samantha Meklir, and Al Taylor from ONC to talk with us on this subject.

Samantha Meklir – Office of the National Coordinator for Health Information Technology – SME
Thank you, Carolyn, this is Sam, I just want to recognize the availability and expertise of Alex for joining us today. Alex, did you wish to kick it off and speak to this slide, or would you like for me to do that and transition it to you?

Alex Kontur – Office of the National Coordinator for Health Information Technology – SME
I was going to speak for the next slide, I believe.

Samantha Meklir – Office of the National Coordinator for Health Information Technology – SME
Okay, we developed this slide. This is not new content; the task force has seen this before. But what we wanted to do was again, restate the overarching charge of the task force. You'll see that at the top of the slide. This has been available since the kickoff and then throughout, and really identify that part of this charge is regarding the task force providing recommendations on a specific proposal regarding

data segmentation for privacy that is in our proposed rule. It is a regulatory proposal. It is described both in the regulatory text and in the preamble the proposed rule.

So, while DS4P, or data segmentation for privacy is something we have discussed in the task force as it relates to pediatric health I.T. recommendations, it is also relevant for the opioid use disorder use case. It is also its own proposal in our rule. That is something that Alex is going to walk to describe what we are putting forward. That specific proposal is what the task force asked to provide a recommendation on. We recognize again, the relevance of this proposal as it relates to the topics of pediatrics and the OUD use case that has been the focus of this task force as well. With that, I would like to turn this over to Alex.

Alex Kontur – Office of the National Coordinator for Health Information Technology – SME
Thank you, can we go to the next slide, please? All right, thanks.

I think as most people on this call are aware, the data segmentation for privacy standard provides a technical capability to enable a system to tag the patient's record in the CDA format, such that the recipient, if that recipient has also implemented the standard, could be able to recognize that the patient's record or the CDA was considered sensitive and needed special protection under federal or state privacy laws.

So, the 2015 edition to Health I.T. Certification Criteria included two criteria based on the HL-7 data segmentation for privacy and CDA standards. There was 170.315 B7 that enabled the user to create a summary record, a CDA document, tagged as restricted at the document level. Then there was 170.315 B8 which pertained to the capability to receive a tagged summary record sequestered from other documents, and to view the document without incorporating the data from the document.

Certification to these two criteria was not required to meet the definition of certified EHR technology, nor was it required by any other HHS program. These two are provided 2015 certification criteria provided initial steps towards the ability of interoperable systems to use technical standards to compute and persist security labels, to permit access, use, or disclose protected health information, in accordance with applicable policy and patient preferences. However, stakeholders shared with ONC through mediums like public forums, listening sessions, and written correspondence, that focusing criteria for segmentation at only the document level did not permit providers the flexibility to address more granular segmentation needs and patient preferences.

So, in consideration of particular feedback, as well as ONC's data policy approach to adapt certification criteria on a glide path, in this 21st century cures NPRM, ONC has proposed removing the two existing certification criteria completely and replacing them with two new criteria, also based on the CDA and DS for P standards. The new criteria are 170.315 B12, which pertains to the ability of a use to create a summary record tagged as restricted at the document section and entry or data element levels. So, those are two new, additional capabilities above just tagging at the document level. 170.315 B 13 pertains to the capability to receive a tagged summary record and preserve the privacy markings on that record to ensure fidelity to the tags.

Additionally, ONC proposed a new certification criteria beyond these two, that is 170.315 G 11, which pertains to the capability to respond to requests using the FHIR standard in accordance with the consent to share consent resource profile design, which was called the consent IT in the preamble. Certification to this criterion would be at the health IT developer's discretion. It would indicate that a system is capable of responding to requests through an API, for patient consent directives that include standards-based security labeling. The consent IG provides instructions for using the FHIR consent resource to capture the record of a healthcare consumer or patient's privacy preferences and those are expressed using these tags or security labels.

