ONC | HealthIT ADVISORY COMMITTEE

Transcript

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) MEETING

April 11, 2024, 9:30 AM – 3:30 PM ET

VIRTUAL & IN-PERSON

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

MEMBERS IN ATTENDANCE

Medell Briggs-Malonson, UCLA Health, Co-Chair
Sarah DeSilvey, Gravity Project, Co-Chair
Shila Blend, North Dakota Health Information Network
Hans Buitendijk, Oracle Health
Michael F. Chiang, National Institutes of Health
Derek De Young, Epic
Steven (Ike) Eichner, Texas Department of State Health Services
Lee Fleisher, University of Pennsylvania Perelman School of Medicine
Hannah Galvin, Cambridge Health Alliance
Rajesh Godavarthi, MCG Health, part of the Hearst Health network
Bryant Thomas Karras, Washington State Department of Health
Hung S. Luu, Children's Health
Trudi Matthews, UK HealthCare
Anna McCollister, Individual
Deven McGraw, Ciitizen
Katrina Miller Parrish, Humana Health Insurance
Aaron Neinstein, Notable
Eliel Oliveira, Harvard Medical School & Harvard Pilgrim Health Care Institute
Kikelomo Oshunkentan, Pegasystems
Randa Perkins, H. Lee Moffitt Cancer Center & Research Institute
Rochelle Prosser, Orchid Healthcare Solutions
Dan Riskin, Verantos
Mark Sendak, Duke Institute for Health Innovation
Fillipe Southerland, Yardi Systems, Inc.
Zeynep Sumer-King, NewYork-Presbyterian
Naresh Sundar Rajan, CyncHealth

MEMBERS NOT IN ATTENDANCE

Steven Hester, Norton Healthcare

FEDERAL REPRESENTATIVES

Keith E. Campbell, Food and Drug Administration
Jim Jirjis, Centers for Disease Control and Prevention
Meg Marshall, Department of Veterans Affairs
Alex Mugge, Centers for Medicare and Medicaid Services
Ram Sriram, National Institute of Standards and Technology *(absent)*

ONC STAFF

Micky Tripathi, National Coordinator for Health Information Technology
Steve Posnack, Deputy National Coordinator for Health Information Technology
Elise Sweeney Anthony, Executive Director, Office of Policy
Avinash Shanbhag, Executive Director, Office of Technology
Seth Pazinski, Director, Strategic Planning and Coordination Division
Wendy Noboa, Designated Federal Officer

PRESENTERS

Peter J. Embí, Vanderbilt University Medical Center
Laura Biven, NIH

Troy Tazbaz, FDA
John Brownstein, Boston Children's Hospital
Gil Alterovitz, VHA
Rachel (Rae) Walker, University of Massachusetts Amherst
Inioluwa Deborah Raji, University of California Berkeley
Maia Hightower, Equality AI
Alexandra Valladares, Health AI Partnership
Dominic H. Mack, Morehouse School of Medicine
Ashley Beecy, NewYork-Presbyterian
Samantha Burch, America's Health Insurance Plans
Christopher A. Longhurst, University of California San Diego Health

Call to Order/Roll Call (00:00:00) (Recording 1)

Wendy Noboa
Good morning, everyone and welcome to the April 2024 HITAC meeting. As you can see, we are all here in person in Washington DC at ONC headquarters. And we are so glad you could join us today. We would like to welcome everyone who came in person but also our virtual attendees who are on the line. Today, this meeting is open to the public and your feedback is welcome. If you would like to make a comment, please feel free to use the Zoom chat feature. Or you can make a comment during public comment today around 3:20 p.m. First, I would like to introduce our ONC executive leadership team. With us today is our National Coordinator, Micky Tripathi, our Deputy National Coordinator, Steve Posnack, our Executive Director of the Office of Policy, Elise Sweeney Anthony, and our Executive Director of the Office of Technology, Avinash Shanbhag. I will now get started with roll call beginning with our co-chairs.

Wendy Noboa
Medell Briggs-Malonson

Medell Briggs-Malonson
Present. Good morning, everyone.

Wendy Noboa
Sarah DeSilvey

Sarah DeSilvey
Present and good morning.

Wendy Noboa
Shila Blend.

Shila Blend
Present. Good morning.

Wendy Noboa
Hans Buitendijk.

Hans Buitendijk
Good morning.

Wendy Noboa
Michael Chiang will be joining us later.

Michael Chiang
I am present. I am sorry to be in Austin, Texas instead of DC.

Wendy Noboa
Hi, Michael. So glad you could make it. Derek De Young.

Derek De Young
Good morning.

Wendy Noboa
Steve Eichner.

Steven Eichner
Good morning.

Wendy Noboa
Lee Fleisher.

Lee Fleisher
Good morning.

Wendy Noboa
Hanna Galvin.

Hannah Galvin
Good morning. I am also sorry to be remote but glad to be here.

Wendy Noboa
Raj Godavarthi.

Rajesh Godavarthi
Good morning.

Wendy Noboa
Steven Hester. Bryant Thomas Karras.

Bryant Thomas Karras
Present.

Wendy Noboa
Hung Luu.

Hung Luu
Good morning.

Wendy Noboa
Hi, Hung. Trudi Matthews.

Trudi Matthews
Present.

Wendy Noboa
Anna McCollister. Deven McGraw.

Deven McGraw
Good morning, everyone.

Wendy Noboa
Katrina Miller Parrish.

Katrina Miller Parrish
Good morning.

Wendy Noboa
Aaron Neinstein.

Aaron Neinstein
Good morning.

Wendy Noboa
Eliel Oliveira.

Eliel Oliveira
Present.

Wendy Noboa
Kikelomo Oshunkentan.

Kikelomo Oshunkentan
Good morning, everyone.

Wendy Noboa
Randa Perkins.

Randa Perkins
Good morning.

Wendy Noboa
Rochelle Prosser.

Rochelle Prosser
Good morning.

Wendy Noboa
Dan Riskin.

Dan Riskin
Good morning.

Wendy Noboa
Mark Sendak.

Mark Sendak
Good morning.

Wendy Noboa
Fil Southerland.

Fillipe Southerland
Good morning.

Wendy Noboa
Zeynep Sumer-King.

Zeynep Sumer-King
Good morning.

Wendy Noboa
Naresh Sundar Rajan.

Naresh Sundar Rajan
Good morning.

Wendy Noboa.
And now for our federal representatives. Keith Campbell.

Keith Campbell
Good morning.

Wendy Noboa
Jim Jirjis. Meg Marshall. Alex Mugge.

Alex Mugge
Good morning.

Wendy Noboa
And Ram Sriram. Thank you. Is there anyone who I missed or who had just joined us? Hearing none, please join me in welcoming Micky Tripathi for his opening remarks.

Welcome Remarks (00:03:34) (Recording 1)

Micky Tripathi
Good morning, everyone. It is so great to have you in person and welcome to ONC galactic headquarters. Since we are covering artificial intelligence (AI) today, it feels like we need to have something a little bit more aspirational. So, I am really excited for the day today. We do have a pretty packed agenda. I am looking forward first to hearing from the co-chairs of the Interoperability Standards Workgroup, Sarah DeSilvey and Steve Eichner who I think is on the phone and all of the members of the Workgroup who worked really hard on that to develop some recommendations on the Draft United States Core Data for Interoperability (USCDI) Version 5, which we very much look forward to getting your comments on. And then, we are going to transition to the AI hearing. I think it is 10:40 a.m. And we are really honored to welcome a number of experts across the healthcare delivery landscape and from across the country to help inform both ONC and what we are doing with respect to our regulations, Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1), and the predictive decision support intervention provisions that were a part of HTI-1, getting some early reports from the field on the thoughts on that and how things are going.

Also, as you may know, I co-chair the United States Department of Health and Human Services (HHS) AI Task Force with Dr. Syed Mohiuddin from the Secretary's Office. And this hearing will also be very informative to that as we look across the department at the various uses of AI and all of our operating divisions and staff divisions. I very much look forward to that as well. I want to extend my gratitude to all of the HITAC members who contributed a lot of time and effort. I know Medell, Sarah, as well as Mark Sendak spent a lot of time helping us identify who are the correct representative people for us to be able to get. As you know, the pool is enormous. We have got a lot of expertise across the country and a lot of people who are willing to volunteer their time for this. I know a lot of careful consideration went into that and I really appreciate all of that. There is, obviously, a tremendous amount of interest in this topic. I think there are a lot of people listening today. Again, it speaks of the importance of what we do and the importance of all of your contributions.

There are just a couple of updates, and I am going to turn it over to Elise Anthony. Today, ONC has released our Health Equity by Design concept paper, which is bringing together a whole bunch of concepts and thoughts that we have actually put into place in a variety of areas that we do and in terms of some of the mission areas that we focus on as well. We thought it would be useful for us to consolidate those thoughts into something concrete and put that out for comment. We appreciate I know a number of members of this committee have helped us a little bit with that. And I want to give a ton of credit to Dr. Tom Mason and the clinical team who did a lot of work on that. It is a very big topic, a very important topic. We very much

appreciate that. That is now available on our website and is available for public comment, so we very much look forward to that. Obviously, we have a health equity focused panel today, which will be a part of the feedback on that and providing context for that.

Finally, the HITAC Annual Report for FY23 was transmitted to the Secretary's Office and to the Congress. I want to thank the committee for all of the thoughtful work that is represented in that report. And I think it is safe to say that the report does not represent all of the efforts and all of the thoughts and all of the work that you put in. In and of itself, it demonstrates a tremendous amount of work. Thank you for all of that. Now, let me close and turn it over to Elise Anthony for her opening remarks.

Elise Sweeney Anthony

Thank you, Micky. Good morning, everyone. It is so exciting to be here today for a number of reasons. It is always great when we get to meet in person at the HITAC. And thank you to everyone who volunteers their time at all of our meetings, as well as coming into town today. I think it is going to be a great meeting and really looking forward to the hearing as well. A tremendous amount of work has gone in. I really want to thank the chairs for all of the work they have done as well as my team in helping to bring it all together with the HITAC. I cannot tell you the amount of work that the team executes to bring the meetings together. It is always our pleasure and really much appreciated to work with such amazing people. There are a couple of updates I wanted to share today. One of the things I wanted to note is that Federal Health IT Strategic Plan update, which will be the 2024 to 2030 edition is out. And that is out for public comment. We want to encourage folks to please take a look at it.

It is a great way to really see what we as the federal government is thinking about. And I say federal government because while ONC does a lot of work to bring it to paper, there are a number of federal agencies who come together within HHS and beyond to really think about how we see health IT in the coming years. For all of the contributions from our federal partners, we definitely appreciate that and look forward to you taking a look at it. But it is also a great opportunity to see how folks outside of the federal government can engage and think about health IT and understanding what we, as the federal government, are committed to and working towards in the coming years. A couple of things on that in particular. The draft plan is open for public comment through May 28. We are going to have at our next meeting, May 16, a presentation on the strategic plan draft and also an opportunity for feedback at that meeting. We really encourage folks to take a look at the plan in advance and then, we will have opportunities for discussion at that meeting.

And that will be really helpful to us as ONC and to the entire federal government as we are thinking about the final. This also is particularly in line with our hearing today as well. We will be focusing on AI. We also think about AI in terms of the strategic plan and how we are going to support and think about safety, equity, and efficiency in AI as well. A couple of other things, one on USCDI+. I just want to thank our USCDI+ for a great presentation at our last meeting and to note that there is more to come. That was a wonderful opportunity for us to share our platform, what we are thinking about, how we conceptualize USCDI+ at ONC. And coming up in the spring and summer, we are going to be bringing back to the HITAC more discussion on aspects of that. So, the USCDI+ initiatives related to public health, cancer, quality, and others will be bringing up for further discussion at HITAC meetings. We are looking forward to that as well.

The other thing is United States Office of Management and Budget (OMB) published updates to their Statistical Policy Directive No. 15 and that relates to standards for maintaining, collecting, and present federal data on race and ethnicity, SPD 15. So, you can find that in the federal register. We can also drop a note in the chat as well for folks. And we just want you to know that we will continue to provide technical input and expertise with our federal partners as that is coming into exploration of how to update and where to update and where the updates may be appropriate to existing standards. So, I want to thank everyone for that. Those are a couple of updates I am looking forward to getting started.

Opening Remarks and Review of the Agenda (00:10:46) (Recording 1)

Medell Briggs-Malonson
Thank you so much, Micky, as well as Elise for all of those comments as well as updates. And I, too, want to say welcome everyone, especially to all of our brand new HITAC members. This is our very first meeting where we are actually here in person. And as both Micky and Elise said, there has been a large amount of work that has gone into this meeting. I also want to sincerely thank the ONC staff as well as the Accel staff for all that you did in order to make this meeting possible. We have an incredibly exciting meeting ahead of us today. Not only hearing more from the IS WG but also incredible experts from across the country who are rooted in their expertise of artificial intelligence and thinking about how we continue to refine and shape the future of artificial intelligence so that it is safe, so that it is ethical, and that it is as equitable as possible. Today, we are going to have an exciting time. We will go through some of the housekeeping rules in just a moment. But I want to say thank you and it is such a pleasure to see all of you. Sarah?

Sarah DeSilvey
I also want to welcome you all to my first in person meeting as a HITAC co-chair. I am glad to be accompanied by the expert, Medell. And I also wanted to state my sincere thanks. One of the best things about being co-chair is being able to work directly with the ONC team, their thoughtfulness and their care and their preparation, again, the Accel team as well. So, my thanks to ONC for gathering us here together. And we do have an incredibly exciting agenda today, which centers a lot with the work we did in IS WG. And so, I am looking forward to a very robust day with topics that are very near and dear to my heart personally. So, thank you so much.

Medell Briggs-Malonson
So, now to get into some of the fun. Before we move on, we are going to do a little bit of housekeeping and especially because our in-person meetings do differ from our virtual meetings. So, the very first rule is that all of us who are not federal employees, you have to be escorted. So, if you leave this room, you have to be escorted. I want to make sure we are all very clear on that. In addition to that, now that we are in an in person setting and also, thank you so much to all of our HITAC members that are virtual but in front of you, there is a sheet of paper that has all of our standard rules. And I am going to go over that so that everyone is very clear. When you start speaking, please say your name because we also still want to capture it in all of our public notes. In addition, you are more than welcome to join the Zoom. However, please keep your cameras off and your mics muted. But you can still engage with the public as well as place some of your comments in the Zoom. If you are here in the room and you want to speak, this is what you will do. You will flip your name card like that. And when you are done speaking, you can flip it right back down.

All of our HITAC members that are on our virtual world, still please feel free to raise your emoji hand the way that you always do. And what will occur is that Sarah and I will be monitoring the room as well as the

Zoom. And we will do our best to go in order to make sure that everyone has the time to speak. Because we cannot function without wi-fi, the wi-fi is on all of the white boards around you. So, please feel free to log into that. In addition to that, I think I have everything on this piece, this is going to be a very jam-packed meeting. And so, in order to promote inclusivity of voices, what we will ask everyone to do is keep their comments as well as their questions concise and focused, meaning less than two minutes because we want to be able to get around to as many of our HITAC members as possible and especially with all of our amazing speakers that are coming. Our speakers have very brief but yet very impactful presentations. So, we want to make sure that we can get as many questions in as possible. Are there any other housekeeping items?

Micky Tripathi
Just so you know, Medell enforced these rules at dinner last night, too.

Medell Briggs-Malonson
It is all about structure and efficiency. Thank you, everyone. Sarah, I will turn it over to you for us to go through our agenda for the day.

Sarah DeSilvey
Wonderful. Our agenda for the day is we have already completed some of these elements. But we are going to be going into the report out from the IS WG Workgroup, which I have the honor to co-chair with my colleague, Ike. We will have a brief break after that to ensure that we have time for the HITAC to comment on the IS WG transmittal letter. We will transition into our next phase of work for the remainder of the meeting, which is the three series of panels for the three different topics on critical elements regarding artificial intelligence. Again, I want to thank ONC for its care in curating these panels. And I also want to thank all of the experts who have gathered from across the country to help guide ONC and HITAC in the critical elements on each of the panels. We will then adjourn at 3:30 this afternoon. I imagine it is a very tight schedule for all of us. There is a lot of information to cover. And I just want to make sure that everyone is aware that we will close with public comment at 3:20 before we close. Is there anything else to address? I think we are good.

Medell Briggs-Malonson
Without further ado, we are going to move into one of our most exciting topics. And this is going over the recommendations for the Interoperability standards Workgroup. And so, I will turn it over to Sarah and Ike as our co-chairs of the IS WG.

Sarah DeSilvey
Thank you so much. Ike, my colleague, are you with me?

Steven Eichner
Absolutely.

Interoperability Standards Workgroup Recommendations on Draft USCDI Version 5 – HITAC Vote (00:16:44) (Recording 1)

Sarah DeSilvey

Thank you so much. It is our honor to go through the report out on the work of the Interoperability Standards Workgroup. Many of you and many new members of HITAC were part of that work this year. It is an amazing gathering of stakeholders across the ecosystem with a very practical application of the work we do at HITAC creating standards for USCDI. So, Ike and I are going to be alternating our presentation. And then, there will be a period of HITAC questions and answers that Medell will facilitate at the end of the presentation. And so, in order to make sure that we get through everything, we are going to proceed. And Ike and I are going to cover high level versions of the transmittal letter. A few early comments. I just want to note that there were a couple of minor transcription errors in the transmittal letter that were fixed. That is why there was a different version sent out this morning. We just want to make sure that we represented exactly the content as reviewed on the shared drive in our work and in the public sphere. So, just minor transcription errors were fixed this morning.

What we are going to be doing is going through and thanking the roster from the Interoperability Standards Workgroup reviewing for HITAC and the purposes of IS WG as we do with every single Workgroup. The charge is to talk about the work plan, and how we covered the work over the course of the last month. For any new IS WG member, you know the work is dense. We do a lot in a short period of time. We will then cover the ever so important Draft USCDI v.5 recommendations, which is the first part of our charge and then, go into the elevated Level 2 elements that IS WG recommended for consideration in Draft USCDI v.5 after conversation and consensus in that Workgroup. It is my honor to co-chair with the amazing Ike this group of esteemed experts, many of whom are in the meeting today as HITAC members. Again, we are very grateful for all of the new members who came.

We are not going to fully review the roster, but it is important for HITAC to know both the members of the community that are elevated to IS WG because of their longstanding expertise in developing data standards to promote interoperability and the HITAC members who sit on the Workgroup and all of the federal representatives who are there as well. So, that is the roster. Ike, do you have anything to say?

Steven Eichner
We cannot emphasize strongly enough the commitment of the members of the Workgroup meeting every week since the end of January with great dedication to go through the Draft v.5 and then, the additional data elements. There was an incredible team put together and supported, of course, by ONC and the rest of the support team. We could not have done what we did without that support team and really wanted to express our appreciation for them as well.

Sarah DeSilvey
I do want to note that the bliss of being the co-chair of a Workgroup or HITAC is getting to work so closely with ONC. I am just going to note that my thing just went down for the purposes of tracking. This is the review of the charge that the IS WG is given by this body, HITAC. The charge is to review and provide recommendations on draft use of Version 5. And there are two specific sub charges within that. These are well known to IS WG because we review them every single meeting, but I am going to review them for the purposes of the minutes here. The specific charge is to evaluate draft use of v.5 and provide ONC with the recommendations for new data classes and elements from Draft USCDI v.5. This should be considered for the final USCDI v.5 release. Again, as mentioned, review and discuss and elevate any Level 2 data classes and elements not included in Draft USCDI v.5 that should be considered for the final USCDI v.5 release.

These two elements of the charge are what we reviewed every single week as Ike noted. And it could not have been done without all of the many hands making the right approach.

We have a high-level review of the new data classes and elements from Draft USCDI v.5. Ike and on from this point forward are going to start alternating slides because once we get into the recommendations, I want to make sure that we are trading off. But just as an understanding of the new data class and elements from Draft USCDI v.5, they were clinical notes, Emergency Department note and operative note, immunization slot number, laboratory test kit, unique device identifier, medication route, observations, new class of advanced directive, observation and sex parameter for clinical use, with orders and patient demographic information including interpreter needed pronoun and name to use and then, provenance author and author role. I do want to note that part of what we do with an IS WG is take these draft recommendations and refine them. You will see in our recommendations the evaluation of some of these initial elements into more refined suggestions as part of the multistakeholder approach of IS WG.

Is there anything to add there, Ike?

Steven Eichner
There is a total of 13 classes and data elements that were included in Draft v.5. We did make a couple of recommendations to include some minor name changes. We will highlight those as we get through our recommendations at a more detailed level.

Sarah DeSilvey
Thank you, Ike. Here are a few slides detailing the examples of the Level 2 elements that were elevated. Again, we will be discussing these more in detail. You can see elements across care planning, health literacy, specimen collection date and time, substance food, family health history, patient demographics, identifiers, patient identifier types. Health insurance information, additions to clinical notes with maternal social determinants of health note, refinement of medication data classes, including medication administration data elements. These are things that were discussed. And then, again, this is not necessarily put forward as written. Additional within medication and medication prescribed code. These are all things that we reviewed as Level 2 elements as part of our charge. Lastly, this is the last page of Level 2 elements. We have device use, signature, immunization status, vaccination event record type, healthcare agent, portable medical orders, and facility address.

You can see this is a robust vat of things that were discussed every week. It kept us busy, and we are almost to the point of where we can read our recommendations. We have this final set. This includes some additional elements within the recommendations for gender inclusivity including sex, gender identity and then, a comment on assessment of plan of treatment related to care plan refinements and then, request to add an element for healthcare agent within goals and preference and status last. Again, these recommendations as initially presented evolve in the final recommendation through the work of the committee. These were the recommendations as suggested. That does not mean they are as accepted. And we are going to go through the rest very shortly. This is the run of show of what we covered. Ike, do you want to cover this slide?

Steven Eichner

Sure. This slide lays out the work plan we followed. So, really looking at laying out discussion of the new Draft v.5 data elements broken down. You can see the level of detail that we went through. And we came back around and looked at the Level 2 elements not included in the Draft USCDI v.5 and discussed those and then, spent a couple of weeks finalizing our recommendations for transmittal to HITAC and closed that out earlier this week and delivered a letter to the full HITAC earlier this week.

Sarah DeSilvey
The only thing I want to add is we had really great discussion early in IS WG on the way IS WG works. And some of our first meetings were really about process and about ways that we can assist in onboarding and educating new members about the power they have in their role. And I want to thank our colleagues at ONC again for assisting in that level setting and that grounding because I do feel like it allowed members to engage robustly over the course of the Workgroup. As always, we center subject matter experts when appropriate to ground and refine the recommendations. We were honored to have subject matter experts come from across the community. This includes representatives from the Gender Harmony Project, and Health Level 7 (HL7) initiative represented by Carol McCumber and Rob McClure. This was to address the three Draft USCDI v.5 element sex parameter for clinical use pronoun and name to use. Gender Harmony work also relates to some of the Level 2 elements that will be discussed later. We also had Maria Moen from my directive come, a significant expert in the area of advanced directives and patient advocacy.

She discussed advanced directive observations and orders. Again, you will see the evolution of the recommendation from IS WG issuing from her presentation. And then, we also had a robust presentation on care plan as a concept and as a possible data class from representatives Agency for Healthcare Research and Quality (AHRQ) and the National Institutes of Health (NIH)/ National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) multiple chronic condition e-care plan initiative and the staff that supports them from EMI. And also, Liz Palena Hall, well known to HITAC from CMS. That was a really robust conversation on care planning. Is there anything to add, Ike?

Steven Eichner
No.

Sarah DeSilvey
We are almost there to the meat. This is the format of the final report of the transmittal letter. There is a background statement. And then, we go through very much in following our charge recommendations within draft use of v.5 data elements and then, our Level 2 commentary. And then, an area of really forward-thinking strategic reflection, which is called recommendations for future consideration. This is when the thoughts and the findings of IS WG are not directly related to data elements but more suggestions on direction for ONC considerations on interoperability as a concept. And now, we are ready to get into the meat. Ike, do you want to kick us off for the first one?

Steven Eichner
Sure. Looking at the first recommendation, we are looking at recommending the addition of all proposed data elements and all data classes included in USCDI Version 5. We are supportive of the entirety of Draft v.5 as presented by ONC. And we are going into more detail as we go forward. As I said earlier, we do make a couple of suggestions for potentially minor name changes but, generally, supportive of concepts as a whole. Now, we are really going to get into the meat. A little teaser.

Sarah DeSilvey
Ike and I are going to alternate. This is our Recommendation No. 1. And I want to note and elevate what Ike said. We take the Draft USCDI v.5 recommendations from ONC. There is a lot of refinement. There was a full agreement to accept the concepts as represented in Draft USCDI v.5. But there is a lot of commentary. Regarding the two clinical note data elements, remember Emergency Department and operative note, that Workgroup recommends that ONC choose at minimum Logical Observation Identifiers Names and Codes (LOINC) code different than the LOINC code used respectively for the full structured documents. This really comes from our implementation experts who are talking about that we elevated the criticality of the two additions but talked about the complexity of implementation. And so, this was a refinement to the initial data element recommendation with that in mind just understanding implementation and offering that the designated codes could be chose as part of the subsequent data model and discussions. There was a lot of conversation on how recommendations for specific LOINC codes for notes to be represented in USCDI v.5, in general.

