Health Information Technology Advisory Committee

Transcript
September 17, 2019
In Person Meeting

SPEAKERS

HITAC Members		
Name	**Organization**	**Role**
Carolyn Petersen	**Individual**	**Chair**
Robert Wah	**Individual**	**Chair**
Michael Adcock	Adcock Advisory Group	Member
Christina Caraballo	Audacious Inquiry	Member
Tina Esposito	Advocate Aurora Health	Member
Cynthia Fisher	WaterRev, LLC	Member
Valerie Grey	New York eHealth Collaborative	Member
Anil Jain	IBM Watson Health	Member
John Kansky	Indiana Health Information Exchange	Member
Ken Kawamoto	University of Utah Health	Member
Steven Lane	Sutter Health	Member
Leslie Lenert	Medical University of South Carolina	Member
Arien Malec	Change Healthcare	Member
Denni McColm	Citizens Memorial Healthcare	Member
Clem McDonald	National Library of Medicine	Member
Aaron Miri	The University of Texas at Austin Dell Medical School and UT Health Austin	Member
Brett Oliver	Baptist Health	Member
Terrence O'Malley	Massachusetts General Hospital	Member
Raj Ratwani	MedStar Health	Member

	Norton Healthcare		
Steve Ready			Member
Sasha TerMaat	Epic		Member
Andrew Truscott	Accenture		Member
Sheryl Turney	Anthem Blue Cross Blue Shield		Member
Denise Webb	Individual		Member
Federal Representatives			
Name	**Organization**		**Role**
Terry Adirim	Department of Defense		Member
Kate Goodrich	Centers for Medicare and Medicaid Services (CMS)		Member
Adi V. Gundlapalli	Centers for Disease Control and Prevention		Member
Jonathan Nebeker	Department of Veterans Affairs		Member
Ram Sriram	National Institute of Standards and Technology		Member
ONC Speakers			
Name	**Organization**	**Role**	
Lauren Richie	ONC	Designated Federal Officer	
Elise Sweeney Anthony	ONC	Executive Director, Office of Policy	
Seth Pazinski	ONC	Director, Strategic Planning & Coordination Division	

Operator
All lines are now bridged.

Lauren Richie – Office od the National Coordinator for Health Information Technology – Designated Federal Officer
Good morning, everyone. We have a little bit of feedback here. Good morning. Is that better? I hope everyone had a great summer and enjoyed a little bit of a break since our last meeting in July. It's good to be together in person again. I'm going to get started with a quick roll call, and then just a couple of logistics. For those who have not found them yet, the restrooms are out this door, then two lefts to the end of the hall. It's a little bit of a walk there. The magic number for the microphones today is three, so after you have finished speaking, please make sure you turn off your microphone so that everyone can speak during their turn. With that, I will get us started here. Carolyn Petersen?

Carolyn Petersen – Individual – Chair
Good morning.

Lauren Richie – Office od the National Coordinator for Health Information Technology – Designated Federal Officer
Robert Wah?

Robert Wah – Individual – Chair
Present.

Lauren Richie – Office od the National Coordinator for Health Information Technology – Designated Federal Officer
Michael Adcock?

Michael Adcock – Individual – Member
Present.

Lauren Richie – Office od the National Coordinator for Health Information Technology – Designated Federal Officer
Christina Caraballo?

Christina Caraballo – Audacious Inquiry – Member
Present.

Lauren Richie – Office od the National Coordinator for Health Information Technology – Designated Federal Officer
And, do we have Tina Esposito on the phone?

Tina Esposito – Advocate Aurora Health – Member
Present. I'm here.

Lauren Richie – Office od the National Coordinator for Health Information Technology – Designated Federal Officer

Great. Cynthia Fisher? Maybe later. Valerie Grey?

Valerie Grey – New York eHealth Collaborative – Member

Here.

Lauren Richie – Office od the National Coordinator for Health Information Technology – Designated Federal Officer

Anil Jain?

Anil Jain – IBM Watson Health – Member

Present.

Lauren Richie – Office od the National Coordinator for Health Information Technology – Designated Federal Officer

John Kansky?

John Kansky – Indiana Health Information Exchange – Member

Here.

Lauren Richie – Office od the National Coordinator for Health Information Technology – Designated Federal Officer

Ken Kawamoto?

Ken Kawamoto – University of Utah Health – Member

Present.

Lauren Richie – Office od the National Coordinator for Health Information Technology – Designated Federal Officer

Steven Lane?

Steven Lane – Sutter Health – Member

Here.

Lauren Richie – Office od the National Coordinator for Health Information Technology – Designated Federal Officer

Leslie Lenert?

Leslie Lenert – Medical University of South Carolina – Member

Here.

Lauren Richie – Office od the National Coordinator for Health Information Technology – Designated Federal Officer

Arien Malec? Maybe later. Do we have Denni McColm on the phone?

Denni McColm – Citizens Memorial Healthcare – Member
Yes, I'm present.

Lauren Richie – Office od the National Coordinator for Health Information Technology – Designated Federal Officer
Great. And, do we have Clem McDonald on the phone? Aaron Miri?

Aaron Miri – The University of Texas at Austin Dell Medical School and UT Health Austin – Member
Good morning.

Lauren Richie – Office od the National Coordinator for Health Information Technology – Designated Federal Officer
Brett Oliver? Terry O'Malley?

Terrence O'Malley – Massachusetts General Hospital – Member
Here.

Lauren Richie – Office od the National Coordinator for Health Information Technology – Designated Federal Officer
Raj Ratwani?

Raj Ratwani – MedStar Health – Member
Good morning.

Lauren Richie – Office od the National Coordinator for Health Information Technology – Designated Federal Officer
Do we have Steve Ready on the phone?

Steve Ready – Norton Healthcare – Member
Present.

Lauren Richie – Office od the National Coordinator for Health Information Technology – Designated Federal Officer
Sasha TerMaat?

Sasha TerMaat – Epic – Member
Present.

Lauren Richie – Office od the National Coordinator for Health Information Technology – Designated Federal Officer
Andy Truscott?

Andrew Truscott – Accenture – Member
Present.

Lauren Richie – Office od the National Coordinator for Health Information Technology – Designated Federal Officer
Sheryl Turney?

Sheryl Turney – Anthem Blue Cross Blue Shield – Member
Present.

Lauren Richie – Office od the National Coordinator for Health Information Technology – Designated Federal Officer
And, Denise Webb.

Denise Webb – Individual – Member
Present.

Lauren Richie – Office od the National Coordinator for Health Information Technology – Designated Federal Officer
Kate Goodrich?

Kate Goodrich – Centers for Medicare and Medicaid Services – Federal Representative
Here.

Lauren Richie – Office od the National Coordinator for Health Information Technology – Designated Federal Officer
Jonathan Nebeker? Ram Sriram? Terry Adirim? And, joining us today, Adi Gundlapalli from CDC? And, also, from the ONC side, we have Seth Pazinski joining us today, our division director, Dr. Andy Gettinger, our chief clinical officer, and Rob Rensne, senior advisor in our Office of Technology. We may also have Elise Anthony on the phone. I'll do a quick audio. Elise, are you on the phone yet?

Elise Sweeney Anthony – ONC – Executive Director, Office of Policy
I am, yes. Good morning, everyone.

Lauren Richie – Office od the National Coordinator for Health Information Technology – Designated Federal Officer
Great. With that, I will turn it over to our co-chairs.

Robert Wah – Individual – Chair
Thank you, Lauren. Good morning, everyone. Welcome to Washington, D.C. I hope you enjoy the view here. It's been a busy summer for most of us. I hope you had a good time and got some time to relax and recharge. As already noted, we do not have our national coordinator or our deputy national coordinator here, or Elise, so I think Carolyn and I will channel them a little bit, but we also have folks

from the ONC here. Andy's here, as has already been noted as well. Reviewing the year to date, we've gotten a lot done.

I think we should be very proud of all the work we did, particularly on the proposed rule. That was quite a bit of effort to provide over 250 pages of commentary on 750 pages of proposed rule. We also want to thank our current task forces that are under way, and Ken, Steven, Terry, and Christina for chairing those, and all who work on those. As was noted at the beginning of this, the task forces are where all of the work gets done on this committee in large part. We're looking forward to another good discussion today as we review that work and get moving through the reports that we have. We have a number of membership updates that Carolyn will go over, and then we'll go through some reminders about where we are on a number of projects, but with that, we'll kick off. Carolyn, I think you have some comments.

Carolyn Petersen – Individual – Chair
Thanks, Robert, and good morning, everyone. It's really great to get back together again after several months, to start to think about revving up what we started this year, and to look forward to the future. I want to start by introducing a new admission to the committee. Dr. Adi Gundlapalli will be joining us as a permanent federal representative from CDC. Laura Conn was serving as the rep temporarily for Chesley Richards. I want to thank Laura for her contributions and welcome Dr. Gundlapalli. Thank you for coming. Also, as you all know, we are currently working with the GAO to fill at least two vacancies on the HITAC, and I just want to remind everyone to spread the word and encourage qualified people to apply. You should have received an email from Lauren about that, but if you need the information, please let her know, and we will see that you get that immediately. We're also still working with our congressional liaison to help fill Patrick's vacated seat.

A couple of weeks ago, ONC announced that the Sequoia Project was awarded a cooperative agreement to serve on the Recognized Coordinating Entity. The RCE will be responsible for developing, updating, implementing, and maintaining the Common Agreement component of the Trusted Exchange Framework and the Common Agreement, the TEFCA. As that work gets under way, we'll keep the committee informed. In addition, the Interoperability Standards Advisory annual review and comment period is now open. The ISA is an interactive catalog of standards and implementations/specifications supporting interoperability in health care, so you're welcome to share your thoughts by Monday, September 23. Information on how to provide comments is available on HealthIT.gov, along with other documents that support that. And, ONC will finalize the ISA for the 2020 reference edition, which we expect will be published in December. I will now turn the mic back to Robert to handle the minutes and review the agenda.

Robert Wah – Individual – Chair
Great, thank you. So, I think the minutes of the July 11 meeting have been distributed. Are there any comments, suggestions, or edits to those minutes? If there are none, all those approving those minutes, please signal by saying "Aye." **[Many ayes]** All those opposed, say "No." Okay, those are admitted. And, with that, I think we'll go immediately to our annual report update. As you know, we've been working on this for last year, and now, the next year following, and I'll turn that over to Carolyn and Aaron.

Aaron Miri – The University of Texas at Austin Dell Medical School and UT Health Austin – Member
Robert, may I offer a comment before we go? I just wanted to acknowledge to the committee in light of the comments about the RCE award and the work on TEFCA that I'm involved in the governance at Sequoia Project, as well as care quality. I just wanted **[audio cuts out] [00:07:30]**.

Robert Wah – Individual – Chair
Other comments while we're **[audio cuts out]**? They're just sitting there so they can avoid the glare of the window. I'd say this way is a beautiful view, but it's very bright. Carolyn, I'll let you have at it.

Carolyn Petersen – Individual – Chair
Thank you. It's a good thing I brought my distance glasses today. So, good morning, everyone. It's kind of hard to believe that we're already well into the next annual report for the HITAC. It seems like it was just about a week ago that we brought the 2018 version to you for approval, but here we are. We've actually been working over the summer to get a good start on this and try to deliver it to the ONC earlier this year than we did last year. So, with that, we're going to give you a brief update today and hopefully have some brief discussion around some of the items that we're looking to include, and perhaps also, a brief discussion about potential activities for the HITAC for next year, and that's something that we call out in this report. Let's go to the next slide.

This is the workgroup. There are myself, Aaron, Christina Caraballo, and Brett Oliver, and we have support from ONC as well. Next slide, please. The overarching scope is that the workgroup will inform, contribute to, and review draft and final versions of the HITAC annual report that will be submitted to the Secretary of Health and Human Services and to Congress each fiscal year. As part of that report, this group helps track the ongoing HITAC progress. Next slide. This gets into more detail about what's in the report. We have an analysis of our progress on the committee, we have an assessment of health IT infrastructure and advancement, we have an analysis of existing gaps in policies and resources, and we have ideas for potential HITAC activity. Next slide, please.

Here's our meeting schedule, what we've been doing, and what we'll be looking for you to do. This is our fourth meeting – actually, we've had four meetings, and we have five to go. So far, we've worked on the landscape analysis and reviewed last year's progress, gone through the notes that we gathered last year to get a start on this year, and then, we will meet in October, November, and December, looking to bring you all a draft for review in January, with approval, we hope, in February. Next slide, please. As far as the full committee goes, we are presenting to you today, and we'll do so again in October and November. The committee has no meetings in December, and then we look to send you the draft in January. Next slide, please.

So, this fall, the annual report workgroup is working and editing some drafts on the sections of the report and the landscape analysis, which we're presenting to you today, then, in future months, the gap analysis and recommendations, the overview and HITAC progress sections, and the draft annual report as a whole, which we're looking at for the end of the year. The draft landscape analysis outline for the HITAC annual report is what we're covering today. This is the general table of contents for the report. It's very similar to what we did last year, except we now have an opportunity to look back on

what we've done so far. Next slide, please. With that, I will hand the mic to Aaron to discuss in more detail some of the discussions we've had to date on the landscape analysis.

Aaron Miri – The University of Texas at Austin Dell Medical School and UT Health Austin – Member
Thank you, Carolyn. So, there are a couple things we want to talk about that we're proposing for our landscape analysis outline. On the federal activity side, you've obviously got the ONC's regulation for the 21st Century CURES Act around information blocking, certification enhancements, application programming interfaces, known as APIs, U.S. Corps for Data Interoperability, USCDI, the Trusted Exchange Framework and Common Agreement, TEFCA, as Version 2, key changes from Version 1 to Version 2, and the RCE that we talked about earlier, and that awarding, the Centers for Medicare and Medicaid Services' interoperability rule, key provisions that impact priority target areas, such as hospital notification requirements, payer-patient APIs, payer-to-payer coordination, and some other federal activities that we're going to be including, including the ONC Provider Burden Report, HHS Office for Civil Rights, HIPAA request information, and so on and so forth. There's lots of activity this year that we will definitely cover. Next slide.

So, on the priority target area around interoperability, if you look at the current state with HIEs, you've got cross-network exchange and you've got integration of data from multiple external sources with HL7/FHIR standard, which has obviously released a new version, progress on governance issues that were there – some great work with that group – and then, the health IT support for the opioid epidemic response with the PDMPs, which stands for Prescription Drug Monitoring Programs, the SUPPORT Act, of course, patient matching and verification, which is a constant, and social determinants of health, SDOH, which are really starting to come up in discussions. Next slide.

Around privacy and security, the current state – you've got protections for data generated outside of the HIPAA framework, thinking about things around 23 and Me and other types of companies, 42 CFR Part 2 and the Family Educational Rights and Privacy Act, FERPA, which obviously affects a lot of us at academically based medical centers, such as myself, the Interstate Data Exchange and Privacy Considerations, and implications of recent privacy laws and regulations, such as California's Privacy Act of 2018 and the GDPR, which is the European Union's General Data Protection Regulation and Privacy Shield. Again, I can tell you that for organizations, especially AMCs, who do a lot of global business, this is something that's front and foremost in all of our minds. Next slide.

On patient access to information, the current state items there are patient-controlled data collection, access, and sharing, policy and trust issues for APIs, and use and sharing of patient-generated health data, PGHD. A lot of this is around third-party access, who can access what and when, and where that responsibility lies – with a provider or a patient. We're working through those and the various state and federal laws around that. Next slide.

On emerging issues to consider, we've got a couple of topics that we really want to bring to this committee's attention front and center, one being the Internet of Things and the multitude of devices connecting and exchanging data these days. Another topic is digiceuticals. What's the definition of that? It's the use of digital apps in a formal role in treating a disease, whether it's sleep apnea or anything else. There's an app now for just about everything. Sociogenomics – the definition of this

being the scientific discipline that attempts to find the genetic basis of social behavior and its evolution. Of course, artificial intelligence and machine learning – you hear that everywhere now. And then, sharing of large media files. Again, that was something that also came up in the last report workgroup. We want to make sure that we didn't lose any of these topics. Some of these items did transition here for us to look into this year, but as they become more prevalent in society, it's something to look at. Next slide.

So, the question to you all is would you add, remove, or change anything, and what other sources for additional resources that you would suggest? Are there topics other than the ones we talked about and the ones we previously talked about in the prior report that are front and center for you all that you want to go into? Sir?

Steven Lane – Sutter Health – Member
I think the challenges of sharing data to support deep interoperability and integration of outside data is something that we continue to struggle with, and I think it really warrants the continued focus of this group – semantic interoperability.

Aaron Miri – The University of Texas at Austin Dell Medical School and UT Health Austin – Member
Thank you.

Andrew Truscott – Accenture – Member
I might have missed it in the 127-mile-per-hour run you did through it. Did SDOH appear?

Aaron Miri – The University of Texas at Austin Dell Medical School and UT Health Austin – Member
It did.

Andrew Truscott – Accenture – Member
Okay. To Steve's comment, I think it's not just the complexity of data, it's also the complexity of the various stakeholders who are interested in that data, and we very easily jump to technological solutions as opposed to thinking of the people and the process who sit around this as well, so I think maybe we should give some more consideration to that and the ultimate users of information and data. There's a difference between the two. Thanks.

Jonathan Nebeker – Department of Veterans Affairs – Federal Representative
Hi, I'm Jonathan Nebeker. Good to see everyone. So, I'd like to double down on the previous comments on semantic interoperability. There have been a lot of recent developments that **[inaudible] [00:16:53]** can provide a simplified approach to and provide some framework to that. Also, for ONC, I know there's always a tension between cataloguing versus endorsing, but maybe we can get this group to more of an endorsing point and not just be neutral to all proposals that come in to try to move things forward.

Aaron Miri – The University of Texas at Austin Dell Medical School and UT Health Austin – Member
Thank you. Sir?

Terrence O'Malley – Massachusetts General Hospital – Member
Hi, it's Terry O'Malley. I just have a question about the breadth of interoperability and extending it to groups of service providers who currently don't have great access to it. I'm thinking particularly of post-acute care and the long-term services and supports, like a community-based services group, and you can extend that even farther out to entities that are not traditionally thought of as health care, but provide a lot of health care, like schools and prisons. Ultimately, if we're going to bring everyone under the umbrella of interoperability, we've got to meet the challenge of how we get it out there.

Aaron Miri – The University of Texas at Austin Dell Medical School and UT Health Austin – Member
So, you mean across the care continuum, basically – everything, all levels of care.

Terrence O'Malley – Massachusetts General Hospital – Member
Right.

Ken Kawamoto – University of Utah Health – Member
Thanks. So, I agree with the comments on diving deep on the semantic interoperability part, and the way I look at it, I think we've been doing a really good job going toward increasing the breadth of interoperability. For example, we've been tackling exchanging free-text notes and such. That's being added to the USCDI. I do think that once you get into specific use cases – for example, for treating diabetes, hypertension, or whatnot – do people have everything they need to make sure that care is optimized? I think the answer is no. At the same time, trying to tackle everything at a really deep level is very hard because the example might be, "Hey, we want clinicians to be able to order through a standards-based API," but then, if you try to take every orderable or if you say for every kind of observation a clinician may make in a structured way, the record should be available in a standards-based center – that's practically undoable initially. So, my recommendation would be to perhaps take specific use cases or scenarios and figure out how, through that whole continuum of care for that particular type of patient or condition, we realize what the potential for health IT interoperability is. That's one strategy to get at issues that we all know are big issues, but we've never been able to tackle because it seems to be too large.