One thing to note with this labels. One thing to note with this particular criteria is that it is based on a different version of the FHIR standard for trial use three, rather than FHIR use two. This is because the resource was only introduced in three, whereas two relied on the contract resource.

Overall, we believe that health IT's certified to these proposed criteria could support practical settings and use cases, including the pediatric healthcare setting. And again, as Sam mentioned, we are asking. for the task force to consider these proposed criteria, provide a recommendation for whether they should be adopted, and we also welcome the task force to provide recommendations aimed at supporting more widespread certification to these criteria, especially considering any real-world experience with the DS4P standard, data segmentation, and patient consent management.

That is what I wanted to cover, I appreciate the opportunity to come on this call and talk to you a little bit more about these proposals.

Carolyn Peterson – Individual – Co-Chair
Okay, thank you, Alex, and Sam, of course, also.

This is a good overview of the proposals I think, and kind of a bit of the technical background in the changes that are being proposed. I'm wondering what the first task sense these changes are for the other members of the task force.

Steve Waldren – American Academy of Family Physicians – Member
This is Steve, as it relates to this notion of tagging CDA documents relative to sensitivity, I don't know enough to know if these changes are better than the other criteria. Based on the level of confidence I have with ONC staff, I would probably say that to be true, that these are better. But one of the concerns I have is, in regard to privacy and confidentiality, if I receive information from the patient and it is given to me with restrictions on how it is supposed to be used, it is up to me to maintain that confidentiality.

By tagging something in the CDA and sending it somewhere else, I am now pushing that confidentiality obligation to somebody else. It is just like saying, "Okay, I'm going to send you this patient with acyclovir and methadone, and one of the problems is going to be depression, but acyclovir is only shared with infectious diseases and the PCP. Methadone is not supposed to be shared with anybody. And depression, you can share it with the PCP, but you don't have to share it with the patient's spouse." I don't have any ability to say that receiving system is going to be able to maintain those.

What I'm concerned about is, what are the functionalities to make sure that those data are not placed in documents that are sent to places that it is not supposed to be sent? And, how do I as a user a user has the functionality to really maintain those really complex sharing permissions? I don't know that we have that type of functionality. I'm trying not to be negative on where we are at today because I think those things are good, but I don't think it gets us to the point where we need to be. So, I don't know that having them as a part of a voluntary certification gets us to where we need to be.

Carolyn Peterson – Individual – Co-Chair
Do you have any thoughts about that, Al or Sam? It strikes me that trying to determine or have confidence in how information is handled on the recipient end is maybe a concern that relates to a lot of different things that we transmit. I'm wondering if there is other work that has been done in other areas that might address that, or provide some sort of security or enhancement to ensure that that doesn't become an issue?

Al Taylor – Office of the National Coordinator for Health Information Technology – SME
This is Al, and Alex, if you are still on the call, and I say something that is wrong, if you can step in and correct me. But the two criteria are sent and received, so the send means can prepare a document with appropriate markings to each of the data elements. Receive means, receive that marked document, marked entry, marked section, and understand what those markings mean.

So, being able to handle the specific data elements that are marked in that appropriate way, according to the access marking and the disclosure and redisclosure markings that are part of the data segmentation. So, understand that not only does the receiving EHR have to understand the markings, it is always true that the receiving organization has to do appropriate things with the data they receive. So, if it gets past what the machine capabilities are, then that responsibility of proper handling, then does get transferred to the receiving organization. But that is covered, that ability is within the receive criteria, the new receive criteria.

Carolyn Peterson – Individual – Co-Chair
Thank you, does anybody have any other thoughts or questions? Okay. Al and Sam, I really appreciate you coming, and Alex, I appreciate you coming and talking with us today about this information. We are a small group today, and it may be that in the next week or two we circle back with questions. We will be needing to write at least a small number of recommendations relative to this information and maybe additional questions from members. I think with the slides and the transcript from this meeting, we will have a really good start on understanding what we want to do. So, I thank you for coming and presenting to us today.

Samantha Meklir – Office of the National Coordinator for Health Information Technology – SME
Thank you, Alex.