Steven Eichner
Looking at recommending that ONC change the name of test kit unique device identifier to test kit identifier in USCDI v.5 and really looking at emphasizing that the text kit identifier identifies the reagent name and specifies the data element is required to be sent if present and available and the inclusion in USCDI does not imply a requirement of collection. But, again, looking at if it is collected defines how it should be stored and transmitted. And it should be based on the FDA unique device identifier system where available or other appropriate scheme when the FDA naming convention is not available really elaborating a little bit on the inclusion of the elements in USCDI v.5 to help create a method or some guidance for operationalizing it in practice.

Sarah DeSilvey
The next recommendation is an evolution of the recommendation as stated in the Draft USCDI v.5. This is actually driven by the presentation and conversations on the criticality of representing this as a concept. It was a recommendation that ONC create a new advanced healthcare directive data class. We are always thinking about our implementers in IS WG. And there was a recommended definition. It was the documentation of presence and properties of patient expressed goals preferences and priorities should a patient be unable to communicate them to a provider. Examples of advanced healthcare directive information include advanced directives, durable medical power of attorney, living will, and personal advanced care plan. There was a lot of conversation on the correct naming of this class. I want to honor that. And so, I am grateful for the presentation of the subject matter expert, Maria Moen, and grateful for the work of IS WG to get us to this point.

Further commentary, this new data class should also include the following data elements, American Hospital Directory (AHD) documentation observation, AHD unstructured documents plan, and AHD structured documents and plan. And then, the Workgroup also recommended referencing treatment intervention preference and care experience preference data elements in both the goals and preferences and in the new AHD data class. This is a step in curating data classes for specific purposes. You can see that the last comment is really important. It is not the removal of elements within goals preferences but more the inclusion of them in this new AHD data class.

Steven Eichner
Looking at revising the definition of the data element for sex parameter for clinical use. Sarah, you should take this one because you have some additional subject matter expertise.

Sarah DeSilvey
We agreed that if we felt that it was appropriate. I can do this one. This is Recommendation No. 4. This is actually an evolution of the alliance topic in the Draft USCDI v.4 to better align the comments of the sex parameter for clinical use with the work of Gender Harmony Project. It was guided by the representation of Carol McCumber and Rob McClure of the work happening in HL7. This, of course, supports implementation because that is what the HL7 Workgroup is all about. The recommended definition was a use case specific to categorization value that provides guidance on how a recipient should apply settings or reference ranges and interpret results of the associated text, image, or procedure. This is a much more user helpful definition than was present in the original recommendation and includes a usage note that the sex parameter for clinical use values should be based upon information such as examples, anatomical inventory, hormone lab tests, genetic testing menstrual status, and obstetric history.

Again, these are all critical elements in gender affirming care aligned with the Gender Harmony Project. We also wanted to note that since the release of HTI-1, there had been evolution in recommended value sets for this concept. And we just wanted to note that for further implementation and guidance on implementing USCDI and HTI-1.

Steven Eichner
We recommend that ONC add the orders data element with an additional recommended usage note about where the data enters into the workflow as well as looking at a long-term goal in the orders class to be able to include a broader spectrum of orders not necessarily completed and cancelled but all orders signed by a provider to create a more comprehensive library of orders from the patient perspective.

Sarah DeSilvey
Recommendation No. 6 is that HITAC supports ONC's adding the author and author role data elements. And this is very straight forward in response to ONC's public query as to sufficient implementation of these elements. Again, part of our job at IS WG is responding to questions as posed in the Draft of USCDI v.5. When able, IS WG directly responds to that. In response to ONC's public query as to sufficient implementation of these data elements to warrant inclusion of a data element in USCDI v.5, IS WG unanimously agreed that there was sufficient implementation. And then, the further recommendations on the nuances I am not going to read verbatim, but they are all part of the transmittal letter. I want to make sure that we have time to comment on content later on.

Steven Eichner
Recommendation No. 7, recommending that ONC clarify which data elements and classes are relevant to the encounter location data elements. Fast Healthcare Interoperability Resources (FHIR) US Core, USCDI enumerates a reasonable set that USCDI should reflect directly. We are recommending that there be tighter alignment.

Sarah DeSilvey

Before we transition into Level 2, I just want to remind everybody on HITAC that the transmittal letter is a general statement of support for the direction of the Draft USCDI v.5 elements. And what we just read were specific comments, which are applying the expertise and multistakeholder perspectives of Interoperability Standards Workgroup to refinements or evolutions of those initial elements. Again, all of the details of this are included in the transmittal. Again, in order to complete the charge, including the Level 2 elements we are about to go through, the transmittal letter did come through a little bit later than we usually like. Thank you for your patience and diligent reading to get us here. We are now going to be reviewing Level 2 data elements and including some recommendations for refinements to them in the next slides going forward and then, have time for HITAC questions.

This is a recommendation to the ONC to add the data element care plan to the patient summary and plan data class. This is one of those recommendations that comes forward multiple years. And for the sake of time, I think we are going to have to keep on moving just to make sure that we do not delay it again. Thank you. The content is contained in the transmittal letter. This is the finish of it. You can see there is both the recommendation for a care plan data class and recommendations for how this would be structured and a recommendation for specific elements. Care plan data element will often integrate or link to specific values or codes from other data elements essential to care planning, especially in the following data classes. These are recommendations of how that data class might be curated. And this includes care team members, health status, goals and preferences, procedures, and outcomes. And this is a recommendation for specific elements in Level 2 and the creation of a data class, again, in response to the expertise and subject matter experts.

Steven Eichner
Rename patient summary and plan data class as care plan data class. So, looking at continuing assessment plan treatment data element as a narrative based on other recommendations that are adopted. The care plan data class would include the elevated care plan data element and the assessment plan of treatment data element. A little restructuring of the USCDI overall but trying to get it a little more organized and reflect patient experience and providers' needs.

Sarah DeSilvey
I just want to thank IS WG for working hard on that one. There was a lot of conversation on that one. There was Recommendation No. 10. It was recommending the ONC develop an outcomes and evaluations data element class. This is one that is aligned with my other work. Recommendation to ONC includes health literacy as an additional example domain. This is to help implementers again because many of the domains that are in the SDOH realm are addressed by the work that we do over at gravity. And to assist implementers in understanding the support available there, we want to make sure we are updating the submission Interoperability Standards Advisory (ISA) regularly with all of the demands that have been addressed by the Gravity Project.

Steven Eichner
Recommendation No. 12, looking that ONC add the data element specimen collection date and time to the laboratory data class USCDI v.5. Looking at data element specimen collection date and time is critical to understand the utility of the specimen collected and looking at tracking the use of the specimen throughout analysis and subsequent treatment processes. The data element is required by Clinical Laboratory

Improvement Amendments (CLIA). It helps create better alignment between USCDI and CLIA and supports public health reporting and data utilization for public health as well.

Sarah DeSilvey
This is a recommendation to expand the elements within the representative substances with any allergies and intolerances data class and adding substance food from Level 2.

Steven Eichner
Looking at adding criticality as a data element to the allergies and tolerances data class, USCDI v.5 so that we have got better information about potential clinical harm or seriousness of reaction.

Sarah DeSilvey
This is an ongoing recommendation that ONC add family health history as a data element in the new family health history data class in USCDI v.5. This comes back and we are happy to elevate it again at this time.

Steven Eichner
Looking to recommend that ONC add portable medical order (PMO) as a new data element in the orders class for USCDI v.5 supporting the current definition of PMO, which is looking at adding it as a data element.

Sarah DeSilvey
This was a recommendation that we add maternal social determinants of health note data element to the clinical notes data class regarding the criticality of a maternal health crisis in the country at this time and the necessity and importance of representing this in order to address health equity concerns. This is furthering that we recommend that ONC explore the presentation of data elements in the USCDI v.5, specifically to maternal health considering the high priority of addressing maternal and birthing individuals' mortality.

Steven Eichner
Recommending that ONC add several data elements in the health insurance information data class coverage period, Medicare patient identifier, payer name, plan name, group name along with a usage note about how the information might be used both with respect to the primary and secondary coverage for the individual in helping create a more comprehensive record to help facilitate payment as well as identifying what services may be covered.

Sarah DeSilvey
A note on that last element, again, this is where implementers are very helpful accessing whether things are ready for implementation or whether they need to be held. Thank you for all of the insight there. This is a recommendation that ONC advances specific medication administering event data elements to enable access to individuals' administration data used in various analytics and research context. We are grateful for the expertise of our pharmacy friends on IS WG thinking of the pharmacy work that happened in 2023 and grateful to apply this to the USCDI element at this time.

Steven Eichner

Recommending that ONC add facility address data elements to complement other information and facility information, so the necessary information becomes available to identify physical institutions or facilities to link services and outcome data.

Sarah DeSilvey
I am going to give a nod to our public health friends for ensuring that we represent these things well. This is a recommendation that ONC add device to use as the observational data element to the medical devices data class. This is really the assessment of what devices are being used by an individual critical for quality measurement. I am grateful for this one to go forward.

Steven Eichner
Recommending from April 2023 that the ONC include the definition of sex become an example of recorded sex or gender, i.e., what is recorded at birth really reflecting that there may be more nuanced information about proper care and looking at the way information has been collected and stored on a historical basis. Sarah, do you want to elaborate?

Sarah DeSilvey
No. This is lovely. Thank you. This is all pulling for recommendations from the Gender Harmony Project happening in HL7. This is reiterating our prior recommendation on the gender identity data element. I will have an amendment to offer when we enter into public comment.

Steven Eichner
Recommending that ONC add vaccination event record type data element to the immunizations data class. The element would distinguish whether vaccination was based on the historical record or was administered at the facility submitting the vaccination information. There are already standards available for exchanging. But this is just clarifying the information so that there is more accuracy about vaccination status for a patient for a particular vaccine administration.

Sarah DeSilvey
Thank you for your patience as we race through for the sake of getting it on the record and so we can enter into the critical HITAC conversation on the transmittal letter. The final recommendation is recommending that ONC add healthcare agent data elements to the new advanced healthcare directive data class as a critical element of care planning and advanced care planning. Lastly, going into recommendations for future consideration. Recommendations for moving things from Level 1 to Level 2 so they can be considered for future versions of USCDI at some time. So, this recommends that ONC advance the signature data element in the provenance data class to Level 1.

Steven Eichner
Recommending that ONC continue to evaluate methods to synchronize and align USCDI with FHIR, US Core, and Consolidated Clinical Document Architecture (CCDA) to provide clarity and assist with implementation. This is really looking at the idea of are there options for better alignment in terms of adoption so things line up better from an adoptions process and utilization process.

Sarah DeSilvey

This is a recommendation that ONC just might continue to consider and evaluate whether USCDI criteria should be broadly applied to all past certification given the limited scope and use of cases of certain Electronic Health Records (EHRs) and other health IT that might benefit from certification but might not be able to implement the full set of USCDI.

Medell Briggs-Malonson
I want to sincerely thank the co-chairs, Sarah and Ike of IS WG and all of the incredible work by the entire committee for all of these 29 recommendations. Thank you all. This was a tremendous amount of work. We are going to open it up for discussion as well as for the vote. If you have a comment or question, if you are in the room, again, flip up your name card and we are also watching all of our HITAC members online. I recognize Sarah.

Sarah DeSilvey
Because this was not part of the transmittal letter, I want to add a possible addendum to include in the gender identity recommendation the full text of our prior HITAC IS WG recommendation, which includes the examples of the existing USCDI gender identity concepts. They were included conceptually in the recommendation, but we did not copy forward the exact prior recommendation from prior IS WGs. And to replicate the intent of the recommendation and fully copy forward the things we have said before, we would just add in the additional two elements from the optional and additional not mentioned. Those are the two and I can put the in the comments.

Medell Briggs-Malonson
And for this because we are going to a vote, if you do have a friendly amendment to this, please put it directly into the chat so that we can incorporate it for the vote. Put whatever language directly into the chat. Thank you. Hans, I recognize you.

Hans Buitendijk
Thank you. I appreciate all of the work and the great discussions that we have had and that are representative in the document that we have pulled together. There is one area where I also would like to offer a friendly amendment and I will put the text in the chat in a second. And that is related to Recommendation No. 28 to provide a little bit more context around the rational to synchronize USCDI or align USCDI with FHIR, US Core, and CCDA and add to the recommendation clarification statement that it is particularly because of the subsequent publication of FHIR, US Core, and CCDA is not always in sync with the expectation that the USCDI sets on scope and that, therefore, the suggestion is to continue to figure out ways in which they can be better aligned. I will put in the chat the actual text that I would be suggesting to clarify that.

Medell Briggs-Malonson
Great. Thank you so much, Hans, and thank you for putting that into the chat. Is there any other discussion? Yes. Hi, Lee.

Lee Fleisher
As the ONC knows, I have a significant interest in the USCDI+, particularly around public health and around quality measures. It is just a statement more than I think the group did a great job. But I think with the desire for the CDC to collect more hospital-based data as well as other data that could be better aligned through

USCDI as well as the quality measurement going to electronic clinical quality measure electronic clinical quality measures (eCQMs). The rapidity at which you move forward to USCDI 6 or 7, whatever the next version is, versus putting it into USCDI+ and folding them together would be really important.

Medell Briggs-Malonson
Thank you so much for that comment. That is very important notation. I appreciate that. Any other questions, comments, revisions?

Steven Eichner
This is Steve Eichner. I do think there are opportunities to continue to work with USCDI and improve alignment between USCDI and USCDI+ both for public health and for other areas that USCDI+ is considering as well. I know it is an evolutionary process.

Medell Briggs-Malonson
Thank you, Ike. I am looking around the room. I am also looking around the virtual room on Zoom. And I do not see any other comments or questions. I was waiting for you, Jim.

Jim Jirjis
Does red mean it is on?

Medell Briggs-Malonson
Yes, it does.

Jim Jirjis
Maybe a suggestion would be at a future HITAC event that we check in again around progress made with USCDI+ and how it interdigitates with USCDI because I think there has been some work done about that. And that may help tee up discussions. It is just a suggestion.

Medell Briggs-Malonson
Thank you, Jim. And Rochelle?

Rochelle Prosser
This one is more to address Hans' question. I just wanted a little bit of clarity on what you were seeking because I find in sitting in the public comments of the other spaces will make a comment or a suggestion and then, they will adjust accordingly. And then, it might not actually match, or they may act first. Is it a chicken and egg scenario? Not stirring the pot. Quickly rephrasing. Is it a chicken and egg? When I sit in the other comments, I hear where they react to what we say and then, we are reacting to them. Is it better to wait to see what their process is and then comment? Or do you want us to go first?

Medell Briggs-Malonson
You can do that and then, we are going to go to Bryant and then, we are going to go to the vote.

Hans Buitendijk
To clarify the sequence of the chickens and the eggs, it is always a tricky challenge because of the way in which these documents are being produced. USCDI comes first, the discussion around it, it gets approved

and then, subsequently, FHIR, US Core, CCDA that is being used by implementers to then address how to do that and where there is the need for that. That comes second. That comes sometime after that for any kind of data that USCDI introduces that is not yet covered by those standards. In that process, there is discussion, there are clarifications. And in the end, those are being published, balloted and published by HL7. What we have seen and that has happened less with Version 2 starting with Version more clearly and Version 4 is that when you compare and read USCDI Version 3 and then, you read later on the published five-year score of CCDA, the scope is not totally in sync. Up to a point, that is okay because of the language used and the terminology used.

But there are some areas where the gap between the interpretation of what you read when you just read USCDI or if you just read FHIR and CCDA is a gap that creates different expectations on what actually should be interoperated using FHIR, US Core, and CCDA. What this is about is trying to find out how can we better synchronize it because it is one after the other, there will be changes. How can we recognize that the changes, not just that it is balloted in HL7 but that it is recognized totally that it is still now the interpreted and intended scope of USCDI? As an implementer, we not only read USCDI, we read FHIR, US Core, CCDA, and we read the rule. And in the rule, it clearly states that USCDI provides the scope to ensure that then the standards support what they need to do. If the gap is too big that becomes problematic because now, we have different expectations on software of what they are going to do. What can we do? Are there better ways to get them much closer? Will that be perfect? No.

But right now, we have at least five or six or seven areas where that distinction, the gap between what happened with Version 3, Version 4, and what will likely happen with Version 5 that occurs. Is there a way to move forward to close the gap?

Medell Briggs-Malonson
Thank you so much, Hans. Thank you, Rochelle, for that question. Bryant, go ahead and bring us home.

Bryant Thomas Karras
I just wanted to touch back to the comments Jim and Lee made. I think in addition to revisiting USCDI+ and some of the public health data elements that potentially should be in future recommendations from the Workgroup, I would also like to think about checking back in with the past and matching up with the past recommendations from the public health data systems task force to see how much progress we have made on those recommendations because there were some data elements or activities that were suggested to be highlighted or accelerated in that that could have consequences on USCDI elements that are needed to make it work.

Medell Briggs-Malonson
Thank you for that as well. That is really important.

Steven Eichner
I support that. I do want to make sure folks are aware that USCDI+ was not within the IS WG's scope this year. That was not part of our charge.

Medell Briggs-Malonson

Thank you, Ike, for that clarification. That shows that we definitely have some really great opportunities ahead of us for also weighing in. We are going to move towards the vote. I would like to ask if there is a motion on the table to approve the IS WG recommendations as written in addition to the two amendments that are now in the public chat. Is there a motion? Great. There is a motion by Lee. Is there a second? There is a second from Hans. Is there any additional discussion or revisions? This is a vote. There is a motion and a second to approve what has been distributed as written as well as the two amendments that are in the public chat. Not seeing or hearing any additional discussion, I will call for the vote. All in favor say aye.

Group
Aye.

Medell Briggs-Malonson
Thank you for the emoji hands. All opposed? Any abstentions? And Accel, if you can help me clear the hands. Any abstentions? We appreciate that. Thank you. Excellent. The motion carries. Thank you so much. We really appreciate all of the work by IS WG and by our co-chairs and also by HITAC for all of your input. We now have our recommendations approved by the HITAC committee. Thank you so much. At this point in time, we are going to proceed into a quick break. We are two minutes over so we will have everyone come back at exactly 10:40. Again, if you do leave this room, you have to have an escort. We will see everyone back really promptly.

Artificial Intelligence Hearing

AI Hearing – Panel 1 (01:02:00) (Recording 1)

Promoting Safety and Quality of AI in Health and Human Services

Wendy Noboa
Hi, everyone. Welcome back. I hope you enjoyed your break. I would like to quickly turn it over to our co-chair, Sarah DeSilvey, to get us started with the first presenter.

Sarah DeSilvey
Welcome back, everybody. It is my honor to kick off a series of panels that we have convened on artificial intelligence to help inform ONC's and general HHS's direction on AI. Just to kick us off, we are going to be having three different panels, one of them this morning and then, we will break for lunch and we will have two more. In general, before we kick off, I just want to note those of us in healthcare are very well aware of any requirement, even with the most simple tool to learn how to use that tool well to ensure that the system monitor is ongoing, whether that tool is being used as designed, and to ensure that we monitor for principles of health equity as well. This is fundamental in everything we from the scalpel we used in procedures to the tools we use that are much more sophisticated. That principle is inherent in the approach of HHS as we consider AI, principles of how to use it, principles of monitoring its use, and principles of ensuring health equity by design as ONC is so careful to do as its use is employed.

I am going to kick off the first panel. October 30, 2023, in the Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence, it directed the secretary of HHS to establish the Health and Human Services AI task force. This task force was established to develop strategies and policies on responsible deployment and use of artificial intelligence and artificial intelligence enabled technologies

in the health and human services sector. The panel presenters in this panel, which is the first panel promoting safety and quality of artificial intelligence and health and human services will focus on development, maintenance, and use of predictive and generative AI enabled technologies and healthcare delivery. What I am going to be doing because we have some in person and some remote presenters is introducing each of the presenters in turn. They will then give a brief presentation and then, we will complete all of them. And then, we will have a period for HITAC discussion. Our first panelist, again, on the promoting safety and quality of artificial intelligence in health and human services panel is Peter Embí, Professor and Chair of the Department of Biomedical Informatics at Vanderbilt University Medical Center. Welcome, Peter.

Peter Embí

Thank you so much. Can I just confirm that you hear me? Thank you. It is an honor and pleasure to be with you and presenting along with my esteemed colleagues. As you alluded to, I will make my opening remarks and then launch into that. I am Peter Embí. I am the Professor and Chair of Biomedical Informatics and Senior Vice President for Research and Innovation at Vanderbilt University Medical Center. And among other things, I have responsibility for jointly overseeing some of our AI governance and we are doing quite a bit of work, so I am pleased to be speaking with you about this. Since I knew I was the first presenter, I thought it would take the opportunity to quickly review what I know. It does not need to be belabored for this group. When we develop our AI solutions, be they predictive or analytical models or generative models, we do this by acquiring data and training our models using best available data. And there are many considerations we take into account when we do that.

We train our models and then we, ultimately, deploy them to ensure that they are going to have the intended effect, that they are going to be beneficial, that they are going to address the issue, and importantly to the best of our ability, that they are going to result in an effective and equitable care. Oftentimes, one of the things that we are challenged at doing even still today is the ongoing monitoring and optimization of these. That is incredibly important, not only because it is something we should be doing routinely anyway, but because as many recent high-profile publications and news items have pointed out, there are potential downsides. Even though it is critically important that we advance the work of deploying AI solutions to improve health and healthcare and achieve the developments we all desperately need, we do have to be careful how we do this and that involves monitoring. Monitoring is still something that is a bit challenging to do, frankly, in the real world.

The ongoing development of these kinds of tools and capabilities is really critical. This leads me to one of the topics I wanted to highlight here and certainly be happy to talk more about, which is this concept of algorithm of vigilance, a concept that we wrote about a few years ago and are in the process of operationalize as are some others, which is akin to pharmacovigilance and defined as the scientific methods and activities related to the evaluation, monitoring, understanding, and prevention of adverse effects of algorithms in healthcare. Much like we think of for pharmaceutical molecules for devices, we need to be thinking about it similarly. The analogy is not perfect but is very beneficial. There are various reasons why we need to do this. We know that there are biases both known and unknown in the underlying data that we use to train these models and sometimes conscious or unconscious in those that are developing them.

We need to be conscious of generalizability. There are a lot of examples of where, for instance, if we develop an algorithm that performs extremely well at Vanderbilt University Medical Center, it is not going to necessarily perform as well if we were to be transported to a different location. If we can expect anything,

as you all know very well, it is the unexpected with any health IT intervention. And we have to do this to promote trust among the users and among the patients and the public. And we need new systems and approaches to do this in order to affect essential safe, effective, and equitable care. This is just a depiction, and I will not belabor this one either in the interest of time. It is a cartoonish depiction of what we are building here. In the top left of the diagram of what we call the Vanderbilt algorithm of vigilance monitoring and operations system, we are developing a sociotechnical system where we will have technologies that allow us to take various feeds and display those in various ways for end-users to be able to monitor and in near real time.

Think of an analogy to air traffic control. We are monitoring the various algorithms that are having an effect in our system and looking at that across example metrics with accuracy and precision. Drift we know occurs with these algorithms. Degree of responsiveness if they are being deployed in a decision support capacity, and issues of fairness and equity. Are they differentially impacting different groups? We are building in feedback loops and capabilities to be able to send messages back and forth to the relevant users or those who might need to take actions. And the possible actions could include investigating the cause, correcting, or updating the model, notifying teams if appropriate, and even pausing the algorithm if we think it is having harm. In conclusion, I just wanted to thank you and look forward to a further discussion.

Sarah DeSilvey
Thank you so much, Peter. We look forward to discussion later on. It is my honor to invite our next panelist to the microphone, Laura Biven, the Integrated Infrastructure and Emerging Technologies lead at the Office of Data Science Strategy at the NIH. Laura, welcome.

Laura Biven
Thank you so much. Can you hear me?

Sarah DeSilvey
Yes, we can.

Laura Biven
It is a pleasure to be with all of you and I am honored to be here with the other speakers. As was mentioned, my name is Laura Biven, and I am the lead for Integrated Infrastructure and Emerging Technologies in the Office of Data Science Strategy at NIH. The Office of Data Science Strategy is part of the Office of the Director. We work with all the different 27 institutes and centers at NIH, and we think about the entire waterfront of the NIH mission space. And that mission space is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, length in life, and reduce illness and disability. We are a basic research arm for HHS. We have discovered that NIH supports very data rich research. Our research creates and consumes large amounts of data. We have a relatively long and established culture of data science at NIH, which has laid the foundations for this intense interest and I would say productivity around artificial intelligence. I am going to tell you about a handful of investments that NIH is making in AI. And I think these will elucidate a few key observations.

The first is that AI has enormous potential to advance the NIH and HHS missions. In addition to data and AI tools, AI models are increasingly shared and re-used commodities. That means by the time a model hits the biomedical research space, a lot of the characteristics of this behavior might already built in. In

particular, any biases or potential behavior with respect to some of the things that we would consider to be ethical concerns might already be baked in. What that means is that we cannot really afford to be just consumers of those models. We really have to be in on the development path and co-innovating some of those models. NIH is moving from being a consumer of AI capabilities to being a co-innovator of those capabilities in a very multidisciplinary context. As was mentioned, I think some of the open research questions are impeding progress in AI. Those include some of the open research questions around AI assessment, human and AI interactions and trust. And we look forward to partnering with other agencies in addressing that gap.

