

Meeting Notes

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC)

February 19, 2020, 9:30 a.m. – 12:25 p.m. ET

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EXECUTIVE SUMMARY

Donald Rucker introduced several new members of the HITAC and gave a short update on ONC's work on the proposed final rule. Then, the HITAC reviewed the agenda for the meeting and approved the January 15, 2020, meeting minutes. **Lauren Richie** gave an overview of the new Intersection of Clinical and Administrative Data (ICAD) task force, which will begin meeting weekly on March 3, 2020. The ICAD Task Force will continue meeting until September when a public summary of its findings is expected to be released. **Carolyn Petersen** and **Aaron Miri** presented a review of the HITAC Annual Report for Fiscal Year 2019, and the HITAC approved the report by voice vote. **Seth Pazinski** and **Peter Karras** from ONC presented an overview of the draft 2020-2025 Federal Health IT Strategic Plan, which was first introduced at the January 15th meeting of the HITAC. A discussion followed, and several comments and items for consideration were submitted by members of the HITAC. There were several public comments, including one public comment submitted over the telephone and multiple comments submitted in the chat via Adobe. **Lauren Richie** reminded members that the next HITAC meeting is scheduled for March 18, 2020, and this is also the final deadline for comments on the Strategic Plan.

AGENDA

09:30 a.m.
09:35 a.m.
09:40 a.m.
09:45 a.m.
09:50 a.m.
10:50 a.m.
12:05 p.m.
Call to Order/Roll Call
Welcome Remarks
Review of Agenda and Approval of January 15, 2020, Meeting Minutes

12:25 p.m. Closing Remarks and Adjourn

ROLL CALL

Carolyn Petersen, Individual, Co-Chair Robert Wah, Individual, Co-Chair

Michael Adcock, Magnolia Health

Christina Caraballo, Audacious Inquiry

Tina Esposito, Advocate Aurora Health

Cynthia A. Fisher, PatientRightsAdvocate.org

Valerie Grey, New York eHealth Collaborative

Anil Jain, IBM Watson Health

Jim Jirjis, Clinical Services Group of Hospital Corporation of America (HCA)

John Kansky, Indiana Health Information Exchange

Kensaku Kawamoto, University of Utah Health

Steven Lane, Sutter Health

Leslie Lenert, Medical University of South Carolina

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

Brett Oliver, Baptist Health

Terrence O'Malley, Massachusetts General Hospital

James Pantelas, Individual

Steve L. Ready, Norton Healthcare



Abby Sears, OCHIN Alexis Snyder, Individual Sasha TerMaat, Epic Andrew Truscott, Accenture Sheryl Turney, Anthem, Inc. Denise Webb, Individual

MEMBERS NOT IN ATTENDANCE

James Ellzy, Defense Health Agency, Department of Defense Arien Malec, Change Healthcare Clem McDonald, National Library of Medicine Raj Ratwani, MedStar Health

FEDERAL REPRESENTATIVES

Amy Abernethy, Food and Drug Administration
Adi V. Gundlapalli, Centers for Disease Control and Prevention
Jonathan Nebeker, Department of Veterans Health Affairs
Michelle Schreiber, Centers for Medicare and Medicaid Services
Ram Sriram, National Institute of Standards and Technology

ONC STAFF

Donald Rucker, National Coordinator for Health Information Technology Steve Posnack, Deputy National Coordinator for Health Information Technology Thomas Mason, Chief Medical Officer Lauren Richie, Branch Chief, Coordination, Designated Federal Officer Cassandra Hadley, HITAC Support Seth Pazinski, Division Director, Strategic Planning and Coordination Peter Karras, Lead, Federal Health IT Strategic Plan

WELCOME REMARKS

Dr. Donald Rucker welcomed members to the virtual meeting of the HITAC, and he introduced several new members, including **Dr. Michelle Schreiber** (Centers for Medicare and Medicaid Services), **Dr. James Ellzy** (Defense Health Agency, Department of Defense), and **Dr. Amy Abernethy** (Food and Drug Administration). He asked **Amy Abernethy** to describe her role at the FDA and to give an overview of recent activities there. She noted that she is the Principle Deputy Commissioner and acting CIO, and she described the five parts of the FDA technology modernization action plan. The parts include modernization of the FDA's internal technical structure with emphasis on a cloud forward strategy, the creation of a product development center, opening up communication channels with the larger community of data and tech innovators, development of a new enterprise data plan, and the determination of an analytic strategy.

Steven Lane welcomed **Amy Abernethy** to the HITAC, and he noted that he and **Ken Kawamoto** cochaired the Interoperability Standards Priorities Task Force in 2019. One area that the task force identified as a potential point of focus was the interface between the FDA and other health IT systems.