Aaron Miri – The University of Texas at Austin Dell Medical School and UT Health Austin – Member
Ken, if I could just paraphrase for a second, it seems like you're saying for every level of acuity, whether it's inpatient or outpatient, taking various comorbidities, mapping those out, and seeing where the gaps are – some sort of spot analysis of each?

Ken Kawamoto – University of Utah Health – Member
Yeah, and specifically taking the approach – we're not going to be able to boil the ocean. We just don't have $100 million to spend towards trying to solve that, but maybe we can take an important slice and figure out how to do it, and then figure out how we gradually scale from there.

Aaron Miri – The University of Texas at Austin Dell Medical School and UT Health Austin – Member
Thank you.

Clem McDonald – National Library of Medicine – Member

This is Clem. I have my hand up, but I don't know if we're working that way.

Carolyn Petersen – Individual – Chair
Hi, Clem.

Clem McDonald – National Library of Medicine – Member
I'll wait until it's my turn.

Carolyn Petersen – Individual – Chair
Go ahead.

Clem McDonald – National Library of Medicine – Member
Okay. I have two things. First, to Ken's point, for things like heart failure, you really should have the ejection fraction. It's not a horribly difficult thing to get, but if all we do is a text report for our cardiac, you won't get it, and I think that's kind of what he's leading at. But, I wanted to bring up the point that there's not a single mention of research in any of this, ever. Now, I'm from NIH, and NIH has gotten very interested in FHIR recently. I think we need help because there's terrific value in all this data that's going to be available, and other countries are very assiduously using broad sets of data, so I think we ought to have some discussion about how that could be facilitated or used because it's really important to mention if we're going to reduce health care costs and improve health care.

Aaron Miri – The University of Texas at Austin Dell Medical School and UT Health Austin – Member
Thank you, sir. John?

John Kansky – Indiana Health Information Exchange – Member
Thanks. I have a comment related to the target area of interoperability, and specifically, health information exchange and cross-network exchange, and I admit that this may be more relevant to a suggestion for a future focus of HITAC than it is current landscape because the landscape is so early. So, the comment is that prior to TEFCA, there was an evolving landscape of national networks figuring out how to reach some equilibrium with each other, the health information exchanges moving toward an equilibrium with the national networks, and now we have TEFCA that will be rolling out, and the RCE will be making decisions relevant to how the TEFCA-defined ecosystem and the existing ecosystem that is in flux… It's going to be very critical to national interoperability how that settles into a working equilibrium. So, to the extent that there is a landscape now, I think that's important, but it's going to need to change quickly.

Robert Wah – Individual – Chair
I just want to let everyone on the phone know that I think Clem showed the way to do this, but if you're on the phone and have a comment, just go ahead and announce yourself, and we can get you in the queue. Right now, in the room, we're all sort of one-sided, but we've got both sides of the room that we'll be checking on, but those who are on the phone, please announce yourself to allow us to know that you have a comment as well. Sheryl?

Sheryl Turney – Anthem Blue Cross Blue Shield – Member

Thank you. I think we should be adding to our list of scope some work around cost transparency, especially in light of the executive order, and also, along with that, certification requirements for consumer-based apps, especially as they lean towards cost transparency. I can tell you that in the examples I've already seen with some of our health partners, the app developers don't understand health care costs, and I've seen examples where they've taken data from multiple payers, averaged it together, and then provided that back to the patient or the member, and the member has already selected a specific plan, so that's never going to give them their cost, and it's not meaningful to any of the members for those groups, but the app developers don't understand it. So, I think there needs to be more work around that, and also, authorization of the members and education, because they don't understand what rights they're giving away and what app developers are going to do with their data, and that's going to be very important as we really focus on a consumer-centric model going forward.

Aaron Miri – The University of Texas at Austin Dell Medical School and UT Health Austin – Member
Great points. Thank you. Cynthia?

Cynthia Fisher – WaterRev, LLC – Member
Yes, thank you, Sheryl. Just to follow up on that, being that both the CURES Act with the proposed rule and the Outpatient Payment System Act have price transparency as part of the measure, I'd also support what Sheryl said, and we have a precedent for price transparency through the HIPAA financial standards in payment through ASC X12, and whether it's inside or outside of their plan, we're really looking at providing patients broad-based access to information.
So, the secretary has broad authority under HIPAA to similarly do the standards for financial and administrative care transactions, and as HHS has supported HL7 and FHIR standards, I do believe firmly that we can address this in a timely way, and there are a couple of us who volunteered, as of the last meeting, to put together a draft. Jack Po was one of those. I don't know if he's on the call this morning, but he and I are at least looking to put together an outline that the committee can consider in a very timely fashion since these proposed rules are impending, and it behooves us to be able to get that work done.

I would also just add that earlier in the process, Les had preauth and some really brilliant ideas that I think he and Steven had put their minds together on, but I think we could look at potentially catapulting for looking at preauthorizations, and basically empowering patients with this information and saving doctors inordinate amounts of time in their practices from trying to understand that there are options for their patients in access to MRIs and those types of things that are in their everyday lives that debunk and are problematic in the patient/doctor interaction, and unnecessarily administratively cost society and our services substantially.

So, there's that, and I would say the third place – I think it behooves us to put those recommendations forward as well. As explanations of benefits are all digital now anyway, why not look at a standard for EOBs? Finally, let's look at where radiology and MRIs can exist in the cloud. We brought this up in our subgroup session. Can we catapult as a standard for cloud-based sharing of imaging, for instance? That would greatly benefit the constituents of physicians and patients to have a standard not just on a radiology report, but actually on the digital sharing of the images, catapulting us into sharing through cloud computing. So, I'll just throw it out that we could add these on.

Carolyn Petersen – Individual – Chair
Thanks, Cynthia. Arien?

Arien Malec – Change Healthcare – Member
Excellent. So, I'll just endorse the things that have already been mentioned relative to research, relative to patient access, patient engagement, cost transparency, cost sharing, and electronic prior auth. The whole area of administrative simplification, particularly in areas that cross over between administrative data and clinical data, is a significant emerging area. SSA has been working in this area for disability determination for a while. There's a long way to go to more broadly roll that out, but that provides a model for simplifying a large number of administrative processes, which has the possibility of taking out significant amounts of cost in the U.S. health care system, so this topic of administrative and clinical interoperability and overlap should be a high-priority area. Thanks.

Aaron Miri – The University of Texas at Austin Dell Medical School and UT Health Austin – Member
Raj?

Raj Ratwani – MedStar Health – Member
Great, thank you. I want to also call out patient safety as a key area I think we need to focus on. There's an increasing number of patient safety event report data and legal claims data that is showing a strong association between EHRs and patient safety, so I think that's an important part of this, and there are two sides to that. There's the safety of health IT as it stands now, and then, leveraging health IT to advance safety through algorithm development and so forth, so I think it's important to focus on both of those. And, as a quick side note, today is the first ever World Patient Safety Day, so it's timely.

Aaron Miri – The University of Texas at Austin Dell Medical School and UT Health Austin – Member
Great points. Thank you.

Steven Lane – Sutter Health – Member
I know you guys are probably getting more than you bargained for here –

Aaron Miri – The University of Texas at Austin Dell Medical School and UT Health Austin – Member
This is why I went fast. I wanted everybody to be able to talk.

Steven Lane – Sutter Health – Member
– but another area that I think may be worth our discussion is the scope of the data that needs to be available for access, exchange, and use. In the draft tests and in the proposed rules as they came out, they referenced either all electronic health information or USCDI. I think a lot of folks have identified a problem with all electronic health information in that it's so big, and frankly, probably impractical for us to be able to manage with regard to having standards, methods, governance, privacy, security – really, the ability to be able to share that.

On the other hand, while USCDI is very important, it's too low a bar to set for what data should be available, and while we're going to be hearing about the advancement process that's being proposed,

it's very deliberative, and intentionally so, to give the industry time to be able to keep up with it. So, there's a missing piece in this puzzle, which is where can we look between all EHI and USCDI to be able to set a target for data to be accessed, exchanged, and used? USCDI is missing past medical history, family history, social history beyond smoking status, social determinants, omics data, device data, patient-generated health data – lots of things that will eventually make their way into USCDI, but hopefully, while we're all still alive. I think that we may want to spend some time working with our ONC colleagues to look at other points that could be **[inaudible] [00:31:47]**.

Aaron Miri – The University of Texas at Austin Dell Medical School and UT Health Austin – Member
Great points. Denise?

Denise Webb – Individual – Member
Good morning. I'm going to see if I can keep my voice here. I know we're just looking at the outliers at present, but I just wanted to suggest – we have a lot of topics in our landscape analysis, and I'm not sure where we're going to go next after our outlying, but what might be helpful is if we are able to articulate the opportunities and challenges of each of the areas that we're analyzing, and possibly have a scorecard in our report that reveals the level of progress in each of these topic areas in terms of interoperability as far as policies, standards, and actual implementation, and also, maybe a score around the clinician burden, whether it's red/yellow/green, whether we're helping clinicians in those areas presently in the landscape, or whether it's gotten worse.

Aaron Miri – The University of Texas at Austin Dell Medical School and UT Health Austin – Member
Great points. Thank you.

Andrew Truscott – Accenture – Member
Just briefly, we're very dependent upon the standards world and the standards community, and I wonder whether we should be actually engaging with them more tightly and better, not just HL7, but SNOMED, LOINC, AIMA, et cetera. Pardon? Okay, good. I like to be correct. On information blocking, there are a whole bunch of regs coming down the tunnel, and I don't know how the rest of the membership feel, but there seem to be very different levels of understanding and appreciation out there in the community at large. In my day job, we've actually commissioned some research, and others have commissioned research as well, and it's incredibly different.

I'm not sure whether this is our role, maybe because of what I've been seeing, but actually getting a consistent message that this is happening, this is real, this is what you need to do, and the regs are putting up a bar that everyone needs to attain, not just simply saying, "Everyone, do a bit better" – that's missing, so I want something we can actually focus on at pace, ahead of when the regs come out. And then, finally, to Steve's point, we could very easily try and boil the entire ocean one kettle at a time, and we will fail if we try and do that. I think it would be prudent of us to make affirmative statements of what we are doing and what we're not doing.

Clem McDonald – National Library of Medicine – Member
This is Clem. I've got my hand up again, but I'm not sure if someone else had their hand up first.

Aaron Miri – The University of Texas at Austin Dell Medical School and UT Health Austin – Member
Clem, hold on one second. We're going to get Kate, and then we can come to you.

Kate Goodrich – Centers for Medicare and Medicaid Services – Federal Representative
Thank you. Not to add to the list of things, but I'm going to add to the list of things to think about. So, my world of CMS revolves around quality measurement, and so, we are very interested in CMS in part in response to the executive order that was mentioned before on price transparency, which also talks about alignment of measurement across the federal space, so, CMS, other agencies within HHS, the VA, and DOD – and, we've been working with VA and DOD in particular on this for a little while now – but, there's also a great interest in CMS at putting our resources toward the acceleration of the use of electronic sources of data for the purposes of reducing burden, more accuracy, better reliability, et cetera.

And so, I think we would very much welcome some input into the path forward for that. We're starting to really dig into that and getting some expertise to help us with that, but I think that's an area – especially as you're talking about interoperability and interoperable data exchange for the purposes of improvement – let alone measurement for federal purposes, but just for improvement – as well about whether you're talking about clinician burden or provider burden generally. That's an area where I think we would welcome guidance from the HITAC as well.

Carolyn Petersen – Individual – Chair
Thank you. Let's go to Terry, and then Clem.

Terrence O'Malley – Massachusetts General Hospital – Member
Thanks. So, Denise's comment, Steve's comment, and Ken's comment before raises in my mind the issue of process for prioritization of data. Where is that process, and do we have one? Should we have one? Will we have one? Where is it going to live? Who is it going to be? Whose priorities? So, that gets to the "boiling the ocean" question. We can, and it's not clear to me which pot we should pick, but there probably ought to be a process to pick them that we can agree upon.

Carolyn Petersen – Individual – Chair
Clem?

Clem McDonald – National Library of Medicine – Member
Following up on all the previous comments, especially Steve's and Terry's, I think a prioritization – I think an easy bet is to first grab those things that come out of machines and are already fairly structured. I can name three, and there are probably more: Electrocardiograms – at least, parts of them – have been structured for at least 30 years, spirometry and a lot of cardiac echoes, and a lot of obstetrical ultrasounds. These are relatively easy technically, and I just urge us to stack them in quickly because they're valuable. That's all.

Carolyn Petersen – Individual – Chair
Thanks. Do we have comments from other HITAC members on the phone? Les?

Leslie Lenert – Medical University of South Carolina – Member

I just have a comment about trajectory. We really need to do that prioritization exercise that people have talked about because there is a very short time window for our ability to influence things until the next election cycle, when things will change, but not just because of politics. There will be doubt and those things there. So, we really need to focus on choosing a few of these topics and having that prioritization process so we can achieve critical results, and I think price transparency would be a great area to work on. I think a patient-centric view for prior authorization would be awesome. It's not part of the…current standards development process – letting patients viewing that. And then, research – we haven't really spoken much about that at all. So, those are my preferences, but it's the prioritization process and really trying in the next six months to say what we can achieve as a committee in that as far as recommendations that are clear and implementable because it's all going to get very mucky after six months.

Carolyn Petersen – Individual – Chair

Thanks, Les. Jon?

Jonathan Nebeker – Department of Veterans Affairs – Federal Representative

I just have one last comment, with three parts. So, in terms of boiling the ocean, the VA has pots on the stove now, and we're trying to solve problems, and we're entering a new cycle of next-generation systems, including in our EHR program. I think we can be helpful in cooperating with the committee to help prove out some things, and there are three areas I'd like to put on the table that have been mentioned previously. One is interoperability from a business cooperation point of view instead of a data exchange point of view. Again, looking at other industries, next week, OMG will launch its community on BPMN Plus – Business Process Management Notation Plus – taking cues from other industries and translating them to health care with several large and successful health care organizations participating. There is lots of potential here. Also, at the AHRQ task force meeting, there was a discussion about using that for guidelines and the cooperative execution of guidelines versus the exchange-based execution of guidelines.

The second area in terms of data is – to Kate's question, we're measuring quality, but again, taking lessons from other industries. It's not clear to many of us in the VA that we know what our unit of production is from health care, and some of us are starting to coalesce around the idea of patient experience – comfort, function, and dignity. Where is that in our data? Nowhere. Is that really what we're trying to do for health care? A conversation around that and a drive towards data for that will be helpful.

Finally, back to the cooperative use of data and data platforms – other industries are using these platforms, they exist, and they're real. The VA has collaborations with the Department of Defense and the Department of Energy that are currently using these platforms for enterprise purposes so there is not vaporware. Again, these are some things that may be on the more distant horizon, but maybe the committee can take them for prioritization.

Aaron Miri – The University of Texas at Austin Dell Medical School and UT Health Austin – Member

Excellent, thank you. And, Christina?

Christina Caraballo – Audacious Inquiry – Member
Great. Through our task force work, we have definitely identified what Steven pointed out, that we've got this major gap. We've got all the information requirement through EHI, and then we've got this little amount of data perfection that is USCDI, and I do think it is something that we really need to focus on. Looking at – and, I see that as a big gap, as an area where we can go for what's next for HITAC to look at. But, when we're looking at what this landscape is, I think this ties into some of the conversations we've had as a workgroup on how we measure the quality of data, how we better understand what type of data is being exchanged, and what's meaningful. I'd like to see if we can understand that a little bit better and maybe put that in part of our landscape analysis. Sheryl brings up some excellent points on cost transparency and what app developers are doing, and any information we can gather on that on what is actually being exchanged would be extremely valuable for landscape as well.

Aaron Miri – The University of Texas at Austin Dell Medical School and UT Health Austin – Member
What is, and also, what isn't.

Christina Caraballo – Audacious Inquiry – Member
Yeah, exactly.

Carolyn Petersen – Individual – Chair
So, Robert, how are we doing on time?

Robert Wah – Individual – Chair
I think we're actually right on time. It's looking very good. I'll give everyone one last chance to have commentary and make sure you guys have the input you need, you have a summary of where you are with your group, and then we'll wrap that up. I'll have a couple comments after that.

Carolyn Petersen – Individual – Chair
It looks like Arien's got a card up.

Arien Malec – Change Healthcare – Member
Yeah. Sorry for not getting this up in the first round, but supportive and enabling business models are some of the largest blockers of interoperability. There are more things that we can do today than we actually are doing because the business models aren't necessarily enabling.

Carolyn Petersen – Individual – Chair
I want to go to the phone one more time – a last chance for our members on the phone.

Clem McDonald – National Library of Medicine – Member
Don't forget research. Everything that's been written from ONC seems to be totally silent about research.

Carolyn Petersen – Individual – Chair

Thank you. So, I really appreciate all the feedback we received from HITAC today. This will help us immensely as we start on the gap analysis. It gives us something to work with in terms of identifying some possible future activities for HITAC next year, and hopefully, it also helps ONC to understand what our interests are and to start thinking about how they can support the work that we want to do in the coming years. So, thanks, everyone, for your engaged participation.

Aaron Miri – The University of Texas at Austin Dell Medical School and UT Health Austin – Member
Thank you.

Robert Wah – Individual – Chair
And, thanks, Carolyn and Aaron, for your hard work in chairing this group, and to everybody who serves on that task force as well. I'd also say that I think this discussion and this venue – or, this particular workgroup – is a good place for us to think through and air out some of our interests as an overall committee. As your chairs, Carolyn and I have worked to figure out how best we get a sense of where the committee wants to go. We've had a couple conversations of next steps for the HITAC.

As we wrap up 2019, I think it'll be appropriate to think about where we should be going in the next year as a committee as well. So, even though this is focused on the annual report, I think it's also appropriate to think about where we want to go as a committee and as a whole, and we'll be working with ONC as your co-chairs to figure out how best to maximize our efficacy and impact as a committee. So, if there's any other input you have as you think about those kinds of things, please send them to Carolyn and me. We're looking for input in that regard.

We had a session earlier about where we want to go as a committee. We may do something like that again as the schedule permits, but I think this is the kind of thing we want to make sure we're getting at as a committee as well. So, even though we're talking about the annual report, I think it's been a good opportunity to bring up a lot of issues that are top of mind for many of you from your various perspectives from which you come to this committee, so I think that's great. With that, I'd just say that our next plan is to take a break – since I think one time, we took away your break, I want to make sure we get our breaks in. We're going to have a break, and then I think we're going to go to our next task force on interoperability priority. So, with that, we have a 15-minute break until 10:30. Thank you all.

Robert Wah - Individual - Chair
All right. Great to see everyone have an opportunity to talk a little bit during the breaks, and love the enthusiasm that you all bring to this meeting. So, I always hate to throttle that, but at the same time, we've got a little bit of work to do here. So, without ado, we'll move on to our next topic, which is our Interoperability Standards Priority Task force. That just rolls right off the tongue. And I'll turn to our co-chairs, Ken and Steven.