And finally, the infrastructure that is needed for AI is huge and probably beyond the scope of any single agency. We are continuing to partner with the private sector and with our other agencies and activities like the National AI Research Resource to try to enhance the capabilities that are available to our researchers and to influence our mission. It is impossible for me to give you an adequate sampling of all the different AI activities happening across NIH. Let me just pique your interest with a couple of notes. One is that there are uses of AI in precision health to understand how people respond to food and to different dietary patterns to really influence our understanding of metabolic health. There is AI that is being leveraged to identify genetic variance that are contributing to Alzheimer's disease to help understand prevention and cure. AI is being used to help rapid diagnosis of autism spectrum disorders and other rare childhood diseases where time is really of the essence.

We also have developing precision oncology in areas where we are partnering with the Department of Energy. And then finally, AI is being leveraged for clinical images for the evaluation of macular degeneration and other retinal diseases. We have a wide variety of areas in which artificial intelligence is being used to accelerate discovery, being used to open up new potential avenues of investigation, all of the above. I am going to highlight just a couple of crosscutting activities across NIH flagship initiatives that we have in artificial intelligence. The first one is our Bridge to AI program. This program is focused on a handful of about four grand challenge problems. What this program is doing is it is creating data generation projects. These projects are looking, not just at what data is needed to test a certain hypothesis or what data is needed to power a particular study, but rather all of the data streams and metadata that is needed to characterize this large complex system thereby creating a broadly reusable and AI ready data resource.

We also have our AIM-AHEAD program, the Artificial Intelligence and Machine Learning Consortium to Advance Health Equity. This is supporting a consortium of projects that use or develop artificial intelligence algorithms to help address health disparities and improve health outcomes in underrepresented and underserved communities. This is our flagship initiative at the intersection of AI and health equity. And the goal is to ensure that the benefits of AI are shared equitably across populations. Our National Institutes of Minority Health and Health Disparities has the Science Collaborative for Health Disparities and Artificial intelligence bias REduction (ScHARe). It is a cloud platform that hosts social determinants of health and AI ready data as a resource to test biased mitigation strategies and to use AI to advance health equity. We have our newly launched program in advancing health research through ethical multimodal AI. This initiative aims to develop ethically focused, and data driven multimodal AI approaches.

Bringing in multiple modalities of data, we hope to more closely model and interpret and predict complex biological and behavioral systems. And this is really an opportunity for experts from ethics and social sciences, biomedical research, and quantitative research areas like computer science, statistics, applied

mathematics, and AI to collaboratively innovate new capabilities of multimodal AI. NIH is also a partner in the Interagency National AI Research Resource, now in its pilot phase. This program aims to connect US researchers and educators to computational data and training resources needed to advance AI research. They have a number of different components. NIH has contributed with our data resources and our analysis platforms. We are also co-leading with the Department of Energy, the secure component of the National Artificial Intelligence Research Resource (NAIRR), which will be focused on providing these NAIRR capabilities with data that are either controlled access or sensitive in some way.

And finally, I want to mention a workshop that we held earlier in January of this year on transparency for data and AI model re-use. This is a first step towards developing an ethical framework for AI in biomedical and behavioral research. I see that Maia Hightower is going to speak with you later and she was one of the key components of this workshop. A common theme from this workshop, and I think it speaks to Dr. Embí's diagram from earlier, a common theme from this workshop is the need to tool up that entire cycle and that entire path from the research planning to the dated generation to the model deployment and post model deployment assessment with technical tools, but also practices that help researchers and end-users make more informed, responsible, and ethical decisions about how to re-use data and models. With that, I will be happy to take questions later on. Thank you.

Sarah DeSilvey
Thank you, Laura. It is my honor to now introduce our next panelist on this panel, Troy Tazbaz, the Director of Digital Health at the FDA.

Medell Briggs-Malonson
Troy, microphone. Thank you.

Troy Tazbaz
I will spend a little bit of time talking about what The Digital Health Center of Excellence (DHCoE) is at FDA. I am Troy Tazbaz. I am the director for DHCoE as we use that as an acronym. If I knew I was just going to be the entertainment for today, I probably would have dressed slightly differently as well. DHCoE is made up of four divisions. We have clinical staff that is working on clinical integration looking at emerging technologies and how we are going to integrate this into the practice itself. We have a technology team that works on evaluation frameworks for new types of emerging technologies that are coming into FDA for evaluation and authorization. We have a partnership team that invests heavily in our public/private partnerships that we have to establish given the fact that these are very complex topics. And we believe that it is going to be solved at the ecosystem level, not with individual either agencies, federal government, or the industry alone.

Finally, we have a policy division that is coming up with the policies that you all see coming out of FDA that are specific to emerging technologies such as software as a medical device, but also artificial intelligence types of guidances, such as predetermined change control plan that we published last year, the draft guidance. And this year, we will publish the final guidance, including what we have already published around draft guidance on artificial intelligence lifecycle management, which is something that I think we are all very interested in talking about today. On the Executive Order, and I know this discussion started with the Executive Order and the HHS task force, and I have been part of the task force with Micky and a few

other people who are actually in the room as well. What we wanted to hone in on with that task force is the concept from the FDA perspective, the concept of assurance.

I know Peter started this entire discussion with a very important part of what we are all trying to accomplish here, which is how do we assure the different constituencies that are going to be leveraging AI and benefiting from AI across the entire lifecycle? From our point of view, assurance really starts from the beginning stages of the development to how you integrate this, how you deploy it, all the way into how you monitor this. And Peter touched on the complexity of monitoring. And the analogy always talk about is that we have to start moving from this being a data science initiative using artificial intelligence, especially applied to some critical areas like healthcare, to more of an enterprise driven operations. Hospital systems, developer community have to start thinking about this thing from the context of lifecycle management. The assurance standard, at least that was one key component of the Executive Order that Micky and I have been leading in trying to respond to is really a set of a combination of best practices that are what I call suite of best practices that really the industry has to develop. And we are part of that ecosystem, as well as the policies that we have to design to enable this. When I joined FDA, I came in with four guiding principles.

One is we have to take advantage of government as a whole dealing with this issue with artificial intelligence. The intellectual muscle, the resources, when combined if you remove some of the siloed nature of operation, can be very beneficial. And luckily, Micky and I shared that perspective and approach. And we have been working very closely with ONC on trying to address these very key and complex issues. The second part is we have to make a lot of investment in public/private partnerships. This is not going to be done alone by the government. It cannot be done alone by the government itself. The third piece of guiding principle we came up with as part of the Office of DHCoE is we have to enable the innovation with parameters. This is an interesting topic because I am from Silicon Valley, so a lot of people thought I was going to share the same principles of a lot of Silicon Valley, which is move fast and break things. I did work for a very large corporation prior to coming FDA, and that is not how it works when you are dealing with very critical and highly regulated industries.

What we wanted to focus on was how do we enable these safeguards? How do we enable this parameter that people can actually innovate within? And I always say there is not a single industry that I am aware of that does not have safeguards, whether it is flying to the moon or flying in general or driving a vehicle.

I am not sure why we were thinking very differently in healthcare, especially something as critical as healthcare. The final piece that I will cover, and I think both Laura and Peter covered this as well, is that we have to invest in infrastructure. What I mean by that is that is essentially the safeguards. You have to build understanding the infrastructure that you are going to build on. What has happened with the excitement, particularly with generative AI, is we immediately went to work and reapply this instead of what problem are we trying to solve? As a federal agency, we are trying to influence the industry to start with let us solve these safeguard issues, let us solve the monitoring issues before we immediately dive into the application of it. Those are the four guiding principles that we have. And I look forward to having this conversation. I apologize I did not prepare much more of a prepared statement here. I look forward to the questions.

Sarah DeSilvey
We look forward to that, too. I have two more panelists to introduce. I am now introducing John Brownstein, Chief Innovation Officer at Boston Children's Hospital. Welcome, John.

John Brownstein

Thanks so much. It is a pleasure to be here among such amazing giants in AI and IT. What I am going to do is tell you a little about some of the work we are involved in bringing AI to the bedside, bringing AI into our health system. I am the Chief Innovation Officer. Like Peter, part of my responsibility is the AI strategy, selecting our use cases, building against our division around AI. I will tell you a little bit about how we are tackling that in the pediatric institution. You can imagine the amount of excitement and enthusiasm that exists across the organization. Trying to find a way to prioritize quality and safety when sourcing AI is a bit of an undertaking, especially when you have the wide range of our employee base looking to bring small-scale innovation with high impact, low risk use cases, while at the same time trying to drive change with enterprise-wide efforts.

Our group, among others at the institution, are trying to source these pain points, both large and small, and trying to bring together a shared set of prioritization and evaluation efforts. You can imagine risk levels, considerations around the impact, model accuracy, implications for patient care, data privacy and compliance, and making sure we are adherent to privacy norms and compliance metrics, and we will hear about this later today, equity, diversity, and inclusion. Considerations around access and equity, especially as we implement these tools. Of course, there are other measures like return on investment (ROI) and implementation ease and the workflow management. All of this is built into our ability to filter through all of the amazing numbers of high impact use cases that are coming our way. From an enterprise lens, of course, we have actually built an enterprise-wide chat GPD that is now available to our employee base.

About 10% of our employees are accessing and using the chat GPT internally, a Health Insurance Portability and Accountability Act (HIPAA) compliant version. We have modernized our data infrastructure with access to LOMs. And, of course, like many organizations here, we have used ambient listening as a tool to improve clinical documentation while at the same time building against low risk, high value, smaller scale efforts like medical education, accessing our clinical policies and guidelines, and, in fact, developing machine learning (ML) tools to support capacity management. As you know, during the triple demic, pediatric institutions were faced with extreme amounts of capacity constraints so using AI tools to predict bed capacity was a big priority for us as well. We have been very lucky in the sense that we have a data infrastructure that is been already put into place at the hospital.

Establishing standard protocols and guidelines for AI governance and limitation and use is actually now adjacent to our existing infrastructure for data and analytics steering committee, which is really in charge of building the strategy for the use of data. That was already put into place a couple years before the wild craziness around LOMs. And our AI efforts now sit against that. We have a data governance council that is in charge of building the policy and the framework for how we implement AI. And underneath that, we have analytics implementation unit, which is in charge of bringing these tools to the bedside. Our innovation group does the work of sourcing and use case prioritization and enterprise education, while IT is responsible for Application Programming Interface (API) access, machine learning operations (ML Ops) and, of course, all the informatics work. And the elements that guide implementation are developing usage guidelines and education.

We are spending a huge amount of time educating our staff on the responsible use of these tools. Of course, ensuring data privacy and compliance. And building research and validation tools, and I will mention that in

the next slide. Ongoing measurement of accuracy of efficacy of AI tools and the involvement of the institutional review board (IRB) where relevant. And, of course, making sure that all of the tools we are bringing have a human in the loop. I am sure that will come up over and over again. Making sure there is human oversight and approval of these tools as they come to either clinical decision-making, and especially as they reach patients. Finally, and I think this is very much aligned with Peter's leadership here, thinking about the ongoing monitoring and evaluation of our AI efforts. That is critical. This is not just set it and forget it. Making sure that our efforts are aligning with regulatory standards.

And making sure that we are reviewing all output for accuracy, appropriateness, constantly evaluating our large language model performance. Making sure these are the right models in place. Making sure they are best in class. And this is where I think Troy's mention assurance labs is critical because for us, we are going to be looking to those labs to understand which models we want to bring into our own environment. And of course, establishing metrics to evaluate overall initiative success and efficacy. While we have a lot of that infrastructure in place, like many health systems, we cannot do this alone. We are looking to our technology and industry policy partnerships. And I am sure Commission for Healthcare Audit and Inspection (CHAI) will come up later today. That is a big part. And we are one of the founding members of that. As well, the new effort from Microsoft Train, which will help us evaluate our models in our own environment. Assurance labs are necessary but not sufficient.

We are going to want to make sure we are evaluating accurately in our own environment, taking advantage of the tools from Epic and open AI as well as part of our partnership. I ran through that quickly but look forward to questions. Thank you so much.

Sarah DeSilvey
Thank you so much, John. We do have time for questions at the end. It is my honor to introduce our last panelist on the panel, Gil Alterovitz, Director and Chief Artificial Intelligence Officer at the National Artificial Intelligence Institute at the VHA. Welcome, Gil.

Gil Alterovitz
Hello. It is great to see a lot of familiar faces both in the room and in the panel online. I wish I could have been there in person today. And it is great to have a chance to talk to all at least virtually. I will be talking today about the AI in healthcare at the United States Department of Veterans Affairs (VA) and our emphasis on trustworthy AI and safety towards those elements that are part of this panel. I will walk you through these three different ways that we have been looking at enabling, essentially, trustworthy AI, including its components of the quality and safety. Depending on which avenue there is, whether it be research and development, whether it be operational use cases, we have different pathways that we have been exploring. On the research and development side, we have been piloting these research and development (R&D) committees that get people to think about asking the right questions. Rather than inventing a new IRB process, we contribute this module that gets the committees to think about the right questions to ask about AI from the very beginning.

On the other hand, for operational use cases, we have been piloting the AI Oversight Committees. And we have these for medical centers currently that are part of the National Artificial Intelligence Institute at the VA that was mentioned at the very beginning here. And so, what happens here is that there are these policies that are based on national policies, federal policies, executive orders, and guidances that allow the

medical centers to really look at different parts of AI that relate to either quality improvement, contracting procurement and so forth for executive order and other guidances that we have adopted. That includes something that was just mentioned by Dr. John Brownstein just a second ago, these voluntary commitments, which includes the ONC's fair, appropriate, valid, effective, and safe (FAVES) principles. At the Veteran's Health Administration, we have adopted a line to those principles as well. That includes, as part of the voluntary commitments that were made several months ago by a number of different health systems.

The model cards are really around enabling transparency. The thought here is that, depending on how an AI system is used, may influence, essentially, this safety and quality. Essentially, it is important to communicate the types of data that was used for training in some cases. And in other cases, to inform patients of how it is being used. There are different audiences that need to receive different types of information of how the AI is being used, how it was constructed and so forth. We have been working on creating guidances that are tailored towards the audience that we have in mind for these different applications, whether it be patients, providers, caregivers, and so forth. And yes, we can share the slides. I think I see a chat and I am happy to share the slides. There are also papers and things we can refer to.

The AI text prints are one area where the VA specifically called out in an executive order that came out in October on enabling safe, secure, and trustworthy AI focusing on as an executive order the federal government. And it called out the VA to have these AI text prints, which are, basically, a three-month engagement whereby organizations work together with us around special use cases. At the end of the day, there are prizes, basically, that are awarded as part of this competition. The fact that we had this national competition then can be leveraged toward potentially awarding contracts to, obviously, a subset of organizations that participate and were potentially recognized in the prize part of this. This year, we have as part of this executive order, two of these all focused on healthcare worker burnout. One is around ambient dictation. And the idea here is to really go from capturing those conversations to the medical documentation.

And the other one is more around community care records. Veterans have the ability to go to the community and then, they may come back to the VA. And how do you get information into an AI ready format that can be used for their care when they are back? The VA is the largest integrated healthcare system in the US but there are different programs where they can go and get that care. What is interesting is we have also signed up to an interoperability pledge, which involves leveraging FHIR to communicate also between these systems that has been piloted. There is a number of potential synergies in terms of AI interoperability and how we can process these types of information. We have a couple of hundred organizations that have been participating in these. They are now going through the process. And we will look forward toward announcing the results of that in a couple of months. We have had a lot of interest from other organizations to see what are the winners, what are the approaches that we have leveraged to look at these use cases so that others might benefit from that as well as people look towards assuring quality and safety.

We developed a number of mini AI assurance lab type of procedure with our SimVET environment, which is, essentially, an instance of a couple of different medical records, the Cerner and the Vista environments so that we can test these for these different principles in an actual AI assurance lab type setting. We are looking to learn from that and share lessons and learn from others about that. Thank you very much. I will

go to the final slide. We do have an AI network where we have been building this. It is expanding and it has grown at this time. So, looking forward if there any thoughts and move on to the rest of the panel. Thanks.

Sarah DeSilvey
Thank you so much. I want to thank all five of the esteemed expert panelists for presenting the initial groundbreaking work that they are doing. And that gives us time as HITAC members to ask questions of these esteemed experts. ONC has intentionally left a good bit of time for us to engage with these experts and address any questions that you may have. Again, raise your sign if you want to be recognized and we are also going to try to make sure we recognize individuals in the chat. Thank you all. And I think Lee, you might have been the first HITAC member.

Lee Fleisher
Thank you. This is fantastic. I have almost a philosophical question, which is AI will reduce noise. We worry about bias. But the question is humans' ability to interact with all these algorithms is what I am most concerned about. How are the different groups thinking about it? Or is that even the instructions for use so to speak to ensure that once it is approved through some governance process that it is actually used in the correct way? As I said, it is a philosophical question, but I have significant concerns. We are focused so much on making sure that the algorithm does not have bias. But realistically, one of the nice things about humans is that they have so much noise, good or bad, that now what we are doing now is we are taking away and anchoring on a number, as opposed to a range of the way clinicians make decisions. That may complicate how we push this out and how we display it may be as important as people use the information.

Peter Embí
I am happy to jump in and speak to that first perhaps. I am very interested in what my colleagues think. That is a great question and I think you are right. It is part of why as we are approaching this, we are approaching it importantly with humility and recognizing that no matter how well our algorithms perform in a lab setting or in a controlled setting, when you actually put them into the real world, if you can anticipate anything, it is the unanticipated and you have to watch for that. I think part of this reason for this push to ensure that we do as much testing as we can ahead of time and we try to adjust as much as we can, and we do testing on our select populations, if we move an algorithm from one place to another. Let me be more concrete. If we were to deploy a predictive algorithm on one floor of the Vanderbilt University Medical Center and move it to a different floor, it might perform differently because it is not just about how the algorithm performs, especially when interacts with people. It is also about where it is in the workflow and how people interact with it and, to your point, the human computer interface issues, and various other parameters.

I think all the more reason why we have to ensure that we are doing as much monitoring as we can and that we are looking at, not only process measures, but also outcome measures to ensure that we are not causing harm unintentionally and we are, in fact, seeing the benefit and that we are adjusting as we need to. That would be at least the beginning of an answer to your thought-provoking question. Thank you.

John Brownstein
I will just chime in. I totally agree with what Peter is saying. Of course, the amazing work that is going on around assurance labs and model validation, that is only part of the story. And I see Aaron's comment in the chat as well. That is part of it but the workflow management and change management that is required to bring these tools into our own interface, obviously, working with our EHR vendors or others, that is going

to be truthfully the bulk of the work. I think about what it took to bring in ambient listening. We have an implementation of Dragon Ambient eXperience (DAX), the work that is taken around patient consent and provider education and creating a whole new workflow. Yes, ultimately, these tools are saving a huge amount of time and giving clinicians time back. But there is a lot of learning that is required and a change in workflow that is necessary in order to bring these tools and to understand how they are supposed to operate. That is where almost all of our resources are going into, which is the education and workflow management side of the equation.

Sarah DeSilvey
Thank you so much. We have about 10 HITAC members who have questions for this panel. For the sake of trying to be as inclusive as possible, referencing Medell's original housekeeping elements, we will try to quickly move along. And if additional panelists want to respond to questions, if they can do so in the chat that would be appreciate. The next question comes from Medell.

Medell Briggs-Malonson
Thank you so much for this amazing panel. And I am going to be very brief as well. I do want to echo my colleague's sentiments of what was just discussed and especially looking at outcomes. When it definitely does come to populations that have been underrepresented in all of our data models as we know, as well as populations in which we do not know the impact on them. And I think Ike mentioned those with rare conditions. That is really important. I want to shift us to a different topic, and I spoke a little bit to Troy about this and Micky about this, but I would love to hear any of your comments. That is really related to accessibility. When I say accessibility, I am referring to accessibility of ethical as well as equitable AI models in our more under resourced communities, as well as our under resourced providers.

As we are thinking about all the various different forms of assurance labs and other types of mechanisms, where do we think we need to go as an industry in order to ensure that more of our under resourced providers are not left behind? We already see the gap. And what my primary concern is, is that we will widen that gap unless we start building the infrastructure as many of you all have mentioned, but that it gets to those areas that absolutely need it in order to have appropriate diagnostics treatment, admin efficiency. I just wanted to see if there are any thoughts about how do we ensure that we do not leave anyone behind as we are building out all of these various different technologies?

Troy Tazbaz
I guess I could start this one. It is a highly nuanced issue here because I think when we talk about biased considerations and equitability, we are always referring to the data itself. But what we are also not talking about is how do we actually ensure that these products get integrated into places that need them the most? A perfect example is what John, Gil, and Peter just presented was how complex it is. Those are three institutions that have the resources to be able to effectively address this issue. And they are still struggling with trying to figure out how do we actually assure these things are going to be operating as is. The fundamental problem is not just the data aspect of it and how you train the models, but it is also to understand how do you actually reduce the complexity of integrating these things into healthcare delivery? Recently Mark and I talked about this. And I always refer back to the natural occurrence of what happened with technology over the last 30 years.

I started about 30 years ago and I was developing my own monitoring tools and observability. All the sudden, slowly the industry took over and said it is actually business. Now, when you buy an enterprise grade application, a lot of that governance is already built into the product itself. Where we are with the current capabilities is that we purely only focused on the capabilities and not necessarily all of the governance that you have to include in what I would determine to be an enterprise grade application like an EHR. Two things really have to happen. One is I recently read World Economic Forum did something like 97% if all healthcare data is never really accessed. And it generates about 30% of all the data. If you adjusted the data itself and we do not leverage it, but that means we also have to educate all of the different populations to say why it is important for technology providers to have access so they can train the models.

Then, you have to really accelerate this natural organic development of how applications get developed and deployed into these critical systems, healthcare delivery organizations. I would answer it kind of in that lens, not just necessarily to access data but also, reducing some of the complexity of being able to leverage these tools.

Sarah DeSilvey
Thank you so much. The next HITAC member with the question is Anna.

Anna McCollister
This is Anna McCollister, which I will state for the record or whoever. I think that was one of the rules, was it not? Am I following the rules? I am not good at that.

Medell Briggs-Malonson
You are the first one to follow that rule.

Anna McCollister
Thank you. That is not my forte. I have a number of concerns, as do all of us. As somebody whose primary hat that I wear in this committee and a few other places is as a patient, I am incredibly excited about the potential AI. I live with a continuous glucose monitor on me 24/7. As those algorithms become more sophisticated, my glucose control has become much easier. So, I see that sort of an "AI" as being amazing. I met somebody recently who has a voice detection AI tool that is just as accurate as the Patient Health Questionnaire-9 (PHQ-9) for accessing states of depression. That to me is incredible, the potential for those kinds of applications that are I am sure flooding your door at FDA. My concern as somebody who lives with complex chronic disease, takes 20 meds, has 16 doctors, I generate a lot of data in the healthcare system. I have seen a lot of that data and most of it is complete crap to be honest. When I think about the idea of that data, which I know pretty well and I have got great providers, it is probably pretty clean compared to most peoples'.

When I think about that data being used to train models that might potentially be put behind a black box to inform or determine, more likely, clinical options and activities, it is kind of frightening, particularly when I think about all of the effort that it has taken as a patient just to get people to think beyond the analog algorithms that we use around clinical decision making such as the overuse, in my opinion, of hemoglobin A1c as a biomarker. If it is so difficult to change clinical guidelines that are analog, what is that going to look like when that stuff gets calcified and put behind a black box based off clinical data that maybe is not all that precise, maybe does not consider ethnic differences, age differences, etc.? As we think as a committee

and advise ONC and other agencies about how to think about what data should be in scope and what the benefits are, I am highly concerned about the use of clinical data and electronic health derived data combined with AI, unless there are lots of points along the way where people can pick holes and identify issues.

Prior to this meeting, I sent little texts to a number of my friends who are smarter about these things than I. Has anyone seen any examples of any EHR databased AI that has actually provided something that is A) remotely accurate or B) useful except for the use of it as a way of excluding people from access to things? Nobody had an example of anything that was not either laughably inaccurate or somehow diabolically evil. From the perspective of a patient, there are some well-known cases of insurance companies using AI to exclude people and make it more difficult for them to access benefits. That is my concern. Speaking in a very high level, which you have to do in a meeting like this across so many different federal agencies, it is interesting. But the devil is in so many details. And I am concerned and I hope that as we think through governance structures that there are lots of points along the way where a diverse group of people can pick holes in a process because we all have our blind spots. And well intensions do not get rid of blind spots. We need multiple perspectives at multiple points along the way identifying what might work and what might not. That is my biggest concern broadly speaking is how do we, as an advisory committee, work with HHS or FDA and all of these agencies and the brilliant people in academic institutions to make this better and reasonable without being so burdensome that it slows down and stops it from happening? I suppose that is more of a speech than a question. My apologies. I think I did just break that rule.

Sarah DeSilvey
Do one of the panelists want to lean into Anna's observation, especially honoring her patient perspective?