Al Taylor – Office of the National Coordinator for Health Information Technology – SME
Thanks.

Steve Waldren – American Academy of Family Physicians – Member

Thank you very much.

Carolyn Peterson – Individual – Co-Chair
And, it looks like we are we are three or four minutes ahead of schedule, but I'm wondering if we can address the opioid use disorder discussion now ? Sam, it looks like you and Al are teed up for that.

Samantha Meklir – Office of the National Coordinator for Health Information Technology – SME
Sure, thank you, Carolyn.

These are questions, discussion questions that roll up to the broader charge. Here, really, we are responsive to the interest of the task force to focus on PDF in the context of the opioid use disorder request for information. So, what we have on the screen are discussions questions that align with the broader charge, asking to explore health I.T. for OUD, that really focus on asking the task force members to provide a general value statement for how health I.T. can support health I.T. prevention and treatment, as relates to the use of criteria advancing interoperability. Then, looking at some more granular input on the health I.T. solutions and effective approaches that could improve prescribing practices and CDF. We have now heard two presentations focused on CDF.

With that, Carolyn, I think if we could have the task force members focus on really the two components as outlined on this slide, around a value here and relevance of this topic for this space. And really on exploring an approach that we laid out for pediatric health I.T., where we look at clinical priorities and how they can be supported at clinical priorities and how they can be supported by existing new or proposed criteria.

Then, looking at CDF, we can have a few minutes of discussion here, then we would integrate that discussion into the updated Google document and share that with members. Then this would ultimately help inform some of the content then this would ultimately help inform some of the content that we offer as part of our transmittal letter.

Carolyn Peterson – Individual – Co-Chair
Okay. Do we want to start with the questions? Or do you have a different idea for how best to approach this?

Samantha Meklir – Office of the National Coordinator for Health Information Technology – SME
We created the bullets here, just to help prompt the input and discussions. If folks have another preference for the approach, that is welcome as well. We don't want to be overly prescriptive here, but these were meant to aid and facilitate input.

Carolyn Peterson – Individual – Co-Chair
Okay, we can start with these, I know we are a small group today, but we can at least get some thoughts down and use that as a starting point for, hopefully, making it a little bit more robust or at least more nuanced.

So, let's see, in general, what is your general sense of how the existing program requirements and the proposal in the rulemaking support use cases related to OUD prevention and treatment in additional areas for ONC consideration for effective implementation for health I.T.?
So, the general sense and value for how the existing and new criteria can support clinical priorities and advance interoperability for OUD.

I would say, I think it is great to put something in the sand, and to start thinking about how to move forward. I'm guessing that we are fairly early in our understanding of all the different things that we can do as a society and as medical professionals to try to address OUD. But, this is the way I'm starting to organize activities that are specifically related to the medical environment, and advancing interoperability of course is important because we want to make sure that all of those providers who need to know what is going on with opioid use are aware and can make the best medical recommendations and follow through with the treatment plan.

That, of course is speaking as a non-provider, so I'm interested as a non-provider, so I'm interested to get Steve's input as well.

Steve Waldren – American Academy of Family Physicians – Member
I was struggling to figure out how I would respond to these. I think a couple of things, so, one, I might have seemed a little negative on the data segmentation. I'm not, because I think that is one of the pieces of the proposal that would help in this regard of opioid management. Once I share information with somebody that I need to share it with, have permission to share it with, to make sure that they know what the requirements are around that data, to share it beyond or outside of their control. That allows us to be more confident, I think, in the sharing of opioid -related information that can be sensitive or seem sensitive by a number of patients.

I think the proposals around supporting the continued movement toward FHIR and API allows us to be able to exchange information about opioids more widely, where appropriate. So I think those are also important provisions that are in there. Those are probably the two that come to mind.

Carolyn Peterson – Individual – Co-Chair
Okay. General sense and value for how the successful implementation of health I.T. can support OUD and aid in the achievement of national and programmatic goals, especially where they may align with initiatives across HHS and with stakeholder and industry led efforts?