Steven Lane noted that as the FDA modernizes its systems, it may be helpful to bring together the HITAC and/or the public to contribute to the direction of the FDA. He said the task force was particularly interested in looking at the issue of adverse drug events and how, potentially, to automate the process of identifying those events when they occur using health IT systems.

Robert Wah asked **Donald Rucker** to give the HITAC an overview of the progress of the proposed final rule. Donald Rucker summarized the process of rulemaking in the Federal Government and explained that the Administrative Procedures Act guides the notice of the public comment period and what ONC can and cannot publicly say about a rule that is not released. He said that there are complicated issues at play in the creation of the rule, but, ultimately, solid progress has been made to get the rule out.

Jim Jirjis welcomed Amy Abernethy to the HITAC and described the comment period about FDA guidance around regulation of clinical decision support, AI, and advanced analytics coming from device data. He mentioned that a HITAC subcommittee, which has been focused on the liquidity and the marketization of data, could work with the FDA to determine the degree of regulation versus freedom for innovation that should occur in the clinical space. Amy Abernethy responded that she would welcome that conversation with the committee.

Jonathan Nebeker introduced himself and noted that the VA is doing an activity with their data and analytics platform product line that is similar to the work being done at the FDA.

Robert Wah summarized the two major tasks before the HITAC, which are the review and approval of the HITAC Annual Report and the review of the 2020 to 2025 Federal Health IT Strategic Plan, which was introduced at previous HITAC meetings. Also, he announced the launch of the Intersection of Clinical and Administrative Data Task Force. Finally, he introduced the new representative from CMS: Dr. Michelle Schreiber. She is the director of the quality measure and value-based incentives group and is part of the Center for Clinical Standards and Quality. She gave an overview of her background and related previous roles and noted that she has an interest in quality measures and their intersection with electronic medical records and digital data. Also, she noted that CMS is working on a project, which is similar to the FDA's tech modernization strategy. CMS is moving its programs to the cloud and is looking at making all their measures digital. This way, she said, they can be leveraged for timely feedback reports to providers, as well as more actionable information, and better information for patients as they choose their healthcare.

REVIEW OF AGENDA AND APPROVAL OF JANUARY 15, 2020, MEETING MINUTES

Robert Wah welcomed everyone, and he thanked **Carolyn Petersen** for running the January meeting. Additionally, he asked **Lauren Richie** to give an overview of the new task force. He invited members to review the summary from the January 15, 2020 meeting of the HITAC.

The HITAC approved the January 15, 2020, meeting minutes by voice vote. No members opposed, and no members abstained.





Lauren Richie gave an overview of the new Intersection of Clinical and Administrative Data (ICAD) task force. She explained that the vision of the task force is to support the convergence of clinical and administrative data to improve data interoperability to support clinical care, reduce burden and improve efficiency—furthering the implementation of "record once and reuse." Also, she specified that its overarching charge is to produce information and considerations related to the merging of clinical and administrative data, its transport structures, rules and protections, for electronic prior authorizations to support work underway, or yet to be initiated, to achieve the vision. She stated that the task force will leverage existing information from HITAC and NCVHS prior authorization hearings, and other sources, to inform its activitiesand analysis efforts. A public summary of findings from the task force will be released no later than September 2020. She thanked **Thomas Mason** for his work in setting up the task force and **Sheryl Turney** and **Alix Goss** for agreeing to be co-chairs. She informed the HITAC that the roster was still in draft form. She noted that the first task force meeting will be held on Tuesday, March 3, at 3:00 p.m. The meetings will last for 90 minutes and the task force will continue to meet from March through September. She reminded the HITAC that all task force meetings are open to the public and encouraged them to consider attending the meetings, though attendance is not required for non-task force members.

HITAC ANNUAL REPORT REVIEW AND APPROVAL

Robert Wah thanked the members of the HITAC for their comments and all of the work everyone contributed to the annual report. He noted that, if there is a substantial discussion, the annual report would have to go back to the workgroup before being brought back to the HITAC. Carolyn Petersen and Aaron Miri thanked Michelle Murray of ONC and everyone else for their work on the report. Aaron Miri noted that, at the last workgroup meeting, every comment from HITAC members was documented and an effort was made to incorporate them into the document. He gave an overview of the next steps for the revised annual report, and he noted that, upon its approval, the HITAC would transmit the report to the National Coordinator for Health IT, and the National Coordinator will then forward the final report to the Secretary of Health and Human Services (HHS) and Congress. Carolyn Petersen told members that their comments were collected into a 28-page document, which was used by the workgroup to update the report, and she noted that the full, revised report is about 70 pages long. Instead of going through the report in its entirety, she invited members of the HITAC to raise their hands to continue the discussion. Robert Wah directed members to the document containing their collected comments and invited them to begin the discussion based on those comments.