Peter Embí
I would be happy to stay a couple of words. Thank you for all that. I think it goes back to really keeping that perspective front of mind as we are doing all this work and making sure that we are sort of humble in the face of what we are doing here. I actually agree with most of what you said. I will say there are examples, and forgive me for the sirens in the background, that I am aware of effective clinical benefit. A lot of them remain relatively small use cases I would say. There are certainly some that have made their way all the way to certified AI solutions. But a lot of them, just far too many, are still in the testing phase. I think that is really one of the things that we do need to lean into. I would say for the sake of this committee, and it is not an unenviable task but a very important one, walking that line between making sure we have enough regulation and enough guidance to be able to make sure that we have the guardrails to do this properly but not get too far ahead of where we are in terms of still figuring out how to do the very things you are asking for.

And we need to put a lot of time and attention into making sure we do this equitably and that we do this in a way that is going to address the issues. And that is going to require more study and more actual demonstrations in the real world to show the benefit that you are talking about.

Sarah DeSilvey
Thank you, Peter. We have a few more HITAC members who have questions. I am now moving to one of the members, my colleague on the IS WG, Ike.

Steven Eichner
Thank you so much. Thank you all for presenting today. How do we import policy foundation and import technology foundations, can we put in place with AI to ensure that the needs and interests of individuals with rare conditions and populations of individuals with rare conditions are adequately addressed and protected by AI thinking about groups of folks, 500, 600 or so people nationwide with a particular condition adopting and utilizing AI that recognizes the existence of those conditions so that it is not recommending something that would be contraindicated for that patient population?

John Brownstein
That is a great opportunity of AI, of course, from the perspective of it as a copilot in clinical decision making because it will have access to broader range of insights where local knowledge may not have all insights about the rarest of conditions. I will mention Boston Children's. We specialize in rare and complex. A lot of our development is focused on this particular domain. We spend a lot of time around the online second opinion program. By augmenting those efforts with AI, we can actually democratize more access to the ability to help support identification of rare conditions on diagnostic odysseys. That for us is a priority as opposed to a secondary thought around where we might place our efforts. From our perspective, anyone in the world that may have some combination of phenotype that is on the diagnostic odyssey can use our phenotyping tools that are sort of AI-driven with clinical decision making to help support them on that journey. I know it is not exactly what you are saying, but there are plenty of places where AI can help support leadership in the rare disease space.

Steven Eichner
Obviously, there is a lot of potential in AI. My question is focused on looking at what policy positions or what policy foundations can we adopt to support that on the technology side so that it is an included base factor in consideration in technology development, not an afterthought or we got lucky we included it.

Laura Biven
I can chime in a little bit in saying that I do not think we have a solution to your question. But one of the ways we are thinking about it is through this lens of transparency to try and give as much information as possible to the people making who would be making the decisions about whether an AI tool is appropriate for a particular patient or a particular population. Hidden in the question are both biological uncertainties as well as uncertainties around artificial intelligence and the way that information is absorbed into that tool. I think it is a complex question. And what we are trying to do right now at least is to try and start making the research community and the sort of basic research part of that development chain part of the solution as opposed to part of the problem by trying to shed light on all of the different attributes that go into a model in the end so that we can start focusing on biology as opposed to the AI tool.

Sarah DeSilvey
Thank you, Laura. I want to appreciate that HITAC members are also putting their comments in the chat and panelists are engaging in those comments in the chat as well. Thank you for the panelists for being so receptive. Our next HITAC member with a question in order is Michael.

Michael Chiang
Thanks. Great presentations. I have a question in the chat box, but I am going to ask a different one about the data that is used for AI algorithms. John, your slide mentioned data privacy and that Boston Children's

was making policy to ensure confidentiality. My question is should these decisions be made institution by institution. What I see is that there is sometimes a fair amount of inconsistency and definitely reinventing the wheel at each institution. What constitutes deidentified data? What requires patient consent? I am concerned that different world-class institutions sometimes come up with opposite answers for that. And it is especially becoming tough that deidentified medical data are sometimes now being sold to industry. My question for the panel is do you feel that there is more that should be done in government to develop more clear rules about privacy and deidentification than applied globally without sort of doing this institution by institution? I would love your perspective on that.

John Brownstein
Quickly, I will say, of course, we had to figure out a lot of this ourselves because some of the tools we are building are in some ways first out of the gate, which means you have to figure this out. At the same time, we are sharing best practices. I made mention of the AI commitments of the White House and the network of volunteer organizations that have come together to share the best practices. And, of course, that is happening with CHAI and others. The hope is there is going to be some commonality in approaches and actually learning from one another rather than having to do this ourselves. We are having to educate our employee base because we let an AI tool like ChatGPT become available to anyone who wants it, understanding what is allowable on the internal tool versus external tool. That was what I was referring to. My reference is relying on networks of organizations that were aligned in our approach around data privacy. I am sorry. I do now know who I cut off there.

Sarah DeSilvey
Thank you. For the sake of time, if other panelists have responses to the question as posed, if they could do so and put their responses in the chat. We do want to make sure we get to as many HITAC questions as possible. The next HITAC member with a question is Rochelle.

Rochelle Prosser
Thank you, everyone. Rochelle Prosser. I have a few other questions that were highlighted by Michael. Thank you so much for bringing that up. But I really welcome you to put a response from the panelists to these specific questions. As a clinician and a healthcare provider and a caregiver, patient privacy and certain state laws prevent the use of ambient recording. I noticed that you had not addressed that from that perspective. But that should be called out. And then, also in certain facilities, there is no bidirectional ambient recording allowed because patients are not routinely allowed to record when they interact with clinicians and providers. But yet, we are doing ambient recording of what they are saying. What becomes the source of truth in that statement? How is that used? And understanding that different populations express themselves differently and use different words in terms of mental health crisis in crisis moments? How are we training this tool to identify and take that into account?

As we have seen in the general public, when these are not taken into account, it becomes punitive on certain populations. And I just want to make sure that we are not building machine learning to become punitive in the healthcare space. Can you address that?

Sarah DeSilvey
I heard three questions in there. Is it okay if we focus on just one?

Rochelle Prosser
It would be the last one. How are we making sure we are not building NOP to become punitive based on population differences?

Troy Tazbaz
I can maybe answer this. This is Troy for the record. By the way, that is a very difficult question because we have to assume that people to build products punitively, which I am not sure that is the case. Here is how I would probably answer that question. Generally speaking, what I have seen so far is people get access the data and then, they go build a product. That is a fundamentally wrong way of doing it. That right there is the first introduction of bias. So, the question that we should be answering or asking, first of all, is what are we trying to address? What problem are we trying to solve? And then, going and trying to acquire data that allows you to solve those problems. And this is a very complex product design considerations that you have to use. You have to look at things like is my intended population X versus Y?

If that is the case, then how do I ensure that the data that I am using to train these models are representing that population? There is this unfortunate fundamental issue within the current healthcare systems that data is so siloed at this point that data acquisition becomes your fundamental starting point instead of actually trying to truly address what the problem that you are trying to go after is. I want to make sure that this is not an FDA perspective but more my perspective. We are trying to accelerate the adoption of this because it is exciting. And I think that is where maybe the problem starts, which is there is also a misunderstanding of what the total addressable market is in this industry. People see the $4.5 trillion dollars that we spend, and a lot of developers think that is a very large market, 37ut that is not the case. All you have to do is break down where dollars are being spent. Then, you realize that the IT part of that equation is a quite smaller number.

I think that there is this educational issue across some of the folks who are actually building these products for industries that they do not necessarily understand what the problems are. And I think that as an industry, again, I view government as a government agency that is focused on healthcare regulation, I believe it is our responsibility to invest heavily into the educational aspect of it. We are trying to build programs that are directly catered to developers who do not have 50 regulatory affairs folks working in their company. We are trying to be able to address these things, ask the questions around are you thinking about your product development lifecycle in a certain way? What problem are you trying to address? How are you going about this? What questions are you asking? What data are you collecting? I think that is where the investment has to happen.

But on also the population side, there has to be an investment because you do touch on that investment of why it is important to make sure that your data is part of that representative data population that gets used. And that is also something that I do not believe that the government is ever going to resolve. And I think that has to be done more at the community level. But we have to work across the ecosystem to come up with a very common educational material that actually makes it consistent around why this is necessary.

Sarah DeSilvey
Thank you so much. We are running short on time for this incredibly important panel with all of these wise voices. Naresh.

Naresh Sundar Rajan
That is a great presentation. Thank you, all the panelists, for bringing in your expertise. The question that I have is very foundational. We all can agree that trust on AI can come into play depending on the quality of the data underneath. A question to panelists might be more along the lines of what are the initiators that you have to go through initially to understand the use cases aligned to the quality data? That seems to be the biggest problem that we have. And at the point of collection, or the producers of the data, it is not always the same. It is not always complete and cohesive to the point of AI models. An example is quality has multiple dimensions, completeness, accuracy, trust, comparison. So, when the dimensions change, your scores are going to be drastically different. And the way the models are built and developed is not just picking the data to put into the model specific approaches but also to the point of understanding the foundational quality of the data whether it is fit for the model. Were there any initiatives or were there any methods that you had to follow? I just would like to know.

Peter Embí
I will just quickly say that I think this is a problem that has existed before AI in terms of the reuse of data that are being collected primarily for clinical care purposes where inconsistency and variability has been tolerated because when it comes to taking care of one patient at a time, it is satisfactory. Even though it is not optimal, it is satisfactory. When it comes to the kinds of things that we are trying to do now, I think you are exactly right. It definitely becomes evident in terms of all of the use cases that you have discussed. And while we have ways of trying to address it, I do not think there is any doubt that as we increasingly realize that we need to use data for these purposes to be able to train these models to be able to deploy them actually have them work, we need to really start thinking more deliberately about going upstream and really thinking about the ways in which we are collecting data for the purposes in mind that go beyond the traditional ones of individualized patient care at the moment and billing capture and what have you.

I think that is a really critical exercise that needs to be engaged in. And I do not think we can put enough effort into that.

Sarah DeSilvey
Think you so much. Eliel?

Eliel Oliveira
Eliel Oliveira with Harvard Pilgrim. I mention that also to say that one of the things we do is we house the FDA's Sentinel surveillance program for post-market surveillance of drugs. I am thinking about this problem the same way on the drug development side from the beginning in a lab and all of the clinical trial phases until market surveillance. And when I think about the lab that is testing a new compound, they are usually getting their oxygen or any other material from a source that already has some certification in place to produce that, whether it is pure water or hydrogen or whatnot to test the proteins. Even instruments are certified by somebody to be utilized. And on the final end, we have a separation between drugs that need to be approved by the FDA. But we have a series of things that do not all like vitamins. Following on that category, individuals can take it to market very easily.

I think along the lines of the points that folks were saying earlier here related to data quality and how it is produced, it seems to me that a basic aspect here is just in determining or certifying the creation of data sources that can then be utilized by researchers and scientists. We do a lot of that at the Harvard Pilgrim

as well. But as you all know, it is so hard to get hold of data. There are so many legal agreements. But if the resources were available in some standardized fashion, even synthetic data, which is highly available these days that could be utilized but also validated that the results are reproducible would be of tremendous value to just advance the development of new solutions. And then, on the other end, some definition of what is okay to just produce and use on AI today without any oversight? And what needs to be looked at more carefully that can affect somebody's life? Anyway, I think if there is a question, that is to just say if you know of resources that are not going to define those key aspects? To me, I think we are both talking about the beginning and the end of the utilization of AI models. Thank you.

Troy Tazbaz
First, as government, we do not use the word surveillance. We use post-market performance monitoring. It is much cleaner. Do you know what has been interesting? I think all of the questions are highlighting how complex this issue is and to a degree, how rich of an environment it is to go fix things. To your point about assurance, this is a really hard question to answer. Whether government should be responsible for creating those repositories of clean data versus the industry, that is a philosophical issue. And unless we completely change the healthcare system to be a single payer system I think we are going to have to deal with what we do have. What I can tell you is that in my previous life, I did a study on if I can aggregate. And I did it for oncology and just to give you the scale of the problem, I wanted to aggregate 3 million patients of oncology patients, just 3 million. There are about 17 million or so living with cancer in the United States right now and about 2.40 million new patients every year. It was something around 5.6 EB of data that I would have to collect and roughly about $1.6 billion in a 5-year operating cost. That is just 3 million patients. Then the question becomes I do not think that anyone can really have the financial capabilities to want to invest in something like this, unless you are just going to create an entire marketplace that you sell data.

I am not sure that is going to fly, which means we have to start thinking less so about data from a protection of this is of value to us, the fact that I just also said 97% of the data does not get used that healthcare generates to actually saying as a healthcare system, is that our value proposition? Is that our intellectual property? Is that how we generate revenue? About your comments on synthetic data, synthetic data has the exact same problems as deidentification as regular data. I think Rochelle talked about this from a deidentification perspective. But we do not have an agreement on even that around what anonymized data means. I think what we are really experiencing today here is that there are just too many problems. And so, I am a fundamentalist when it comes to saying that maybe we need to start with the ones that really have the biggest bang for my buck and go after those. And that means that the healthcare system has to agree on what the biggest bang for your buck projects are and then align on that because we all have different equities that we are going after.

I think that healthcare has to come together and address some of these things. And government, I think Micky has said this quite eloquently and many times I have listened to it, is there to enable that infrastructure. You have said this in the past. Maybe I am probably butchering it a little bit. Nonetheless, it is not to solve all the problems. It is to enable others to be able to solve the problem. And if the system can agree on the types of priorities, then perhaps the government would be able to essentially support those priorities from us addressing them. I guess that is how I would really answer that question. We are trying to solve these issues. We come up with ideas like quality assurance labs. We are trying to enable the industry to be able to provide access to data. But then, you have to actually fix the data models. It is not just about the access. They have to standardize it, too. And I think that is what you are all here to really address.

And some those are all of the critical areas you have to go after, but you have to agree on a set of priorities first. We are probably going to have the same conversation 10 years from now if we do not agree on the those set of priorities. I hate saying that but sometimes you have to be very honest about these issues if you want to address them.

Sarah DeSilvey
Thank you so much. I am so sorry to have to truncate the questions that we have from our HITAC members. We have time for one final question. You can see we went over to allow for our late start. We do have to head into our break. Dan, it is your turn to ask a question.

Dan Riskin
Thank you to the panelists for the great discussion. I am Dan Riskin, and my question is around secondaries of data and appropriateness and how that is evaluated. This will be to the health system representatives. I have had the opportunity over two decades to apply AI and work on projects in both primary and secondary use of data. It is very clear that if done really well, primary use is good. It directly helps the patient. It is less clear in secondary use as has been mentioned here. There are some uses that feel evil. There are certainly some uses that are no-brainers. Outside of healthcare, I would be devastated if I lost access to Google Maps or Amazon search recommendations. I certainly want secondary use of my data and others' data. The question is for the health system representatives. How do we know good from bad? How are you thinking about it and is there any government role in thinking through when secondary use of data is appropriate versus inappropriate?

Sarah DeSilvey
I think that was a direct question for government folks or for health system folks?

Dan Riskin
No. Dr. Embí, Dr. Brownstein. I know, Dr. Alterovitz, that your data infrastructures are spectacular. I have worked with most of your health systems. You have the ability to provide high quality data for secondary uses to understand healthcare and enable many things that will work in a population level. How do you decide when to do that and does the government have any role?

Peter Embí
I will be quick about it, but I see Gil off mute. I think we have various approaches by which we do that and sort of assess fit and quality of data and appropriateness and, frankly, adjust accordingly to use cases in mind. We are often dealing with very messy real-world data when we are trying to do this. And we recognize that. To the extent of the government's role, that is an excellent question. I do not have a ready answer for you, but I will give that more thought. Perhaps Gil has an answer. I saw him come off of mute and I am hoping he does.

Gil Alterovitz
Certainly. Just to say at the VA, we look at the use cases, analyze them, get veteran input as well. I just put a link up in the chat data.va.gov has data sets out there that are open that essentially you could use for other purposes as well. We also do these Cooperative Research and Development Agreements (CRADAs), cooperative research and development agreements, where we may share information in some cases as

well based on certain constraints. We evaluate for different criteria. We have a trustworthy AI framework, which takes all of those executive orders and all of those different pieces together, as well as VA specific regulations like a data ethics framework. That is what we look at to ensure we are both meeting our mission but, at the same time, meeting those challenges. I wish there was an answer like in this case, it works and in this case, it does not. But as technologies change and there are different interactions between different variables, we have to evaluate each case essentially individually to move forward on that.

In terms of overall government approaches, some of you may have heard of there is other work that was announced as part of the executive order around some of these topics. I put a link in the chat if people want to look into that. It is about 100 pages. So, there is a lot of pieces there in terms of what the government is thinking about in terms of processes there. And then, there are congressional bills as well that are in the works. I will stop there.

Sarah DeSilvey
Thank you. Thank you to any panelist who is able to stay over. We apologize for the delay. Our final question comes from Mark. The co-chairs and I want to thank Mark for his help in setting up this panel series. Thank you so much.

Mark Sendak
I promise I will be quick. Troy, I have a quick question for you. We are in the early stages of AI entering healthcare. Obviously, I am grateful to be in touch with you. We have engagement from ONC. I know you are inundated with folks who want to work more directly with you, developers, adopters. Medell's comment about there are folks who are going to be lagging in the adoption. I am just curious. You have a partnerships team. As people reach out to you, how are you prioritizing the types of stakeholders and the collection of perspectives you are trying to proactively engage?

Troy Tazbaz
We do get inundated by a lot of requests. How we have been trying to address this is staying true to our priorities of what we are really trying to go after. And again, I start with that comment of we have to enable infrastructure first. I am consistently seeing how are we enabling infrastructure? How are we enabling any partnerships that are going to help us with that part of that? You have to formulate partnerships based on common goals. That is effectively how we are using that to drive our prioritization as well.

Medell Briggs-Malonson
That is an excellent way to end his hearing about partnerships and common goals in every way. Once again, we want to sincerely thank all of our panelists and your expertise. We want to also thank all of the HITAC members and the public for all of your comments. We are going to now transition into our lunch break. As a reminder, I do not have to say it, but if you leave the room, please have an escort. If you ordered food, food is directly right over here in the kitchenette. And if you are leaving the premises, again, please make sure one of our colleagues are aware. Please be back here because this is one of three amazing panels. Please be back here at 12:50 p.m. Notice I did not say 12:55 p.m. It is 12:50 p.m. so we can start at 12:55 p.m. Thanks, everyone and we will see you soon.

AI Hearing – Panel 2 (02:24:25) (Recording 1)

Building Equity into the 3 D's (Design, Development, and Deployment) of AI in Health and Human Services

Wendy Noboa

Hi, everyone. Welcome back from our lunch break. I hope you had a nice restful hour. We are back for the second part of our day. And I am going to turn it over to our co-chair, Medell Briggs-Malonson to introduce our first panelist.

Medell Briggs-Malonson

Thank you so much, Wendy. And welcome back, everyone, to the HITAC committee. We already had an amazing and very inspirational first panel. And this second panel is also going to be just as amazing and directly intersects with some of my own interests regarding the intersectionality between equity as well as artificial intelligence. One of the key themes that the Office of the National Coordinator has made sure to highlight is health equity by design. As was mentioned earlier by Elise, the new health equity by design concept paper is available and was led by Dr. Tom Mason with his team. But as we are thinking about deploying artificial intelligence across our country ensuring that it does not perpetuate health inequities is key in this process. And ensuring that we are really adopting those equity and justice principles from the idea of the technology so that design, development as well as deployment and ensuring that we are not having any other type of unintended consequences, especially for those that are marginalized, as well as other vulnerable populations.

We have a highly esteemed panel of experts who have been very gracious to come and share their knowledge with us about equity and artificial intelligence. And so, this is building equity into the three Ds, design, development, and deployment of AI in health and human services. And it is my pleasure to introduce all of the various different panelists right before their talks. As a reminder to our panelists, each one of you has five minutes. We will hold all of our questions and answers until the very end and then, I am sure we will engage in some very wonderful conversation. The very first person that I would like to introduce is Rae Walker who is an associate professor in Nursing PhD Program and Director at the University of Massachusetts Amherst. Rae, I will turn it over to you.

Rae Walker

Thank you so much. I am Dr. Rae Walker. I use they/them pronouns and I bring a nursing perspective to this discussion about how to build for equity. In my remarks today, I will add two more terms to the three Ds, maintenance and ongoing evaluation. My views are informed by my experiences as a nurse scientist who builds AI and as a registered nurse for over 16 years. I have worked for the VA and large academic medical centers in urban and rural community care and emergency services. I was introduced to AI in 2010 working triage for tent hospitals set up in the wake of a devastating earthquake. We relied on AI assisted apps to interpret labels on supplies coming in from around the world. However, even with this remarkable technology, mistakes were still made. A clinician using such an app missed a critical part of a label that would have told them the Tylenol they were distributing was also mixed with a narcotic called codeine, accidentally overdosing everyone they saw with opioids.

As the only nurse in our understaffed triage area, I not only detected the error through my assessments, but I became responsible for continuously monitoring and recovering the many patients affected, a scope

of work that vastly exceeded what any single nurse should safely manage on their own. While that disaster was extraordinary, my situation resembled that of so many fellow nurses where often the care workers, most proximal to those we serve, whether that is in a hospital, home, prison, primary care, school, on the street, or in another community setting. When an error occurs, we must take corrective action to address the harm and support those we accompany in care. And this is labor much of which, like so much care work, presently and historically is underrecognized, precarious, often unpaid or underpaid and goes unreported in the EHR.

I have three points today. First, although AI is increasingly invoked as a solution for chronic issues like understaffing that drive both clinical errors and the decimation of our workforce, we must remember that all AI requires human labor in the form of care work much of which remains invisible in our policies, workflows, and EHRs by design. Scholarships documenting histories of care work and tech from experts like Joss Stiller Bright, Virginia Eubanks, MR Hicks is essential reading for policymakers. Second, designing policies that account for the invisible labor of care and repair work associated with maintaining and evaluating AI and its impacts is an equity issue that translates directly to health outcomes, especially for communities marginalized in our current systems. Documented here by data in society introducing AI to clinical workflows often creates profound disruptions and introduces new forms of care work, especially for nurses.

Repair work is what is required to integrate new tech into a complex care setting. COVID has stressed already tenuous care systems to the breaking point. And in some areas, critical infrastructure like pediatric acute care, primary care, mental health services, and long-term care has already collapsed leading to an influx of industry driven AI solutions as proposed fixes for these chronic issues like understaffing and increasing acuity. But we should absolutely use tech to support those we serve, and nurses want this. We also cannot allow AI to cement a fundamentally unjust, understaffed, and dehumanized status quo. Research on the work of repair remains vastly underfunded compared to research building new AI. Scholarships like that of **[inaudible] [02:30:13]** demonstrates while some automation actually increases nurses' labor and sedentary time without necessarily improving patient outcomes, even if some physicians notice reduced burden. If we are to differentiate between what AI truly helps and what is hype, we need more focus and research on patient and care workers' invisible labor and the work of repair.

Finally, current lack of AI policy ensuring a culture of consent transparency and accountability for patient and care worker safety threatens our capacity to practice ethically, problem solve, and maintain clinical licensure. This is a fundamental barrier to equity and health justice as defined by Dr. Sherry Lang and Oni Blackstock. Health justice is about redistributing power, including power over who decides what the problems are and how to solve them. Nurses must be able to explain to patients what tech is being used in their care and how it impacts them. But even those of us who study AI cannot tell you where or how it is being deployed because there is no universal requirement for label and transparency. And even if we have model cards, we do not necessarily have human alternatives. So, it is not actually consent. It is coercion.

AI affects the degree to which we can practice safely, consentingly, and within our scope of practice so building for equity will require protection of patient rights and plans for holistic, intersectional, and ongoing evaluation of AI's impacts on consent processes beyond model cards, including human and local alternatives, clinician evaluation and licensure, and care workers' labor and occupational safety. I implore policy makers to recognize and value the invisible care work inherent to AI and its maintenance and to

ensure power over problem definition, design, and ongoing evaluation is shared centering communities and/or care workers disproportionately impacted by these systems. Thank you.

Medell Briggs-Malonson
Thank you so much for that. We are now going to move on to our next panelist, which is Deborah Raji. Deborah Raji is a researcher at the University of California Berkeley.

Inioluwa Deborah Raji
Thank you so much for the opportunity to chat today. I am Deb Raji. I am a researcher at UC Berkeley. I have also done work with various Civil Rights organizations. And I am currently a senior Trustworthy AI fellow at the Mozilla Foundation. A lot of my work is oriented around vetting claims of performance from these companies as they build these AI products. And a lot of my concern is increasingly around how these product claims manifest in the healthcare space and how that disproportionately impacts marginalized populations. I am going to start with a statement, which is that if AI does not work for everyone, it does not work at all. And I will share a couple of stories of the in which these systems fail and how that disproportionately impacts those that we tend to underrepresent or misrepresent in the data that we use to train these systems disproportionately deploy these systems on. The first story I am going to tell is one that you might have heard before of Tammy Dobbs who was a patient with cerebral palsy. And after she had moved to Arkansas, she had her nurse assistant hours cut from 56 hours to 32 hours a week.

And the Medicaid assessment tool that was used in her case supports intensity scale, or SIS, is used in over 20 states throughout the US. When the American Civil Liberties Union (ACLU) Idaho in 2012 tried to investigate the system to understand it better, they identified multiple engineering mistakes and flaws in the way in which the data was compiled for this system and how the system was being used by practitioners. The conclusion from that case only happened 10 years later in 2022 when ACLU Idaho finally settled in order to gain access to the user manual and model details for this case. Still until today, Upturn, which is a digital rights group in DC, through their benefits tech hub has continued to file for Freedom of Information Act (FOIAs) to understand better these risk assessment tools that are used to determine access to care throughout the United States. One of the lessons from this entire story is that transparency is key to understanding what these systems are doing and how well they work.