Steven Lane - Sutter Health - Member
Thank you so much. Great to be back and to present the work of our task force to date. On the slide here, just as a reminder, the task force was charged to make recommendations on priority uses of health IT and the associated standards and implementation specifications such uses. And specifically, what we've done is we've looked through the – we determined what we felt were priority uses, that

this was a very broad charge that we had, as consistent with the CURES Act, and then we investigated the standards and implementation specifications that support those uses, and really looked for opportunities to improve the exchange of information – where the standards were lacking or absent, and especially where their implementation has been inconsistent. And then what we're doing now is putting together a report for the HITAC to review and approve, and then we will forward that on the National Coordinator with the results of our findings.

On the next slide, you have a list of the participants, many of who are here in the room. We really want to thank everyone for your active engagement. You can see that this task force also included a number of members of the public who are not on the HITAC that really provided invaluable input to our process. But for those of you here on the HITAC, again, thank you so much for your time. And we're in the home stretch now. Next slide.

So, we have drafted our report. We have an initial draft that has been distributed to all of you. We hope dearly that if you didn't read through it entirely, you at least had a chance to flip through it. This is the layout of the draft report. We started with the executive summary, a little overview, reviewed our charge, membership, as we just did here, and a little bit about how we went about developing our recommendations. We then are presenting recommendations in a number of specific areas. Some of the recommendations that we've come up with really crossed domains. They have to do with a number of different areas, and therefore were separated out. And then the three primary domains that we focused in on in greater detail were orders and results, closed loop referrals, and care coordination and medication and pharmacy data. These were our highest priority domain areas that the task force identified and worked on, but there are other areas that we also identified that didn't make the cut, we didn't have the time to get done. So, we finished with conclusions, including areas for further work, if this task force or another task force is asked to continue. The other thing that we don't include here is within each of the domains, we did include – actually, Ken wrote up very nice clinical vignettes kind of explaining what could be possible from a patient perspective, if and when our recommendations are implemented broadly. And I think those make for some nice reading.

So again, the draft report has been distributed to all of you. We're really interested in people's input in a number of specific areas. And we're going to spend the rest of our time this morning kind of going through and giving you all a chance to provide some of that. Next slide.

So, now I'm going to ask Ken to just sort of walk us through our first broad domain area, which was orders and results. And again, I just want to remind everyone that you've all heard most of this before. We've come to you, to the HITAC, after each of our segments was drafted, and we've gone through it, so none of this should be particularly earth-shattering for you. But again, it's a great opportunity to weigh in.

Ken Kawamoto - University of Utah Health - Member
Thanks, Steven. So, as Steven mentioned, there's one section of the report on cross-domain recommendations. We're not covering it here because we have a discussion time at the end where most of those are covered. And then, as Steven mentioned, there were three priority areas that we did focus on, and after each of which we did come to the HITAC provider for recommendations and got

feedback. So, this should be basically just a summary. If you do have specific comments, issues on them – for example, if you had the chance to take a look at the report and have comments, we would welcome them. But I think assuming these don't generate too much controversy because you've seen them before, we'd like to focus on the discussion topics that we think are potentially a little bit on the – require a little bit more discussion.

Okay, so just to summarize, for all these, we have what we term Tier 1 recommendations, which we feel are the more important of the recommendations in each area, and then Tier 2, which are the ones that we feel should be looked at, but aren't at the same level of importance. So, for orders and results, so the notion of when you order something and when you get results back, the Tier 1 recommendations, first and foremost was the need for consistent encoding of testing, tests and the results. For example, the observation is that for labs, about half of labs, it's estimated don't have things like line codes associated with them, which have – lead to a lot of inconsistencies and inability to make use of them. So we have recommendations to basically make sure that those are encoded properly so that they can be interpreted properly.

Another recommendation was around the level of granularity of standard codes needing to be different according to use. So for example, whether you want to report the very fine-grained details, exactly which type of assay was done, versus you just want to know this is an LDL cholesterol test, and the fact that there's work needed there so that it's meaningful at the level of use.

The third Tier 1 recommendation was touched on earlier today around semantic inoperability for both information models, including the metadata and associated terminology. The observation we made was that for simple types of results, say simple lab results, say white blood cell count or red blood cell count, etc., I think we're pretty much – we have a good way to solve that. For harder, more complex issues, say microbiology results – let's say, as simple as it seems, blood pressure, because you have to keep track of, well, is it an orthostatic, was it a home blood pressure, was it a 24-hour blood pressure, was it an AOBP? We don't really have good consensus on this. And this does lead to real issues, like management of hypertension, which affects, I think, about 70 million Americans. So, this was an issue we identified, where we said we really need to go beyond the simple things that we've been able to accomplish really good semantic interoperability, and go beyond that.

Another recommendations, Tier 1, was around non-medication orderables. So, medications, when they're ordered throughout the system, we tend to have good standard coding. Everything else, really, we don't. So, things like procedures. So, we need those to be standardized between systems and with mapping to standard terminologies.

And our final Tier 1 recommendation was that results need to be available for patients and their proxies in a timely manner. And we have some more discussion on that. Next slide, please.

Okay. So, these are our Tier 2 recommendations in the domain of orders and results. So, the first was in CCDAs, it's not easy to – there's no standard way to differentiate between, say, an imaging order and a non-imaging – sorry, imaging results and a non-imaging result, etc. So, there's a recommendation to make that possible.

Also, second one around CCDA, it doesn't prescribe how to group result components – for example, when it's part of a panel. So, that's a recommendation to do so.

Third one, there's a lot of effort going on in integrating external **[inaudible] [00:56:45]** support using standards like CDS hooks. And the good thing is, it seems to be moving forward without too much external pressure. But we were thinking about something that should be really supported and prioritized.

The fourth one is around supporting the integration of prior authorization into EHR-based ordering workflows. And we specifically covered this in the medication context in our third topic.

Another one of the recommendations revolves around result data being exchanged between HIQ systems not including sufficient provenance metadata. And this of course has been covered through other channels in the HITAC around provenance and making sure that gets included. And this is something we also cover in our medication-related recommendations.

Also, another overlap with medications is around unique reference IDs for results data. This is the notion that we need to identify that something that's being exchanged is actually the same from the source system. This is important for things like reconciliation. And then finally, that we need ways to make sure that we have protections against tampering or other data modification if data gets moved throughout the system.

So, I think we'll pause here to see if anybody had any specific comments around these recommendations, which again, you've already seen before, but now we're just recapping. Okay, Steven, please move on to the next one.

Steven Lane - Sutter Health - Member
Yeah. Another thing that we want to mention is that we're very interested in any feedback you have regarding the prioritization that has been assigned to these. As you've heard, we've separated things out into Tier 1 and Tier 2, so higher and not so high. But one thing that's come up within our recent task force discussions is that there's a lot of recommendations here. And for the HITAC and for even ONC to really make use of this, we felt that it might be worthwhile to really identify kind of a top two or three within each area that kind of got platinum status, I think, as Ken called it. So again, interested in your input, both about the prioritizations that have been suggested, as well as whether there would be value in pulling out specific items to highlight even further.

Kate Goodrich – Centers for Medicare and Medicaid Services – Federal Representative
Hi. Thank you. On that question, or that you've asked for feedback on. A couple of things on prior authorization. That's one that just, a little bit selfishly, for CMS, is a very, very high priority to think about how we can reduce burden related to prior authorization. As we go around and spend a lot of time in the clinician community as part of our clinician engagement body of work, prior authorization has risen to the top, actually above EHRs, as the biggest burden for clinicians. So, it's an area we're very interested in looking at, and we think that this type of work, and the work that's being done by

daVinci, is really, really important, and probably more important than regulatory levers that we may have. So, this is an area that I would argue should be prioritized highly.

And just one question based upon what you said on that, which is, in the context of the report, I guess you're talking mostly about medications. And I don't know if that means that you're prioritizing this work as it relates mostly to medications, the other area that is obviously, particular for Medicare, a big deal, is DME. That's an area that we certainly hear a lot about. So I just wanted to put that out there as well.

Steven Lane - Sutter Health - Member
Yeah. I think that prior authorization is really one of those areas that does cross domains, as does price transparency and some other things. These are not specific to one of these areas. And we're going to attempt in our report to call that out and make that clear. Thanks, Kate. Any other comments? Good. Yes.

Adi V. Gundlapalli – Centers for Disease Control and Prevention – Federal Representative
Thank you. Adi Gundlapalli, CDC. The result data exchange places a separate burden in terms of updating of results, and especially for any reporting. I mean, not just chemical and sort of laboratory, but even microbiology, where the results come in waves and then get updated. So the problem then is metadata. And for public health, that becomes a very important one, because if you're ordered to test for anthrax, that we want to know. But if the result comes back, we want to know what the result was. And so, there's always a delay in those.

Steven Lane - Sutter Health - Member
Absolutely. Great. So, we'll now go on to the second major domain the task force tackled, which had to do with closed loop referrals and care coordination. So this is really primarily about communications between members of the care team. And it was really felt that it was critical that this communication be supported in standardized ways to support multiple use cases. And we call out two in particular, which is the referral transitioning of care from one provider to another, and then getting that information back, closing the loop to the referring provider, but then ongoing communications to support care coordination being equally important.

One area that we've talked about here and that we've done sort of a – kicked off a side project with the AMA around is the importance of standardizing the clinical data that should ideally be collected prior to and sent along with a transition of care, really starting initially with referrals, simple referrals from, say, primary care to a subspecialist, and identifying those common reasons for referral within each clinical specialty area, identifying what data should optimally be collected and sent, and then also looking at what data should be sent back from the consultant to the referring provider. And as we've discussed, the AMA has embraced the idea of becoming a home for the effort of standing up and developing these standards. And we wish them well. And we're also continuing to stay in communications with them, both from our task force, but also from the perspective of USCDI, because this will clearly impact the work of that group as well.

Clinician to clinician messaging. Again, very high value. As we coordinate care between members of the care team, I think for those of us who are in large systems, we can typically do that if we're on the same EHR and they have messaging built in. But as soon as the patient's care crosses between different providers, especially if they're using different EHRs, this is a very difficult thing to do with high fidelity, with privacy and security and tact. So really, an area that we identified as a high priority here.

Then referral management and care coordination, as I've mentioned, really two specific uses cases of closed loop communications. And here, we referenced the fact that Direct Trust is now a standards organization. They continue to support the use of that technology. Other references to messaging have come up in the TEFCA version two. And I think it's going to be important for the HITAC and for ONC to continue to support this kind of communication across systems, across different EHRs. It's also come up that there's not clear governance of this kind of communication, that everyone's kind of winging it, if you will, trying to make this work as well as they can. And we need to have clarification of what are the expectations of the senders, of receivers of messages. In my own practice, trying to use direct, it's very difficult to know what – even if you've got someone's direct address, in another institution or working on another vendor system, it's hard to know whether that's really set up, whether their workflow's in place, etc. And we need to figure out where we can come together and set expectations and standards so that we can do this kind of communication safely.

Tier 2 in this domain on the next slide, the idea of automatically incorporating patient information into a recipient EHR was identified as something that's important. Some vendor do this. Some don't. Sometimes the data gets put into a holding tank. Sometimes it's automatically incorporated. And this clearly improves the efficiency and the value of communication between providers, between systems, between members of the care team.

A different domain, separate from care team members communicating, is patients communicating directly with their clinicians and other members of their care team. Today, much of this happens through portals. But other opportunities exist – direct messaging, etc. And we feel that this is an area that ONC should focus on, trying to develop some standards that would support patients, because patients of course are receiving care often from providers in different systems using different EHRs, different members of their care team, home care, etc. And I think it's a rare patient that can manage five or six different portals to communicate with their care team and to keep that all coordinated.

It did come up in our discussions, the value of a care plan for a patient that could be contributed to from clinicians and other care team members in multiple institutions, and could be available to the patient. I don't think this really exists. There's some standard work going on about the concept of the care plan document, but really getting into what should be in this care plan, how it's gonna be made accessible and utilized by the various stakeholders is an area where additional standards could certainly be utilized.

Real-time text messaging has come up primarily in the inpatient setting, but certainly, in addition to the sort of asynchronous messaging that we discussed between care team members having that be available through real-time text is going to be very valuable, but an area where standards don't really exist. Here again, Direct Trust recently launched an effort to try to develop a standard implementation

guide around this. I think it would be very valuable, and our committee thinks it would be valuable for the ONC to help this along.

We also made a number of general observations in this area of closed loop referrals, communication, coordination of care. And that is that there are some very clear early examples, low-hanging fruit of, say, referral from primary care to specialty. But there are a lot of other examples of closed loop exchanges of information, such as ordering a test and getting the result. And there are probably opportunities to look for the commonalities between these different uses of communication and try to standardize across them as much as possible. As we look forward to a world of Fire and evolving standards, trying to use the same sorts of tools to accomplish closed-loop exchanges, regardless of their purpose, is gonna be very valuable. And then also, as we discuss transitions of care, there's the simple primary care to specialist. But of course, the transition is into and out of acute care, into and out of post-acute and long-term care, transitions in and out of community services. All of these are examples of transitions of care, where again, ideally, common standards would be developed and supported that would allow all of these transitions to occur in an equally efficient, secure, and safe way.

So those were again our Tier 1 and Tier 2 recommendations at a high level. Again, I want to remind everyone that this goes a lot deeper. Within each of these bullet areas, we've made very specific observations, specific recommendations. And for many of them, specific recommendations about policy levers, things for the ONC, for CMS, for other stakeholders to try to effectuate the changes that we've suggested. So all of that detail is in the draft report. There are some areas where we still have some blanks that we're filling in, especially around the policy levers. But we'd be interested in feedback in all those areas. I'm going to pass the ball back over to Ken. Or we can just stop and take any questions or comments at this point. Ah, Jonathan.

Jonathan Nebeker – Department of Veterans Affairs – Federal Representative
I have a question. So, a lot of what you have on this – so, it's Jonathan from VA again. About this tier, there's a lot in the coordination that could be viewed as exchange-based coordination versus cooperation-based coordination. And if you'd just clarify that, if you're addressing both or just one? And if not, we should address the cooperation-based coordination.

Ken Kawamoto - University of Utah Health - Member
I'm going to have to ask you to define your terms.

Jonathan Nebeker – Department of Veterans Affairs – Federal Representative
So, there're things like – so, I guess it's the difference between – so, there's choreography. So, it's different choreography where you define business rules, and then everybody kind of plays by the same business rules for operating. And so, there's a certain amount of choreography for online ordering systems, online vendors that have expectations. And you have some catalogue type issues here that you put on the board. And so, it's not just a matter of exchanging the data. There're expectations about how the data will be used and how also the return of the data will be used. And so, when you get into service-oriented architectures, there's a certain amount of choreography as well as exchange that has to be set up. And to have commonly understood and adopted business rules for using data, a

limited amount of data that's exchanged just can accomplish a lot more work than the data that is exchanged – I think it's a very powerful concept – again, used in many other industries. Not so well-used in health care. But it can address the burden issues and explicitness for care quality issues, everything else.

Ken Kawamoto - University of Utah Health - Member
Those are great comments. I think that you're using somewhat different terminology than what we've used. We speak of governance of this. But I think that's great. Again, we would welcome your detailed review of our draft. And if you see opportunities where you think additional clarity can be added, please let us know. That'd be great. Andy.

Andrew Truscott - Accenture - Member
Yeah. Just picking up on Jonathan's comments, that one of the principle issues we were going through with the Information Blocking Task force was that we would not be seeking to govern, guide, manipulate, or otherwise influence how the end data was being used specifically. We were pushing for the blocking not to be dependent upon having some kind of discovery and exploration about what was happening at the end. And that was the position that the committee kind of accepted and pushed for. Are you proposing – I want to understand your comments here about whether you're proposing that actually we should be interested in that.

Jonathan Nebeker – Department of Veterans Affairs – Federal Representative
So, yeah, I think that the kind of end use you were referring to for data blocking is fundamentally different than – so for what purpose is it being used rather than what is the business expectation for when you exchange data and expect something back. And so, and I think other industries have demonstrated that you do need a certain amount of choreography principles and expectations if you want to do cooperation. If you're just sending data, that's okay.

Andrew Truscott - Accenture - Member
Yeah. I think that's slightly different than the first time around with language. And actually, that feels like something that TEF could usefully get involved in as well with the TEFCA people.

Steven Lane - Sutter Health - Member
Yeah. And I'll just add that we – again, when you look at the specific case of the ambulatory referral, there I think we've really called out the importance of saying this is what you expect me to send. This is what I expect you to send back. But you're right. I mean, certainly orders and results, if I'm sending an order, I expect the result. But there are clearly many cases like that. I love the use of the term "choreography" too. Terry.

Terrence O'Malley - Massachusetts General Hospital - Member
Thanks. Terry O'Malley. So just a little expansion on the closed loop referral. This is based on the 360X project. So, highly recommended if you haven't looked at that lately that you do, because 360X represents really a new paradigm, or it expands beyond just the exchange of information, I guess to Jonathan's point, about sort of the governance and how is that information used. And what 360X does it sends the payload. But it also creates in the background a series of administrative messages that

keep the loop closed. So, if the loop breaks, the system identifies it, creates a new loop to fix the break, and so on and so forth. And so, what happens is you've got an administrative system that runs in the background to make sure this actually happens, rather than having some **[inaudible] [01:15:04]** or front office staff worker who's trying to track that stuff by phone. And the great thing about this process is that it doesn't apply only to closed loop referrals. It's really any process that involves complex communication among multiple players that has to be sequenced and coordinated. So, just think of where that applies. I mean, it's care coordination. It's medication reconciliation. It's a whole bunch of processes that have really bedeviled clinicians, so. I think this is certainly a Tier 1 issue, so thanks to this task force for raising it.

Steven Lane - Sutter Health - Member
Carolyn.

Carolyn Petersen - Individual - Chair
So, kind of one of the watchwords in health care is this concept of "nothing about us without us" as a way of sounding out the patient's perspective. Patients want to be involved and able to communicate with providers. And when I look at the breakout for this particular domain, I see in Tier 1 this clinician to clinician communication is facilitated, but the patient clinician messaging is in Tier 2. I'm wondering if you can talk a little bit to why – how that evolved, or what the value is perceived to be in organizing it that way.

Steven Lane - Sutter Health - Member
I think it's a great question. It's perhaps historical. But it's not a differentiation that I would care to particularly defend. I don't think there was a general feeling that we needed to prioritize clinician communication over patient communication. I think that patient communication is happening today. Patients for the most part do have access to communicate electronically with their clinicians. Certainly in my system, and I think in many, many systems. And as I said, provider to provider communication is happening inside of systems but not between systems. So I mean, one might argue that the net value to patients would be greater if we fixed the problem of cross-organizational provider community, insofar as the patients can already for the most part communicate with their clinicians by one means or another. But I think if the purpose of your comment is to suggest we should move patient clinician messaging up from Tier 2 to Tier 1, I certainly wouldn't have any objection to that. We can certainly take that back to the task force.

Carolyn Petersen - Individual - Chair
Thanks for that. I guess I would just caution the task force to be aware that just because the technical means of communicating exist does not mean that the cultural, organizational, and other things that are needed, like broadband and other things that facilitate that are necessarily at the same level of achievement. And it's I think something to keep in mind in terms of making sure that we facilitate that patient clinician messaging.

Steven Lane - Sutter Health - Member
I couldn't agree more, though I think that addressing broadband issues – at least, we didn't identify

that within the task force as a priority for our efforts. Other questions, comments, observations, feedback? Great. So, we'll then go on to the third major domain that we focused on with Ken.