To me, this suggests that we are starting to edge into the public health environment, talk about national goals, and aligning across initiatives within HHS and others. It seems to be a broader take. I think it is certainly important that health I.T. and development is organized and structured in such a way that it can engage and facilitate in interoperability with a broad range of engaged parties. Certainly that certainly that would involve clinical parties across multiple settings . But I think also getting the public health aspect is something that would potentially interact with public health systems, such as they are today, would be useful.

Although, opioid use disorder is treated at an individual level, we do understand that it has systemic components, and at least the initiative that we undertake in this century will be at a more systemic and broad level.

Steve Waldren – American Academy of Family Physicians – Member
This is Steve, I would add to that as well, making it available to the clinician, the community resources that are available to support drug dependency and addiction making it easy for those referrals to community resources for patients I think would be helpful.

The other is continued harmonization and hopefully merging of the prescriptive drug monitoring programs, e-prescribing of controlled substances. And making it to the point, at least from a clinician perspective, there is not anything different there -- that I'm able to get the opioid history able to get the opioid history for multiple states, no matter where the patient got those things filled, brought into the EHR, just like I have all the other med history stuff being brought in.

It doesn't require the clinician to go out to another app or another portal to pull that information in. I think that is another thing that could be done to improve the opioid situation that we have.

Samantha Meklir – Office of the National Coordinator for Health Information Technology – SME
Just to clarify, you are referring to medication history from across states.

Steve Waldren – American Academy of Family Physicians – Member
Yes, so, using the e-prescribing stack in the infrastructure, you can get that med fulfillment history, so there is a set of standards to do that. And it would be nice to make sure that is the way things can happen with the PD MPs as well. I know that MCPDP people have worked on what that would really look like. I have read somewhere between the two proposed rules and some of the proposed legislative language, there was somewhere talking about PDMP, e-prescribe, and controlled substance all using the same set of standards, which is a great push forward. But also, there's this notion of a single point of entry for the clinician to get that information available and make that information available to those monitoring programs.

Samantha Meklir – Office of the National Coordinator for Health Information Technology – SME
Thank you.

Carolyn Peterson – Individual – Co-Chair
And, I think the point about not winding up with a system that involves the required use of a number of different portals is a really good one because with whatever we create, it is going to be important that it is in some ways streamlined for provider use, so that we get good buy-in and so people are willing to do that. And the technology actually gets used. I think we know there are sometimes when things are not convenient or are overly burdensome in the way that providers have to go about using them, we don't get good uptake. It would be a pretty important thing I think, for the providers and the people who support them and support their work.

Steve Waldren – American Academy of Family Physicians – Member

And in Ken's presentation also, this notion of how do we continue to bring the best evidence and best practices through clinical decision support that is well integrated into the workflow to make it easy for clinicians to do the right thing and know how to treat these patients with addiction dependency, or how to manage patients on chronic opioid, I think, would also be something that we may want to look into.

Carolyn Peterson – Individual – Co-Chair
Yes, that is a good point. And the last bullet point, discussing health I.T. solutions and effective approaches to improve opioid prescription practices and clinical decision support. I think that is my cue to put that in your hand, Steve, since you are actively working in the field, do you have any thoughts to share about that aspect?

Steve Waldren – American Academy of Family Physicians – Member
That was directed towards me. I'm sorry, I thought you said Ken, I apologize, ask me one more time.

Carolyn Peterson – Individual – Co-Chair
Okay, the last bullet point gets at health I.T. solutions and approaches to improving prescription practices CDS, and since I'm not a prescriber, I'm not that very well placed to address that, but you might have some good thoughts to share.

Steve Waldren – American Academy of Family Physicians – Member
Sure, it has been a while since I went through that process, too. But, I think it is this notion of, how do we get CDS to make it easy to do the right thing, and hard to do the wrong thing? And this notion of pop-ups, when Ken talked about monitoring responses to their interventions, he talked about some people just cancel the pop up but they go out and do the task that you asked them to do.

