

Meeting Notes

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC)

November 10, 2020, 9:30 a.m. – 12:30 p.m. ET

VIRTUAL



EXECUTIVE SUMMARY

Donald Rucker welcomed members, discussed ONC's COVID-19 response efforts and other recent work completed, and provided an overview of the meeting agenda and upcoming reappointments and membership changes to the HITAC. **Carolyn Petersen** and **Robert Wah** reviewed the meeting agenda, and the minutes from the October 21, 2020 HITAC meeting were approved by voice vote. **Carolyn Petersen** and **Aaron Miri**, co-chairs of the Annual Report Workgroup (ARWG), presented an update on the ARWG's recent work on the draft crosswalk of report topics. HITAC members submitted feedback, and a discussion was held. **Sheryl Turney** and **Alix Goss**, co-chairs of the Intersection of Clinical and Administrative Data Task Force (ICAD TF), presented the TF's Final Recommendations and Report for submission to the HITAC. HITAC members approved the final ICAD TF Report by voice vote. **Lauren Richie** presented the HITAC 2021 draft work plan, and HITAC members submitted feedback. No public comments were submitted by phone, but there was a robust discussion and comments in the public meeting chat via Adobe.

AGENDA

09:30 a.m.	Call to Order/Roll Call
09:35 a.m.	Welcome Remarks
09:40 a.m.	Review of Agenda and Approval of October 21, 2020 Meeting Minutes
09:45 a.m.	HITAC Annual Report Workgroup Update
10:45 a.m.	Intersection of Clinical and Administrative Data Task Force Final Recommendations and Report Vote
11:45 a.m.	HITAC 2021 Draft Work Plan
12:15 p.m.	Public Comment
12:30 p.m.	Final Remarks and Adjourn

CALL TO ORDER/ ROLL CALL

Lauren Richie, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC), called the November 10, 2020, meeting to order at 9:30 a.m.

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 Kinsky, Indiana Health Information Exchange

Ken 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

Raj Ratwani, MedStar Health

Abby Sears, OCHIN

Alexis Snyder, Individual

Sasha TerMaat, Epic





Andrew Truscott, Accenture
Sheryl Turney, Anthem, Inc.
Denise Webb, Individual

MEMBERS NOT IN ATTENDANCE

Amy Abernethy, Food and Drug Administration
James Ellzy, Defense Health Agency, Department of Defense
Adi V. Gundlapalli, Centers for Disease Control and Prevention
Arien Malec, Change Healthcare
Clem McDonald, National Library of Medicine
Steve Ready, Norton Healthcare

FEDERAL REPRESENTATIVES

Michelle Schreiber, Centers for Medicare and Medicaid Services
Ram Sriram, National Institute of Standards and Technology
Jonathan Nebeker, Department of Veterans Health Affairs

ONC STAFF

Donald Rucker, 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
Lauren Richie, Branch Chief, Coordination, Designated Federal Officer
Michelle Murray, Staff Lead

WELCOME REMARKS

Donald Rucker welcomed members to the meeting of the HITAC. He acknowledged that COVID-19-related resources were still available from the Office of the National Coordinator for Health Information Technology (ONC) on the healthit.gov website.

He provided a brief overview of agenda items for the meeting and explained that, on October 29, 2020, ONC announced its Interim Final Rule with Comment Period (IFC). The IFC was published in the Federal Register on November 4, 2020 and gives health IT developers and healthcare providers flexibilities to effectively respond to the public health threats posed by the spread of COVID-19 and extends compliance dates and timeframes for Information Blocking and the ONC Health IT Certification Program. Also, he stated that ONC published its final version of the 2025 Federal Health IT Strategic Plan on October 30, 2020.

He thanked the current HITAC co-chairs, **Carolyn Petersen** and **Robert Wah**, for their service, as they would be completing their terms at the end of the year. New HITAC co-chairs will be announced on or before the next meeting of the HITAC in January 2021. Also, he noted that several congressional reappointees would be announced within the next few weeks.

REVIEW OF AGENDA AND APPROVAL OF MEETING MINUTES

Carolyn Petersen, HITAC co-chair, welcomed all the participants and thanked them for attending the virtual meeting. She thanked the individuals who have worked on the presentations for the current meeting.

Robert Wah, HITAC co-chair, welcomed HITAC members, thanked ONC for its ongoing support of the HITAC, and briefly reviewed the agenda, which included presentations from the HITAC Annual Report Workgroup (ARWG) and the Intersection of Clinical and Administrative Data (ICAD) Task Force. He reminded members that this is the HITAC's final meeting of the year.





Robert invited members to examine the minutes from the October 21, 2020, meeting of the HITAC. There were no comments or corrections submitted, and he called for a vote. The HITAC approved the October 21, 2020, meeting minutes by voice vote. No members opposed, and no members abstained.

HITAC ANNUAL REPORT WORKGROUP UPDATE

Carolyn Petersen and **Aaron Miri**, co-chairs of the Annual Report Workgroup (ARWG), presented an update on the group's recent work. **Carolyn** explained that she and **Aaron** would present updates on the draft crosswalk of report topics and invited HITAC members to submit feedback and questions.

Carolyn gave an overview of the ARWG meeting schedules and action items/deliverables for the ARWG and the full HITAC. The next steps for the ARWG include discussing the outline and draft of the annual Report at workgroup meetings in November and December 2020 and then presenting the draft of the HITAC Annual Report for FY20 at a HITAC meeting in early 2021.