Ken Kawamoto - University of Utah Health - Member
Yeah. Next slide, please. So, the final area that we had time to get to at the task force was medication and pharmacy. So, these are our Tier 1 recommendations. A number of them are closely aligned and really come at the notion of the process of choosing and getting information on prescriptions with cost and prior authorization as a key part of it. So, our first recommendation is around making real-time prescription benefit checking being available. Closely related to that, to have this information available to patients through patient-facing APIs. And again, related, having the ability to check on eligibility and formularies to get prior authorization and to identify alternative therapies that are available.

So, big picture issue here is, as you, I think, know if you've encountered it as a patient or if you're a provider, it can be really, really hard to figure out what a medication's going to cost. It is, in certain drug classes – I mean, it can even lead to things like having to have your pharmacy tech put in sample actual prescriptions and then to immediately cancel them after seeing how much it actually would have cost the patient. I mean, it's insane. So, this issue here is – this should be really made available and made so that you can tell not only ideally how much it's going to cost now, but what's going to happen when, say, your Medicare donut hole hits so that the cost this month isn't $20.00; the next month, it's $500.00. Those kind of things. Or at least be able to tell what's likely to happen. Because I think medications are such an important part of our clinical care. And this cost issue is really a big deal, right, for a lot of works. So, we really identified this as a major barrier to good clinical care and good clinical experience that we identified as priorities.

After those, related to this notion of being able to know what's covered and how much it's covered for, etc., we identified medication reconciliation as a big pain point, where it is currently a pretty inefficient process. Things like being able to know that you've already reconciled this before, and it's the same thing, that you're being asked to reconcile where does the source of truth lie, etc.

We also identified the need for a discrete structured medication sig. Information is a key issue. So, as you know, sigs are things like take this there times a day by month, or as needed for pain, etc. The issue here is that oftentimes, that information is just in free text. It's not in a structured form. And that means we can't actually assess it for things like, are you at your maximum daily dose, or for opioids, are you taking too much. And this is a pretty substantial issue. So, this is an issue we wanted to hopefully address without having to require clinician users to have to enter it in a structured form. So for example, if it's in a free text, can we come up with public resources to come up with the structured information using things like natural language processing.

We also identified medication administration dispense history as something that really needs to be shared widely. It's pretty common knowledge that patients, I think it's like 30% of the time, don't fill their prescriptions, whether for cost issues or whatnot. And patients typically only take about half of the medication regimens that they're prescribed for chronic conditions. So as you can imagine, if this is a core part of medical care and taking care of patients, and taking care of our health, and we have 50% compliance, that's something we need to know about. And as of right now, it's almost novel to have

this information. So, I think this is something that our task force identified as a really important issue that needs to be addressed.

And then finally, kind of relating to this, all this, is the translation and mapping between RxNorm and NDC codes. Most prescribing systems and EHRs tend to deal with RxNorm level codes from the National Library of Medicine, whereas most prescription and pharmacy systems deal with national drug codes from the FD, or NDC codes. And they're very different levels of granularity. And this leads to issues such as, you want to prescribe as a provider with your patient a particular drug, identified as RxNorm code. And how do you then identify what it's going to cost to the pharmacy system? Do you check every single NDC code that could be related to that RxNorm code? Do you come up with a representative one? This is a really big issue because a lot of the priorities we have, we can't address unless we have a good way of doing that walking through between those two. Next slide, please.

We also had some Tier 2 recommendations in this space. One was around provenance. Again, the notion of being able to tell when information that we're sharing across systems – we've seen it before, it's the same one, etc. We had a fair number of recommendations around PDMP, prescription drug monitoring program data, both policy-related and also cost-related, where accessing this information currently can be exorbitantly expensive, which seems that is a real barrier toward actually being able to make use of this information to help address things like the opioid epidemic. Related to this, we had some recommendations around specific transactions with querying and reporting on PDMPs. We also had recommendations around making it easier to share and get information on adverse drug events.

And related to the prior authorization information, so here, we were noting that some medications are not covered under the medical benefit and can't be therefore covered under some of the standards being worked on. They're covered as – sorry, not as a prescription benefit. It's covered as a medical benefit. And this gets at this notion of, well, there's more than the typical prescription benefit coverage approach for prior authorization. And that also needs to be considered. A more difficult space for sure, in the sense that whereas medications are standardized in terms of the coding we use, it is not the case for non-medications right now.

We also talked about medication indication, noting that in many aspects of care, such as ordering labs, you have to actually say why you're ordering it, whereas for medications, it's not required. And we had a lot of discussion on do we want to add that burden to clinicians? I think the task force felt this was perhaps something that would be worth the requirement to actually say why you're prescribing medication, so both the patient and other clinicians know why this medication is on the patient's regimen.

And also, a small recommendation around RxNorm codes for discontinued drugs. At least our current understanding is that the National Library of Medicine's RxNorm API, if you call for it, it doesn't actually tell you about any discontinued drugs, which means, for example, if you're relying on it to say, has the patient ever taken a hypertensive drug, or a chemotherapeutic drug, whatever, that if it's not currently on the market, you may actually miss that. And it's an acknowledged issue. It's just the kind of thing that just seems strange and should be fixed.

Okay. So I think that's all we have for medication and pharmacy. Before we go on to the discussion items that are broader, Steven and I would be happy to take any comments or questions on these topics. Great. Maybe we can move on to the discussion items, then.

Steven Lane - Sutter Health - Member
All right. So, in lead-up to today's presentation, our friends from ONC said, oh, you can have 90 minutes. You can two hours. You can have as long as you want to go through this with the HITAC, which was very nice. And but we really weren't quite sure how best to utilize all of your time, as well as how best to gain your input. At our next meeting, we are going to be bringing back our final draft report, or final report for HITAC review and approval. And so, we really do want to get all of your input now so that we're not surprised, or delayed, or have our wheels slashed at the last minute. So, really interested in hearing from folks, has this been helpful? Is there another approach that we should be using to get additional input? Because really, at this point, we're kind of filling in some blanks, as I said, polishing up the report and hope to bring it back to you in a final form. So maybe we can kind of just pause there. Arien?

Arien Malec - Change Healthcare - Member
Nice anticipation of me about to raise the placard. I think this work has been – obviously, I'm a member of the task force. This is a little bit of patting myself on the back, although I haven't been as involved as I should be for the last few meetings. There is a needed – this workgroup still is a needed gap in the policy space. I think we've got a number of efforts that are going very broad and are aspirational in pushing the frontier of interoperability forward from a policy direction. We don't have as much of finishing what we started work. And this task force has really focused nicely on looking at gaps in areas that – so, if we take an example of electronic records achievement, CMS removed the associated measure as topped out.

And yet, when we look at the clinical experience in the field, and we look at the patient experience of receiving structured records, when we look at the prevalence of LOINC-encoded labs from lab systems, we see a tremendous number of ecosystem gaps relative to getting clear interoperability experiences in place. So, this kind of cleanup batter approach, we don't have to hit homeruns all the time - there's a lot of space for people who are good at hitting singles and doubles – is incredibly necessary in order to move the ball forward for interoperability. So that's a general piece of feedback that this task force fills a really important gap.

With respect to some of the discussion topics, or if you want me to hold off on that, I'm happy to hold off on that.

Steven Lane - Sutter Health - Member
No, no.

Arien Malec - Change Healthcare - Member
So, you know, we talked a lot about free standards availability. And sort of the elephant in the room is AMACPT. And really, the driver of the adoption of AMACPT and the use of AMACPT is the federal government, particularly CMS, endorsing a non-public standard as absolutely necessary for any work in

administrative transactions and processing. So, in many cases, the policy levers for driving the ecosystem for complete open availability standards are firmly in the federal government's arms. There's a lot information or a lot of discussion about the proper role of patients in managing their own care. And this is one of those strange areas where the paternalistic demand of medicine and the goal of true patient engagement often come into conflict. The only vote that we ever saw back in the Policy Standards Committee's days that went to a real knockdown drag-out vote was over this concept of patients getting access to their own data with the app of their choice, which everyone supports in theory. But when it comes down to practice, there's a lot of "concern" that patients might use the wrong app. We can't trust the patient to make decisions. And that institutions have a role to play in protecting patients from their own data.

Likewise, with respect to real-time records release, what you find is a support in theory, but then a lot of concern that patients are going to get access to something and then, gosh forbid, ask questions, want to know more, get involved in their own care, or even worse, discover that they've got a serious condition that needs treating. And as anybody who's gone through a significant diagnosis and course of treatment knows, it is almost impossible to manage your own care without access to the data that's involved in managing that information. And also, the concerns that will drive patient anxiety if we give them access to too much information, in my experience, has been quite the other way around – that the more we withhold and manage access to data, the more anxiety we're driving, because – so in my case, getting access to CBC results is pretty critical to understanding where I sit relative to my own care and driving my own treatment plans, and the longer the lag time between getting the results and finding out what the actual information is, the fewer degrees of freedom I have to managing my own care.

So, I think there's a lot of – this is an area where the standards are there, but the policy and cultural factors are not. And I think there's a fair amount of policy work and cultural factors, culture of medicine work, that needs to get worked out and needs to be exposed to the surface in order for us to make progress in truly patient-involved care. Thank you.

Steven Lane - Sutter Health - Member
Thank you, Arien. And yeah, you did kind of jump us ahead into some of the other areas. For the remaining comments now, any other comments about the approach to the review here? And then what we're going to do is actually go through and hit on each of the other areas in turn. So, Sheryl.

Sheryl Turney - Anthem Blue Cross Blue Shield - Member
Thank you, Steven. So, a couple of comments. I think that regarding the work that we're going to be looking at for cost transparency, there is no standards-making organization for anything like that right now. So, looking at who should be creating standards, and in fact knowing that there is a need for that. Because as I mentioned before, we've seen real world examples where app developers average costs together and said, this is what your estimate for payment's going to be, and we know that that's not accurate. So, that's going to be really important. But also, for consumer engagement and also consumer transparency, applications and tools, I think there needs to be more work regarding standards and who really owns those. I mean, daVinci – I was looking at more of business to business

type arrangements. Maybe some of the organization we need to be looking at are things like CARIN, that's trying to focus on consumer engagement.

And then also, when it comes to AI applications, I see there's a difference between AI applied to a person's care management or care strategy versus AI applied to what's the administrative process we should follow. And there needs to be a different governance process over those. And who's going to be the standards organization for that? And right now, that doesn't exist. And then when we get to social determinants of health, we have many organizations that want to start using that. And as a payer, we're very concerned with what is the standard of care in terms of notification to the member and the patient. And shouldn't they be aware that these datas are going to be used? And who's required to notify them? And how those are going to be used, and how they affect the care plan or the benefits that are provided to the individual. And there is no organization today that covers those types of standards.

So, I think that we've talked a little bit and touched a little bit on all of those, but then we need to talk a little bit more about what is the organization that we're going to be working with, and who's going to develop those types of standards and loop them in, and then use them as a base that can be built upon. And then I also was just wondering about NCVHS, because they do have a role in standards recommendations, et al, and we didn't really include them in our report. So maybe we need to add them as well as a possible influencer or someone to provide input.

Steven Lane - Sutter Health - Member
Thank you. Cynthia.

Cynthia Fisher - WaterRev, LLC - Member
Thank you. First of all, I'd like to make a recommendation that instead of the words "cost transparency," that we actually change nomenclature to "price transparency." I think that's consistent with the rules and the guidance that we have out of HHS. I also believe that if we standardize just the terminology as price transparency, it's the actual prices. And in the business lexicon, typically cost is at the basic cost, and the delta is the margin, and then you have a price. So, that would be my recommendation, that we decide. And I would recommend we go with price transparency, that the committee consider that.

I also, to Arien's point, would applaud his recommendation on twofold levels. One is that I would look that we – that HHS and CMS consider, and the Standards Committee standards look at enabling consumer-facing nomenclature for bundled and unbundled pricing that is independent of proprietary fee-based structures such as CPT codes, and that we could instead use standards that would actually be open and – how would you say, Arien, more –

Arien Malec - Change Healthcare - Member
Yeah. Open is the right term.

Cynthia Fisher - WaterRev, LLC - Member
Open. And then not be cost prohibitive for participation. So at least as an alternative in parallel as we

transition. Thirdly, I look at to really have a discipline to consider that what we do today is not just for our aging parents or ourselves, but we're looking at children. We're looking at multiple generations down. And I don't believe the millennials would tolerate paternalistic perspective of not having access to their information real-time. And I think as we go to deliver health care information, even being able to have your test results bedside, even while your physician does, it makes a marked difference. And I'll give you an example of a severe aplastic anemia patient who's CMV negative who needs blood product platelets that are CMV negative. And having seen B positive and negative platelets is a significant difference to that patient. And it's going to be a family advocate that's going to be looking at that blood bag or looking at that result for the safety of their loved one. So, having real-time access to data and allowing the caregivers and the patients is, I think, really imperative on our side to go away from our paternalistic standards, in our standard-setting, to delivery of real-time testing and lab results and information.

And finally, as we go to set, how do we go about setting price transparency settings? I think we want to not reinvent the wheel. And there are marketplaces, transportation, financial services, grocery, retail, where everyday payment systems are transacted financially every single day on setting prices and actual fees. And the health care industry could catapult itself if we learn from our brethren industries and also didn't reinvent the wheel because we already have some standards in the payment system. So I guess I would just say, let's behoove ourselves to leverage existing standards.

Steven Lane - Sutter Health - Member
Before going to Terry, I just want to take a minute to respond to some of the comments that Arien and Cynthia offered. And we sort of lost control of our discussion topics because we're kind of all over the place, but that's fine. We're getting this all done. In the area of free standards availability, what the task force has discussed is really simply saying that the standards that are required by ONC – certifications, CMS, etc., that they should be available to developers to be able to see what it is that they're expected to build to. I think, Arien, you raised a somewhat separate issue, which is the AMA's business model is charging people to download and utilize CBT coding. The task force has not discussed that in particular, that notion of – it was really just being able to get to the standards to see them as opposed to the question of whether someone can actually charge you for utilization of the data.

So, the purpose of these discussion topics really was to get kind of the HITAC's input and feedback. Are there things where we've missed the mark, where we should be making last-minute adds? The problem is we don't really have a lot of task force time yet to consider new suggestions. But I did just want to differentiate, Arien, what I think you were saying about do people have to pay to license CBT to utilize it in their EHR, as opposed to people have to pay to even go read the standard that they're expected to go build to.

Arien Malec - Change Healthcare - Member
Yeah, that's right. If I might respond to that, yeah, we did discuss code sets as well, but as a policy principle, I would endorse the notion that those standards and code sets that are in use and required for interoperability be freely available. There're a number of business models that can be put in place to do that. One of the most successful ones is the ILM national licensing of code sets, that's really helped us in the area – SNOMED, LOINC, and others. So, there are well-established mechanisms for

making sure that we have open standards and open content. And I think each of those is equally important, because you're going to have to – at some point, you're going to have to figure out all the licensing of all the constituent parts.

Ken Kawamoto - University of Utah Health - Member
And maybe if I can jump in a little bit on this. So, I think in my view, I was thinking of both, both being able to see the standard and actually to be able to use it. It originated with the discussion on NCPBP standards, where we learned that it's available during comment period, and then it just goes behind a pay wall. So, I think the overall desire that the task force was coming at was we want the standards that are required in federal regulation to be actually available to the US public to be able to review and to use. So, I think some of the issues there are, again, there are some things that you have to pay for to access to do these. Another issue that I brought up in my role of seeing this from my unpaid board member role in HL7, and Andy's in the same boat as well, is that organizations like HL7 that have decided to make all their IP free have seen precipitous declines in things like membership, because you can now just access it for free.

And I wanted to bring into the discussion the notion that we shouldn't just support the folks who haven't decided to make things available for free, that we should also support the folks who have made things available for free, because those organizations may actually cease to exist if we don't support it or can't support the standards in the way that they need to. And there are real examples around, for example, issues around Fire and the daVinci project, etc., where there're real issues with the way those are straining the organization.

Steven Lane - Sutter Health - Member
And I'm sensitive to the fact that Terry's had his card up for a long time. Do you want to jump in on this one, or should we finish this with Andy and then come back?

Terrence O'Malley - Massachusetts General Hospital - Member
Go ahead with Andy. That's fine. I'll wait.

Andrew Truscott - Accenture - Member
It seems like I've got brought into the discussion **[inaudible] [01:45:20]** opened my mouth. Yeah. You're right, Ken. We rely and we're intrinsically dependent on **[inaudible]** voluntary organizations around the standards creation. And that's not a sustainable model long-term to effect the change we want to effect. I'm constantly surprised about the struggles – and it's not just HL7. It's any of the **[inaudible]** organizations. The struggles that they have with actually soliciting membership, let alone input, falls on the shoulders of a few people. I'm constantly surprised – I'm very surprised, it would appear, constantly, that those implementers of health IT standards elect not to be part of those organizations because there's no pay wall there any longer, which means they can get access to open standards in a very open way. Sustainability is going to suffer, and eventually, who's going to be doing that work? I'm pretty sure the ONC doesn't want to pick up writing standards. And I'm pretty sure all of our task forces don't actually want to pick up the authorship of those standards. And we inside the US have a massive dependency upon those being right. And I can look down the table at my friends from the VA and DOD. You guys are absolutely dependent upon those being done right. When I look across

the table at people from National Library of Medicine, etc., we need those. So, do we as a group here have a point of view on how we should be promoting the support of those groups?

Steven Lane - Sutter Health - Member
I think it's a really key question. We're going to finalize a recommendation from our task force, whether it is that the standards should be freely available, and/or the code sets should be freely available. It is hard for me to imagine how these organizations will sustain themselves if there's not some revenue coming in. I mean, HL7 has experienced it one way, and AMA has experienced it another way. And one of those is probably the right way to go. It would be – but clearly, there needs to be a revenue model. Okay, Terry.

Terrence O'Malley - Massachusetts General Hospital - Member
Thank you. Terry O'Malley. So, I hope this is responsive to your question about sort of the role of HITAC. But I actually have three questions. So, the first is, so who is going to play the role of the IFP task force once you guys turn off the lights? Where in the health care system is there a group of essentially non-market-based folks who are looking at the holes in the system? That's really, to Arien's point, the guys who are hitting those singles and doubles, finding the holes in the defense and plugging them. Where is that role? Where is that function? Is that a HITAC function? And if it is, and I think it probably should be, if it's not HITAC, then certainly ONC, perhaps. But I think we ought to have a discussion about that where that role fits, who continues it. Because it's really critical to, again, knitting the web of standards that underpins interoperability. That's one question.

Ken Kawamoto - University of Utah Health - Member
Maybe just to respond to that, that is something the task force explicitly discussed. And options would include convening other task forces, maybe on specific areas that you can imagine on price transparency, not cost transparency or prior authorization, etc. It could be a continuation of the equivalent of an IFC task force. It might even still be called IFC task force. I think our general sense is that there still are – we didn't get through the things that we probably should get through, so that probably would make sense. But yeah, it definitely does seem like something along the lines of what this task force has worked on probably should be continued.

Terrence O'Malley - Massachusetts General Hospital - Member
And clearly, some of this work is being managed through the ISA process. But it's not nearly so active, right? I mean, it's just waiting for comments to come in, as opposed to a dedicated group that's been tasked to sit down and think it through. Actually, that's one. The second is, and sort of again, a coordinating role. So, we have a bunch of task forces. And there's clear overlap between ISP, UCSCDI, and certifications and maintenance of certification task forces. One's the hammer. The other two are the – whatever we are. How does that function occur? Where're the shared priorities among those three task forces? How are they established? How do we coordinate the three task forces working together? Because they're all parts of the same process. They're all important. And they're mutually reinforcing. So, another question, I guess for the HITAC, that I would have is, so, how do we do that? How's that being done? How should it be done? Should it be done? And then I have one more, if you want to comment on that.