Discussion:

- Ken Kawamoto thanked the workgroup for incorporating the comments he made at the last meeting.
- Carolyn Petersen accepted the thanks and noted that the workgroup had tried hard to incorporate
 everything that they received into the final document. Also, she stated that no other hands were
 raised in Adobe. Aaron Miri indicated that he had not received any further comments.

Robert Wah placed one final call for comments, and, seeing no further comments, he called for a vote.

The HITAC approved the Annual Report for Fiscal Year 2019 (FY19) by voice vote. No members opposed. No members abstained.





Seth Pazinski and **Peter Karras** presented an overview of the 2020-2025 Federal Health IT Strategic Plan to the HITAC. **Seth Pazinski** began by summarizing the strategic plan and the related timeline for discussion and public comment, and he reminded the HITAC that their feedback would be collected at the meeting or in writing. He provided the timeline for the publication of the strategic plan, which will remain open for public comment until March 18, 2020. He noted that the HITAC Annual Report for FY 2019 was used as a source, and ONC partnered with other federal agencies for a broader scope. He gave an overview of key aspects and the direction the strategic plan, including ensuring that individuals have access to their electronic health information and can better manage and shop for their care. Also, he noted that some of the goals of the strategic plan are to create new business models, leverage APIs for individuals and providers' benefits, and to establish data-sharing practices within the healthcare industry.

Peter Karras presented a refresher on the focus and themes of the strategic plan. He described the key challenges the strategic plan aims to alleviate through its implementation and listed some related opportunities in the digital health system. He emphasized that this is an opportunity to describe societal expectations of how a modern health IT enabled healthcare system should look, and legislative expectations outlined in 21st Century Cure Act have been included, as well. Also, he pointed out that specific HITAC priority areas have been reinforced in the strategic plan. He outlined the opportunities in a digital health system provided in the presentation slides. He listed the four goals of the strategic plan, which are:

- 1) Promote health and wellness
- 2) Enhance the delivery and experience of care
- 3) Build a secure, data-driven ecosystem to accelerate research and innovation
- 4) Connect healthcare and health data through an interoperable health IT infrastructure

Peter Karras invited the HITAC to consider and comment on the strategic plan. He began by reviewing questions posed by members at the previous meeting, and then **Robert Wah** asked **Carolyn Petersen** to moderate the discussion.

Discussion:

- John Kansky asked how he and his peers should view the plan coming from the Federal
 Government, as it is different from a corporate strategic plan and involves the Federal Government
 and many agencies. He sees this strategic plan as something the entire nation must achieve and
 invited the presenters to comment on it from that perspective.
 - O Seth Pazinski responded that the audience is broad. He noted that it addresses the direction for the access, exchange, and use of electronic health information to perform the first three goals in the plan, which are promoting health and wellness, enhancing delivery and experience of care, and building a secure data-driven ecosystem for research and innovation. He said that he sees the plan as a tool to engage both federal and private sector stakeholders and is a way to provide a broad strategy for collaboration and coordination between those stakeholders.
- Alexis Snyder commented that, regarding the area of digital health information, it is important to talk about patient engagement and to make sure that the patient is incorporated throughout the health



system. Also, she emphasized that access to the correct information and more points of access to medical records with easier ways for patients to update and correct data are very important. Finally, she noted that some of the strategic pieces for value-based care are not always accessible to those with a rare disease, as they may need to travel out of state to receive treatment, for example.