Tammy Dobbs is a disabled individual, one of millions of individuals throughout the country who has had her life completely transformed and destroyed by the reality of a system that until today we struggle to understand and to characterize appropriately. Aside from the obscurity of these systems and how that interferes with our ability to understand how they work; it is increasingly clear that there is a network of products on the market that just do not live up to their claims of performance and especially fail for marginalized groups. My first experience with auditing was working with Joy Buolamwini at the Algorithmic Justice League. And we evaluated commercially deployed facial recognition systems for the performance on different subjects of different skin types and gender expressions. And what we found was that these systems were performing significantly worse for darker skinned female faces than they were for lighter skinned male faces.

The performance on darker skinned female faces was less than 70%, which is below the threshold of what would be deployable. And the companies that we audited, IBM, Microsoft, and Amazon in particular were in the process of pitching those products for use in immigration and law enforcement revealing again the

discrepancy between what they were declaring about their product's functionality and how well it was working, especially for these marginalized populations. This kind of finding is not just specific to facial recognition. In 2015, there was a similar finding around the use of melanoma apps. So, these are mobile applications that had claimed, if given a picture of a patch of skin, to make declarations around the probability of melanoma and other related skin diseases. As recently as 2021, Google tried to attempt to bring a similar product to the market. Again, recent studies have found that there has consistently been a disproportionate performance of these type of skin disease detection apps on darker skinned individuals versus lighter skinned individuals.

And so, that first point is really this that a lot of the technology that we have out there does not work or has not been adequately tested on marginalized populations. And so, we need to create barriers for deployment. We need to have adequate AI inventories. And we require audit access documentation and model cards in order to understand what these systems are doing. My second point is that although we like to use the term AI, we need to be incredibly specific about what technologies we are talking about. Most of the commonly deployed "AI systems" are really not fancy or complex systems. But, typically, EHR trained clinical risk assessments that fall out of the purview of AI ML under the software as a medical device categorization for FDA approval. In fact, in many cases, there had been evidence of purposeful regulatory arbitrage by certain companies reformulating their products to fall outside of explicit FDA oversight.

And so, what that means is that we need to be incredibly careful in how we identify and articulate what technology we seek to regulate and exactly how we want to regulate them, what those concerns are, and what mechanism we have available to control the scope of their application and their release on the market. Finally, I want to advocate or push for the practical investment in increasing the participation and feedback from impacted communities. Some of the risks or the biases inherent in the technologies today are things that are difficult to identify outside of engaging with the perspectives of those that are marginalized. I mentioned a lot of my early audit work was in facial recognition. And it is no surprise that both Joy, Timnit, and I are darker skinned women ourselves. I remember I was working at a startup company, Clarify, when I first identified the fact that the facial recognition systems that I was training did not include faces like me in the training set or the test set. And that was really the impetus of my participation and the participation of a lot of my minority peers in this space.

I want to reiterate how important it is to have marginalized folks in the room when discussing and analyzing these systems. A lot of the discrepancies and a lot of the failures when it comes to bias are incredibly subtle and grounded in a history of prejudice that can be difficult to identify without engaging those populations. As an example, Roxana Daneshjou from Stanford Medical School identified that a lot of ChatGPT's responses to medical queries were actually informed by misinformation that had been grounded in racial prejudices from decades earlier and had been since debunked in medical education but not debunked in the way of the responses of the technology itself. And so, when it comes to that, I would advocate for patient notification of AIUs, the enablement of investment and technical infrastructure for participation such as incident databases for post market surveillance and other mechanisms for community engagement. Thank you.

Medell Briggs-Malonson
Great. Thank you so much for that. And now, we are going to transition to Maia Hightower who is the CEO of Equality AI.

Maia Hightower

Thank you for this opportunity to contribute to the HITAC hearing. My name is Maia Hightower. I am the CEO and founder of Equality AI. I am deeply committed to ensuring that AI technologies in healthcare are deployed and developed in a way that uphold equity and fairness. By background, I am a physician, a four-time C level healthcare IT executive. A vast majority of my career has been in academic medical centers where I have served as Chief Medical Information Officer, Chief Population Health Officer. And most recently, I was the executive vice president and chief digital technology officer at the University of Chicago Medicine. About five years ago, I was the Chief Population Health Officer and Chief Medical Information Officer (CMIO) at an academic medical center when Ziad Obermeyer and his team identified a population health algorithm that was found to be biased and unfair. The patients impacted were like Tammy Dobbs. And I as a leader did not have the tools to detect, mitigate, or protect my patients. I did not have the tools to ensure that the AI deployed in my healthcare system, nor my population health management platform was safely deployed and did not cause harm.

And I am confident that harm was caused. And I feel very responsible for that. AI in healthcare should be fair and equitable. It should work and provide value for everyone. And that is how Equality AI was born. Equality AI is an AI audit, validation, and monitoring technology that enables institutional level management of AI across the AI lifecycle. It enables health equity by design in the deployment of AI in healthcare. Today, I will highlight how we can build together equity into the three Ds of AI in this health and human services design, development, and deployment process. Equity is built into the three Ds through bias mitigation methods deployed throughout the AI lifecycle beginning from problem formulation all the way to development and deployment to retirement so that full AI lifecycle. And these bias mitigation methods are a combination of social mitigation methods and technical mitigation methods. Often, we will talk about technical mitigation methods.

But there is so much opportunity in the social mitigation methods as well, including diversity of teams, ensuring that we have adequate representation throughout all of the roles, all of the stakeholders that are impacted by AI in healthcare making sure that we are skilling and upskilling our current and incoming data scientists and researchers on these bias detection and mitigation methods. To ensure that we have the AI governance at that local level that is robust and that adheres to institutional standards that roll up to federal standards that roll up to even international standards and that it includes a diversity of participants at the table. Ensure that we have regulations that help to guide our technical mitigation methods, including standards and frameworks. So, the International Organization for Standardization (ISO), the National Institute of Standards and Technology (NIST), and then, of course, at the local level are the industry level ensuring that we have these aligned standards. AI and ML methods, our prior speakers have talked about some of these methods. But there are really good methods for detecting emanating bias and yet the adoption of these methods has been poor.

And so, we need to ensure that we have tools to be able to do these audits from both an internal and an external perspective. And then, ongoing validation and monitoring, solutions that allow for that local institutional level monitoring as well as validation of models in their system. We each have a role to play to ensure that the future of AI enabled healthcare is equitable and fair. The role of policy makers, when it comes to standards, it is defining our standards and aligning international, federal, and even a variety of states have introduced these standards but ensuring that they align, including our industry and institutional

standards. Streamline them and decrease the administrative burden of adopting them thereby enabling greater adoption. Supporting research and innovation that advances the use of AI for health equity and then, educating our workforce and making sure that we have that development to both promote the diversity of our workforce as well as proficiency and expertise in the use of bias mitigation and detection methods.

And then, incentivizing adoption of AI that has actually undergone the rigor of a three D process at the bedside. And there are many mechanisms that policy makers have to incentivize the adoption and make ensure that our search for value in healthcare are also aligned with responsible adoption of AI in healthcare. Thank you very much and I look forward to your questions.

Medell Briggs-Malonson
Thank you as well. And so, last but definitely not least, we have Alexandra Valladares, a representative from Comunidad de Durham as well as Health AI Partnership.

Alexandra Valladares
Hi, everyone. It is so great to be here. I just wanted to thank you all for sharing so much. I think a lot of what has been shared is near and dear to what I want to share. But I wanted to take just a little bit of an approach and just introduce myself. And in my introduction, it is not just the roles and what you see listed on there but it is also the journey as somebody who is an immigrant, somebody who is a first generation college student, somebody who is in current elected office with the school board and has been grappling with families that have struggled, not just since the pandemic but there has been a lot of conversations as a result of some of the experiences that happened during the pandemic about how healthcare systems can be more equitable. And the conversation about artificial intelligence is definitely a very important part of these conversations. How do we increase access? How do we increase care? How do we approach every individual with the dignity that is owed every individual?

How do we acknowledge the intersectionality of individuals who walk with not just one identity or two or three or four but pretty much all of the digits on our hands and more. When you start thinking about how folks want to identify, how do they want to be engaged? Really tailoring healthcare to meet the needs and never exclude or harm and intentionally cause harm. That is something hard for systems do and especially in the healthcare system when you have to grapple with what are the priorities, what are we looking at? What are the winnable things, the things that are tangible? I come to this space as somebody who holds a lot of identities, intersectional identities. And I wanted to share that my experience coming into this work actually came during the pandemic when Mark Sendak was working on on a research project. I told him the community right now is understanding that research is important, but we need frontline support.

He was able to navigate many things and him and his team and Suresh and everybody else were able to set up community health worker folks from the communities. People who are connected to neighborhoods, people who know and have trust with different marginalized community members to actually empower through opportunities with community health worker program. That continues in Durham with many different groups and stakeholders and affinity groups. Now, we are talking about artificial intelligence as the frontier that is happening right now in healthcare. I told him I have watched the approach of many researchers that just want to get the information and know what they need to know and then, not have relationship and not have the accountability with people, actual real people have their numbers and will show up and smile on

your face and say, "Can we talk?" That is powerful and that is the most powerful thing we can have when we bring any technology. Relationship is key.

I just wanted to move to the next slide and tell you some of the conversations that in the health AI Partnership, we have had. I would not put my name, especially for all the communities I am connected to that understand that equity is a continual effort and we are never really reaching the equity that we deserve. But collaborations are important, especially collaborations with grassroots. The institutions are great but there is a whole network kind of like a forest. Think about mycelium. There are invisible networks of people who care connected to people they trust. And we have to take account of those collaborations, broader collaborations, broader stakeholder input.

We have to have cultural humility. Definitely, I have heard from many folks today in a low resource setting, so we are all saying the same thing. Access to language. There is a lot with identity and a lot with trust building that relies on having people invest in language access. Transparency. Communicating with people, especially with some of these background, ambient AI, other kinds of generative AI. All of these things can run in the background and are collecting data. Where is that data going? Who has access to that data? What systems are working together and having that interoperability that can actually land some people in trouble, especially for immigrant communities that lived in the shadows. When you are thinking about a company that is working with detention facilities for undocumented immigrants and is helping track and monitor where undocumented immigrants live, thrive, and where they can be, and you have these same vendors working in the healthcare system.

There is something to be said about also Hippocratic oath and some of the tenets of healthcare. But when you have technologies that are already vendors for particular work, how do you continue to have that transparency? This company may be doing this project, but they are also doing these other projects. There is a lot that we can go on. And I do not want to take too much time. I do not know if I have 30 more seconds, but you have to have multi-stakeholders. You have to think about responsible use of AI. You have to think about that accountability. Relationships are key. I am not just a community representative. I, literally, have Mark Sendak's number and everybody in the health AI partnership that I can call on. And I do message. There is something happening even in education because we have had AI with monitoring in education. Thank you so much. I appreciate your time. I am available to talk further with anybody who is willing to talk. Thanks.

Medell Briggs-Malonson
Thank you so much, Alexandra. Thank you for bringing the voice of the people to this hearing and also that you have Mark's number. There were lots of chuckles here in the room. We are going to open it up for discussion. I first want to start off with any of the HITAC members in the room. If you do have a question or comment, please flip your name card up and we are also looking on Zoom as well. While everyone is thinking, I will put my card up to get things started. Once again, I want to thank all of you for joining us today. This question I am going to point it more towards Dr. Maia Hightower. It is great to see you again. I have to commend the Office of National Coordinator, especially with HTI-1. One of the things that HTI-1 focused on was specifically adding greater levels of transparency in terms of the build, as well as performance of our various different clinical decision support or decision support interventions of what is identified in HTI-1 and ensuring that is promoting greater trustworthiness.

The thing about HTI-1 is that it is sort of scoped on all of our developers that are interacting with certified health IT. So, it does not necessarily touch all of those other areas. However, we know especially when you are thinking about EHRs, a lot of that is making up over 80% of the country in terms of the technologies that are touching patients. My question is we already have ONC, and we also have FDA, we also have Office of Civil Rights and others that are starting to make some of those different foundations about fair, just, and equitable practices in order to ensure that we are not having any unintentional outcomes when it comes to marginalized populations. But what do you think is the possible solution as we move forward at partnering between what is happening on a federal level and a regulatory level with some, for instance, companies such as yours and other type of private partnerships? We can even say the Algorithmic Justice League and all the groups you are involved with.

What do we do in order to ensure, especially once these models are out in the world that they are actually acting as designed but then, there is that private/public partnership that everyone is upholding?

Maia Hightower
Absolutely. Great points, especially around advancement of FAVES is wonderful. ONC has been very forward thinking in, not only proposing but actually getting that into final rule. As you pointed out so wonderfully is that it is limited in scope. It really is focused specifically on the EHR, but even within the EHR environment, you have third party vendor solutions. You have institutionally developed models, as well as the historical rules based clinical decision support tools. There are hundreds of those that are embedded within the electronic medical record and are out of scope with **[inaudible] [02:54:53]** is just expanding that scope where it is not so focused on just the EHR. We definitely need to be focused on EHRs, but that scope extends to the institutionally internally developed models, vendor models, as well as those that are historical. Models that would not even be considered machine learning Artificial Intelligence Markup Language (AIML) models but are rules-based algorithms that are based on anecdote, on evidence-based medicine, and if there is some evidence behind them, are out of date and likely did not reflect the population today that is impacted.

I think there is incredible opportunity for expansion of the principles around the federal ONC final rule. But I also think from a public institutional partnership that there is opportunity to increase the robustness of the capabilities at the institutional level. This is for health systems but as well the robustness in implementing FAVES at that vendor level.

Medell Briggs-Malonson
Great. Thank you so much. We are going to go first to Katrina.

Katrina Miller Parrish
Thank you. I am Katrina Parrish, family physician, clinical informaticist from Humana. When I think about trust or loss of trust that has happened with so many people, so many cultures, so many groups, one of the ways I know a lot of us in healthcare approach improving trust is interaction. A safe interaction with honesty, transparency, clear language and things like that. When we are talking about all of these technological tools for improving healthcare, obviously, that is going in a very different direction. Rae, I think you were talking about how we need to maintain or even improve on the human interaction to make sure that not only the healthcare process can continue as efficiently and appropriately as it can, but also for that trust factor. I

was wondering if any of you could just comment on how we really either maintain or improve that human interaction.

And I know this is a very interesting one, but how do we embed that into the technological process, i.e., scripting within an electronic medical record (EMR) to say you know you better ask how the person is doing today, or some kind of guiding question that is just conversational and supportive and caring and comforting in nature. That kind of thing if you could comment on that. Thanks.

Medell Briggs-Malonson
Go ahead, Rae. We recognized your hand.

Rae Walker
Thank you and thank you for the question. Yes, I feel as if so many of these discussions today we are talking about AI, building AI, and regulating AI. There are very much yes and discussions. It is like yes, we need to get the tools right or the monitoring right or the scripts right. We need safe and flourishing staffing models. We need adequate time in the clinical space to do an assessment that not only attends to whatever critical issues that person is showing up with that day but also, health promotion and in a way that is accessible and gender affirming. We need whistleblower protections. We need consenting practices. We are really not there in healthcare. I have the honor of assisting on the research advisory board of a clinic called Trans Health. It is in all trans led, gender affirming, full-spectrum primary care practice.

One of the beautiful things about that space is whatever tools we use, whatever AI might be getting deployed, it is being done by humans who also have the lived experience of knowing what it is like to navigate the world as a trans or gender diverse person and aware, too, of some of the reasons I think Alexandra noted this, you might not want things in the health record. You might intentionally silo certain data because we know it can be easily weaponized, including against healthcare workers who deliver certain kinds of care. I think even in terms of how we convene discussions about the issues, I appreciate the multidisciplinary, multisector nature of today's hearing. To have it continue and to have that coincide with discussions about what is the future we actually want to build for health and care and not just in terms of AI but in terms of all of the ways in which we are going to need policy to support change to make this all sustainable.

Medell Briggs-Malonson
Excellent. Thank you so much for that answer, Rae. As a note to the panelists, we have lots of questions already in the room. If you do want to add an additional plus one or amplify any answers or have your own answer, feel free to put it in the chat everyone. We will go to the virtual world. Mike, you are up next.

Michael Chiang
Thank you to the panel, first of all, for three great talks. I have a question specifically for Dr. Hightower. Maia, one of the things you mentioned was incentivizing adoption of AI that works and that is equitable. You mentioned CMS payment and service delivery models. I thought that was a really important point. One of the challenges is that I do not think we always have AI systems that work and are equitable. And we need to do the research for it. I think there is a little bit of a chicken/egg because the researchers without knowing the model, they cannot tailor the research towards answering the questions the model would require. There is no model yet. Do you have thoughts about how we might be able to marry those a little bit

better? Should the researchers be collaborating more with the payers upfront, and should we establish systems for that? I think it is confusing. I should have said at the beginning, I am Michael Chiang, NIH. I would love your thoughts. Thank you, Maia.

Maia Hightower
You're absolutely right in that our current paradigm is very disjointed when it comes to the research efforts on AI. You will have a researcher that develops a model and is focused on the performance of the model. You will have another researcher that may be focused on a clinical trial to show efficacy of the model. But there really is not a good mechanism for being able to innovate on the care delivery aspect of AI model deployment. And actually getting in that information and incentivizing some innovative approaches when it comes to aligning the value that AI models are supposed to bring with the financial incentives to the health system that is taking on the risk of deploying AI models. My thoughts are really around, we do have existing mechanisms to align value-based payments or incentivize value-based care, including the Capability Maturity Model Integration (CMMI) is a wonderful example of some of the innovation that has advanced say hospital at home through aligning financial incentives with the goal of improving access to hospital level care at home through digital solutions.

That is where I think there is great opportunity to thread the needle on our existing programs, shift how we test our AI systems instead of this very siloed approach to a full value capture approach, including health equity by design.

Medell Briggs-Malonson
Thank you, Michael for the question. Thank you, Maia, for the answer. Hung, we will turn the mic over to you.

Hung Luu
Thank you. This is Hung Luu. My question is data is essential for these models. And a lot of the data currently comes from either clinical trials that have already been performed or from EHR data that is derived from larger institutions. We know from the literature that the populations for the clinical trials and for the EHR and resource rich institutions are skewed towards a particular demographic. I have had experience working in psychiatric institutions and county hospitals and lower resourced hospitals. Appropriately, there are additional safeguards for these institutional populations because of the fact that they are indeed vulnerable to potential exploitation. But what I have seen is that these additional safeguards have sometimes had the functional effect of, basically, showing this research so there is no meaningful research occurring at these institutions.

How do we balance the need to protect these vulnerable populations while at the same time ensuring that they are not rendered invisible by these models, which we all hope will serve them as well as everyone else?

Medell Briggs-Malonson
If I can add, Hung, thank you for the question. That is very similar to a question that Hannah also put into the chat. We will leave it to the panelists if someone would like to respond to that.

Alexandra Valladares

I would like to say something because this is definitely something I have seen and understood when it comes to visibility and invisibility. There are reasons why, at certain times, there are identities or factors that are rendered invisible for a reason. It is for protection. As I mentioned, in the education system, nobody needs to know who is documented or not documented. It is safer to not have that information. However, when it comes to resources and needs, it is important to know what are the criteria that will not tell you who is documented or not but will tell you about language access needs. How many families are monolingual and do not speak English? That criteria can get to English as a Second Language (ESL) families, English as a second language families or English language learners. You can make sure you are serving, you are deploying resources where you most need them because you have a percentage, you have metrics.

There are ways that the metrics can approximate certain of those sensitive identities or certain sensitive factors. It is not to say it will give you a full answer. Sometimes, we have to be okay with not knowing everything about everyone, as long as we are making sure we are staying attuned and we are working with the stakeholders, we are working with the leadership, people who have connections to people who have asked them to advocate on their behalf. You have to have those stakeholders that are connected that can bring the nuance to the work as to what are the compromises we can live with. What are the things we should not make a mistake about? That could actually lead to potential impacts downstream. Invisibility, visibility, it is a spectrum.

Medell Briggs-Malonson
Thank you, Alexandra. I think that was a really important piece of sometimes our standard metrics that we use to build or collect data needs to be transformed in a way that is more patient and people centered, especially when we are dealing with various different identities in which we cannot always keep a status quo. We need to engage the people and say what is a better way we can still proceed but still add those protections. Thank you for that. Lee, you are up.

Lee Fleisher
Thank you. Lee Fleisher from Penn. I want to get to the question of the solutions because I think Micky did a wonderful job and the ONC staff in making it transparent. Those of us who have been in predictive analytics and are old clinicians know that we put out the limitations of any of our predictive analytics. And with AI that makes it clearer. Almost all the algorithms are as my teacher at Penn would say from the global north. There is very little from the global south. So that the understanding of immigrant is really very small. Do we oversample? Do we just say we should not apply that to certain populations because the algorithms may not work there? How do we move from today with all the information you are saying we need to collect, but we will not have that for five to ten years? And maybe USCDI will help to acknowledge some of the work they did in the transparency. Thank you.

Medell Briggs-Malonson
Does anyone from the panel want to address that question or comment?

Inioluwa Deborah Raji
I can chime in just because with the work we did on facial recognition, we faced similar problems to the problems being raised today. Questions around transparency, questions around data collection. Do you collect more of the biometric information of this marginalized community? Or do you shut down the entire system because of the fundamental issues of the technology itself? What are the parameters in which this

system can be used, etc.? I think in the facial recognition context, the way this was resolved was being cautious around the way in which things are being used. I think even before getting into the context of constraining the way in which these systems are deployed, starting with the development stage and asking the question of are we adequately evaluating the system on a range of potential populations and in a range of the context in which it will be used?

I think one of the challenges of this technology is the fact that it is not being advertised with the full scope of its strengths and limitations. Often with the technology that we are talking about, everything from simple EHR based risk assessments to these upcoming large language models, generative AI models, there is not a very clear acknowledgment of the limitations of the systems when they are being advertised. It is often the work of independent auditors or other stakeholders to call out these limitations in a very anecdotal basis. Even just requiring a more comprehensive communication of what these limitations are is an incredible starting point to allow for those that are either purchasing the systems or developing the systems to understand when it is appropriate to use the systems or not. In the case of facial recognition, for a really long time, facial recognition was seen as a solved problem. The performance on the benchmarks at the time were at 99% plus. And people were very confident in the use of facial recognition in high stakes scenarios like immigration and law enforcement.

And after gender shame and some of the work that happened with the Algorithmic Justice League highlighting how poorly performing this technology was on darker skinned faces, it became common knowledge that this is not appropriate for use in those high-stakes scenarios, especially when there is a high probability of those populations it is not working well on to be impacted by the technologies. I feel like the same attitude should be used here. If this is technology that is not working for a marginalized group that is likely to encounter the technology then, it is not mature enough to be used and definitely not to be widely deployed without adequate oversight. I think that is the attitude we should be taking here, which it feels a little harsh, but it is probably the expectation we would have of any other type of engineered artifact and product. It is a basic product safety expectation we should also apply to AI products.

Medell Briggs-Malonson
Thank you, Deborah. Rae, you have a wonderful comment in the chat. I do not know if you wanted to mention that if it is related. I think this is the core of what our work is in this space when it comes to equity injustice and artificial intelligence. If you have something else to add, we would love to hear that.

Rae Walker
I want to note my appreciation for the Algorithmic Justice League and all of the leadership provided in this area. I wanted to push back on this idea that this knowledge does not exist. I think a lot of this knowledge does exist. But the perceptions around who is the expert and where are the reputable sources of knowledge has been very narrow to some extent. I think we live in a system right now where, unless you have NIH funding or National Science Foundation (NSF) funding, you are not necessarily considered an expert. But I will say federal funding agendas have structurally excluded so many of the groups that have been leading in these areas up until recently. Trans and gender diverse people were almost complete absent from the literature. Not the whole literature. The literature that is federally funded in part because the only place you could find them is something in studies involving HIV/AIDS funding, which is a very particular view on the health of trans and gender diverse people.

We have mutual aid models that communities have used for generations to get their needs met sometimes actually being blocked by some of these data systems and federal policies. We have literatures from the humanities, nursing, allied health sciences, anthropology, history, and so forth that document some of the critical needs and solutions. And those do not tend to be the ones incorporated into the white papers and the planning, which still tends to rely heavily on public medical indexed articles, articles coming from federally funded studies. I think part of the answer here is not just how do we include more groups in the data set, but to avoid those groups just being continually harmed by the narratives that those data sets have been constructed to represent, including EHRs, which is billing software. And that reflects a structure. I think we really need to shift our view on who are the experts and/or what constitutes legitimate knowledge to guide our decision making about models and also, about as so many others have said what are the problems? And where and when should we consider AI as a possible solution?

Medell Briggs-Malonson
I want to sincerely thank Deborah for all of your powerful comments and also Rae, for all of the knowledge you provided here as well. Those are two incredibly important pieces for us to consider. The time is now for us to do the right thing. We are going to go on to the next, which is Mark.