Steven Lane - Sutter Health - Member
Well, yeah. I'll just say that I think these are great points, and ones that we will try to include in our conclusion at the end of our report, that these remain open questions that the ONC really needs to figure out how this is going to be done going forward.

Terrence O'Malley - Massachusetts General Hospital - Member
Thank you. And then the last question, and not to pick on Kate – oops, Kate's not there, so I can pick on Kate – is sort of the role of CMS in helping to drive the adoption of these standards across the health care system. It's really involuntary adoption, or driven by the market. So in that sense, it's involuntary. But there are perhaps opportunities for a much more powerful set of levers to be brought to bear on the adoption of interoperability through the mechanisms that CMS has, particularly conditions of participation? You will exchange things using standard-based and semantically interoperable language, or you don't get paid. I mean, that's a very simple business model. And it would be very compelling **[inaudible] [01:52:02]**. Oh good. So, Kate. Kate, I was just asking about perhaps CMS's role in using conditions of participation as a powerful lever to drive adoption of interoperability and standards-based exchange.

Kate Goodrich – Centers for Medicare and Medicaid Services – Federal Representative
Mm-hmm. So, we've obviously shown that we are willing to make some proposals in this area. We always have to keep in mind a couple of things when it comes to COPs. One is they do have to have an evidence base to tie it into health and safety, because these are health and safety standards. And I think with interoperability, we've been able to make that case in particular around the ADT referral and so forth. The other is, I think we don't really have the ability to – or it's very difficult for us sometimes to have exceptions for providers who may not be able to meet some of these. And given that with ties to COPs, this payment by Medicare and Medicaid, which is like the biggest hammer that we possibly could have, we have to be pretty certain that the vast majority or all providers are ultimately able to meet that standard. Because they are the floor, don't forget. That's what the COPs are. They are the floor of health and safety standards.

But having said that, it is obviously a huge priority for us at CMS. And like I've said, in the first interoperability rule, we've shown that we're willing to use them. But those are the considerations. So if there are suggestions for us, we are open to them.

Steven Lane - Sutter Health - Member
Great. I see Jonathan. And Arien. Sorry.

Jonathan Nebeker – Department of Veterans Affairs – Federal Representative
So, I have kind of a response. So, I feel like somehow I need to channeled on record here. But one thing that's really interesting is, especially about the comments about how do we sustain the standards communities. And I'm involved with some more unusual communities. But there's a clear business interest for participants where they can see gain for participating in the standards development. And some of these other areas, it's not clear, because there's overwhelming rewards and punishments that wash out business benefits for a lot of the things that we're talking about in this group. I wonder if it – and I really personally, as a government employee, don't like the government saying, you have to do

this. And so, I think it'd be interesting and maybe something – I don't know what I can do as an ex officio member, but participate kind of from the policy point of view in this and say, how do we look at the recommendations that the committee's making, and what are some kind of not tricky but more foundational policies that could create business interest to implement these advances that we have here? And so, there's like, look, so this is the technology that we're imagining now. But there may be better technology or better methods. But this technology or this method's not going to work unless we have these types of business incentives. Here are some examples of policies that might promote those business incentives. So, not to volunteer myself for work, but I'll volunteer myself for some work, especially after November, when we have some new contractors coming onboard.

Steven Lane - Sutter Health - Member
Arien.

Arien Malec - Change Healthcare - Member
Yeah, just real quick. I did want to also offer up, we do have the annual report as another mechanism to go to communicate back, especially if we as a group collectively feel there are other opportunities for perhaps legislative means, particularly around – I look at standards as patient safety, right? Updated standards allows for interoperability, allows for a lot of these things we're trying to get done, all in the name of patient safety and quality and whatnot. And so, we do highlight an area of discrepancy, or a major issue, or a potential risk. That is something we probably could take it back and say, we recommend looking into this, and potential other avenues of ways that we could do this. So, to the degree of it – that's what I'm saying. We have a lot of other mechanisms at our fingertips that we could utilize in other ways.

Steven Lane - Sutter Health - Member
Oh, I think that's a really great point. And perhaps you could just copy and paste what'll be the last three pages of our report, work yet to be done, and put it right into that.

Aaron Miri – The University of Texas at Austin Dell Medical School and UT Health Austin – Member
Just seconding and supporting here in this comment that the annual report can be a place to accomplish some of this work.

Ken Kawamoto - University of Utah Health - Member
I think we're at public comment time, right?

Robert Wah - Individual - Chair
Yeah, so let me just – as you all know, I've been the keeper of the flame about the public comment period and our commitment to our public about when we publicly say what time the public can comment. I want to try to honor that timeframe. At the same time, you also know I don't want to stifle discussion of this group. So, I propose that what we do is we take a break right now at 11:45 – that's the time we publicized as the public comment period – allow the public to make their comments. We will resume this conversation as soon as the public comments are finished. And I'll frame shift the lunch hour, depending on when we finish here, so you'll still get your hour. But I may shift it just a few minutes depending on how the discussion goes. So, you guys all know I do this all the time. So, I'm just

going to continue to do it. And so, I'm going to turn it over to Lauren to open up the public comment period.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Great. Thanks, Robert. So, just as a reminder to those providing public comments, please state your name first, and we'll ask you to keep your comments to no more than three minutes. We will start in the room to see if there is anyone. And we'll ask you to actually come to the table. If we can ask Ken and Steven just to hang back, and we'll ask you to come to the table and state your name first. You can press the button, the one at the bottom.

Mari Savickis
Got it. Lot of buttons over here. Good morning, everyone. My name is Mari Savickis. I'm with the College of Health care Information Management Executives, also known as CHIME. And I'm here today on behalf of seven provider organizations. I'm going to read them all out for you. The American Health Information Management Association, also known as AHIMA; the American Medical Association, known as the AMA; the American Medical Informatics Association, known as AMIA; CHIME; Federation of American Hospitals, FAH; and the Medical Group Management Association, MGMA; and Premier Health care Alliance. Sorry, I have to read this. I want to make sure I get it straight.

We are pleased to offer comments and feedback to the HITAC as this body continues their deliberations around information blocking, certification, and spurring an interoperable health care system. We appreciate the countless hours this body of volunteers has committed toward helping advice ONC on these important matters. The 21ˢᵗ Century CURES Act has ushered in a new era for health IT and is furthering the digitization of health care, including helping facilitate more engaged patients through the use of APIs. We appreciate ONC's work to carry out the provisions in CURES and support the work related to supporting standards through the USCDI, open APIs, fostering better access to health care data for clinicians and patients, and efforts to further patient matching. However, we are cognizant of the fact that significant work related to the implementation of the CURES continues. There are areas for improvement with regard to certain proposed policies around the CURES Act, including interoperability, information blocking, and the ONC health IT certification program proposed rule. Specifically, we recommend ONC take the following steps.

Number one, publish a supplemental notice of proposed rulemaking. As ONC moves forward towards the publication of a final rule, we recommend they issue a supplemental notice to additional time to address the myriad of questions raised by a variety of stakeholders around the data blocking proposals. These include but are not limited to confusion regarding the definition and scope of EHI and health information networks.

Number two, we recommend staggering deadlines. Proposed implementation timelines under the rule, when combined with deadlines set by CMS, including promoting interoperability programs, appropriate use, ePrescribing updates related to NCPCB standards results in overlapping deadlines and layered complex requirements for both providers and vendors. Furthermore, the proposed cadence of deadlines under the rule does not account for competing priorities and adequate compliance

timelines. Additional consideration should also be given to the entire suite of deadlines that providers and vendors need.

Number three. We recommend creating a new version of certification. Given the substantial challenges for vendors to comply with the new changes **[inaudible] [02:01:04]**, and for providers to deploy and test them, as well as the fact that providers recently adopted the 2015 cert in 2019, we recommend ONC establish an entirely new edition of certification to reduce confusion among providers and vendors, as well as to enhance implementation.

Number four. Education enforcement flexibility is needed. Given substantial industry shifts associated with this rulemaking and confusion regarding definitions contained in the rule, including the exceptions to the information blocking rule, we believe a more fruitful approach would be one that centers around education and opportunities for corrective action. Along these lines, we recommend the final rule include a period of enforcement flexibility that allows actors to absorb lessons learned and address specific issues, rather than a punitive approach.

And number five. We think there needs to be an enhanced focus on privacy and security. The proposed rule does not sufficiently address CURE's directive to protect patient data privacy and health IT security, which could potentially exacerbate these issues moving forward. Further, it is imperative that the committee continue its oversight of privacy and security issues that fall outside of HIPAA regulatory framework. Thank you, and I'm happy to take any questions.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Thank you for your comments, and thank you for participating. We will certainly take your comments under consideration back to ONC.

Mari Savickis
Thank you.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Do we have any other public comments in the room? Just as a reminder, please state your name. There's a soft button on the bottom to turn the mike on.

Marni Jameson Carey
My name is Marni Jameson Carey. I am the Executive Director of the Association of Independent Doctors. We're headquartered in Florida, but we have over 1,100 physicians who are members, and they're in 45 states. They're not often represented, and I'm here today to be their advocate, as well as an advocate for patients and consumers who also don't get to have a say at the table at times. So, as the name implies, the Association of Independent Doctors works to help independent doctors. So, a third of them who are practicing of all physicians to survive, we believe they provide the most affordable care. We believe that they are the least at risk for burnout. As you may well know, physicians are at the highest rate of suicide in any profession. One physician a day dies by suicide. But

the least burned out are independent doctors, because they like to be able to be in control of their information, their patients, their tests, and their destinies.

So, we aim to stop some of the consolidation that's going on. And we believe that there is an opportunity for IT to step in and really help stop that consolidation through true price transparency. If consumers could really shop for outcomes and prices and availability, they could steer the market in a way that could help correct some of the abuses that we're facing now. So, while I think IT is the solution, I do have some concerns. And I recognize that you are all way more expert in IT than I am. But I would like to bring you news from the front about what some of the doctors are concerned about and what some of the patients are concerned about. They're concerned that some of the additional burdens that are going to be required of them through this data entry will already burden an overburdened doctor. Seven out of 10 hours of their workday are spent providing – entering data, and they feel like the most expensive data entry clerks on the planet. And I know that they would appreciate my speaking out for them and trying to lower that burden.

I am concerned about how electronic health record requirements will continue to drive doctors into employment. Many doctors are afraid of choosing the wrong EHR, of making an investment that won't be able to mesh with the health systems in their communities. And so, they throw in the towel and throw up their hands, and go to work for the health system, which is a default. It's not their real choice.

I'm concerned the EHR will drive further consolidation and lead to higher costs, which consolidation in the health care system has proven to achieve, and further erode that patient-physician relationship. Again, the more time that is spent on data entry, the less time is spent with face time with the patient. So, I'm concerned that we'll lose some of the nuances that that human element in health care offers, because not all medical situations can fit neatly into a checked box. I'm concerned that if not done carefully, the move to comply and control – for people to comply and control that data entry and data will benefit the status quo, and some of the stakeholders, like the hospitals, insurance companies, IT companies, at the expense of the doctors and patients – that the benefits really won't accrue to them. But they could if we did this right. And I really think that our time is now.

Finally, and then I'll be out of concerns, I'm concerned about while we focus on the level of granularity with the data that you all want to try to capture, I think we need to again focus on that patient doctor relationship that can only happen human to human. And my doctors tell me repeatedly, they want insurance companies, the government, and hospital administrators out of the patient room, and they want to be one on one with their patients. And I don't want any of that to get lost. As we move toward a high tech world, we still need high touch.

So, if there was ever a time to revolutionize, which is why I'm here, because I really believe that IT is the moment, and I do have children that I want to have a future in health care. And I want them to be able to access things on their phones with real-time and real information. I think if Amazon, and Google, and Zillow, and Uber can move major mega-sets of data into your phone app, we can too – that it's time that health care does at least as well as some of these other interesting – Travelocity, heck. That's the travel industry. We're better than that, right? So, I'd love to see us – and I know a lot

of people say it's really complicated, and it is. But we can make it into an app on our phone where I can look and see who has the best outcomes, what is the best price, where can I go, and when are they available. And I then as the patient and the consumer can take into my own hands the access and availability and the outcomes. And that alone will steer the market and correct some of the egregious imbalances in cost that we are seeing right now.

In no other industry, as you know, do you walk in and get a procedure done, and you don't know the cost until you're out the other side, and it's non-negotiable and non-refundable. And I think that needs to stop. So, IT can do it. And I would love to be part of that role and help independent doctors stay independent and help, because they would have patients who would choose them over the more expensive employed physicians. And I'm asking you to put it in our fingertips – put it in our hands. It's at hand. The solution's at hand. And I would love to see it on our phones. Thank you.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Thank you for your comments. We want to make sure we leave enough time for additional commenters on the phone, but one more call for commenters in the room? Okay. Seeing none, Operator, can you please open the public line?

Operator
If you would like to make a public comment, please press *1 on your telephone keypad. A confirmation tone will indicate your line is in the question queue. You may press *2 if you would like to remove your comment from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the * keys. Our first comment is from Seth Denson with GDP Advisors. Please proceed.

Seth Denson
Ladies and gentlemen of the committee, my name is Seth Denson, and I've spent my entire vocational career advocating for patient's rights and working to drive down the costs of care for those patients. I'm also a dad, and as such, a frequent user of our health care system here in the United States. We've spent a lot of time this morning discussing pricing transparency. But I want to caution you that to many Americans, they see the cost of health care as health insurance or coverage issues, rather than the cost of actual care. And one of the challenges of pricing transparency is undoing the training of the American consumer who's been taught to think about copays and deductibles rather than cost. Insurance networks, in an effort to discount the cost of delivering health and thus provide the consumer have unintentionally created a wall by which I believe the delivery system often is able to hide the true cost of its services. Whether it's how PBM structured the flow of prescriptions and hospital systems and has unbundled fee for service structures, Americans oftentimes will think about insurance benefits rather than cost. And this process has resulted in an insurance industry functioning almost more like a finance system than that of a risk transference one or of a navigational one for patients.

And so, I firmly believe and would encourage that for our free market system to be effective, information must be free, but it also must be clear and understandable to the average consumer.

Because the average consumer does not have a medical degree. And so, it's not enough for miles and miles of data to be available, as the majority of Americans just quite frankly won't understand how to read it. It's an awareness of the total cost and the ability to drive those costs down via free market enterprise. And by that, I mean cost, quality, and competition. So, I applaud your work, the work of HHS to disclose hospital pricing transparency, for example. But most people don't even know what they're looking at when they see that type of data. Nor would they know what to do with it if they did. The American consumer knows how to be a good consumer. We must promote a system that allows them to do just that in health care. And if we do, I firmly believe that the consumer will accomplish on its own what Washington has failed to do for years. Thank you very much.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Thank you, Mr. Denson, for your comments. Operator, do we have any other comments?

Operator
Yes. Our next comment is from Dr. Tom Delbanco with Harvard Medical School. Please proceed.

Tom Delbanco
Hello?

Operator
We were unable to hear you. We can hear you now. Thank you.

Tom Delbanco
Okay. Yeah, yeah. My name's Tom Delbanco. I'm a doctor, primary care doctor, professor at Harvard Medical School, and I'm also one of the cofounders of the Open Notes movement, which is a philanthropically funded effort to get patients and clinicians to communicate much more openly and easily, particularly by giving access to patients to their doctor's notes, to their nurse and practitioner's notes, to their therapist's notes. We've had a lot of luck with that. We have more than 40 million people now in American who have access through patient portals to their notes, and we've learned the patients love this and benefit enormously clinically from it, and that doctors who are nervous when it starts gain comfort with it over time and actually become advocates for it as they get more used to this kind of transparency.

So, I've listened to you folks this morning, and I congratulate you on what you've done. And I also moan at how difficult your job must be. The thing I did not notice so much in what you wrote up, which I reviewed beforehand, was how you do not really turn to the role of the patient as someone who can help in these efforts and really get to work on these efforts. Ms. Peterson referenced "nothing about us without us," which is actually an old Polish aphorism from 400 years ago, and then it became "nothing about me without me." And the basic notion is that patients have more interest in what's going on than anyone else concerned. And if that's true, my own feeling over many years is that we should activate patients and ask them to really chip in and do that. So, as I listened to you talk about care coordination, as about care plan documentation, as about medications, I sit here thinking, these are tremendous opportunities for having patients at the table and really contributing.

We just published a paper in the Annals of Internal Medicine showing that patients who read their doctor's notes understand their medications far better and are much more lucky to adhere to their medical regimens, which is a big national problem, as I think you all know. 14% of patients say they're taking medicines differently as a result of reading the notes that their doctors write. Just as a little nugget of what can happen with this.

Standards are difficult. The new apps and the new APIs – all of this is very exciting. What's happening right now, though, is that patients have portals. More and more Americans have them. The portals are not very patient-friendly. They make it difficult to get their data back. They make it very difficult to read their notes. They give very little clue about that incredibly important area, price transparency, although they're just beginning. And I would urge you to think positively about the information patients can get and can give to you as you worry about blocking, as you worry about bringing all these amazing machines to life over time. The problem is that right now, people need to get more involved, need to communicate better with those who care for them, have to understand better what the care plan is, have to understand better what the pricing myths associated with that is. And that will move the nation forward much more quickly, I think, than getting down to the very fine-tuned, most recent API that will probably be outdated, then again in about a year from now.

Difficult issue. A difficult thing to have all of this swim together. But I would urge you to bring the patient's voice into everything you're considering. Thanks very much.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Thank you for your comments. I believe we have one more commenter in the queue. And if there are others after that, hopefully you are able to join us again for public comment around 2:00. But Operator, do we have any other comments in the queue?

Operator
Yes. Our next comment is from Jeffrey Gold with Gold Direct Care. Please proceed.

Jeffrey Gold
Hi. Thank you for having me on the line. I appreciate it. I'm a family physician on the North Shore of Boston. And I opened a direct private care practice four years ago, where I have eliminated all third parties from my practice and directly contract the patients for an affordable monthly fee that's about less than a typical cell phone. And what we're trying to do is really kind of focus on the fact that – sorry about that – the fact that we have, to echo some of the other sentiments, lost sight of the fact that medicine is about the patient physician relationship. And primary care is really the foundation of it. And we have completely eroded that and devalued it to the point where if you were able to watch the video that I put together, that was truncated down to 30 minutes from over an hour of me being on the phone three different times to get approval of payment for a shoulder MRI.

And I think that that's – we mentioned patients being involved. And I think what they need to see is full transparency of this is where their premium dollars are going to, is unnecessary checks and balances

that are getting in the way of us doing our job to take care of people. Technology and data, it's all great. But we've focused on building a mansion while the foundation of our system is eroding. And I think the value that primary care is put on is about 7% of the overall spend. So you have a foundation infested by termites while we're focusing on APIs and technology, which should not replace the relationship but enhance the relationship. And I think our focus has to be on how do we allow government to be government and do their job, which I know is not an easy one; insurers to actually be insurance.