I think making sure that these implementations of CDS it is a way that, here is what you need to do. It is kind of that one click, the Amazon one-click purchase, making it as simple and easy as possible to do the right thing. And I think you will get a lot more uptick and it also makes it a little bit easier to track and show the outcomes you are wanting.

But I don't know if I have anything specific from a clinical perspective that I would be able to add in regard to what types of CDS would be extremely helpful.

Carolyn Peterson – Individual – Co-Chair
Okay. I think we will probably circle back on these as we wrap up the recommendation in the next meetings. So, we don't have to get it all today, but this is a good start for coming up with some broad recommendations for ONC and for the full HITCC.

I know I discussed a bit with ONC on Wednesday at the in-person meeting, what they were looking for. And although they are back in the format of recommendations, it is not a case where we need to provide a large number or any specific detail. We need to provide them general feedback that can help them move in a particular direction. So, I think we have a good start on that today.

Does anyone have any other thoughts regarding this discussion? Anything else we should be thinking about in terms of addressing the opioid use disorder prevention and treatment?

Samantha Meklir – Office of the National Coordinator for Health Information Technology – SME
This is Sam, I would just add, in addition to any thoughts, if any of the ONC subject matter experts have any clarifying content and report information based on the discussion they wish to offer, please do so as well.

Carolyn Peterson – Individual – Co-Chair
Yes, we would very much appreciate that. Thank you.

With that, we will roll up in the slide deck towards the top. We have some feedback from the ONC in-person meeting. On Wednesday, Chris Lehmann, my co-chair and I, presented information about recommendations seven through ten from the pediatric portion of this task force's charge. We were at the March meeting and people were pretty comfortable with what we had, there wasn't any real controversy. At this meeting, we had quite a bit more feedback about the other things we had discussed. And some thoughts for us to consider as we go forward with this and bring back our final proposal to the meeting on April 25.

So, our colleagues at ONC have captured this on a couple of slides for us to look at. I think being that we are small today, we probably won't be able to do a lot of in depth discussion, but I did want to put this out there for consideration because I think it would be valuable for us to circle back and at least read these things briefly and be sure that we are confident with what we have brought forward or make any changes if we think that is appropriate.

So, with regard to logistical comments and questions related to the charge and our approach, the members were looking for clarification on the framing for recommendation that they are voting on. Members sought clarification on the pediatric recommendations as pertains to supporting certain settings or universal settings. They thought a listing of functionalities that should be included in the technology and reference each standard, if the time will allow us to do that. ONC is going to work on this for us, developing a visual table based on the correlated items in the technical worksheet that we went through, that will be helpful. And, there was also a comment to limit certification requirements because it may cause regulatory burden, a caution to avoid creating redundant certification criteria or requirements. That came up from a couple of individuals and I think while there is some understanding that we have some different needs with regards to the pediatric setting, there is also a concern that that doesn't become a significant alternative structure that providers and others have to conform to.

With regard to recommendation eight, that is the one to associate maternal health information into demographics with the newborns, there is some disagreement on the statement that there are no standard nomenclature available. There was a question on what process has been used to look up the certification criteria in the pediatric setting, and if there has been input from consumers. There if there has been input from consumers.

There was also, related to a separate question, if there was any discussion about newborns and adults who are privately adopted, they should be able to link to the birth maternal information that is critical and crucial for the care of the child. And a suggestion to where look where we can push out and allow the consumer to be able to transfer and be able to determine privacy and control?

So, we can go to the next slide. With regards to recommendation four in the supplemental, the problem specific age of consent. There's a comment that removing this children's EHR format requirement to the main recommendation can be a red flag. It is not vendor responsibility to know all the state and local laws, and people were aware of that. But there is a feeling that they should be required to provide certified technology that fits the customer's practice.

With regards to recommendations five in the supplemental, that is the synchronized immunization histories with registries, it was noted that there are school forms in certain states and local areas that cannot be digitized.