Mark Sendak
My question is for Alexandra. And you can still text me anytime. I have a question that I know is still an uncomfortable question within my own home institution. I know that we have built a relationship where there is accountability felt both ways. Working in a health system in AI, you do things that community members are unaware of. You use a lot of very private, personal information to run algorithms. Some of which are built in-house, some of which are built by external vendors. You sometimes build technologies on that private data. Typically, community members have no idea. Community members may not even know when these things are used in their care. My question is thinking about there are 6,000 hospitals in the United States, I would say it is a pretty big problem for trust in healthcare for the status quo to persist. How do you start to think about creating accountability with community members who understand their safety and privacy in ways that health system personnel may not? And what is the role of the federal government in making sure that folks do that? I do not think it is going to happen just naturally.

Alexandra Valladares
That is a really great question. I was thinking about transparency when it comes to apps and technology. Sometimes, you get the disclaimer at the front end that tells you, "Your use of this app will constitute access to your location." You cannot toggle that off. What can you toggle on and off? In the discussions the health AI partnership just recently had this week, there were so many rich discussions about ambient AI. Can you toggle ambient AI on and off? That is just one example. When it comes to marginalized community members who are wanting to access even the basic minimum care, just give me language access. Explain things to me. Take time. And you are constrained to a 20-minute window that is not equitable because when you have to have an interpreter, many of those minutes go towards even securing the interpreter who is going to be in the room or the technology, whether it is a monitor that is going to be doing this and setting that up.

Your 20-minute period is up. The system is not yet equitable in the sense of giving double time just because somebody has either language access or disability rights, accessibility. Different kinds of things. The system as it is right now, there are a lot of things happening on the back and for efficiency's sake that are not really going in the direction with transparency. And I think that we have to have those conversations. I do think

the EHR needs to be able to have that disclaimer just like any app saying through your engagement with this EHR system that you get to see on the outside as whatever the institution uses for the consumer. There is background. In the background, these things are running. I think those disclaimers need to be there. I think policies also need to be very explicit about protections. Where do people go when they have a grievance as to how technologies are being used? Where do they go to get their questions answered? Who are the mediators or ethical boards that are there?

It is here. It is actually here. I think that there is a lot in terms of technology that I think is showing us some of those aspects about where policy needs to be in place to reduce harm. I say reduce harm intentionally because harm is inherent in any system that is trying to advance innovation at a fast pace the way that healthcare is moving with AI. There is some harm, but how do we really intentionally reduce the harm, especially harm that is going to fall on folks who do not have the resources, the power, the status, the academic degrees, the networks? Folks that need more of those supports because they have essentially been marginalized, not because they are marginalized themselves. There is no marginalization that is inherent to any human being but because the system has yet to grapple with how do we engage diverse stakeholders in this conversation. Thank you.

Inioluwa Deborah Raji

Just add very quickly to what Alex mentioned, and also something that Maia mentioned in her opening statement around tools for facilitating some of this, I really think there needs to be investment in some of the technical infrastructure necessary to enable participation at a broader scale. We have incident databases and that is something that exists across various agencies. And now, people are thinking about how to leverage that for increasing the opportunity for people to give feedback and to lodge complaints that they might have about AI related systems through the executive order. There is already the instantiation of the AI inventories that increases the visibility of the types of vendors. What does that look like at the hospital level? What does that look like at a community level? To just make community members aware of what types of technologies that they are interacting with.

What does that look like at the individual user interaction level, like Alex mentioned to notify individuals of how AI is impacting their care when they enter a particular hospital site. Reflecting on ways to raise awareness and educate people that are impacted by the systems and then, give them opportunities to file complaints and to express feedback requires actual investment in that technical and institutional infrastructure. If that is something that ONC is in a position to invest in, I definitely encourage that. I will also flag, one of the hats I put on is at the Mozilla Foundation, I lead a project called the open-source audit tooling team. We think about resources that are leveraged by AI auto practitioners throughout the audit execution process because it is still very hard to do an audit. A bunch of tools that we realized were deeply under invested in were these harms discovery tools. Resources to support practitioners in identifying which targets to audit or identifying or soliciting feedback from impacted populations to figure out which harms to evaluate for.

Investment in these harms discovery tools is definitely something that is often an overlooked aspect of the process.

Medell Briggs-Malonson

Great. Thank you so much. Just as a reminder, we have about 15 minutes left for this panel. I want to make sure that we also get to all of the questions. And so, I am going to move us right along. Eliel, you are next.

Eliel Oliveira
Thank you. Eliel Oliveira. It might not be a question but a comment and a recommendation. I thought about it earlier in the Interoperability Standards Workgroup but I decided to skip it. The discussion keeps bringing up important facts. As you all know, I also work designing, developing, demonstrating the use of technologies that use audit standards in real settings. Some of that for care coordination, especially for social care coordination. What that means is in the design, we work a lot with the underserved communities to understand and treating them as specialists on the challenges that they are facing. We think we do a great job on that. Some of those projects are two years of intensive work listening to those communities to understand and translate what they feel is necessary. But we missed the mark badly. And I can say that because I am hearing from others as well with some language access. It is the fact that we built this amazing technology using standards with the feedback from the community and then the users do not speak the language. They have no way to utilize that technology.

That is a comment that I think is resonating with the comments that I am hearing here. But I think the recommendation may be to start small here for ONC and looking at USCDI. Not even trying to do standards because we do not have standards for anything, but just the labels of the categories and the key data elements inside of the USCDI. If we put in other languages as well, that helps developers because they do not know how to even translate what is -ologies to another language or first name and last name and accelerate the process of adaptation of the technologies at least in some way. And give the signal to others of how important this is to continue involving language access. It is a big challenge and I hear that constantly from our community health workers and people on the ground. Thank you.

Medell Briggs-Malonson
Thank you, Eliel. I completely concur with what you are saying in terms of not only language access, but language concordance and justice, especially with any patient facing technologies. We have to ensure that we are pushing forward this work by ensuring that we are communicating with those in the most appropriate way. And that has to be part of our health equity by design approaches as well of taking in those elements. Thank you for that comment. Rochelle, you are next. I did not mean to startle you.

Rochelle Prosser
I was reviewing some of the comments in here. First of all, Rochelle Prosser. Thank you, Rae. Thank you all of you ladies. You are the bomb. Thank you. There was a question here that I wanted to make a very quick comment. They were talking about citizen and nursing science. Nursing is not seen as a "science" as a profession. I think once we transition that, we can start looking at funding and getting that access that you are talking about, Rae. I relish to collaborate and work with those who want to do that. And my question goes along the lines of what do you believe are the public reasons that public and private organizations are not adopting generative AI for the current tools that are out there? And then, as women being 51% of the population, how and what are your thoughts on generative AI depictions and what areas do you feel in this area that we can come together to improve or remove equality and inequality in those areas? Thank you.

Medell Briggs-Malonson
Would anyone like to answer? I believe, Rae, this may have been directed to you.

Rae Walker
I am sorry. Thank you. Generative AI, that has been on the tip of everyone's tongues recently, at least in a lot of the spaces I have been showing up to. I confess, I am of many different minds about it because I know that from an accessibility standpoint, there is some potential versatility and just in time support potential there. Already, we see so much of this tech is built in behind the scenes, both in EHRs, Outlook inboxes, Word documents, whatever. I also sit with work of the distributed AI research network and others looking at the implications of large language models, of what it means when we have groups where technologies are grounded in some degree on the scraping and theft of information from the internet, from artists, from others' intellectual property to drive them. I know there are various efforts right now to build engines for generative AI that are not necessarily just scraping from here and there and Reddit and we all know if that is the model to drive our models, we are not going to be in a very good place very quickly.

I think there is, even for me, a certain distrust. Generative AI does pattern prediction and pattern prediction is grounded in what data has it been exposed to? We live in a society. And Dr. Patricia Collins' concept of the matrix of domination. We have all these different structures that influenced outcomes. When we rely on automation to be the main source of interactive experience, we are exposing people to variable levels of risk depending on who they are and whether or not that experience reflects their needs, their identity and, frankly, their safety. I spent more than two hours in three different instances in an automated loop the other day trying to get access to my child's electronic health record for an extremely critical health interaction that we needed to have that we could not have without that access. And I know so much about how these systems function and I still could not get past the loop that I was in. And that is with a system that was recognizing primarily my language but still did not seem to recognize the problem I was having.

And even human alternatives were not well-equipped to help me out. They sent me back to the automated system. And so, I think that is where things like generative AI, many folks find it really exciting. I see them increasingly incorporated into clinical training, people building case models, or chat bot patients to replace the simulation experience. I think there is also still so much work to be done to understand how they are functioning to ensure that they are functioning on data that we have permission to use, and that they are reflecting the needs and experiences of everyone who has to interact with them. Those are some thoughts for a start and I think the consenting tech curriculum and also made open access and that I shared in my slide is another lens to think about how and where these types of technologies are deployed.

Medell Briggs-Malonson
Thank you, Rochelle and Rae for the answer. We are going to go over here because we have two of our HITAC members. And I want to make sure to get Trudi as well as Derek in these last few minutes. Trudi you are up first.

Trudi Matthews
As we have been talking, it occurs to me, this discussion could be a very tension ridden discussion, because we have multiple values that are in conflict where the justice and autonomy of the patient is concerned. There are justice principles and autonomy of the patient that we are trying to protect, while also dealing with the fact that we have an expensive, complicated healthcare system that we are trying to make better for patients. These things are tied up into one another. It occurs to me that Jon Rawls' principle of maximin in this particular conversation is relevant in that those who are the least privileged should be given

greater involvement in the process. And so, my question for the panelists is around that. How do we ensure that underrepresented groups are more involved in the process and are really co-developers in AI?

And I think what Maia shared related to the work you are doing is illustrative of that. Do we have more co-development occurring in AI with those who are underrepresented. I would love to hear thoughts and I think this is a good, rich conversation to have around that.

Medell Briggs-Malonson
Thanks for the question, Trudi.

Maia Hightower
I am happy to add to that comment. Unfortunately, we do not have really good models for co-development of AI problems or co-development of AI with community being at the forefront. Right now, the current paradigm is community is and as an afterthought perhaps included as a user as a byproduct of the recipient of AI. We need better models. We need investment on how do we effectively engage community in a meaningful way? With your vocabulary, emphasizing co-development and even at the forefront, defining the problems that are most important to solve. At this point, the health system, the complexity of the health system, the incentives, misalignment of incentives are really around payment and fee-for-service to some extent value-based care. But we do not have the right incentives to get immunity in the room and engaged in defining what problems are important to solve. How we solve those problems across the AI development lifecycle all the way from the design to the actual modeling process, which labels are important?

There are so many errors that occurred during the development process where there are just little decisions made, a proxy label that may or may not reflect the true experience of a community based on no lived experience of what that community is experiencing. But decisions are being made on what label may be the best proxy. So, what we do not have are really good models, even A model. There is a research community out there that currently has an engaged community voice. We have some pretty good models on patient engagement and that is what I would love for us to begin with is how we currently leverage patient engagement, including the community needs assessment and how we collaborate with community on the community needs assessments, what we have learned with digital solutions, and how to co-develop with digital solutions without the error of the language barrier that was not addressed in the co-development of a digital solution.

I do think we have good evidence to support how we might go about engaging community in a meaningful way and co-developing starting with the problems that are most pressing for community members.

Medell Briggs-Malonson
Thank you so much for that. This will be our last question for the hearing. Derek?

Derek De Young
My name is Derek De Young. Thank you for talking and bringing up a lot of these areas of concern and worry and things we need to look out for. I think it is critical for us to be successful in this space. I changed my question last minute because I ended up being the last person. I was just going to flip it. We have been focused a lot on what do we have to be careful about. And it is very important. It is critical. I 100% agree with that. I also think the technology allows us specifically in equity and underserved and people with

different knowledge barriers or education levels, this technology has the opportunity to bring a lot of equity into the picture as well. I am wondering if we could flip it and almost ask the question of what are you all excited that this technology could bring to help in the space as well?

Just some examples off the top of my head that I know we are working on in terms of equity and really health literacy of being able to ensure that when the patient is coming in, they can understand their benefits because benefits and health literacy and understanding what that is and using things like generative AI to explain what the benefits mean or explaining notes from doctor speak, which is a very different thing than someone with a fifth grade reading level to help understand what this means or translating to a different language in the correct reading model. We can all help with this equity. My question to you is what you excited for with the understanding that we have to do this right? We have to put the right guardrails in place and do it right. What are you all excited for that this technology can bring to help in this area as well?

Medell Briggs-Malonson
I know we are all excited about it so feel free to jump in. It looks like your hand is up, Rae. Please feel free to jump in.

Rae Walker
I will keep this brief because I see others want to speak as well. I am partially excited about the potential to reimagine accountability for institutions and our policies. And a concept called **[inaudible] [03:37:35]**, this idea of that we have had a lot of surveillance of patients and communities. We have had a lot of collecting and extracting of data about them to say what their problems are and how we are fixing them or going to them. We have had far less attention to what all this means in terms of how are our institutions structured. How well are they actually serving communities? How well our policies, including labor policies and protections actually serving people? And that is work I see coming out of places like the distributed AI research network for instance. The wage theft calculator is an exciting application. We see efforts to better document harms and potentials for healing and show where that is happening in ways that have not made as visible as yet. I think with intention, we can build a system where power is redistributed to better hold to account those entities, including our government, that have historically wielded power in ways that did not fully represent and often serve communities that have been marginalized to date.

Medell Briggs-Malonson
Thank you, Rae. In the spirit of inclusivity, if the other panelists want to respond in less than two sentences, we can go across the board. Does anyone else have something they look forward to with AI?

Maia Hightower
I will quickly say I am excited about AI aligning with health equity. If we all take that pledge that AI is going to help health systems to advance health equity then, we will get there. I am extremely excited about that.

Medell Briggs-Malonson
Thank you so much. Alexandra.

Alexandra Valladares
I could go endless on particular cases where folks have talked about technology saving lives, especially when it comes to diagnoses or screenings that have stigma, whether it is prostate cancer, high elevated

prostate-specific antigens (PSAs), whether it is black maternal health. There have been some definitely optimistic comments about how technology can queue folks for follow-ups or queue folks to come to the postpartum visit, especially for migrant farmworkers when some of those visits do not happen and the missing data is revealed because of AI. I am grateful and I think that is a high point there.

Medell Briggs-Malonson
Thank you. Last but not least, Deborah.

Inioluwa Deborah Raji
I wanted to plus one the comments that Rae mentioned. There is a bunch of literature on the idea of studying up. Using AI systems to scrutinize institutional decision making or flipping the script. The ACLU has developed algorithms to rank the bias in judges Ziad Obermeyer and Sendhil have a paper on using algorithms to assess bias in clinical decision making around testing. That idea of using the models to detect human decision-making bias is an interesting direction that I am excited about. And then, I am also really excited about the use of AI systems to increase accessibility in different ways. A lot of open-source development for large language models has been disproportionately focused towards access. Speech to text transcription and things like that. I think there is a lot of opportunity there but also, accessibility in other ways as well. Making things more readable or legible to a different audience, language translation, those are the applications I am most engaged in.

Medell Briggs-Malonson
Thank you, Derek, for that wonderful closing question. Sincerely, we are grateful for your time and expertise to all four of our panelists to really shed some light in terms of some of the ideas that we have to think about as we proceed forward in order to safeguard equity injustice as we deploy additional technologies but also what you are excited for. Thank you all. We appreciate your time. We are now going to transition into break so we will reconvene here at 2:18 p.m. Again, you all know all of the various different rules so thank you, everyone.

AI Hearing – Panel 3 (03:42:04) (Recording 1)
Putting FAVES into Practice

Wendy Noboa
Hi, everyone. Welcome back from your final break. We are going to move into our third panel today. I am going to turn it over to our co-chair, Sarah DeSilvey to introduce our first panelist.

Sarah DeSilvey
Thank you all for being here for this final very important panel in our series this afternoon. It is my honor to introduce the putting FAVES into practice panel. In the HTI-1 final rule, ONC established FAVES representing Fair, Appropriate, Valid, Effective, and Safe as our quality framework describing the characteristics of “high quality” algorithms in communicating how we may get the best out of predictive models and health and human services. The HTI-1 final rule establishes an industrywide baseline of information that will enable users to determine the quality of predictive AI models. The panel presenters and discussion will focus on how to put FAVES into practice and no doubt will integrate much of the wisdom we have heard in the prior two panels. Our first panel speaking today is Dominic Mack, Director of the

National Center for Primary Care and Professor of Family Medicine at Morehouse School of Medicine. Welcome, Dominic.

Dominic Mack
Thank you for having us today. I am glad to be here. A lot of the comments I will start off with the last panel especially, will echo some of these things that they brought up, especially Dr. Hightower. What I would like to say is when we think about how medicine and how medicine basically started, tools and technology was introduced into the medical field. Electronic health records, some of the tools that we use today were not necessarily developed within the field. To implement rightfully within communities, diverse communities, challenges us to think about these tools were not necessarily built for various communities. If you see the diagram that is on the slide, this was started by Vanderbilt et al, some of the authors. It was in a journal for the American Medical Information Association. And it talks about those things that Dr. Hightower talked about when it comes to the stages of development of AI. It starts with the problem definition. I challenge you to look at this.

When we think about diverse communities, those who are underserved, think about those under resourced and low resource providers, rural hospitals, how are they included or are they included within the stages of development for AI? That is a challenge for us to think about today. Where does the ingenuity of AI begin, at what stage? I would challenge us to say that it begins with the problem definition. Where does bias begin? I would challenge us to think that it begins in the same place. As we look at the adverse effects of innovations on at-risk populations, AHRQ made a statement that improving quality does not necessarily reduce disparities of racial and ethnic minorities. Quality and equity are not synonymous. What we want to get is an integration between the two where they become one circle. But really, that is not necessarily synonymous. And we have to look to further integrate the two. If we look back to HITECH Act, we were one of the 62 regional extension centers, the Morehouse School of Medicine, who led the efforts within Georgia, we are partners across the state, we must be realistic with ourselves.

As we developed the HITECH Act and as we implemented the Health Information Exchanges (HIEs) and electronic health records, the smaller practices closed. The rural hospitals closed because of the impact of the technology on the practice. You look at the solo practices, the cost of the technology, this is all documented. The cost of the technology, the up staffing that practices had to make, the imposition of the metro hospitals on rural communities, their inabilities for those critical access of rural hospitals to sustain. We look at the data, 70% of US physicians are employed by hospitals and corporate entities. Now, some say that is good, and that is a good thing. But what happens to the local medicine, the homegrown, things that make the field of medicine rich, the art of medicine but also, when it comes to the discipline and the research etc.? With this, the previous panel focused on the patient. I would just like to bring to the table about the providers, those who are providing this care.

It starts with those who are employed. If we look at the McKinsey and Company's 2022 report, there is low minority representation at the 15 highest AI largest companies who you all know. And 29% of the companies surveyed say they have no minorities working in AI solutions. And if you look at the statistics under that report, probably the highest number for the top 15 AI companies was 6% black. And most of those blacks were in executive level positions so they were not in the different stages we looked at in the first slide. If you look at post-secondary education, let us look at the pipeline, two scientists in the field. And 73% of post-secondary teachers, faculty are white, 12% Asian, 6% black and Latino, and only 1% American Indian

and Alaskan Native and less than that when it comes to other racial and ethnic groups. When you look at high research institutions, it is below four percent. Just to touch on it and I will get to it in my last slide, I will talk about this a little later.

But the map that you see just shows the efforts of Magan Pearson at CDC during COVID but also the gaps in connectivity that comes with the safety net providers that have control centers networks with the very qualified health centers in the center. To my last slide, just looking on the solutions side, we are going to have to use innovative equity models as the foundation for the implementation of AI. There are models out there. This is one from Morehouse School of Medicine that we use in the National Center for Primary Care called the petal model. We have to integrate these existing models with the implementation of AI. But it has to be a community centered partnership, not just with academic institutions. And I will leave it with this. They must not only be included in the efforts, they must be funded to be part of these efforts and to lead the efforts. Thank you.

Sarah DeSilvey
Thank you, Dr. Mack. One of our panelists are coming to us from Zoom, Ashley Beecy, Medical Director of Artificial Intelligence Operations at NewYork-Presbyterian. Welcome.

Ashley Beecy
Thank you so much. My name is Ashley Beecy. I am the Medical Director of AI operations at NewYork-Presbyterian and also a practicing cardiologist at Weill Cornell Medicine. It is an honor to join the conversation today with such esteemed colleagues. NewYork-Presbyterian is comprised of 10 campuses with over 4.000 beds, more than 10,000 affiliated physicians. We see more than 5.2 million visits annually and we are affiliated with two Ivy League universities, Columbia and Cornell. We wanted to tell you little bit about how we have been thinking about the framework to put FAVES into practice. And that consists of the people, process, and technology. We started by creating an AI deployment process. This is closely based on the software development lifecycle, and you can go to the next slide. We have used the process to drive the technology stack and oversight we need to be effective in implementing AI and thinking about the risks at each point of the lifecycle, some of which have been mentioned earlier today in conversation.

As one of the steps in risk evaluation, we partnered with our Dalio Center for Health Justice to develop an internal guidance document for the evaluation of bias in AI. We created guiding principles for the use of AI in clinical care for providers. And we created a template model brief document to standardize the information collected about the models being deployed to assist with the transparency and knowledge management. As it relates to people, wherever possible, we have tried to enable existing government structures to evaluate and mitigate the risks of AI in general, evaluating digital tools, and applying best practices in information security is something we have done well for a long time. We know there are some aspects of AI, especially concepts like bias and fit for purpose, explainability and model drift and need for long-term follow-up, periodic updating that are distinct to AI and need to be addressed. For that, we created a multi-disciplinary governance structure with domain expertise, legal, privacy, compliance, regulatory data science, health equity, and informatics to focus on the AI implementations lifecycle.

We have engaged our providers by providing a pathway for translational research to grow prospective evaluation of models because we do know and understand that the best way to advance this field is going to be through the collection of more evidence. We have engaged patients and family advisory council and

plan to give out patient surveys and focus groups around the use of these tools. From a technology perspective, we are building our data strategy to support the development of effective model building and we are exploring various deployment pathway architectures, both inside and outside of the electronic health record to bring these models to the point of care. I want to provide some practical insights and some lessons learned from use cases because one of the things that we have seen is that we are learning actually something new from each and every model deployment. We have had to address model inputs that include protected classes information and evaluate the model's performance.

For example, its impartiality towards patients of different races aiming to address and mitigate any inherent biases and ensure fairness. We have learned that ongoing vigilance and adaptation to ensure these technologies contribute to equitable patient care is really going to be necessary moving on to some of the conversation happening around monitor and surveillance that other speakers have mentioned earlier. We have reviewed clinical trial designs and have seen really well orchestrated workflows but have learned that these dedicated workflows for the trials related to opportunistic screening will require more long-term permanent care pathways if they will be successful. We will ensure there is long term solution performance and not just model performance. We have created a framework for evaluation of large language model solutions within out electronic health record and have learned to better identify our Key Performance Indicators (KPIs) in advance.

We have learned there are new metrics needed to assess risk. For example, not just thinking about how much time did we save with the intervention but was too little time spent reviewing the draft in which case we may start to see things like automation bias and making sure that we track things like these metrics to ensure safety. I do not want to leave you with the impression we have it all figured out. We have some of the same internal challenges that you see nationally. One of those is trying to strike the right balance of innovation and oversight understanding that our investigators do not see each of these oversight committees in silo but see them end to end. So, we do not want to create unsurmountable barriers to exploration. We know more education is needed, not only to explain the technology to providers but also to help them learn to work alongside the tools. For example, how do you explain to a patient that they are referred to a test because AI said they were at risk?

These are new concepts that we are continuing to learn about as a health system. We also continue to seek opportunities to engage our care teams and sharing where there is opportunity to improve how we provide care to patients knowing that we do not want to start with technology but rather the problem. We know there is a lot of unknown risk. And I think this is really an important point is that we do not know everywhere that risk is going to be introduced. Including how the models will react to changing data by having a technology system and platform or solution to monitor these overtime will be essential for us to continue to do this in a responsible way. We are actively working through what that technology stack would look like. For commercially available products, vendors need to spend more time in this area specifically. And this will need to be a partnership with the vendors and healthcare systems because we will have to collect the data together and make sure we evaluate it appropriately.

The last thing I want to mention is that we are not doing this alone. There are many national AI collaborations like the health AI partnership, Coalition for AI that have helped to inform some of our decisions and we look forward to continuing to partner with them, not only to standardize best practices but to actually operationalize them. Thank you.

Sarah DeSilvey
Thank you so much. It is my honor to introduce our next panelist, Samantha Burch, Vice President of Technology and Public Policy at America's Health Insurance Plans.

Samantha Burch
Thank you for having me. I was mentioning earlier it is very nice to be talking about something other than cybersecurity today, which I am sure many of you can relate to. On behalf of AHIP, we appreciate the opportunity to share our perspective on putting the FAVES into practice. We think this is a really important conversation to engage in. As most of you probably know, we are the national association whose members provide healthcare coverage, services, and solutions to hundreds of millions of Americans every day. We are committed to making healthcare better and coverage more affordable and accessible for everyone. It goes without saying that AHIP supports the FAVES as an overarching quality framework but also as a trust framework. We think it is important that there is a really important role for the FAVES to play there has been mentioned many times throughout today the importance of trust. We share ONC's commitment to ensuring the highest levels of consumer protection when it comes to Health IT.