As I think his name was Seth mentioned, we have created a public that is addicted to using health insurance to pay for everything. Insurance should not be a form of payment, but should be insurance. When we talk about a free market, we're talking about everything that is done before you put foot in that hospital door, there should be clear price and cost transparency. Price and cost are two different things. I have a statement from a patient who had labs done that's on Medicare. A Vitamin B12 level was billed at $112.00, which was paid at $100.00 or $112.00 by our taxpayer-funded Medicare. We get the test for $12.00. So, who is better at negotiating? Is it an informed consumer and physician, or is it third parties? I think technology, again, is great. I think it's important. It allowed me to do the video that I did and edit it down so that people could watch it without being bored out of their mind. But this is a day-to-day occurrence in a typical insurance-based family medicine office, where there's 20 people of staff trying to do this that aren't clinically trained solely to jump through hoops to take care of patients.

So, I'm glad I'm out of the system. I'm happy to work with insurers and with government. I just don't want to work for them. I think there's a role for everybody involved. But my hope is that we can actually create a fully transparent about price and cost in where these premium dollars are going. We have more and more patients here in Massachusetts, which the media loves to tout how everybody's covered and insured up here. Well, I'm working with an organization now that has found $9 million worth of medical debt in Massachusetts. So, it's all great to spin a story about coverage, but when you have hard-working people that are paying $600.00 a month or more to carry a $3,000.00, $6,000.00 deductible insurance plan, we're their savior, because we tell them what things will cost and help them navigate this completely unnecessary labyrinth that's been created.

So again, I'm all for transparency. I'm all for technology. But to echo the other people's sentiments, I think we really need to start focusing on what patients and physicians need, not what everybody else needs. We're the core of the system. Without us, there is no system. Primary care is a dying field, and we're trying to create a model that is more attractive to medical students and residents to actually pick up the weight that this fractured system has created, being so specialty-driven. But I hope that we understand that coverage and care are two totally separate things, and without the care, coverage doesn't even matter. So, thank you for your time, and hope you enjoy my video if you get to see it. Thank you.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Thank you again for participating and providing your comment. At this point, I'll turn it over to Robert and **[inaudible] [02:22:45]** for lunch.

Robert Wah - Individual - Chair
Thank you. Thank you to the public for your participation in our deliberations here. As I said before, I thought it's important that we maintain our commitment to the public when we publicize a time that we allow them to comment. They took us up on it today more than usual, but that's great. I'd like to – if we can, I'd like to finish the conversation on the ISP Task force. And as I said, what I'd like to do is frame shift our lunch. I don't think it'll be a big shift. But let's finish that conversation, because we were far along with it. And then once we finish that up, depending on where we are, my plan is to frame shift the lunch to be a full hour. It'll just depend on where we end as what time we start. So, Ken and Steven, if we could have you back, I think we just have a couple more comments here.

But I hope you recognize that this is an open committee. I'm really encouraged by the fact that the public is watching us and wanting to participate. So I think this is an important thing that we have as part of our deliberations here. So with that, I'll turn it back over to Ken and Steven.

Steven Lane - Sutter Health - Member
Sure. I wanted to make a couple of comments about what we were hearing just before public comments. Really great input on the different interpretations of free standards availability. Again, our task force doesn't have a lot of time to deliberate on some of these issues. But what we'll try to do is reflect in our report that we bring back to all of you that this is a key question that needs to be addressed. I think we discussed at some length real-time results release. I really appreciated Arien's comments that in the prior HIT standards and committees, that this was a point of contention. I get the sense that history is marching along, and a number of the public comments in fact touched on the importance of real-time results release. And I think we will try to reflect that in our final recommendation.

And there were some mentions, Cynthia in particular, about price transparency. We are going to be sure to capture in our report really what we see as the work that we've identified that still should ideally be done, including these areas here. So, I think we wanted to capture the last recommendations from this group, especially if you have anything to say about how we're approaching bringing this to you, because again, we're going to be bringing back a final report that we'll look for your approval for, as well as the prioritization question that I raised earlier. So, Sheryl?

Sheryl Turney - Anthem Blue Cross Blue Shield - Member
Thank you, Steven. I did want to bring it back also to the standard-making organizations. And I do think we should include a component of our report that speaks to that, and also maybe the state of the current landscape. Not that we're going to do a landscape variation, but that we have one extreme where we have organizations that charge for the standards and others that do not, but the sustainability is an issue. And really speak to that, and really talk about maybe what we might put forward as a business model for those organizations that allow the free standards to basically continue to live, because those are really important to us, and they need to have a life if that's the way we want to move forward. Especially as we want these standards to be adapted. And the more hurdles you put in place, the more difficult it is going to be. And so, we've already seen that through history.

I also wanted to make a comment about one of the comments an the results release, where the gentleman spoke about open notes. I mean, I can tell you from a personal use case, which I brought a family member who has a very rare bone disease, but the use of those open notes has proved to be so significant in the care of a patient that really is taken care of by multiple health care systems, completely diverse, Connecticut and California, and wherever your organization is, which I keep forgetting. **[Inaudible] [02:27:11]** Yeah. Because at the end of the day, when you have a patient that requires that kind of coordination constantly, my family member is saying, hey, there's something in the open notes. My doctor didn't get the results who ordered the test. They sent them to the wrong place. Calls the doctor, emails the doctor. I mean, we've in our family actually been so lucky to have physicians that have been willing to share emails, telephone numbers, and be able to coordinate the kind of care where most people don't have access to that. And I have been an advocate that has literally lobbied national institutes of health, congressmen – literally 40 years of effort to exchange data to further learning about health, encouraging people to get involved in research. This is too important for us to put aside.

Now, everyone was nervous giving the person the information. What are they going to do with it? If you expect much, much can be gained. And the amount of responsibility that my daughter has taken for her own health amazes even me, the level of understanding that she has gained by having access to the information, asking questions, really trying to understand. It is really important. So, I want to put that out there that I think that's something that definitely needs to be talked about. And we should be less afraid of how the physician responds to the data being available and empower the patient, because the patients can gain their life. And that's what we're talking about.

Steven Lane - Sutter Health - Member
Thank you, Sheryl. Emotion is good. Okay. **[Inaudible] [02:29:07]**, Robert. Oh.

Robert Wah - Individual - Chair
Well, I'm going to step out of my chair role for just a moment and put on another hat that I haven't worn for a while, and that's the AMA. There's been a number of comments about CPT coding and the AMA's charging for those. And I just feel obligated to say a couple of words about that to remind everybody that the AMA got involved in CPT coding because we felt that this is a process that was important for physicians to be in the leadership role of as opposed to abdicating it to a government or a private sector entity to run it. So it is an open process convening our 300 or 400 people every three months to figure out, how do we describe the work that physicians do? It is not an inexpensive process to do that.

There is a – as we've already talked about the cost and price here, there is a cost to create those codes. I think, Arien, what you're talking about is making availability, not necessarily that somebody would just make it free – that somebody has to pay for that. And whether, like LOINC and SnowMed, the government chooses to pay for those to make them available for everybody else. But there is a cost to doing these things. As already recognized by HL7 people, none of this is done for free. Bringing together 300, 400 people three times or four times a year, doing the editing, all of that process does not happen without some cost incurred. And the question, I think, is really who pays that cost? How do we best equitably do that in a way that makes maximum availability? And but I just want to make sure

we put that frame on there. It's not a matter of the AMA's out there somehow doing something different than anybody else. They're trying to cover their cost for what they're doing. And I just wanted to say that and make sure that we're balancing the discussion here. Like I said, it's been a while since I've worn my AMA hat, but I had to just speak up about that. And so, I wanted to just put that out there, so.

Steven Lane - Sutter Health - Member
Yeah, Robert, thank you. Thank you very much. And I hope none of the comments have been construed as vilifying one or another standards organization for their business model. To me, and what I will bring back to our task force and consider, including in our recommendations, is we need a standard for how we manage the standards – that this diversity of business models and approaches I think is frustrating. And we've identified some key issues. So, I think your points are well-taken.

Robert Wah - Individual - Chair
Yeah. The other thing that I was reminded of is having now been in the private sector and the public sector in my career, there's a constant tension between the role of what's the role of government in all this? What's the role of private sector, right? So, there are people that believe should have a larger role, and then other people believe the private sector should have a role. And I think that tension's actually healthy – that we try to find the right balance between whether government funds it all and then prescribes it or requires it. We talked about the levers the government has to influence this process. How do we best maximize those levers without becoming too intrusive? Others would argue that the private sector, the marketplace can find the right answer because it's competitive and all of that business. So, I think striking that right balance is always a challenge. But I think there is benefit in trying to strike that balance between the role of government and the role of the marketplace in finding a solution to this. I'll just put that out there as well.

Ken Kawamoto - University of Utah Health - Member
Great. Well, we realize we're quite into the lunch hour, so I think we will end. One request we would have, the draft report you did see, if you really could just download that Word document and comment. We have two more sessions of the ISP Task force where we'll be reviewing comments. It would be great if you could provide comments, for example, on the flight home, and just skim through it. It's in bullet format, so it should be easier to read. It's not all paragraphs. And we would really appreciate it. Carolyn.

Carolyn Petersen - Individual - Chair
Can you give us a hard date for that? It will help people respond if you give us a date.

Ken Kawamoto - University of Utah Health - Member
I think it would be most helpful if we could get it probably in the next two weeks.

Robert Wah - Individual - Chair
By our next meeting. So, it's a 45-page Word document that's in your batches that you can get to that as well, right? So.

Steven Lane - Sutter Health - Member
And based on the comments today, we anticipate the final will be a little longer.

Robert Wah - Individual - Chair
All right. Well, thank you to Steven and Ken for your leadership and for your entire task force and all the great work you've done. And thank you for all of you for participating and contributing to this process. As I said, my plan is to frame shift the lunch. So, I've got 12:21. Let's be back here at 1:20 if we can for starting up our next – bringing back the meeting. And then we'll just move everything down from there. Thank you all. We'll see you back here at 1:20. Thank you.

All right, everyone. Welcome back. Welcome back, everyone. I understand lunch is going to be a little bit of a picnic operation as we go into the rest of the meeting. I appreciate everyone's indulgence. As I said, with this frame shift, we're off a little bit, but I think we'll be able to do okay. I recognize that jet fumes will start filling the room about 2:00, so I'm sure that'll also be a motivator for us to keep our comments brief but still substantial.

So, where we are right now is we have the USCDI draft recommendations that will be discussed. On your agenda, there was a vote listed for both these and prior ISP. There is no real voting that we'll be doing, just to clarify that in case anybody's worried about that. Again, as keeper of the flame for public comment, we have a public comment period scheduled at 2:00 p.m., and we will suspend our discussion at that point to allow that commentary and resume our discussion. And I still think we'll finish up pretty close to our 2:30 scheduled time. So, with that as our expectation and our roadmap, I'd invite Terry and Christina to join us at the center table to start the discussion on the USCDI recommendations. Sorry, Christina, but you can't take your salad with you. **[Inaudible] [02:36:08]** And we can bring the slides up for that. If you're still getting your food and boxes, please proceed. So, with no further ado, Terry and Christina, take it away.

Terrence O'Malley - Massachusetts General Hospital - Member
Okay. Thank you all. We're delighted to be able to present. What we're going to do today – this is the USCDI Task force – we're going to give you an introduction and a preview of what we're planning to finalize in our report, which will be out in October at our next virtual meeting. We have two more meetings of the task force between now and then where we'll finalize everything. So, what we really need from the HITAC is some comments about whether there are omissions, whether there are things that we ought to correct, and certainly would appreciate your comments on the further issues for consideration, which are at the end. But just a preview of what those are, one is sort of prioritization of data elements. How are going to do that, or are we going to do that? So again, if you could think about that as we're going through.

And another sort of related issue is harmonization of data elements. How do we – what do we do with data elements that are similar but not quite exact? And so, what's the process going to be for cleaning that up upstream rather than trying to clean it up downstream? And then finally, thoughts about how USCDI needs to handle bulk data. So if we say all lab work has to be mapped to X, Y, Z standards, how does that ever get done, or does it get done, or should it get done? So, those would be some things that we'd appreciate your thoughts on. So, our agenda is basically to go through the charge, get to the

goals, and give you a summary of what we've done. And then we'll give you a detailed description of the promotion model. How was the data element get into USCDI? How is it introduced? How does it mature? When does it finally make it into USCDI, and what are the steps along the way? So, can we have the next slide, please?

And our charge through all this was basically to provide feedback to the ONC model, promotion model, and then to particularly make comments about the details of the promotion model and the life cycle, how data elements are introduced or submitted, sort of what's the process for doing that, and then the exact promotion criteria. And we were then given supplemental charges so we could add additional details as we wish. And our informal chart was to add those details to try to flesh out the really nice outline that ONC presented us with.

So, this is the task force membership, which is, from my vantage point, illegible, because – but it was a great group. Very engaged. Really appreciate everything, and really appreciate as well the ONC support, Elle Taylor, Adam Long, who really helped us move things along. So, it's much appreciated. The next slide, please.

So, our overarching goal. And this is really – I think Robert brought it up. It's really a balance between – we're trying to strike the balance between ease of entry, sort of the democratization of data elements being presented to USCDI. So, anyone can do it, but balance that with the real need for tight technical specification and maturity. The two are really at odds. And so, the question is, how do you get from one to the other? So, the process, we thought, had to be open, public, and transparent. And we really wanted to encourage as many stakeholders as possible to propose data elements into this process and really have no barriers, or very low barriers, to making – to proposing, right? So, if you can – I just had to make it easy to get in. Once the data element made it into the pipeline for USCDI, then there was a series of steps that are clearly – I mean, we tried to be very explicit about what the requirements were from going to one step to another.

And it was just a pathway for increasing specification and maturity of the data element. The ultimate price being getting into the USCDI, because it was ready for United States nationwide adoption as a required data element. So, a long path. And we wanted to make sure people – submitters understood what that process was and give them a roadmap on how to get there. So, we also added a user's guide. What do you need to know if you're a data submitter? What are you going to be called upon to do? What are your responsibilities of moving the data element through?

One of the big advantages of USCDI is because – and we'll go into the timeline. It's actually a fairly long timeline. It gives advance notice to industry about what's coming down the pike and hopefully allows industry to begin to pick winners. Because once you get into USCDI, once you get beyond the middle level, you're pretty much assured of getting into a certification at some point. And so, it gives industry some confidence that these data elements are likely to be something that'll be required, given a head start on working on. The next slide, please.

So, this is a summary of what we did. So, we've reviewed the promotion model. We added details. We added more details. And then we discussed some additional issues. And so, let me move this on. And

we're going to give you the first substantive slide. So, the next slide, please. So, this is courtesy of ONC. And I think you have seen this before. But let me take you through this slide. It's got a lot of information on it. But it's really a high-level view of the entire data promotion model. And it starts, if we look at the boxes, one level on top of another, there are really four levels – the comment level, level one, two, and then USCDI. And then across the top, there's a timeline. Cycle one, two, three, four. Cycles are each about a year long, to give you an idea of what the promotion model looks like. And then the process of the arrows. All right, so it's a series of sort of small arrows. They take you from comment to level one, level one from level two, level two to level three. A larger area from comment to level two.

But the important thing to note is there is no arrow from comment to USCDI, which means there's no data element that's going to be proposed as a comment. It gets immediately elevated to USCDI. The farthest it could go is level two, and it's again at least one cycle before it gets from level two to USCDI. That's important, because one of the concerns by the vendor industry was things would come down on us too quickly. So, I can assure you, it looks like this process is actually fairly long, and there will be some lead time. We'll get into some more details about it. But the important thing is that you can go from comment directly to level two, but not to USCDI. And you can go from comment to level one, and advance one level at a time. Okay? So, that's the big overview.

And the next is . . . So then we're going to do some detailed presentations. We're going to go detailed presentations on four things. One is sort of how do you move? What are the criteria for going from level to level? What's the role of the HITAC and of ONC in determining what data elements to get from level two to USCDI? And then the submission process and the submission form. And then finally out of that will come a user's guide, which we're going to come show you today.

Instead of my final slide, it's just sort of an overview of the process, all right? So, it starts in the upper left with a submission process that anyone can participate with. Has demonstrated value to the community. And then demonstrate increasingly technical qualities for the data element. And so that's sort of – there's the open to everyone piece. There's the how do we make it technically specified piece. And then there's sort of the review by HITAC and ONC, which is kind of the strategic piece. Where does this fit in the landscape of information needs for the country? And that will include public comment, I'm sure. And the last slide just says it's going to take at least a year to go from level two to USCDI. It's just the fastest any data element can go. And more likely, it's going to be several years.

So, Christina is going to go through sort of the details of the promotion process – how you get from one level to the next.

Christina Caraballo - Audacious Inquiry - Member
Great. Thanks, Terry. So, moving on to the next slide. When we were kind of going through our task force discussions, we started thinking about this concept of a user's guide. And so, the next couple of slides, we're going to go through kind of where we got – going through each of the items from the process, from comment to level one, level one to level two, level two to USCDI. And in this, we originally started to think about what are the details in each of the criteria to create a user's guide? And we think that is this column on the right, which are more comments and concerns for ONC to

consider as we move forward and as we look at each of the criteria. So, as it goes through each of these, these map to the questions that are in our submission form. But I wanted to take the time to kind of go through this chart.

So, the first three slides are where we're gathering the most information. It's the comment to level one. So, what are you submitting? So, when you're first coming in to submit, the first item is the actual justification for the data capture for nationwide exchange. This is to be used to kind of estimate, get a general sense of the impact. If this is missing, it doesn't affect the level. This is simply the comment. And this helps determine the potential impact.

The next few things that we're going to mention are just really just that significance of the data element. One thing we were trying to level set as we think through the information we try to capture is leveling the playing field from the really technical comments to ones that have a high need, but may have less technical details during the submission. So, I think that's where these first three items are really important.

So, the next one is the use cases that the data elements are used for. This just helps provide clarification on why we actually want to capture this data element, and is required to get into level one. The next item is capturing whether there are podcasts currently underway using this data element. Again, this is used to help gather clarification on how it's being used on the market. It is a requirement to get into level one. If it's missing, the data element stays in comment period. And again, that helps just to determine the impact.

So, moving on to the next slide. The next item is that the data element is currently captured electronically in one or more systems. This is really for us to gather information on just the feasibility of capture. It's required for level one. And in absence of this information, then the data element would stay in comment. One thing to note in kind of our comments and considerations for ONC is that any format is acceptable. The purpose of this item is to simply demonstrate that someone wants the data electronically, and they're starting to capture it.

The next item is collecting information regarding how the systems cited above capture the data element and in what format? Is this free text or is it coded? This gives us more clarification on the feasibility of electronic capture. It's a requirement for level one. In the absence of this feature, we're proposing it stays in comment. And this is really important to begin to capture these data elements that are being collected and in exactly what format they're being collected in.

Moving on to the next slide. This is the last slide capturing information on level one. The next item is a content standard exists for this data element. Now we're moving into more of the technical maturity and feasibility that exists around the data element for the next slides. Well, backing up, we were talking about kind of just the need to capture. And then we move on to kind of more the technical pieces in the last two slides. So, this next item is required for level one. In the absence, it stays in comment. I'm going to discuss the next one, which is, an implementation guide exists that actually contains the data element. So, any implementation guide has the presence of that data element somewhere in it.