- Carolyn Petersen noted that she had several comments.
 - First, she commented that, regarding the goal to build a secure, data-driven ecosystem to accelerate research and innovation, the patient-reported outcomes, for example, have been used largely in clinical trials but are now moving into care in some settings and will likely be more apart of clinical care in the future. So, she stated, when thinking about data movement, it is not necessarily a matter of transfer between providers or health systems, but also sharing from patient to provider and, perhaps, even from providers to patients as a more electronic environment for providing care is adapted.
 - O Second, she emphasized that patient empowerment has more aspects than simply accessing information. It is about having controls within the systems so that patients can make meaningful decisions and can better understand consents, terms of use, and other aspects of the systems. She stated that patients should be able to direct care in terms of providing information to various providers when they see a gap in their care or information that needs to be corrected.
 - O Third, she thanked them for keeping privacy front and center. She emphasized that it is one of the focus areas for HITAC members, but, also, it has a very important role in the broader discussion and the health IT community at large.
- **Terrence O'Malley** echoed Carolyn's emphasis on privacy and recommended the HITAC continue to discuss the topic in detail. He submitted several comments.
 - O He inquired if there is a role in the plan to call out the potential for the Federal Government, as an example, to become more coordinated in its use of data and more uniform in its adoption of data standards.
 - O Also, he said that, for the long term post-acute care section of the healthcare ecosystem, there is no compelling, existing business case for them to adopt health IT or that the business cases are very narrow and limited. As a result, he stated, though this is a critical piece of the healthcare system that produces lots of data and includes in-home, daily observations, it is not part of the overall conversation around the care of individuals. He worried that, currently, this data does not get collected or transmitted in a systematic way.
 - He stated that the work of the HITAC is to create a business case of adoption for the items he highlighted, and he recommended that the HITAC require a basic infrastructure for interoperability and develop terms for clarity around the issue of consent, related to the process.
- Anil Jain submitted several comments.
 - O He requested that the word "open" be included before any references to standards, in order to differentiate between proprietary standards, which have been a challenge in the industry, and promoting open standards to allow for more interoperability. He noted that thinking about open terminologies or open-source terminologies would be helpful.
 - Also, he noted that, because the strategic plan addresses the time period of 2020 through 2025, there are emerging technologies that intersect health IT that were not mentioned or focused on sufficiently. Examples he gave included blockchain and artificial intelligence (AI).
 - Finally, he inquired if the Federal Government planned to start work with the industry to fund some of these initiatives and gave the example of the AI grant challenge from CMS.
- **Seth Pazinski** commented that there is an active federal coordination group for standards, and ONC is actively emphasizing this topic. This group is looking to identify and align efforts in investments related to the FHIR standard, and, also, it is striving to coordinate on the US Core Data for Interoperability and federal interest in advancing and expanding that standard.



- Peter Karras responded to Anil's comments and noted that ONC is looking at the strategy and content from a point of care level and would like to leverage some of those automation points and the role of emerging technology in terms of care delivery itself. Also, he noted that they were looking at leveraging emerging technologies to integrate data sets and statistical modeling on overall population groups. Anil Jain clarified that getting the Federal Government's point of view on how the data of individual patients, as well as populations and Al/machine learning, intersects with health IT is interesting for those who invest in and work with it every day. Peter Karras thanked him for his feedback and noted that these areas in the plan would be examined and, possibly, reiterated in a future version.
- Valerie Grey gave several pieces of feedback.
 - O She said that she was struck by the amount of work that the HITAC has to do that is foundational, especially in the area of value-based care. She mentioned several sectors that she thought were left behind in the plan, including post-acute healthcare, behavioral health agencies, Emergency Medical Services, home care, and others.
 - She encouraged the HITAC to think about some of the comments that Terry O'Malley made, with regards to business cases for adoption, incentives, and things that can be done to bring them more into the fold.
 - Then, she commented that she was glad to see Objective 1C the incorporation of Health and Human Services information and social determinants of health
 - Lastly, she echoed many of the other HITAC members' comments about the need for a more robust conversation on privacy.
- Andrew Truscott requested more focus around enabling patients to control how their information
 flows and asked for illustrations of the types of controls that should be available to authorize patients
 to make suggestions and amendments to that body of work. He stated that this information should be
 useful to the patients.
- **Ken Kawamoto** echoed the others' comments on the importance of focusing on privacy and security, which are topics that have been in the news recently. He noted that the annual report has good ideas on how to address these topics, and it might be helpful to incorporate some of these into the strategic plan.
- Aaron Miri echoed Ken Kawamoto's statement that the annual report could be used as a reference for specific ideas, and he submitted several comments.
 - O He addressed the question of what can be done to build a secure and data-driven culture to accelerate research innovation. Research, he emphasized, is a particularly difficult space. In his experience, research is often a collaborative activity involving partners from across the world, and laws surrounding research vary, creating a broken system that hampers and impedes progress. He would like to see the federal IT strategic plan callout research as a topic.
 - In response to a clarifying question from Peter Karras, Aaron Miri stated that other individuals besides researchers could look at fostering data to support a platform of stakeholders, including researchers, payers, vendors, and more, and these individuals could look at shared uses of health data and integrated data.
 - Peter Karras noted that ONC is doing work in the health IT priorities for research space, and he said that he would share these comments with his internal colleagues. Also, he said that prioritizing the topic as something that could be brought back before the HITAC was a possibility.