And just some general comments , they encouraged the task force and chairs to listen in on USCDI meetings for the discussion on pediatric vital signs. There was a comment that there are substantial overlaps and that our task forces should stay in sync. There was a suggestion of FIHR-based apps as we move toward the app economy and to make sure there is nothing specific in our regulations to prohibit that.

Also, a commendation to the task force for taking on complex issues. So, on the one hand, there are some, I feel like the feedback echoed some of the discussions we had within the task force. At the same time, while I understand the desire not to create a parallel universe, I am challenged to think about how else to address some differing needs from the adult use case. And I'm also wondering how we can meaningfully, how we would sync up with USCDI. Perhaps there is some role for them, in looking at our specific concerns in shaping they do to be broad enough to address our concerns.

It seems to me that if it was as simple as us going with their recommendations, maybe we wouldn't be in this situation of needing to look at pediatric health records in the first place. But, I'm eager to hear any thoughts you might have, Steve, just off the top today, and any feedback from ONC as well.

Steve Waldren – American Academy of Family Physicians – Member
This is Steve, I did listen in to that part of the conversation with Chris, and the folks. For me, I think it is if it can be harmonized into one, and it is just part of the USCDI for any EHR, awesome. Let's do it, and having something separate, just to be separate doesn't make any sense whatsoever. But, I think, and Chris started to try to make this case in the meeting, there are content and vocabulary things that are different.

You know, I think about head-to-rump versus height, other things that are slightly different. So, I think the strategy that makes sense for us is to say, "That is great, but here, the concepts and the data in the vital signs and the things we need to represent to take care of kids, show us that you have that, and that makes sense." Not just saying, oh, cranium-to-rump, that's close enough to height, so we should

just use height. That is where we start to get a pushback, and say, no, there are different concepts that need to be separated out.

Our task is just to say, here is what we need to represent and demonstrate to us that you can represent it, and if not, then we need to create a representation.

Samantha Meklir – Office of the National Coordinator for Health Information Technology – SME
This is Sam at ONC, I'm happy to provide some general remarks, but Al, if you're still with us, can you just provide some clarifying information on pediatric vital signs as proposed in the USCDI?

Al Taylor – Office of the National Coordinator for Health Information Technology – SME
There is specific discussion in the USCDI task force around adopting those three vital signs. The point was, one point we brought up, only one of those is an actual measurement and the other is a calculation. The other two percentiles are calculations, but from the three that we were considering, USCDI is also considering, adding that particular vital sign to the demographics, or I'm sorry, the vital signs section of USCDI. So, there is that.

As far as the other, I'm not 100% sure about the rest of the crosswalk because I'm just getting up-to-date on work from the USCDI task force. Was there more that you wanted me to talk about?

Samantha Meklir – Office of the National Coordinator for Health Information Technology – SME
think that is fine, I think based on the comment, if we can share any further crosswalk input we may have if folks are interested.

Al Taylor – Office of the National Coordinator for Health Information Technology – SME
I did want to say one more thing about the USCDI. Your point is taken, Steve, about there may be, I don't want to say important enough, because it certainly is important and critical for the care of this population that we are talking about, but, it affects enough people, and I think it is easy to make that argument as well for some of the pediatric concerns.

We are still developing the criteria for thresholds to rise to a level of USCDI data elements or data class, but data elements or data class. But when the case is made that it is a mature enough data class, data element, with enough importance overall in the healthcare enterprise, then that is something that doesn't have to be called pediatrics, but it could be. If there is something new that ought to be introduced to become a standard part of the USCDI , then it would just have to meet the criteria that we are setting for what we need to be including. What sort of levels of quality or levels of detail for something that might want to go into the USCDI?

Does that make sense? We are not saying that the pediatric stuff isn't going to go into the USCDI, the pediatric stuff would be considered just like everything else will be considered for inclusion.