These first two on this slide are kind of bundled together. They were originally the same in the USCDI draft that ONC put out. As a task force, we split them, because there were a lot of questions around what's the difference, what does that mean? These are two very different areas to capture information on the data requirement. But in our notes, we did want to note that in order to get into level one, you just need one of these – either a content standard that exists or the presence in an implementation guide.

The next item is that there have been pilots or Connectathons. A note that's come up a couple times in our task force is that Connectathon is a registered trademark, but we're just using that for the purposes of this discussion. And this is really again looking at the technical maturity. It's required to get into level one. In the absence, it stays in comment. And this is really the type of pilot that's just demonstrating that the SDOs have initiated some type of interest, even if it's in the really early stages. They've started to look at it within any of the SDOs.

Moving on to the next slide. We have one item that really gets us from level one to level two, and that is the exchange of the data element has been successfully tested in two or more distinct EHR systems in a production environment. There was a lot of discussion around this about what exactly this means. Is this unrelated? Are they different platforms? Are they distinct EHR systems? We really wanted more clarification, and I think this is an area that would be really great for our committee to discuss in more detail. What does this two systems mean and how is it this scaled?

So, moving on to the next slide. We have one item – and no, that's good – to get from level two to USCDI. And this is the exchange of data has been successfully tested at scale before four or more different or distinct platforms and in production environments. And this is again required for USCDI. And in the absence of this requirement, the data element would stay in level two. We recommended that this item is both about how much the data element has been adopted and scaled, as well as the technical readiness. So, in our last task force discussion, one of the things that came up was, is this really about the largest vendors being able – the data element has been shared at scale? Or is this really just about distinct systems testing, even if it hasn't been necessarily scaled. It's still within the specialties, but the testing exists. And that's something that we haven't quite determined yet on this requirement. But again, is the data element ready from a technical perspective, or has it been massively adopted by major EHRs? And that still kind of – we're in deliberation on that item in our task force discussions.

So, moving on. The next two slides are about the role of the HITAC and ONC in evaluating what's come through in the submission form, what the communities of interest that Terry had mentioned earlier have kind of started to contribute on the data elements. So, the next item is the evidence exists for the importance of the data element on health care costs for individuals or populations. This is really to look at the significance and strategic value. And it's really a chance for a presenter to put the best argument forward to demonstrate impact. So, we had a lot of discussions on that balance between high cost, high burden, and high impact. This is where this item comes in.

The next one is that there is an estimate of the number of providers who would use this data class or data element. And this is a little subjective, where the submitter kind of puts a best case forward for evaluation by the HITAC and also ONC for review.

Moving on to the next slide. The following three items are the last three in kind of our submission form, where we're trying to collect information on the data element and continue to build on these areas to collect more information as the data element continues to progress. So, it's the following restrictions potentially limit the standardization of the data element. This helps us determine what barriers there are to deployment and what might impede advancement. The next item is the following restrictions potentially limit the use of this data element, filling in what those may be, better understanding the gaps. And the next is that there is an estimate of the overall burden to implement. So, this gives the chance for the submitter to provide estimates from a variety of viewpoints, such as the patient, the provider, the vendors, societies, and other stakeholders give consideration. It's really important to also incorporate public comment.

So, I'm going to kind of give a recap of these two in the next slides on kind of how we view the role of the HITAC and ONC. But as we were going through these items, evaluating the submission or the information that's being collected, these are the ones that we saw as falling under HITAC and ONC. So, the next slide is what we've kind of thought through as a task force on what the HITAC's role is. Part of the draft to USCDI is actually for the HITAC to play a role in the review of the elements that are coming into the USCDI. So, we were trying to more clearly assign that.

So, the first item is that the HITAC will recommend for or against the promotion based on a data element achieving technical maturity and weighing that balance between its real value to meet the quadruple aim versus the cost to deploy and burden to develop. For the review process, we have that the HITAC will review evidence of technical maturity. So, all of that information that was collected through the submission process, bringing in industry stakeholders and advocates. Review the evidence for impact on data to health care costs. Review the potential amount of stakeholders, including groups such as providers, patients, researchers, public health, etc. Really start to assess the significance of restrictions that might potentially limit these to the data element, and assess the overall burden to implement.

One of the things that we've discussed in the importance of the role of the HITAC is that really goes back to being able to have an open forum for taking into considering public comments, experts from the industry. This is a public place where we can continue to remain very open and transparent about the evaluation of the different data elements and data classes. So, I think that this is a really good place for this role to live under the HITAC for that kind of practice.

So, moving on to the next slide. It's kind of an overview of how we view ONC's role. ONC will review HITAC recommendations; duplicate any of the process we just went through as needed; take the time to openly review public comments; and make the ultimate final determination on advancement based on overall burden versus overall benefit. And then take the next step and look at how this is mapped to the requirements for certification and maintenance, as well as the actual timelines.

So, moving to the next slide. Am I review this or are you? Perfect.

Terrence O'Malley - Massachusetts General Hospital - Member
I'll take that one. So, how about if we pause here and just talk about the promotion process itself and any additional questions or concerns or comments. And then we'll go on to the submission process, the submission form, and then get to the further issues for discussion. Please. So, Arien.

Arien Malec - Change Healthcare - Member
Thank you. So, two general questions, at least to the feedback. One is, I was struck by the use of the term EHR in terms of the requirements for USCDI to have sharing between two and then four EHRs. Is there no role for patient applications, other digital platforms, other non-EHR systems for sending and receiving data? Or is the intent to be purely EHR-centric? So, maybe just as a question. Was that intentional, or was that an oversight in terms of how it was documented?

Christina Caraballo - Audacious Inquiry - Member
I would say an oversight in how it's documented.

Arien Malec - Change Healthcare - Member
So, the intent would be four different systems exchanging data, but not limited to EHRs. Thank you for that. And then when we design – so, I'm a big proponent of maturity models in these areas and requirements that you have multiple systems testing. This harkens back to some of the work that the Indian Workgroup did as part of the Standards Committee that got published as the famous Dixie-Baker model. One of the things we always struggled with in that area is when you have a regulatory driver for USCDI, where do you get the room to do the piloting and on the ground work that is required to advance through the process? And have we built a system where nobody wants to do the upfront work? It's not required, and so nobody's ever produced the evidence that's required for going through to submission. And again, this is all in the context of thinking this is exactly the right way to go about this. So, maybe just a question on business models or incentives for doing piloting and advancement. Thank you.

Robert Wah - Individual - Chair
So, I hate to interrupt, but as I said before, we have published our public comment time at 2:00 p.m. And so, if we can just suspend the discussion for a minute or two here while we open up the lines for public comment. And then we'll resume this conversation. So, please keep your tent cards up. And unless we have people in person, we'll let you guys stay there at the microphones. And I'll turn it over to Lauren to run the public comment period.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Yes. So, we'll start in the room again. Is there any public comment in the room? Seeing none. And then Operator, can we please open the public line?

Operator
If you would like to make a public comment, please press *1 on your telephone keypad. A confirmation

tone will indicate your line is in the queue. You may press *2 if you would like to remove your comment from the queue. And for participants using speaker equipment, it may be necessary to pick up your handset before pressing the * key. Our first comment is from Paul Epner with SIDM. Please proceed.

Paul Epner

Greetings. My name is Paul Epner, and I'm the CEO and cofounder of the Society to Improve Diagnosis in Medicine. With me on the line are my SIDM colleagues, Tom Lee, a former serial entrepreneur in the HIT payment space, as well as a sitting board member; and Leslie Tucker, a longtime DC policy professional, and now SIDM senior policy advisor. We can all be reached for further comments and collaboration if there is an opportunity.

Let me briefly introduce diagnostic error and SIDM. And first, maybe applaud the HITAC for its careful deliberation and commitment to the public comment process. HITAC and its task forces can play a crucial role in reducing patient harm and avoidable cost from diagnostic error. And the opportunities to achieve positive outcomes are supported by the multiple ways you seek inputs, including the public comment period.

Diagnostic error is the failure to provide an accurate and timely explanation for a patient's problem. Our goal is to eliminate harm from it. But in the meantime, the problem impacts nearly 12 million US adults per year in outpatient settings alone. It kills more than 80,000 per year in hospitals alone. And it costs the US system over $100 billion annually. Very recent published research shows it to be the most common, most catastrophic, and most costly of all medical errors. We have been gratified by the impact we have had in just a few years, including the creation of a coalition, with over 50 members and government agency liaisons, the launching of an awareness campaign, and just last week, the receipt of an award that will allow us to award at least 20 QIC grants every year for the next three years. HIT will have a comment role in our work and will be one of the focal areas of our upcoming conference in DC in November, where Dr. Drucker will be our plenary speaker.

My brief comments about the work of HITAC. SIDM's interest in HIT policy focus on the important role in reducing cognitive burden for physicians and ensuring robust processes for in care delivery. We believe in the need for improved measures, including mechanisms for providing feedback to physicians and engaging patients as a member of the health care team, as they have critical data needed to support the diagnostic process. We are currently involved with closing the loop efforts on referrals and our laboratory tests, as data suggests that failures in these processes are important contributors to diagnostic error. We welcome opportunities to learn from you and to share our learnings specific to diagnosis. We believe clinical decision support and artificial intelligence will be important to improve care, but believe that many AI opportunities will be constrained by missing information from the practice sets – for example, symptoms and their characterization, differentials, uncertainty, and social determinants.

We hope that your work on defining the core dataset will consider the process a clinician uses in reaching the diagnosis and consider whether data elements that support that process are missing. We

look forward to opportunities to learn from your deliberations and to contribute to them. Thank you very much.

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

Thank you, Paul, and your colleagues as well. Operator, do we have any other comments in the queue?

Operator

There are no more comments at this time.

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

Thank you. We will hand it back to Terry and Christina.

Terrence O'Malley - Massachusetts General Hospital - Member

Okay. So, we'll pick up and go through the – well, actually, let's continue our questions or comments. I can't remember which side of the room we wanted to start with.

Christina Caraballo - Audacious Inquiry - Member

Andy had his up.

Andrew Truscott - Accenture - Member

Yeah, thanks. These times seem very long. And the pace of change in our community is getting quicker. When I look at the work that's going on around HL7 Fire and the demand for resources to be written and executed, etc., for us to turn around say, well, the shortest time we can get a new idea through USCDI is three years? People will just – nature abhors a vacuum. And stuff will go off and happen. What can we do and what help do you guys need from the broader committee to actually help accelerate that?

Terrence O'Malley - Massachusetts General Hospital - Member

Andy, thank you. That is an issue that has come up often in our task force, and it's really the tension between the need for the data element and the need for the data element to be usable. And it's hard – and so how do we reconcile that? That, we don't have an answer to. And I think that's going to be one of the tensions that exists.

Andrew Truscott - Accenture - Member

Okay. So, what I heard is, we don't know.

Christina Caraballo - Audacious Inquiry - Member

Well, I think you bring up a really good question. You said, how can the standards development organizations like HL7 help? I think we are trying to really think through that with this process. What's that balance between too much testing too fast, and how can we create a process that groups like HL7 can pick up some of the high priority data elements? We've identified them in the ISP Task force. Maybe how do those all live together? I think that's kind of what we're trying to create in this. We

need these data elements in USCDI to be ready, really ready. So, as I think through what is the USCDI, I've struggled with this even myself, because we want all the information. But it's almost like – think of it as – is it the perfect data that kind of tasks everything, and it's really, really ready for prime time? And how do we get it ready? So –

Andrew Truscott - Accenture - Member
There's absolutely balance in there. You're right. There's absolutely balance. We actually have something which is defensible, which is legitimate, and which is actually going to be beneficial and has been appropriately tested, etc. If you keep polishing something, eventually it vanishes and becomes useless. It sounds to me, if I read between the lines – maybe this wasn't intentional. And if I just peel back what you're saying, actually a greater level of resourcing, probably from ONC, of dedicated people doing this work is kind of necessary to cut down these timelines to something which is legitimate and reasonable for our industry to actually use. Otherwise, all that's going to happen is things move on, and this will be left behind. And if I think about the way that health IT standards have moved over the last 20 years, then roundabout every 10 years, there's a new kid on the block. And we're saying here, well actually, for a new idea to come to USCDI, the longest possible is six years. Well, we could be about to retire by the time it comes to market.

Terrence O'Malley - Massachusetts General Hospital - Member
So noted. Thank you. We will bring that up to the task force. Thank you. And no, it's a difficult issue. And we are struggling with it. And I wish we had an answer and could propose it to the HITAC. But that's why we're here. We want to see what you all have to say. So, thank you very much. John? Just to run this by the table, then we'll swing back to the other side.

John Kansky - Indiana Health Information Exchange - Member
Yeah, I cut in front of a whole bunch of people, but I'm going to do that because it's really directly related to Andy's comments, which is that I was reading the TEFCA task force recommendations that were in the notes for the meeting. And this is really for ONC more than anyone, because I don't have an answer either. But I mean, Andy can't complain to his wife that it takes nine months to have a baby, right?

Andrew Truscott - Accenture - Member
Well, I can. **[Inaudible] [03:15:16]**

John Kansky - Indiana Health Information Exchange - Member
But I just noted in our comments that one of the things that we said is that a compromise in a debate that happened on that task force was that people wanted data beyond USCDI to be required for certain exchange. And we said, okay, I'll tell you what. Here's the compromise. We're going to say, just exchange USCDI. What we're going to recommend is that elements be added to USCDI very assertively, aggressively, quickly. So, now we arrive at this date. And I went, huh, that's an interesting conundrum and a balance. And there you have it.

Terrence O'Malley - Massachusetts General Hospital - Member
Yeah. It's sort of the combination of what's the rate limiting step in this process? It's not the

identification of data elements that are required for improving health care. I mean, that's sort of the faucet. The rate limiting step is sort of how does the data element really reach technical maturity? There's just a lot of work around that standards and testing. And then finally, before it makes it into the USCDI and part of certification, then there's a step of, well, here it is, industry. Now make it happen. And so, there's just some sort of irreducible parts of the nine-month, three-year process that are just going to be hard to square.

But just a potential benefit – and this is where I think having a really open and clear – and I think that lets industry know what's in the pipeline. And being able to see elements that get into the level one, those have actually crossed some fairly high bars already. And their likelihood of making it into certification are probably reasonably good. In a sense, that gives you a two-year head start. It may have only been in the process a year, and you've got two more years to go. But industry knows, and that's – so of course, they might be able to bet on. And I think that's part of having this as a transparent process. Who do we have? Arien. I think you were up like an hour ago.

Arien Malec - Change Healthcare - Member
That's okay. So first of all, great job. I think you've taken a lot of hard work and tried to synthesize it down and throw something out there to see what the reaction would be. So, I appreciate that. I think back to the prior committee before HITAC with the policy committee, and I've said this before, where we had the FDA, who said that we couldn't track Zika effectively because pregnancy test wasn't a mandated field at the time. And that terrified me. How did we let standards get away from us so much that now we have an epidemic going on across the country with Zika, and we can't use the data in front of us effectively for care? And so, I completely echo the need to accelerate in some form or fashion the adoption of the standards. I would propose there's got to be research vehicles or partnership vehicles between industry, and whether it's academic medical centers like myself and others that can try to test out various things, and say, okay, market, this actually works. We've done this in a research, contained with a 100-cohort patient body, whatever that may be, in partnership with the major vendors that are out there.

I think if you did this in a way that there was a fast track program, folks would be willing to do it, and it would help gain adoption, because now you have – I'm making this up – 30 leading AMCs or whatever doing this in partnership with the major vendors, so we're not doing something out of cadence, out of sequence. Because there is R&D time. There is development time. We have to be respectful of that. But do you also have the test standards? I mean, we can't let one go in front of the other and end up like what we had with Zika.

Terrence O'Malley - Massachusetts General Hospital - Member
Thank you. Yeah. And Sasha.

Sasha TerMaat - Epic - Member
Thanks. One of the things I noticed as I was reviewing our materials for this meeting is that the task force, I think, assumed consistently that one of the most important parts of this process would be public input. And but yet a lot of the process steps that we described were about the submitter or about ONC, or about the HITAC. And I realized there wasn't a great sense of clarity for me in looking at

our materials and how the public input would actually happen – if it would have a schedule, what types of the fields that a submitter submitted would also be sort of able for someone else to chime in and say, oh, I have a different estimate of this pilot, or the number of users, or the benefit, and how well that would work together. And so, I was thinking that that might be something that would be helpful for us to elaborate on as we finish so that it would be – the role of the sort of additional public input could be also clear. It might also help with some of the challenges of prioritization and acceleration that are being discussed, if there's a clear sense of how all the different stakeholders would weigh in.

Terrence O'Malley - Massachusetts General Hospital - Member
That's a great comment. And I think it's an important one, and one we didn't really elaborate on. It may be in the submission process. It may not be. But it's the hope that by having an open, transparent public forum for submitting ideas on what data elements should go forward, it then allows the public to coalesce around those data elements and communities of interest, and to add whatever else they know. So, the submitter might know a certain amount, but somebody else may know that's already been in testing somewhere else, which bumps it up a level or comes close. So, I think the tricky part is going to be how does ONC create a public platform that facilitates that sort of input? And so, we're going to let ONC figure that one out. So, Ken?

Ken Kawamoto - University of Utah Health - Member
Three comments. With regard to which system should have done the interoperability to promote, I think it probably is appropriate to make it EHRs, because they are the group that's covered under certification and having to do this in terms of fiat or requirement. So, whoever's going to be bound by those rules, I think it's appropriate that those be the folks who have tried it. I think with regard to the notion of it's too slow versus it's too fast, I totally agree with we don't want to regulate in something that's premature, and we don't want to rush it. At the same time, I think there are ways that, as has been suggested to accelerate it, I think my primary comment on this process in the task force has been that even if we set criteria on what makes things move forward, we don't really talk so much about how is, say, ONC or the government going to help move things that are kind of left orphaned moving forward. And I think this relates to the fact that, I mean, even if something makes good sense, in general from an individual player perspective, it's much less costly for you to just wait for other people to solve the problem and then freeload on it later. So, even with this notion of, hey, academic medical centers may be willing to test this, and some EHR vendors may be willing to test it, honestly, if you take examples like daVinci for example, right? Your best scenario is someone else works on it, gets it working, and then you adopt it after it's been all worked out. And that's where things like funding to do pilots can make a difference, where you say, you know what? I can't justify it institutionally why we should be the ones to R&D it so everyone else can benefit from it two years down the line. But I can certainly – it's much easier to justify if it says, well, and the government is making available the amount of money that if not covers, at least helps cover the cost of participating in the pilot. So, I think that's an important role.

Terrence O'Malley - Massachusetts General Hospital - Member
Yeah. No, thank you for the comment. And yeah, there is a role there, because it's sort of the tension between the market and sort of a strategic oversight body like the government. How do things get

moved forward? So, that's another one of those tensions that we'll discuss more in our task force, I think. And Jonathan?

Jonathan Nebeker – Department of Veterans Affairs – Federal Representative
Yeah. I'm just glad Ken finally mentioned daVinci. So, I think this is the model, right, because we already have established patterns. I don't know how many people are taking advantage of them or of extensions to terminologies based on best practices for the terminology. Then you demonstrate, you implement in a way that makes sense for you, and you get more and more buy-in. But it's money that's going to drive this. The government – there's no way the government's going to keep some of these timelines to do a pure government push. And the government's got to – whoever's controlling the payment model's got to kind of make it work as well. But daVinci controls, to some extent, its own payment model. And so, it's like, yeah, this is how we want to do business. This is how we want to improve our bottom line. Health care systems likewise have an opportunity to implement these things.