Seth Pazinski thanked the members of the HITAC for their feedback, and he reminded them that the public comment period is open until March 18. He said that they would welcome any additional feedback.





PUBLIC COMMENT

Mari Savickis, Vice President, Public Policy at College of Healthcare Information Management Executives (CHIME): Hi. Thanks, everyone. This is Mari with Chime. I just want to reiterate some of the comments that were made. I'm trying to follow who is saying what on the phone. But I think it was Dr. O'Malley who started the conversation regarding privacy. This is an incredibly nuanced topic. And given ONC's coordination function, I think there would be a tremendous amount of value. I think our members would find that to be very valuable and some of the folks that we work with other associations. I think that's definitely something that would be time well spent by this body. So, thank you for considering that.

Mari Savickis: Hi, again. This is Mari, again. Could you repeat the deadline to get the comments regarding the strategic plan? I missed that.

Peter Karras: The deadline is March 18.

Questions and Comments Received via Adobe Connect

Jonathan Nebeker: I will be on and off the meeting today. My comment on the Strategic Plan is as follows: The plan is outstanding and even transformative in that it focuses on outcomes not on technology. There is, however, one exception to this theme: interoperability. Interoperability is the experience of the computers, by IEEE definition, not of people. The corresponding experience of people is seamless care. I strongly urge the revision of the document to focus on seamless care and drop technical references, which are subject to perversity and to enshrining outdated technology.

Carolyn Petersen: Thanks, Robert, for the kind words about the January meeting. I was happy to keep us moving!

Mark Sugrue: Great work !! Excited to participate in the task force

Kimberly Boyd: The new TF - great opportunity.

Andy Truscott: No questions. Great job.

Jim Pantelas: I have no questions - just a comment: I was impressed by the rationale offered for decisions made.

Carolyn Petersen: Thanks! We really do want it to reflect the work and thinking of the HITAC, and we are grateful for your input.

Lauren Richie: To the members of the public, please note we are ahead of schedule and will likely open for public comment earlier than scheduled. thank you

Robert Wah: To the HITAC, if you would like to make comments or have questions, please use the "Raise Hand" tool. We will also ask for questions and comments via audio as well.

Kimberly Boyd: Great point by Alexis - on the importance of the correctness, up-to-date information

Kimberly Boyd: for the patient



ONC

Alexis Snyder: Thanks Kimberly, data is only helpful when correct and can be very harmful when incorrect

Alexis Snyder: and with a push for shared decision making and "empowerment" patients need to be engaged in part of the notes process

Carolyn Petersen: Yes, the literature on the benefits of opening up the notes is growing, and is generally supportive of it.

Alexis Snyder: not just open notes, shared note writing.

Alexis Snyder: and at the very least easy ways to amend records when mistakes are made.

Carolyn Petersen: I agree that ways to get inaccuracies corrected is important. Concerns about how that can be done without creating liability for providers (e.g., if patients' corrections are inaccurate or incomplete, resulting in wrong care being given) need to be addressed before providers and institutions will be comfortable offering that functionality. But it is important.

Alexis Snyder: there are ways that already address that and systems are capable of doing it safely but most patients don't know how or that they can. The bigger point is accuracy before it becomes part of the permanent record and shared.

Carolyn Petersen: Perhaps this is a topic to add to the list for the FY20 annual report.

Sandra Ciuffreda: Regarding accuracy of data/information, what I haven't seen addressed is ensuring that EHR software has the capability of COMPLETELY restoring a patient's record to its original data/documentation when, due to incorrect patient selection, documentation is created on the wrong patient. In working with what is considered a premier EHR software, the capability is sorely lacking, leaving incorrect data that is unable to be corrected on a patient's record.

Alexis Snyder: it is able to be corrected but there is no "law" or standard so the patient is at the mercy of the health system that documented the incorrect information as if they want to correct it etc.

Sandra Ciuffreda: Can always be corrected on paper, but, unfortunately, incorrect data is not always able to be completely corrected and restored electronically.

Alexis Snyder: yea it can, I have done it.

CLOSING REMARKS AND ADJOURN

Co-Chairs, Carolyn Petersen and Robert Wah, thanked members for their thoughtful participation and feedback on the annual report and health IT strategic plan. Robert Wah thanked Donald Rucker for his openness and candor about the progress of the final rule.

Lauren Richie reminded members that the next HITAC meeting is scheduled for March 18, 2020. This is also the final deadline for comments on the strategic plan. She reminded the HITAC that March 3, 2020, will be the first meeting of the new ICAD Task Force. The meeting was adjourned at 10:57 a.m. ET.