Samantha Meklir – Office of the National Coordinator for Health Information Technology – SME
Thank you, Al. This is Sam. I would just offer in regard to what we heard and how we can support that, Carolyn described that at ONC, we think that capturing the existing, proposed, and new criteria ,

aggregated into a visual table, as that aligns with the ONC pediatric health I.T. recommendations would be helpful to delineate that correlation that we confirmed and walked through.

We were also asked, what is the outgrowth in the framing of the vote that the HITAC would be taking? In particular, as it pertains to implementation considerations. So, we would be also framing some clarification as having identified it and spent a great deal of time on this framing and identification of future work and opportunities, particularly as it may inform any type of nonregulatory implementation guide type document, as well. So, we will be focusing on some of that and it was very helpful feedback for us to hear how we can effectively convey and support the process for the larger HITAC.

Carolyn Peterson – Individual – Co-Chair
And, we really appreciate all that you are doing to try to support this work, and to read the leaves, and help us understand how we can best coordinate with other task forces that are related to the NPRM and the broader work. I think sometimes it is really hard to coordinate a number of needs and to bring perspectives and goals all at once, and I am greatly of the work both of these task force members and ONC in helping us navigate this, because we really want to bring back to the full HITAC something that can be agreed upon improved. At the same time, we're wrestling with some complex issues.
With that, we will move to public comment.

Operator
If you would like to make a public comment, please press *1 on your keypad, you may press *2 if you would like to remove your comment from the queue. It may be necessary to pick up the handset before pressing the star keys. Our first question is from Ben Moscovitch, please proceed.

Ben Moscovitch
Thank you very much, my name is Ben Moscovitch I am the director of health I.T. efforts at the Pugh Charitable Trust, which is a large public policy and research nonprofit. Thank you very much for taking my comment, and for all the work that this committee the broader HITAC and ONC has put forward in these pediatric-focused rules.

We have done research that has demonstrated that EHR usabilities, how the systems are designed and used and implemented can contribute to patient safety challenges. For example, in an article published in *Health Affairs* late last year, research showed that of 9000 safety events examined, in about a third of them, EHR usability contributed to those errors.
And we appreciate many of the clinical priorities identified by ONC, which are many of the right ones, which we found in our research, such as around weight-based dosing. We think there are additional opportunities for ONC to improve the usability and safety of EHR's, consistent with the approach currently taken in the regulations, and this is an area where HITAC can provide further comment to the agency.

As an example, ONC maps many of the 2015 additions to the criteria and other changes being made in these proposed regulations to the pediatric clinical priorities. ONC can also map some of the other aspects to pediatric care. As an example, the 2015 edition requires EHR developers to test EHR's with

ten end-users. As currently written, it is unclear whether any developer could obtain pediatric certification if using ten end-users that are geriatricians.

And so, ONC, in finalizing these regulations, should clarify that at least some of the end-users that are involved in testing systems should have a pediatric focus, such as pediatricians or pediatric nurses. Similarly, the test case scenarios that are required to be used as part of the 2015 edition, test case scenarios with a pediatric focus should be used in order to obtain the pediatric focus certification. We would be happy to answer questions from this committee for ONC on how to further map the 2015 edition requirements to pediatric care and would support HITAC also including a recommendation in a transmittal letter to ONC, thank you very much, I really appreciate the time.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Thank you, operator, do we have any other comments?

Operator
No further comments at this time.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Perfect, Carolyn, I will hand it back to you.

Carolyn Peterson – Individual – Co-Chair
Thank you, Lauren. I wanted to again thank our speakers and all of your help coming from ONC in looking at these challenging issues. I appreciate your task members calling in today and look forward to further discussion about some of these topics as we go into formulating some recommendations, and also into further thoughts about how we can address HITAC feedback from the April meeting. With that, I conclude the meeting, and I look forward to seeing everyone.

Samantha Meklir – Office of the National Coordinator for Health Information Technology – SME
Thank you.

Al Taylor – Office of the National Coordinator for Health Information Technology – SME
Have a great weekend.