And we agree that as advanced analytics, machine learning and AI grows, there is a need to address potential risks while working to optimize the uses of the technologies. We are committed also to ensuring that the application of AI is safe, transparent, explainable, and ethical. We seek to ensure these factors are integral components to AI systems, which will strengthen trust in the software, techniques, and outcomes. We also seek to ensure biases are neither perpetuated nor introduced in the development and application of AI that could negatively impact certain subpopulations. While we likely and certainly may not be able to prevent all bias, robust monitoring and governance processes can enable swift course correction. Technology powered by AI can also play an important role in advancing health equity and improving healthcare access.

For instance, health insurance providers can use predictive analytics to identify disparities in care and connect patients in need of additional services such as case management, access to high quality data sets, improving collection of demographic data, and leveraging industry consensus standards can support these efforts to mitigate bias as well. Stakeholders in the private sector have been collaborating to develop governance, ethical, and practice standards for organizations developing and deploying AI to lead the way in protecting consumers while fostering the benefits of the technology. AHIP has joined business and technology leaders, as well as consumer advocates to advance best practices and industry standards. For example, we worked with the Consumer Technology Association on developing standards for trustworthiness and recommendations for bias management, and we are also leading a broad-based multistakeholder effort to modernize and enhance demographic data content standards. We all know that many overlapping and incomplete standards exist today. By seeking to ensure that standards are culturally sensitive, sufficiently granular, and aligned across stakeholders, we can enable the collection of secure, accurate, complete, comparable, actionable, and interoperable data.

In turn, access to these data will support better outcomes, fewer disparities, improve patient trust, and enhance operational efficiencies. Once the content standards are complete, exchange standards will be developed through the HL7 process. This will ensure we not only have the what, but also the where and the how.

This information is critical to identifying disparities and determining where there may be bias in a model using AI so that it can be mitigated or eliminated. AHIP supports a risk-based approach to oversight that differentiates between high-risk, or high-impact, and low-risk AI. For example, the use of deep neural networks in clinical care presents a more significant risk to patients than deploying simple algorithms to support administrative functions. Flexibility to right-size businesses practices and mitigation techniques based on risk is necessary to realize the potential of AI while avoiding overly restrictive, infeasible, or misaligned policies that risk stifling innovation.

To that end, we believe AI oversight should avoid subjecting all underlying AI technology to mandatory outside review. Many healthcare organizations developing AI tools, particularly those that function as covered entities under HIPAA, are proactively employing their own risk-based approaches and optimizing existing data governance structures. This would, of course, not prevent, in our mind, organizations from voluntarily engaging in outside review, as many do with cybersecurity and other risk management initiatives. As mentioned previously, we fundamentally view the FAVES principles as a framework to establish and maintain trust as well as quality. Trust is the foundation of our members' engagements with patients and consumers. Health insurance providers build and maintain this trust in numerous ways, including by protecting privacy of patient information and promoting tools and resources to support patients' active engagement in their health journey.

Transparency, in our mind, is a key enabler of trust and a critical component to the successful deployment and use of AI. Patient/consumer/caregiver education is critical to helping individuals better understand what AI is and how it might be used. Simply put, as we explore this vast new frontier, we must ensure that patients, caregivers, and consumers are partners in this journey with us. The appropriate use of AI holds great promise for improving healthcare for all Americans. Engaging a diverse set of stakeholders is essential to the success, so we thank you for holding this hearing, and we are really happy to be a part of it. We look forward to the discussion.

Sarah DeSilvey
Thank you. We are now on to our final panelist, Christopher Longhurst. He is the Chief Medical Officer and Chief Digital Officer at the University of California San Diego Health. Welcome, Christopher.

Christopher A. Longhurst
Thank you very much. I see a lot of friends and colleagues in the room. I really wish I could be there with you today, but it was not in the cards. As suggested, I serve as both the chief medical officer and the chief digital officer, and so, I sometimes describe this synergy as being able to solve all the problems and challenges in our healthcare delivery organization from the Care Management Organization (CMO) seat, and then helping to innovate new solutions from the seat of the chief digital officer. So, from that standpoint, I am extraordinarily bullish on the opportunity AI presents to us, but as many of our speakers today highlighted, we really need to do that carefully and thoughtfully.

So, if you go to the next slide, I wanted to highlight first of all how we support and endorse AI principles at UC San Diego Health. We actually have an AI governance committee that I stood up five or six years ago, and in our effort to build trust, as was described in the last speaker's comments, we committed ourselves to transparency. We also committed to not taking humans out of the loop in clinical decisions and a variety

of other principles that actually translated very well to the Biden administration's commitments that were released in December. I was fortunate to be part of a taskforce that developed that, and I really feel like the statements, not just about FAVES, but about commitment to transparency and others, were important.

Now, there is one thing that I would point out in the blueprint for AI Bill of Rights that was released earlier in 2023. The administration outlined that testing conditions should mirror as closely as possible the conditions in which AI would be deployed, and that AI-based support should be monitored on an ongoing basis for adverse outcomes rather than a single offsite evaluation. So, a lot of speakers have addressed this today, and I just wanted to reiterate that that local governance and monitoring has been so critical for us. I would like to share an example with you rather than talking in the abstract. Could we move to the next slide?

The example I will share is specifically around generative AI, and partly because of some work that was published at this time last year out of UC San Diego Health identifying that AI chatbots could construct high-quality, empathetic responses, we partnered with our electronic health record vendor to actually implement this in a workflow that allowed our physicians to access draft messages that they could then edit. Our AI governance committee had a really great discussion before we put this in about our commitment to transparency, and where we landed is that even though a doctor would be editing and sending every single one of these messages…

In fact, in the upper right there, you will see there are only two buttons. One says, "start with draft," and the other says "start blank reply." There is no button that says, "just send now." But despite the fact that every message would be ultimately taking accountability from a clinician sending the message, we still decided that full transparency with our patients was critical, so we were actually the only pilot partner that chose to automatically append an addendum to every message, as you can see here, that essentially reads that this message was generated automatically and then reviewed and edited by your clinician.

I will tell you that there was a lot of discussion about this, not just at UC San Diego, but in our community locally, and the vast, overwhelming response from our patients was very positive. They appreciated the transparency, and many of them pointed out that they were concerned about messaging their busy doctor because they knew that their time was limited, and that understanding that their busy doctor had an AI copilot actually made them feel better, but they were also very happy that it was being reviewed by a human before it was just sent. So, that is one example of how we are putting those principles into action of both keeping the human in the loop and transparency, and if you will move to my final slide, I will point out again that local governance is really what has enabled all of this. Just recently, our vendor announced last week that they are making available software that is actually open source for local testing and monitoring of these models.

From our perspective, that is absolutely the only way to ensure that the resulting outcomes are fair, appropriate, valid, effective, and safe, as our commitment suggests. In fact, I will close with one final example, which is that just a couple months ago, we published the second-ever impact of an AI algorithm on sepsis mortality. This is the culmination of work we have been doing for three or four years in this space, but there are a couple of things that I will point out. No. 1, the algorithm that we developed was actually based on our own data set. Many of our speakers spoke about health equity issues, and I will tell you that as we reviewed our own data around sepsis, we identified opportunities to close equity gaps, and so, really

building this with our own data helped us to ensure that we were guiding it in a way that was maximally equitable.

The second thing was that while we have fantastic data scientists who built an amazing multimodal algorithm, we actually credit 20-30% of the outcome to the algorithm itself because, in fact, the majority of the benefit that we accomplished was from workflow redesign. For example, we know and we have found that firing alerts to our busy front-line clinicians was not helpful in terms of the interventions that we wanted to implement, and so, we actually constructed a workflow where our CO team, which is a central team out of the count, receives some of these alerts and can help to close those gaps when appropriate, and so, we credit a lot of that workflow and process redesign for the outcomes that we achieved.

In fact, I will just close by saying that the editor of the journal where we published this actually wrote an accompanying editorial called "Integrating AI Into Healthcare Systems: More Than Just the Algorithm," and in that editorial, they describe all the considerations for implementing AI in healthcare systems that are really beyond the algorithm itself. I think that is particularly important, even as last week, the FDA approved a sepsis AI algorithm that has yet to demonstrate those impacts in a local context. So, I will close there, and I really look forward to the conversation. Once again, I really appreciate the HITAC committee taking the time to dive deep into these issues, I appreciate all of my colleagues taking the time for this important discussion, and I think this is a great opportunity to dive into these issues. Thank you.

Medell Briggs-Malonson
Great. Thank you so much to all of our panelists with all of their expertise, especially about FAVES. FAVES is such an incredibly important set of principles, and especially for those that are actually reviewing all of our various different forms of artificial intelligence and decision support interventions to ensure that it is going to be as safe, fair, appropriate, valid, and effective as possible for all of our patient populations. We are going to open it up for questions. Already, people have flipped their names, and we also have people in the virtual world. Sarah is going to help me with the first one. See? We are getting faster. Everyone knows the drill now. Mark, you are first.

Mark Sendak
Thank you. I know there will not be a lot of time for multiple people to chime in, but I would love to get Dominic's thoughts on this and anything that Ashley and Chris can share. The problem that it most affects for me personally is working in a high-resource environment and seeing what it takes to do internal product lifecycle management well. Chris and Ashley, I think you are both giving examples of how to do that. Dominic, you have years of experience supporting community clinics across the state of Georgia with that last-mile implementation of technology. So, from your vantage point, what should we be thinking about as a federal agency or advisors to a federal agency? What is going to be needed at the last mile? Maybe you are not going to get all the bells and whistles of what Chris and Ashley described, but what do we have to get out there quickly to enable adoption of FAVES in the settings that you support?

Medell Briggs-Malonson
Dominic, before you answer, we have a lot of questions, so we will just have you answer this question, but for the other panelists, please go ahead and put your comments in the chat because I do want to make sure we get to all the HITAC members' questions. Thank you.

Dominic Mack
Thank you, Mark. The map I showed earlier of the safety nets for federally qualified health centers, when we talked about the practices that really do not have the connectivity, and the effect of AI when we use the E out of FAVES, will be effective because of the data that is obtained. When you look at these populations that are underserved and the providers who are underserved, if we are not connecting and we are not able to obtain information and data, we will not be able to access and treat those patients properly with AI. So, I do think it is a right-fit type of implementation for different communities. We have always said that high-tech is not necessarily better than low-tech if it is not right. You look at how they have used mobile phones in Africa, etc., to be really effective.

So, to your question, I think we have to work with those communities. You all brought in one of your publications about the importance of implementing locally and involving social scientists. What I was alluding to on the first slide was the fact that we need these communities involved at all stages of AI development. That is how we are going to get the best out of AI, and that is how it will be developed for the community. So, in summary, the pipeline has to include folks from all communities, from African American to American Indian, disabilities, etc. We need to have a pipeline of scientists who are involved but also communities who are involved as we build these solutions.

Medell Briggs-Malonson
Thank you so much for that answer. Next is Rochelle.

Rochelle Prosser
I feel like we are on a tag team here. You answered the question that was directed to Dr. Mack.

Medell Briggs-Malonson
Sorry, Rochelle, can you get a little bit closer to the mic so that everyone can hear you?

Rochelle Prosser
Okay. My question for Dr. Mack was actually answered under Mark's question, so I will go to the next question for Samantha. Thank you, first of all, for acknowledging that before patients come into a health system, they are consumers, and they deserve protection as consumers and customers. My question is how do we address how patients can engage after they have interacted with the healthcare system, understanding that AI is being used in ways that they had not imagined? Could you talk a bit about that? Thank you.

Samantha Burch
I think there are two parts to your question, and I will be brief, knowing that we have a lot to get through. The first part is that at some point, we are going to have to have a serious conversation about roles and responsibilities across the ecosystem. When we talk about when a patient is harmed as a result of AI, who is responsible for that? It is a difficult conversation. I am not surprised that it has not been at the forefront of what folks want to sit around and talk about, but I think we are going to have to get there because that is part of what you are asking. We can put up 1-800 numbers for folks, we can put out flyers, we can make information publicly available, but ultimately, if there is no next step for them and we are just looping them around, they are never ultimately going to get to that answer, and more importantly, also, without the

information on what was the foundation of their harm or how their harm came to be, their story is never going to get told. To me, those are the two parts of the question you asked.

Medell Briggs-Malonson
Thank you for the question, and for the answer as well. Next, we are going to have Shila.

Shila Blend
Thank you for the presentations. The question I have regards accessibility, Dominic, as you had the map up and you were talking about community providers and different things. I come from a frontier state, and we have a lot of rural health clinics and a lot of critical access hospitals where staff wear many hats and could really benefit from these things. However, they also operate on a tight margin. With that being said, how do we make these tools, implement them, and make them more accessible to some of those organizations that need it the most, that are not connected to the Big Six or the major corporations?

Dominic Mack
I guess Mark's name has been called a lot, so he must be popular. In one of the Stat articles that they wrote, they suggested that, just like we had the 62 regional extension centers, from the federal perspective, we put funds into support for these communities. Now, as outlined in my slides, I do think that we need to do it differently. I think we did a great job, we were part of that effort, but also, we have learned from that. We need to make sure it is sustainable. Some of that is providing sustainable funding to these communities and understanding the safety net. In some instances, independent organizations really do not have the resources to sustain this technology and support it, but if we can support other things across this country, we can surely support this. I think we just have to look at a new effort from the federal perspective to put funds in the hands of these communities, but make sure they are sustainable. I think that model is one we can think about.

Medell Briggs-Malonson
Thank you. Next, we will go to Michael, on Zoom.

Michael F. Chiang
Thank you. These were really great talks. I had a question specifically about either Ashley or Chris's talks. Ashley described AI governance structures within NYP, and Chris, you mentioned how local governance enables clinical impact at UCSD. I just would love your thoughts about to what extent governance should be within an institution because some of these questions you mentioned for governance, like whether something is safe or effective, seem like they should just be part of the regulatory process for everybody, FDA or some other government body. I am curious if you feel like you are doing it locally because we do not have that large guidance yet. I would just love your thoughts about what part you feel like is going to need to remain local and where we draw the line about what should be general regulatory stuff versus local. Thank you.

Ashley Beecy
I think that is a great question, and something that we think about, and we partner with our regulatory team because we know this is an evolving landscape. Things are changing, a lot of the federal organizations are observing to understand how we should regulate this space, so I look at the local governance also as a way to implement the standards that are developing, and as regulation evolves, it would be a mechanism

to make sure that we are aligned with that regulation, but there are also things that need to be regulated locally, like some of that monitoring and surveillance and the implementation of these best practices, as well as the concept of the workflow, as Chris mentioned, which was a large portion of the effectiveness of the sepsis model. Those are things that are going to need to be done at the local level because they are going to vary across institutions.

Christopher A. Longhurst
I will just add onto Dr. Beecy's comments. She is exactly right. The outcomes that we achieve are so dependent on local context that I really do not think that this is something where regulatory bodies at a central level can help to make this happen. Just as an example, there have been thousands of publications about sepsis and AI, and only a very small percentage of those have been evaluated, and even a smaller percentage of those have had impact on outcomes. And so, I really worry when we are providing a national stamp of approval on algorithms and saying we know that they pass muster with, say, a standardized data set. That does not translate to efficacy in many or most cases.

And so, I think that there is no instance in which there should not also be local governance, in addition to whatever needs to happen at a national level. I know that this raises some concerns about resources and things of that nature. I put a comment in the chat about shared instances of electronic health records. A great example is federally qualified health centers. In San Diego County, uniquely, 1 in 3 of our residents gets primary care from a Federally Qualified Health Center (FQHC). Many of those FQHCs now get their electronic health records from a vendor called OCHIN that provides that instance of an EHR to FQHCs in 36 states. So, while the local FQHCs do not have the resources to construct AI governance committees, OCHIN certainly does and can represent a lot of these practices really effectively. I think there are ways we can look at making this happen that I do not see where removing local accountability and oversight makes any sense.

Medell Briggs-Malonson
Excellent. Thank you so much for those remarks. Next is Anna.

Anna McCollister
I am going to follow the rules again. It does not happen often. My question is for Samantha. I have to admit, I am coming to this as somebody whose, again, primary hat on HITAC is that of a patient. I have complex Type 1 diabetes with lots of complications, I take 20 medications currently, and I have 16 different doctors. If you heard my comments earlier, I used the word "diabolical" within the context of the use of EHR-derived, data-informed AI. The implications of most of those case studies that I have seen that have surfaced all relate to access and the use of algorithms by health insurance companies to come up with mechanisms of restricting care and/or making accessing care so incredibly burdensome on individuals that it essentially makes it impossible to access, creating obstructions.

That is truly one of my biggest concerns, and everything you said is wonderful, such as transparency and putting patients first. All of that stuff is great. I love it. How is that actually being operationalized amongst health insurance companies, and has the industry established any kind of standards and accountability for its members to actually live up to that? Because I am really convinced, though I would love to be convinced otherwise, that these tools are going to be a way of putting draconian decisions behind a black box, calling

it AI, and making it completely impossible to understand why the decisions that are being made are being made.

Samantha Burch
I can speak a little bit to process. Like any membership organization, I cannot speak to any one member's particular practices, although we now have several governance committees around AI that we are creating specifically to have those conversations. What we are doing at AHIP is we are in the process of developing a set of principles on AI and looking at potential next steps for that in terms of the industry, but there is a ton of receptivity. I am looking over at Katrina because she has been involved in this process a lot longer than I have as a new staff member at AHIP, but I think that it is being taken very seriously, and what we are trying to do is dig down into experience versus reality of how algorithms are being used by plans. Prior authorization is a scary term, but I think that is one of the main use cases that comes up, and when we speak to members, we hear that AI and prior auth is only used for approvals, not denials, and also for documentation. Again, that is anecdotal, but we do have a process that we are undertaking to create principles in that space.

Medell Briggs-Malonson
Thank you, Samantha. Bryant?

Bryant Thomas Karras
Thanks. Dr. Beecy and Dr. Longhurst, I wanted to call out a conversation we have been having a chat. Chris, you kind of touched on low-resource settings and opportunities to pull in partnerships and representation for those FQHCs, but what about the even lower-resourced partners in this healthcare space, such as public health agencies and public health authorities? AI is impacting our world and our decision making, and I am wondering if there is an opportunity, or could you talk about whether public health partners need to take a seat at the table in governance in the clinical space, or do we need our own local governance of how these AI tools are impacting public health? I am Bryant Karras from Washington state.

Christopher A. Longhurst
Dr. Karras, it is great to see you again. Bryant and I got to know each other through the pandemic, and some work our states were collaborating on around exposure notification, and I would actually point to that as a really outstanding model for two or three reasons. First, there was state-based leadership that enabled local work, so I certainly think that there is a role for public health agencies to help take the lead in this. Second, both California and Washington were partnered closely with academic institutions who helped to monitor outcomes and ensure equity and fairness, and I think those types of partnerships in the public health space can be really effective. I can speak locally here. Our School of Public Health is very interested in partnering with our county, state, and other public health authorities around the use of AI in particular, so I think you will find ready and willing resources to partner.

With respect to where it is actually done, part of that really depends on the workflows and the systems being used, and ultimately, the institutions that are running those systems that bear the brunt of the daily workflow are where the home should be because we have learned that if you do not integrate workflow in these decision support tools, they are not going to make a difference. We can predict all sorts of things with machine learning and AI, but if it does not get predicted at a point in time where there is a pivotal moment

and the decision is being made, it is not going to actually have the impact on outcomes that matters to our patients and the families we serve.

Medell Briggs-Malonson
Thank you for the question, Bryant, and thank you for that answer, Chris. Thank you especially, Bryant, for emphasizing the importance of ensuring that public health and our clinical settings are always in lockstep, and also, of course, when it comes to our local, state, and federal governments, we have to do it all together. I think I see Ike's hand up on Zoom. Ike, you have the floor.

Steven Eichner
Great, thank you. Building on what Dr. Karras was talking about, do you have some recommendations about how we might approach a consensus-based approach or collaborative-based approach that brings together clinicians, academic researchers, HIT developers, public health, and patients to collaboratively develop a framework, both on the regulatory side and in a data governance environment, that helps foster the development of AI that is useful across and between domains so we are using the same basic tool set between public health, healthcare, and other environments?

Medell Briggs-Malonson
Ike, was that a question for a particular panelist.

Steven Eichner
Any of the panelists who care to can respond.

Medell Briggs-Malonson
Would anyone like to answer that question?

Ashley Beecy
I think that is happening to some extent in these national collaborations. They are bringing together various stakeholders to really think about this broadly, and I would recommend taking a look at the work that they are doing. I can put some of the names in the chat, if that is helpful, if you want to refer to those groups.

Steven Eichner
Absolutely. I am thinking particularly about additional attention to looking at the patient because a lot of those, particularly in the rare disease organizations, do not necessarily have a big national presence or are not necessarily on the national organizational radar in that sense, but collectively are still a substantial population.

Medell Briggs-Malonson
Excellent. Thank you so much, Ike, and thank you so much for the response. Well, I think we have actually gone through all of our questions. Are there any other questions from HITAC? Okay, we have six minutes, and especially the two of you all, to the ONC staff, we are no longer going to have these two sit next to each other. We truly only have time for one more question, and then we will end. Rochelle?

Rochelle Prosser

Thank you. Hopefully these will help to address my partner in crime over here. Dr. Mack, this question is for you. Considering before the implementation and use of generative AI in the institution of public health was a widely adopted component to healthcare and healthcare practice and interaction, within the closing of healthcare systems that partner with these public health systems, how are we addressing the equitable use of AI within public health? It is an add-on to Dr. Bryant Thomas Karras's question.

Dominic Mack
That is a loaded question. When I think of public health, I do not think of public health departments. Public health is not owned by any one department, academic institution, etc., but public health departments within the states are important in implementing technology, and there is a difference across the country. We saw that with COVID when it came to the distribution of logistics, vaccinations, and other things, not to get into that, but I think it varies from state to state. Dr. Longhurst just named some things that are happening out in California. Particularly in the Southeast and Georgia, when it comes to the population that we focus on, some people do not want to use the term "underserved," but states approach the underserved population differently with resources, and also with engagement with innovators.

I would answer that by almost not answering it, but it varies from state to state, it varies in different areas, but to the previous question, public health has to be involved in the conversation at all stages, going back to what I said earlier, and make sure that we are not only representing the patient, but we are representing the various communities. Let me just say this, and I will end with this. Poverty is associated with education and health. We know that if you are poor, if you are uneducated, you are going to be unhealthy. Poverty has grown. We have more children in poverty now than we did in 1950. So, AI has to be coupled with other interventions that we have across this country.

Medell Briggs-Malonson
That is an excellent way to end this hearing, really focusing on ensuring that we are centering healthcare, public health, the social drivers of health, and all of these other elements as we are thinking about applying the FAVES principle to the design, development, deployment, and post-market evaluation of artificial intelligence. On that note, I want to thank all of our amazing panelists for being here, especially the two of you also here in person, for lending all of your expertise from across the country, and we want to thank you for being part of this important panel, as well as this important hearing. At this moment, I am going to actually transition to Wendy in order for us to proceed to public comment.

Public Comment (00:36:57) (Recording 2)

Wendy Noboa
Thank you, Medell. We would like to open the meeting now for public comment. If you are on Zoom and would like to make a comment, please use the hand raise function at the bottom of the Zoom toolbar. If you are on the phone only, please press *9 to raise your hand, and once called upon, press *6 to mute and unmute your line. We will pause for a moment to see if any members of the public would like to make a comment. Just as a reminder, our next HITAC meeting will be on May 16th, and all the materials from today's meeting are available on HealthIT.gov. At this time, there does not appear to be any public comment, so I will yield the time back to our cochairs. Medell and Sarah, please proceed.

Final Remarks and Adjourn (00:37:57) (Recording 2)

Sarah DeSilvey
I believe it is my honor to do the first sendoff. I want to thank all of you for joining us today, both in person and on Zoom. It is a pleasure to work with all of you on HITAC toward this critical mission of informing policy. I also want to thank all the panelists who came to present critical topics in artificial intelligence and our responsibility to do it justly. We are all better for your voices and wisdom, and we hope you can come back in future meetings. I also want to thank my amazing cochair. Medell, thank you, and thank you to the ONC team for supporting this in-person event and for supporting our work.

Medell Briggs-Malonson
Thank you so much, Sarah, and I, too, want to echo Sarah's comments of saying thank you all for an amazing day. I want to first acknowledge Micky and Elise for allowing us to even have this hearing. It started off as just an idea, and definitely, through your leadership, Elise, and the support and leadership of Micky, we were able to do this, especially bringing experts from across the country as well as the voices of those that have not been here for us to hear, so I appreciate your leadership and your support of that. I also want to thank Mark for helping us to also organize this hearing, along with my wonderful cochair, Sarah. I really appreciate all of your insight.

Again, to all of the panelists, as Sarah said, we are so much better for your voice and for your expertise. Thank you for your preparation and for taking the time. To the amazing HITAC committee, there is a never a dull moment with you, and all of your brilliance that always shines through every single time that we are able to get together, and especially as we are continuing to drive, thinking about policies, standards, and whatever we can do to help to support ONC and the rest of our federal agencies. As always, a round of applause and appreciation for the ONC and Accel staff. We could never do any of this without you all. On those notes, again, I am looking forward to our next HITAC meeting. Thank you all, and safe travels as you proceed home as well. Wendy?