And so, and there's other examples, like HSPC Logic, that has been a little less successful than daVinci, but has some productivity in this area for a certain amount of things as well. So, I think the model does exist. And the question is, how do we line up all the incentives between the government with industry and pilot projects to make that happen? And I don't know if this is the purview of the HITAC. In the reports, the layout, the line of sight to value. So, this is how we're going to realize the value, or what? Do we just come up with, here's the recommendations that someone needs to figure out stuff on? But maybe I can learn about what a committee needs to do.

Terrence O'Malley - Massachusetts General Hospital - Member
Thank you. And Arien, sorry.

Arien Malec - Change Healthcare - Member
No problem. I've got already a comment in, so this is just a second bite at the apple. Just a point that if there's a number of people who are requesting to be held for the purposes of information blocking only to USCDI. And if we hold industry, both HIT vendors and providers, only to USCDI, and then require a high bar to get new content into USCDI, we've unwittingly created an incentive for nobody to pilot test anything. So, let's just be – again, I'm highly supportive of testing before wide-scale deployment, but let's be really clear about the business models and incentive behaviors that we're designing into our public governance. Thanks.

Terrence O'Malley - Massachusetts General Hospital - Member
Thank you. Any other? And Jonathan, you're still up? You're done. Okay. Great. Okay. That was very helpful, and food for thought for the task force. So, we're going to move forward. So, the slide that was up, we'll go back again. Any comment on it? This is the timeline. And there are two, all right? So, there's the shortest timeline. If you come in qualified to be level two, you go straight to level two. You've already been tested in four systems. And you've got one more cycle before you get through the ONC and HITAC review. But that's the shortest. The longest is if you get stuck anywhere, it's really – the directions were kind of three strikes and you're out. We'll give you three cycles. And if you don't go anywhere in three cycles, we kind of request that you get resubmitted. You can do that as many times

as you want. But you might be there for several hundred years at three years at a time. But no one gets kicked out. You just kind of get put back in. So, that's the proposed timeline.

So, then we have the submission process. So, that's the next slide, please. So, in the submission process, they're really – again, this is just rehash – open. You can submit data elements or data classes. You're going to be making them. And again, ONC's going to have to create this open transparent public platform. It's probably going to look something like ISA, where you're going to be able to enter things. And then the submission process itself has to give ONC all of the information it needs to make appropriate leveling decisions. So, we tried to tie the submission process to the advancement criteria and help ONC figure out where the data element is in that advancement. And we also put some responsibilities on the submitter to – and again on ONC to create this platform that allows us to have the submitter actually look through the submitted at elements and see what's similar to their proposal. And if it's similar, they have to justify why it's not the same. But so, there's work the submitter has to do beyond just submitting things.

And then the submitter has to do all the updates. And when I say submitter, that means really the community of interest that's built up around that data element. So, anyone can submit updates as it's learned by that group. But it's again to inform ONC about proper leveling. So, that's sort of the overview of the submission process. Actually, before I go on, Andy, do you have a comment? Do you want to – **[inaudible] [03:29:34]**. Oh, I'm sorry. I am sorry. I missed your tag. My apologies.

Cynthia Fisher - WaterRev, LLC - Member
Terry, could we go back to your previous slide, please? So, I'm just looking at each cycle time being one year, and the shortest cycle time being a total of three years. Is that correct?

Terrence O'Malley - Massachusetts General Hospital - Member
Well, it depends on where – if you come in through comment and go level by level, yeah, it's a year per level.

Cynthia Fisher - WaterRev, LLC - Member
Okay. And then the longest cycles before requirement, are you proposing that we have an acceptable timeframe over the longest cycles before resubmission being up to six cycles, six years?

Terrence O'Malley - Massachusetts General Hospital - Member
Before you get resubmitted, you can stay in the queue up to that amount of time. But if you don't get out of comment or get out of your level, then yours needs to be resubmitted. Just a thought.

Cynthia Fisher - WaterRev, LLC - Member
I come from the world of business. I'm a former recovering CEO. I'm a CEO and an entrepreneur. So, I just look at these timeframes of business practices. And I remember in the early '80s, just looking at – I spent my career with IBM. So, when we looked at technology and its timeframe of revolutionary changes, five years was expected for a revolution of displacing products, services, and software and technologies that were existent today. So, you knew at the beginning of a "cycle" of a technology that it would be revolutionized and replaced within five years. That was in the early '80s. And I think that

we've seen throughout our lives in the decade since then that to play out to be true. So, my concern sitting here on this panel is that we could even look at technology and iterations of standards and processes to even look at these types of timeframes.

And to me, it just simply screams of kill by delay. And I just think it's upon our duty to deliver to the American public what they've paid with their hard-earned tax dollars to reconsider, as we look at these timeframes, they're acceptableness, and look at – there will be revolutionary technologies that have happened, will happen next year. And I think that we could sit here and put that slide up. It's almost an embarrassment. And I'm sorry to be so blunt, but I think we owe it to the American people to do better. And I just want to relay that. Thank you.

Terrence O'Malley - Massachusetts General Hospital - Member
Point taken, and agreed. We all agree, this is too slow. Again, with the comments that have been made before about where the choke points are in this process. If there's any silver lining to this terrible cloud, it's that we're talking about data elements and data classes, and we're fortunately technology agnostic. We don't really care how it gets moved. But what gets moved, we care about. So, we're focused in our little task force on the data elements themselves. And Fire version 12 may be here by the time we get through the first round. But then it will be able to move our very well-established data elements. And I think our challenge is going to be, so what are the alternatives? And can we promote alternative pathways that speed this up? And that's going to be a challenge. But agree 100%. I mean, I don't think anyone around the table will argue with you about that. And Andy.

Andrew Truscott - Accenture - Member
And I'll be brief, because we've all **[inaudible] [03:33:47]**. Look, beginning of next year, there's going to be a bunch of regulations pop out around information blocking, etc. And there's going to be some kind of timeline for compliance, I imagine. I imagine that this is what the process is going to be. And the **[inaudible]** going to start doing stuff. And if we say, well, the soonest you're going to get anything from USCDI to base that on is two years' time, a lot of stuff's going to have happened that people initially won't be very happy if we didn't say, ah, well, you didn't quite do it right. So, if you go to the next slide, your process that you have, okay, we have to be able to optimize this. We have to be able to create points of entry into the process where for data elements that have already been through scrutiny in a process which we could trust, we say, right, Banshee can come in much further down our process, potentially even at the very end. We just adopt them. Because otherwise, we're going to end up with so many different convoluted processes and checks and balances, that we don't actually make any progress and actually move the ball down the court. I just wanted to – and I guess, actually looking over at nodding heads around the room, there's quite a lot of agreement from the committee. I'll be interested whether we actually all think that way. Do we have to bring this down? And however we can help you, just ask.

Terrence O'Malley - Massachusetts General Hospital - Member
All right. Thank you, Andy. So, I think we have some work to do in thinking about alternative pathways. And currently, the only shortcut exists if you come directly into level two, and you're highly mature, technically sophisticated data elements or class. Then you get into level two, and you've got one more cycle. What we didn't tell you is this is – ONC needs to think this up with the standards advancement

process. So, it's basically half a year is spent advancing data elements, and the other half advancing standards. And it gives ONC a way of managing their work. So, they're going to sort of go alternatively. At least, that was the high-level plan, as far as I can tell. So noted. And Sheryl and Cynthia again?

Sheryl Turney - Anthem Blue Cross Blue Shield - Member
Thank you, Terry. While I'm listening, and I did participate on this group, so I probably should have brought this up earlier. But one of the things I was thinking is kind of flipping the whole script and basically saying that rather than focus on a process, we focus on what the requirements or guardrails need to be for each type of data class. And once we identify that and say these are the requirements that each data element that's brought forward has to prove – whoever's bringing it forward – then once you achieve that, the timeline really only becomes once the standards are proved, how long does it take to get adopted? But any group, like an iOS system or an Android, you have to go forward and say, this is my app. This is the data. This is the exchange. You prove all these things, and then there's a two-week process, or 30 days, or maybe 60 days, because you screwed up and you have to resubmit it.

But the timeline isn't the issue. The issue is you have to achieve all these things. And I think maybe we need to focus on what are all those things for each data class, and then really focus on that. And then whoever's bringing it forward, the time is whatever time it takes them to get through those things. Because that's what important, is that the data element can stand on its own because it's needed for this type of data share, whether – and if that's important to the environment that it's in, then they're going to prove that they can share that across an EMR or whatever it is that's required in order to apply it as a standard. To me, we should be less about that and more about what are the standards and guardrails for each data class? And once it achieves those, then it can be brought into the standard and applied. And how long it takes to get adopted becomes the timeline, not process.

Christina Caraballo - Audacious Inquiry - Member
So, just making sure I heard part of that correctly. You're proposing to have basically the checklist of the criteria, but do away with the actual cycle time? **[Inaudible] [03:38:33]**

Terrence O'Malley - Massachusetts General Hospital - Member
A question back to you. So, are you recommending that we become much more granular in our building that checklist?

Sheryl Turney - Anthem Blue Cross Blue Shield - Member
Right. So, the checklist should be more granular for what needs to be **[inaudible]** for the data class that would make it **[inaudible]** for the options, but focus on those requirements and not the process.

Terrence O'Malley - Massachusetts General Hospital - Member
But so, the process would become checking off requirements for the data element advancement, rather than some arbitrary leveling thing. So, once you checked your way up through level two, and you're about to make the leap to USCDI, and then a different set of criteria come into play at that point. That's sort of the strategic oversight. But you're saying the technical maturity can be done after different – and independent of leveling. Got it. Thank you. And Cynthia?

Cynthia Fisher - WaterRev, LLC - Member
I just wanted to tell Sheryl that I thought she made a brilliant comment. So, thank you, Sheryl, for your insights. And I think it's revolutionary thinking to deliver the checklist on the goals and objectives of what is required and necessary. And brilliant. So, thank you very much for that contribution. And I think what her idea does is it allows for a substantial open door for rapid innovation, which – and opportunities to empower innovators to further engage in this space. I think it's revolutionary. So, thank you.

Terrence O'Malley - Massachusetts General Hospital - Member
And no, thank you again for both of you. And maybe one of the things we might want to look at – and I'm not sure if this is legal or not – but is to look at decoupling USCDI from certification in the sense that the real choke point in getting standardized data is that once it makes it into USCDI, then it becomes, when next cited, the requirement for certification. And that's a big bar and somewhat concerning, because then that has industry having to do a lot of things. So, maybe we should also think about how we can decouple those two things – create a dataset that's actually highly usable can can become the standard, and couple it to certification later, but separates the two processes. Anyway, as a task force, we've got two more meetings. I think we've got some work to do. Thank you. Andy.

Andrew Truscott - Accenture - Member
Okay. Well, whilst I appreciate the attraction of decoupling, history has shown us that by decoupling too many independent parts means we don't actually proceed as a progressive one. I'd much rather try and fix things, etc., so the process can actually allow things to operate independently of each other.

Terrence O'Malley - Massachusetts General Hospital - Member
Okay. Fix and not decouple. Okay. Got it. All right. And Robert, how are we on a time check? Are we . . .

Robert Wah - Individual - Chair
Well, we're clearly beyond the time that is allotted for this, but I think this is an important discussion, and I never want to limit an important discussion. Why don't you go through your submission process slides, and then we'll wrap up.

Terrence O'Malley - Massachusetts General Hospital - Member
Okay, actually I'll zip through the submission process slides because they are the same as the advancement process, except written for the submitter. So, go please advance to the next slide. So, it's again, the submission process divided into five pieces. Tell us who you are and what the data element is. Tell us why you want to do it. Next, tell us how technically advanced is it. And then tell us what the benefits are of submitting this data element – what's the benefit to the country? And finally, what are the burdens and barriers. And that's really what the submission form covers. And then the next four or five slides are just the details of that. So, you're free to read that as you go continue to the last – yeah, leveling and promotion. One more. One more.

Okay. So, issues for further consideration. So, this, I would also appreciate people's thoughts on. If we don't get to having a lot of comments on this, that's fine. But it's really some of the larger issues. And so, raising the issue of prioritization of data elements. So, we've got sort of a market-driven process.

Submitters are going to come in because they value the data element in sort of the market. And the market's going to advance this, because communities are going to form around what they find is valuable and will move it forward. So, the question is whether that's a sufficient process to assure that we get the data elements that are needed to meet the quadruple aim. It may. And this is all hypothetical. But is there – do we need a process that also says, how do we make sure that the data elements that we recognize are really needed are advancing? Sort of a combination. One, are they in the queue, and B, if they're in the queue and not advancing, why not? And should we advance them? So, that's one question, all right? Prioritization. Do we need it? Do we need a way of moving data elements forward? Cynthia.

Cynthia Fisher - WaterRev, LLC - Member
I'll be quick with this one, but I've never seen it in our materials, and I don't know if I've missed it. So, excuse for the granular question. But the millennial generation and the Gen Z, or Gen X, or whatever generation we're now into, they communicate through photograph and video, okay? So, we are still – most of us are in email. They are in – they barely are using text now. They're more in images. So, video and photos. So, my question is, where are photos and video as part of the medical record? Is there a standard for the communication of these assets? And I ask because, I'll give an example of a patient having a burn wound that gets infected. They're at home. They reveal their bandage, whatever. I'm just giving an example. And keeping a traceability of where that infection line, the circles of infection, right, progression in knowing which way or direction you're going, right, of remedying that wound care. But I've seen the sharing of those videos, and I've also seen motion videos for therapeutic regimens as well. So, that would be your video image of movement. So, my question is, where do we cover this next generation world of communication that's happening in the cell phone to cell phone texting with physicians and providers to patients now? But where does that get captured, and how do – where will we have those standards? Just as a question.

Terrence O'Malley - Massachusetts General Hospital - Member
Okay. Very good question. Thanks. And then, so I'm going to bounce that back to the IFP. But no, I believe there are standards for images and videos. I defer to Dr. McDonald, who probably knows more of those standards than I do, I'm sure. But if not, then that's an important area, and we'll flag it. But you're absolutely correct. And it's critical clinical information. I just off the top of my head don't know what the standards are to do that. All right. So, the issue of prioritization, and then the harmonization. So, where in this open submission process where there are similar but not exact data elements, who's going to do the harmonizing? That's just a question. And if anyone's got any thoughts about that, because it's a lot more expensive to do harmonizing downstream than it is at the initial presentation. So, that's one other question.

And then sort of in this open public platform, are there other tools that would help this process along? And we only thought of the ones that already exist around the ISA, or the sandbox, the proving ground, the testing area, where industry could play with the data elements as they're coming through the process, and whether something like that needed – and again, anyone's recommendations about what other tools would help ONC and the submitters get the data elements through this process quickly. And then the final question was the bulk data, the big pieces. So, if we were to say all lab data has to be coded to X, Y, Z standard, and then made available in exchange, is that a reasonable process? What

does that mean for industry, having to retool to do that? It certainly clinically would make huge value. So, it's again the balance between clinical need and sort of industry bandwidth to get that into production. So again, no answers. These are things we're asking anyone's opinion on. Any contributions gratefully accepted. Carolyn.

Carolyn Petersen - Individual - Chair
Don't get nervous. It's not a hard question. I'm just wondering if you can give us a hard deadline for when you'd like feedback, to help people put that into their scope of work with everything else they're doing. It makes it a lot easier to get the feedback you want if we know what the drop dead day is.

Terrence O'Malley - Massachusetts General Hospital - Member
How about in time for our next meeting, which is a week from Friday. So, a week from this Friday, so 12 days.

Carolyn Petersen - Individual - Chair
So, then are you saying we should have our feedback to you by the end of the day next Wednesday, or?

Terrence O'Malley - Massachusetts General Hospital - Member
Next Wednesday, next Thursday. Yeah. We'll keep the ground very –

Carolyn Petersen - Individual - Chair
Give us a date, and Robert and I will ask Lauren to send things out.

Terrence O'Malley - Massachusetts General Hospital - Member
Thursday by 2:00.

Carolyn Petersen - Individual - Chair
Okay. We'll coordinate.

Terrence O'Malley - Massachusetts General Hospital - Member
2:00 p.m. Thursday.

Carolyn Petersen - Individual - Chair
2:00 p.m. Eastern.

Terrence O'Malley - Massachusetts General Hospital - Member
Eastern.

Carolyn Petersen - Individual - Chair
2:00 p.m. Eastern. Oh, okay. So penalize the West Coast people. Okay. Thank you.

Terrence O'Malley - Massachusetts General Hospital - Member

Okay. Any other questions or comments? Did you have questions or comments? No? All right. Then we are done.

Robert Wah - Individual - Chair

Terry and Christina, thank you very much for your leadership on this. And again, thank you to your task force for all the work you've done. I'm going to go ahead and take the prerogative of wrapping this up, because I know we're into the jet fumes part of the meeting. So again, thank you all. As I've said before, it is a happy dilemma for those of us at the front of the table to have more input than less input during a meeting. And I think this has been a good example of us all being very engaged in these very important issues, not only the HITAC committee, but also the public. So, I'm very pleased to see that.

I think a couple of things that I took from overall discussions was that we're going to work to catalogue some of the comments and remarks that we've had here, particularly those ones around the annual report, because I think we got input beyond the annual report that would be very helpful in what I'm calling HITAC 2020, because we need to put plans in place for what we're going to do next year. So, if you have additional comments along HITAC 2020, please send them to Carolyn and myself, and we'll be happy to put those in. It also occurs to me about the discussion about boiling the ocean in points versus pans versus bathtubs that we need to figure out some prioritization process, because we have more to boil here than we probably have time to do it. So, that also comes across as a message to us as your co-chairs.

Another message that I heard was, how do we think about harmonization across all the task forces that we have in play? And I think that's another topic that we'll have to think about, again, with ONC about all of the work that we're doing across the task forces. There's clearly overlap that needs to be harmonized as well. So, those are some of the things that I took from the discussions today. So, with that, I think we are a little bit over, and I apologize for that. But I think it's important discussion that we had. I don't think there was anything that any of us would like to have cut out here, so I feel good that we've had a very robust discussion about some very important issues here. So, with that, I'm going to turn it over to Carolyn and Lauren to finish up the meeting. But those are my comments and observations.

Carolyn Petersen - Individual - Chair

Yes, thanks, Robert, and particularly thanks to everyone on the HITAC. We had some really, really engaging, good discussions today across a broad range of topics that will help us with the current work plan and also help us set some goals for next year, and ensure that we have a work product in the annual report that reflects the views of the committee, and where we see ourselves going, and what we want to do. So, I deeply appreciate your engagement on that and look forward to next month when we can do some more.

Robert Wah - Individual - Chair

I also want to say, as much as I complained about the glare, it's nice to be at the penthouse-level view as opposed to the basement-level view for once. So, I've appreciated that. I think I've got on my list to talk to food service about the demand for time and all that kind of stuff. I think we can work on that

next time as well. But I happen to like this view a little better than the basement view. So anyway, I'll turn it over to Lauren for the last.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
I think you've captured all the sentiments of the committee, Robert. So, with that, we'll just adjourn. Thank you, everyone.

Robert Wah - Individual - Chair
Reminder, our next meeting is a virtual meeting.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Yes, October 16th, virtually.

Robert Wah - Individual - Chair
So, safe travels, everyone, and great seeing you all. Thank you.