Wendy Noboa
Ooh, the final word. Well, thank you again, everyone. On behalf of ONC, we are so, so privileged to have you with us. It has been really enlightening. Get home safely, and if you could give me your nametags, that would be great, in the spirit of sustainability. We will see you again soon. Thank you, everyone, and have a great day.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Steven Eichner: I would like to thank ONC for ensuring these meeting have a virtual participation option. For those of us with disabilities that make travel difficult or impossible, as well as for others for whom travel is a burden, virtual participation facilitates participation across a very diverse set of stakeholders. Sharing information and considering voices and input from across the country is important in developing plans, regulations, policies, and more related to health information technology and health care.

Johnna Litt: Indeed!

Wendy Noboa: Statistical Policy Directive No. 15: Standards for Maintaining Collecting, and Presenting Federal Data on Race and Ethnicity:

https://www.federalregister.gov/documents/2024/03/29/2024-06469/revisions-to-ombs-statistical-policy-directive-no-15-standards-for-maintaining-collecting-and

Hans Buitendijk: IS-WG-2024_ Recommendation – 28 – Recommend that ONC continue to evaluate methods to maintain alignment between USCDI with FHIR US Core and C-CDA implementation guides as these implementation guides are published subsequent to USCDI publication.

Sarah DeSilvey: Requested Amendment: Fully replicate the prior ISWG recommendations by including the four Gender Harmony elements: a) female, b) male, c) non-binary, d) unknown. PLUS the USCDI defined values of e) additional gender category or other please specify, and f) chose not to disclose.

Johnna Litt: lost audio

Johnna Litt: ok, it's back

Aaron Sanchez: This question is relating to HT-1, so I apologize if this is not the time to raise this concern. Nevertheless:

How do you all plan to address concepts of safety and efficacy within the construct of HT-1? HT-1 calls for "model cards", but does not require any information to be populated in the various sections of the model cards, nor does it establish a minimum threshold for safety, accuracy, or fairness. It might be helpful to explore how HT-1 might better support those concepts. It does help a lot in terms of transparency (i.e. transparency in sharing what information EHR vendors are willing to share, but doesn't require the data to be shared, nor establish minimum thresholds for safety.)

Sarah DeSilvey: Michael, thank you for this. the value sets in the submission are much more robust than the examples in the text. This was a topic of conversation in ISWG and we appreciate your elevation of this here at HITAC.

Michael Chiang: Thank you Sarah! Would you be willing to add some of those examples explicitly to the text? Rationale: disabilities such as wheelchairs are easily visible to others, whereas ones like vision/hearing are not always obvious to outsiders - so good reminder that there is more under the surface.

Steven Lane: Thank you for this excellent work by the workgroup and HITAC. These recommendations, if implemented in the final USCDI V5, will significantly advance nationwide interoperability.

Mark Savage: No video in the room, no audio.

Stephanie Reed: We lost audio and video

Stephanie Reed: on Zoom

Brian Ahier: The last think that I heard was “recording in progress” and now the line is dead air.

Steven Eichner: One of the biggest potentials for AI is to help recognize outliers (such as incidents of rare diseases) and bring attention of those incidents to the treating physician and care team. One of the largest

risks, I think, is poorly designed/implemented AI that doesn't account for/identify outliers, resulting in what would otherwise be contraindicated care choices/recommendations.

Wendy Noboa: There are no slides for Laura's presentation.

Brian Ahier: I hope that Dr. Alterovitz will be able to share his slides.

Wendy Noboa: All meeting materials are available on HealthIT.gov: https://www.healthit.gov/hitac/events/health-it-advisory-committee-67

Lisa Myers: For Mr. Alterovitz, how does the V.A. implement the patient consent alluded to in your AI Model Cards, without exacerbating disparities in healthcare? I.e., if patients withhold consent, do they get different treatment? Does the resulting AI data set become skewed?

Rochelle Prosser: This questions is for Dr.John Brownstein: 1. Within the facility space, where does transparency begin and end? 2. Who is the source of truth in accuracy, etc... 3. When and where does Patient consent begin and end in Ambient recording? 4. Most facilities have policy preventing patients from recording Clinical staff. In States where recording people without consent...like Florida, how is MS Ambience Allowable in a Healthcare Use in AI? Is this Ambient AI use Bidirectional?

Aaron Sanchez: How do you all plan to address concepts of safety and efficacy within the construct of HT-1? HT-1 calls for "model cards", but does not require any information to be populated in the various sections of the model cards, nor does it establish a minimum threshold for safety, accuracy, or fairness.

Rochelle Prosser: My Questions can be for all the panel as well.

Aaron Neinstein: +1 to Lee's comments. The algorithm is only a small part of the story. The delivery mechanism and workflow is equally important.

Rochelle Prosser: Lisa +1

Aaron Neinstein: Continuing on Lee's thread… It rarely succeeds to build an algorithm in isolation and then try to deploy it. The algorithm and workflow have to be built and tested together.

Rochelle Prosser: Aron+1

Peter J. Embí: @Aaron - precisely. Critical to the successful use of AI.

Sarah Bluher: Question for Drs. Brownstein and Alterovitz: How are you evaluating accuracy of ambient AI, and are you finding that ambient AI scribes hallucinate? A recent Permanente Group study of Ambient AI included examples of hallucination such as: "In one example, the physician mentioned scheduling a prostate examination for the patient and the AI scribe summarized that a prostate examination had been performed... There were also a few instances where the summary was missing some details, such as missing chest pain and anxiety assessments."

Jim Jirjis: Much of the discussion focuses on AI uses where the developer has control of the algorithm.. What about uses of LLM's when there is not the ability to have the knowledge or control of the quality of the output?

Rochelle Prosser: Are you including the Historical holders of vulnerable populations to use their terms of language and inclusion for NLP and the use of AI as we continue the use silled and teneted AI and ChatGPT within facility and Government spaces?

Gil Alterovitz: Re: question on accuracy. It is possible to test actual and generated data where we know the underlying truth when we compare different approaches.

Sarah Bluher: ^ Great. And what are you finding in terms of accuracy levels?

Michael Chiang: Great talks! With regard to AI monitoring & algorithmovigilance: this of course needs to be done locally (at Vanderbilt, BCH, etc). Do you feel the findings should remain locally, or is there benefit of communicating your findings to the broader community? If so, what would a structure for disseminating those findings to the broader community look like?

Steven Eichner: Please see my comments earlier. Building on those ideas, how/what foundational policy elements can we develop/adopt to ensure AI recognizes and accounts for patient/data outliers, calling providers' attention to these outliers and ensure AI supplies recommendations (where that's it job) that account for these outliers? Even if it's not in the core data model, how can AI account for inputs that are outside the norm? Does the data used to train AI include sufficient outliers to enable the AI to subsequently account for outliers?

Peter J. Embí: Great answer by Troy. I will also add that we are actively testing approaches (with some funding for instance from the Moore Foundation) to determine how we can deploy algorithmovigilance tools in lower-resourced settings, but I agree we have to be deliberate about this and put resources into studying how to do this well beyond our larger systems and academic health centers.

Rochelle Prosser: I don't think most populations are hesitant to use these tools, I think it tis the application and use of their name and likeness and their words within the use and context of AI and how it is currently causing more harm depending upon you population group. How are we addressing this difference in accuracy between the populations and application in use case within the real world. and how are we ensureing these differences within the healthcare spear do not become punative like they are in the public spear from Market, to law enforcement....Particularly in how people express their word within crisis and mental health?

Gil Alterovitz: The AI Tech Sprint is currently ongoing. We hope to be able to have/share the results soon, when winners announced...

Aaron Sanchez: How will ONC would like to work with external entities like quality assurance labs? As mentioned, Commissioner Califf described the need for the FDA to utilize these kind of external testing entities, and ONC has leveraged testing labs previously for Meaningful Use certification. It might be helpful to explore how ONC intends to use labs in the AI space, or what additional regulatory powers ONC would need to use AI assurance labs in the future.

Brian Ahier: https://www.research.va.gov/naii/tech-sprints.cfm

Brian Ahier: I am really looking forward to the results of the Tech Sprint around provider burnout. This is a critical issue.

Steven Eichner: How does AI account for exceedingly small sub-populations, when counted at the national level? For example, a rare disease population with 500 people, when counted at the national level?

Shila Blend: How does the organizations ensure security in applying AI in patient care approaches. Thinking regarding the current issues with ransomware attacks and hacking into hospital systems. How will AI systems be protected.

Gil Alterovitz: Thank you, Brian.

Gil Alterovitz: Full EO (also lists AI Tech Sprint): https://www.whitehouse.gov/briefing-room/presidential-actions/2023/10/30/executive-order-on-the-safe-secure-and-trustworthy-development-and-use-of-artificial-intelligence/

Deven McGraw: The sale of de-identified data is not unique to AI - has happened for years. But in terms of de-identification standards, any entity required to comply with HIPAA has to follow HIPAA de-identification standards and any data that is "sold" by a covered entity or business associate that is not de-identified per HIPAA standards must be consented to/authorized by the patient. FWIW.

Jo-Ellyn Klein: Can someone speak to the nature and scope of coordination with HHS OCR on the relevant privacy issues?

Peter J. Embí: @Michael Chiang - thanks for the question in the chat above about algorithmovigilance and connected to the question you just asked live… We are absolutely aligned in terms of building our systems not only to inform our work locally, but critically to sharing the key findings with others who can benefit - including others who are using the AI/algorithms/models, and those (including perhaps agencies, assurance labs, developers, etc) that should be alerted to adverse effects for spotting signals of concern and determining if/how they should be addressed. As we are building our algorithmovigilance tooling, we are doing so with an eye toward standard approaches that can enable platform use across sites and/or at least common standards so different such platforms can inter-operate. That latter point is definitely one that I think this committee could help advance.

Anna McCollister: So encouraged why @troy Tazbaz's perspective on focus on solving the problems rather than starting with what data do we have/can we get! Very important!

Aaron Neinstein: +1 to Troy. Must start with what outcome you are trying to solve for. The question should not be "can we build an algorithm to predict X?," but instead "how can we positively influence outcome Y?" We saw this difference emerge years ago as the initial appointment no-show prediction models were developed. "Can we predict no-shows" was the wrong question to ask + solving for the wrong problem.

Anna McCollister: My biggest concerns are about a) data chosen to train/run the algorithms b) who determines the issue/solution/outcome that the AI is designed to maximize/achieve and c) who regularly checks for errors or adverse outcomes that may not be obvious to the AI developers.

Anna McCollister: How do we set up governance/input structures that enable diverse perspectives to consider potential issues at each point along the way? And how is that governance process funded/managed, so that it can be effective and efficient?

Rochelle Prosser: Hello Jim Juris, Can you answer the Question from Rebecca Devaney.?

Michael Chiang: @Peter: thank you! I think this is extremely interesting & challenging. Your example that what occurs on 1 floor may not generalize to another floor within the same hospital resonated with me. Given all of these challenges, I wonder how to best strike the balance between “one size fits all” vs. “custom-tailored solutions” vs. not overloading system developers with excessive amounts of data…

Chathuri Daluwatte: Data management also need a life cycle approach for data quality. When trying to develop, deploy and monitor performance of AI, gaps in data quality will become clear and needs to be amended. AI LCM is highly interconnected with data LCM. This also connects to the previous question on data privacy, how long is the retention, if the data is sold, when deleted, is data deleted in the primary location as well as where it was sold to?

This connects to the laws regarding "right to be forgotten" as well.

Jim Jirjis: Rochelle, I am happy to address Rebecca's question if there is time

Laura Biven: To a previous question- NIH has several programs focused on AI-Readiness of data. The Bridge2AI program is focused on new data resources designed to support AI-driven discovery. We have smaller activities to improve the AI readiness of data from individual research activities; and some pilot activities to test the AI-Readiness of our high-value data resources. These efforts focus on everything from improving metadata and the incorporation of standards; improving the completeness and volume of data available and addressing biases; as well as computationally intensive data processing steps to make data ready for AI applications.

Anna McCollister: Perhaps we need to focus regulatory oversight on AI used to determine treatment options/access and recommend treatment (or limit treatment). AI could be helpful in that space, but it’s a very high risk area for prospective abuse caused by limiting or creating barriers to access that make getting care too burdensome.

John Brownstein: Anna: you are spot on! We are trying to build the plane as we fly it. For (c) - at our org, we have a multi-disciplinary group of stakeholders (with data scientists of course) supporting algorithm evaluation

Gil Alterovitz: data.va.gov has some open datasets, including ones labelled for AI R&D.

Peter J. Embí: So many great questions and points here. To @Michael’s followup to me: part of the way we’re trying to address this dilemma is to determine what variations are commonly seen in algorithms we deploy. I suspect there are not infinite options/types, but we need to better classify and then apply approaches, and THEN there will be capabilities we need for the one-offs that we can’t easily categorize. There will likely always be edge-cases, but we will learn more as we start to address them, and hence the need to learn along the way and share experiences with each other to we can eventually develop best-practices for this. Early days.

Jim Jirjis: Rebecca, I think that part of the promise of use of AI and machine language is to address to cognitive constraints of the human mind. Machines, if designed well and unbiased, can help to sift through large amounts of data that exceed the human capacity to help with human decision making. In fact thebest use of AI is to support decision making from humans, not automate decision making. The challenge is that the design of AI has to be managed to avoid bad conclusions. Additionally, the human sometimes either dose not turst a "black box" recommendation from AI if they do not understand why it make the suggestion it did, or WORSE, they treat a recommendation like an automatic action..hence in effect it being automation and not devision support

John Brownstein: Really fantastic questions. This could fill up an entire day alone.

Rochelle Prosser: I concur Dr. Brownstein!

Peter J. Embí: Thank you all. I do have to run, but this has been a great discussion, and I look forward to continuing the discussions and helping you all advance this important work.

Rochelle Prosser: THank - you Pete. It was a pleasure to hear your presentation.

Peter J. Embí: Thank you all. Sorry I have to run now.

Sarah DeSilvey: Thank you, Peter!

Laura Biven: For reference, more about NIH AI activities can be found here: https://datascience.nih.gov/artificial-intelligence

Hung S. Luu: AI and ML models rely on data not only to train the algorithms, bit also execute the model when deployed. There are standards that have developed to ensure that data is represented and transmitted in a standardized manner, but we know this varies by versions adopted as well as HIT vendor. There have been studies published that show a model degraded at single institution following an EHR change., Can we truly build AI/ML models that are agnostic to these data standard and HIT vendor variations or do we need to do more about ensuring standards are more consistent across organizations.

Rebecca Devaney: Thank you Mr. Jurjis, for public record the question was: Question from Rebecca Hunter Devaney. American Society of Clinical Oncology has established clinical/human cognitive capacity is constrained by 3-5 variables. With this in mind, what are you exploring in terms of ai critical decision support systems to limit cognitive overwhelm for better outcomes and the opportunities and challenges do you see?

Rochelle Prosser: Great questions Hung!! this is one that will have to be addressed over time.

Johnna Litt: Will the conversations within the chat be available on the website as well? Thank you.

Johnna Litt: Excellent, thank you.

Beluh Mabasa Ginting: Actually, Who is responsible for validating Elon Musk's Neuralink data that implanted a brain chip in the first human (https://lnkd.in/gcT2HdBq). Thanks

Rochelle Prosser: Bravo!

Lisa Myers: Could someone please address the inherent likelihood of patient consent (opt-in or opt-out) to exacerbate inequities in health care?

Mary-judith Ngie: Mary Judith BSN -RN, MSN informatics student at Chamberlain University. What reliable resources are available for IN to be able to share the benefit of AL our patient who are marginalized.

Mary-judith Ngie: Thank you

Rochelle Prosser: @Maia Hightower What do you believe are the reasons public and private organization in generative AI do not adopt or include the use or review of current AI tools in bias removal?

Rochelle Prosser: Proximity to or awareness of or is it something else?

Inioluwa Deborah Raji: Some of our recent papers that may be of interest: https://arxiv.org/pdf/2401.14462.pdf, https://arxiv.org/pdf/2402.17861.pdf

Inioluwa Deborah Raji: Also @ShellyShapiro, we don't have visibility into many of the training sets for many of the popular large language models so we don't know; its possible that the training data includes research articles but we really don't know

Inioluwa Deborah Raji: @Shelly, here Is the link to Roxana's paper: https://apnews.com/article/ai-chatbots-racist-medicine-chatgpt-bard-6f2a330086acd0a1f8955ac995bdde4d

Beluh Mabasa Ginting: Base on my mind, The extent to which the understanding of the ethical and trustworthy criteria of artificial intelligence and the references used may be still a question today, especially in are of digital health technology such as at mobile health (mHealth), health information technology (IT), wearable devices, telehealth and telemedicine, and personalized medicine , SinMD, Software and AI as a medical device/IVD medical device. Thanks.

Inioluwa Deborah Raji: The ACLU has an incredible article on the importance of institutional trust as a prerequisite for technological trust: https://www.acluok.org/en/news/public-trust-artificial-intelligence-starts-institutional-reform

Hannah K. Galvin: To Rae's point about potential granular segmentation, I'm interested on the panels (or others') thoughts on how to balance patients' privacy preferences with the fact that not including some patients' data in training algorithms potentially leads to increased risk of bias.

Rochelle Prosser: With women being 51% of the general population, how do you believe AI and generative AI is providing Equality/Inequiality for women and depictions of men in women's health? How do you believe this issue in AI generation should evolve?

Inioluwa Deborah Raji: There's a great article by Alice Xiang on the tension between being "Seen" vs "Mis-Seen" : https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4068921

Sarah DeSilvey: Thank you for these amazing links!

Inioluwa Deborah Raji: There's been a long-documented tension between privacy and fairness, and this was an issue we saw in the fallout of our work on facial recognition

Rochelle Prosser: Does the anecdotal and individual based responses causing continued bias since it reduces the depth and breath of the wider response in the impact?

Rochelle Prosser: I Concur Rae

Mark Savage: Amen @Rae! Critical knowledge and experience have been there for generations. We see the same with care around social drivers of health and care in the communities by community-based organizations, social-service organizations, etc. We see the same with health equity issues across the board.

Rachel (Rae) Walker: https://nursepatmacrn.medium.com/why-arent-we-talking-about-citizen-science-in-nursing-8b6c43c1f0c8

Inioluwa Deborah Raji: Here is our latest work on "AI Accountability Infrastructure", including more on Harms discovery tools: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4068921

Zeynep Sumer-King: Excellent. Thank you! Was just typing a request for this.

Inioluwa Deborah Raji: Via the Mozilla foundation, we funded two rounds of AI audit tool development since 2022, so happy to discuss this as well

Rachel (Rae) Walker: Dr. Christina Harrington has been working on this problem of language and access as well: https://www.christinaharrington.me

Mary-judith Ngie: Thank you for the resources

Zeynep Sumer-King: She's excellent

Mark Savage: Re language access. Just like bank ATMs--originally built in English only, even here in California, and then had to be rebuilt. Health Equity by Design considers such issues, considers all user populations, from the beginning at the design phase, and then throughout implementation and developing workflows.

Rochelle Prosser: Very informative Rae. for the other panelists please feel free to share your thoughts on my question.

Inioluwa Deborah Raji: There are several papers on the available participatory approaches to AI development, documentation and evaluation: https://arxiv.org/abs/2209.07572

Inioluwa Deborah Raji: Several folks on the research side have begun really thinking through the practical mechanisms of this: https://arxiv.org/abs/2310.00907

Inioluwa Deborah Raji: V similar to the idea of studying up: https://dl.acm.org/doi/abs/10.1145/3351095.3372859

Hannah K. Galvin: This article came out last month on leveraging LLM's to foster equity in healthcare: https://pubmed.ncbi.nlm.nih.gov/38511501/

Inioluwa Deborah Raji: ACLU has also done similar work on using AI to “flip the script” (ie work for this impacted): https://www.aclu.org/news/prisoners-rights/what-if-algorithms-worked-for-accused-people-instead-of-against-them

Rachel (Rae) Walker: ^^^^

Sarah DeSilvey: Thank you so much. We are all so honored to have your wisdom represented today.

Beluh Mabasa Ginting: You are welcome.

Anna McCollister: Thanks to all the panelists!!

Shila Blend: Love the resources, have them all saved to read later. Thank you

Wendy Noboa: All meeting materials are available on HealthIT.gov: https://www.healthit.gov/hitac/events/health-it-advisory-committee-67

Rochelle Prosser: Well said Dr. Mack. How do you believe the shuttering of local and independent family medical practices from direct AI implementation impact patient outcomes and AI NLP for the furture of Generative AI?

Rochelle Prosser: Thank - you Samantha for acknowledging patients within a health system are in fact Consumers and customers prior to their entry and interaction with Health systems...one addition is that as we consider AI, unlike general public customers, patients truly have no incite or choice in which they engage. So how do we address the consumer protection AFTER patients engage with the use of AI and Healthcare to ensure they retrun to care services when in need?

Steven Lane: The process that Dr. Longhurst describes is absolutely leading practice. As a PCP, these draft messages are a major benefit and burden reducer.

Aaron Neinstein: +++ to what Dr. Longhurst is saying… the power in driving outcomes is from the overall intervention, not just the algorithm

Rochelle Prosser: Looking deeper into co-pilot, could this be a viable solution for Nursing as well rather than the focus on Numerical data point gathering within a flowsheet as they demonstrated as a solution for nursing only...that is not applicable to Nursing entrepreneurs not located within health systems.

Ashley Beecy: There is a role for national collaborations to help disseminate these best practices and blueprints for implementation. With the right support they could also be facilitators in the implementation itself.

Bryant Thomas Karras: And in some cases that low resourced setting may be Public Health Organizations or Agencies. we are better resourced thanks to COVID funds but still not at the level that our clinical partners are at... how do we stay and play in this AI world

Susan Clark: +1 to Ashley and Bryant comments.

Rochelle Prosser: Dr. Longhurst, Can you please share your insights regarding my Co-Pilot? I referred to the broader use of Co-Pilot for Nursing and would welcome your perspective to my question.

Aaron Neinstein: Could not have said it better. Strongly agree with what Drs. Longhurst and Beecy are saying about this.

Anna McCollister: Such a great point by @Christopher longhurst! There is NO instance where local governance isn't needed. We can't just have one, federal stamp of approval.

Susan Clark: Second the shoutout for OCHIN. They do really great work.

Rachel (Rae) Walker: +1 to local governance

Steven Eichner: I am also interested in recommendations regarding a regulatory"floor" that supports engagement across affected and potentially affected populations. What are the opportunities for consensus-based processes that engage clinicians, researchers, patients, public health, and additional stakeholders.

Rochelle Prosser: +1 Steven

Mary-judith Ngie: interesting point

Christopher A. Longhurst: @Rochelle Prosser - thank you for the question about AI co-pilots for nurses. We are actively looking at this with our vendor partners and hope to pilot a solution soon. AI can help liberate many of our clinicians from their keyboards and (re)humanize healthcare delivery!

Michael Chiang: @Ashley @Chris: thank you very much for those comments! I think it would be very helpful to have a blueprint for questions such as (a) how regulatory processes can most benefit (and where to optimally draw the line between broad regulation vs. local validation), (b) how local governance & customization of models should occur (such as what you both discussed), and (c) how those should work together (especially for institutions without resources at NYP/UCSD).

Rochelle Prosser: Thank - you Dr. Longhurst. I hope there will be a significant improvement from what is currently there within this next round of Beta testing for version 2 for Nursing that is truly inclusive with AI.

Aaron Neinstein: I should have been more specific in my comment above about "this" on Dr. Longhurst & Dr Beecy remarks. A centralized algorithm validation will not lead to the outcomes we are hoping for. The majority of beneficial outcomes with AI are a result of the unique local holistic intervention, one part of which is the algorithm. As Dr. Longhurst pointed out, this is exactly why there have been hundreds of academic papers about sepsis algorithms which have not translated into outcomes.

Steven Waldren: Regardless of the best principles and statements, without fundamental incentive reforms, we will not see the full promise of AI. Just as we have seen with HIT yet.

Shila Blend: +1 Steven

Rochelle Prosser: Considering before the implementation and use of Generative AI, the Institution of Public Health was a widely adopted component to Healthcare practice and interaction. With the closing of Healthcare systems that partner with public health systems how are we addressing the equitable use of AI within Public Health.? This is an add on question to Bryant Thomas Karras.

Ashley Beecy: https://healthaipartnership.org/

Ashley Beecy: https://www.coalitionforhealthai.org/

Ashley Beecy: https://validai.health/

Ashley Beecy: and more...

Kathryn Istas: Thank you so much to ISWG and the panelists for their presentations today. I'm so grateful for all of your leadership to keep safety, ethics, and equity at the center of the conversation about AI.

Andrea Hobby: Thanks so much.

Sarah DeSilvey: Thank you all so much!

Shila Blend: Thank you for the informative presentations everyone.

Ashley Beecy: Thank you!

Rochelle Prosser: Thank - you everyone for yourpresentations and questions.

Hannah K. Galvin: Thanks everyone!

Steven Eichner: Thank you, ONC team. Thank you, presenters. Thank you, IS WG, Thank you, HITAC members, Thank you, members of the public.

Beluh Mabasa Ginting: Thank you for all.

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

No comments were received via email.

RESOURCES

HITAC Webpage
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