Carolyn lead a presentation and discussion of topics for the HITAC Annual Report for Fiscal Year 2020 (FY20). She explained that, in preparation for drafting the HITAC Annual Report for FY20, the ARWG developed a crosswalk document that considered gaps, challenges, opportunities, and recommended HITAC activities for a set of key topics. Additional topics were added to the ARWG's landscape analysis to raise awareness. The topics were grouped by several target areas, as defined in the Cures Act, which included: interoperability, privacy and security, and patient access to information. She noted that a fourth target area, use of technologies that support public health, was new for this fiscal year and arose from recent work on COVID-19 relief efforts. **Carolyn** summarized each of the target areas, related topics, gaps, and recommended HITAC activities (as proposed by the ARWG), which included:

Target Area: Technologies that Support Public Health

- Topic: Exchange of clinical data
 - Gap: Need to collect information from clinicians and laboratories for public health reporting
 - Recommended HITAC Activities (Proposed):
 - Suggest HHS guidance on minimum necessary datasets for exchange for public health, e.g., with laboratories, especially for test order entry and case reporting.
 - Hold a hearing to understand stopgap solutions implemented to improve reporting capabilities and assess whether additional long-term solutions are needed.
 - Facilitate acceleration of the practical use of data standards to improve situational awareness for local, state, and federal government emergency response.
 - Conduct a listening session to learn about the successes and remaining barriers to exchange by HIEs to support public health, including how to expand their role.
- Topic: Privacy and security
 - Gap: Issues for biosurveillance efforts, telehealth, and remote monitoring
 - Recommended HITAC Activities (Proposed):
 - Recommended HITAC Activities (Proposed):
 - Help clarify what data can be collected and how it can be used.
 - Identify educational approaches that offer improved transparency of privacy protections applicable to contact tracing applications and biosurveillance technologies.





- Encourage clinical workforce and patient education/re-education on use of technology for telehealth (including smartphones).
- Encourage guidance about privacy and security protections of public health information across varying state laws
- Topic: Vaccine Tracking
 - Gap: Lack access to data about unimmunized populations and where patients are obtaining vaccines so that at-risk groups can be targeted for interventions
 - Recommended HITAC Activities (Proposed):
 - Hold a listening session to identify opportunities and barriers for healthcare and public health organizations and highlight successful vaccine program interventions using predictive analytics.
- Topic: Patient matching
 - Gap: Key information missing when shared from laboratories and contact tracing records
 - Recommended HITAC Activities (Proposed):
 - Develop tactical recommendations based on ONC's forthcoming Patient Matching Report to Congress, including consideration of expanded use of AI and related privacy and security concerns as well as increased alignment of government public health reporting requirements and guidance.
- Topic: International exchange of clinical data
 - Gap: Countries need more information about health status of travelers
 - Recommended HITAC Activities (Proposed):
 - Hold a listening session to identify opportunities and barriers for the use of health IT in international exchange as well as lessons learned that can be applied domestically. Panelists could include the Centers for Disease Control and Prevention (CDC), World Health Organization (WHO), Global Health Data Partnership (GDHP), Dept. of Commerce, clinician representatives, and privacy and security experts.

Aaron Miri thanked ONC and HHS for their support and thanked **Dr. Donald Rucker** and ONC's leadership team for their recent work. He asked HITAC members to watch for reoccurring themes within the topics included in the ARWG's presentation and continued by describing the gaps and recommended HITAC activities for the topics under the target area of interoperability.

Target Area: Interoperability

- Topic: Exchange of health data across the care continuum
 - Gap: Need greater interoperability across the broader care continuum
 - Recommended HITAC Activities (Proposed):
 - Learn more about recent developments in standards and exchange in the areas of patient-reported outcomes (PROs), e.g., 2020 AHRQ report, and SDOH data, e.g., HL7's Gravity project.
 - Identify and help improve data streams where interoperability is a challenge to sharing broader datasets, especially when a pandemic affects healthcare settings, like long-term post-acute care and any transitions to and from those settings.
- Topic: Association between Electronic Health Records (EHRs) and patient safety
 - Gap: Impact of health IT on patient safety
 - Recommended HITAC Activities (Proposed):





- Review changes that could be made to the Health IT Certification Program to support improvements to EHRs to support patient safety.
- Suggest that ONC conduct an initiative to further define patient safety and any gaps where technology does not support that definition, then develop a roadmap for better health IT support for patient safety by 2023.
- Collaborate with the FDA to explore the use of health IT in automating collection and sharing of data about adverse events for drugs and devices.
- Topic: Exchange of Social Determinants of Health (SDOH) data
 - Gap: Lack of standards and data availability, patient matching challenges, and variation among community service providers' IT systems
 - Recommended HITAC Activities (Proposed):
 - Suggest updates on SDOH data for the ONC Patient Engagement Playbook.
 - Convene a group of stakeholders from healthcare entities, payers, SDOH technology companies, community-based organizations, and standards development projects to understand the state of SDOH data exchange in practice and identify gaps and barriers.
- Topic: Increased health equity across populations, locations, and situations
 - Gap: Data is not systematically collected nor used to identify disparities in outcomes, healthcare, and risk
 - Recommended HITAC Activities (Proposed): Convene stakeholders, e.g., healthcare organizations, health IT developers, and patient advocacy groups, to discuss:
 - How to improve collection and sharing of data that can support identifying and addressing disparities in healthcare
 - The current state and potential improvements of the accessibility of consumer-facing health IT by diverse populations
 - Non-traditional sources of health information that could be made interoperable to better serve at-risk populations
- Topic: Sharing data with the research community
 - Gap: Concerns about data quality, governance, and access to data
 - Recommended HITAC Activities (Proposed):
 - Hold listening sessions to learn more about gaps in standards needed by the research community, which is accountable to institutional review boards (IRBs).
 - Identify educational approaches that increase awareness and promote the implementation of the *National Health IT Priorities for Research: A Policy and Development Agenda*.
- Topic: Use of metadata
 - Gap: Many data management tasks are still manual that could be automated
 - Recommended HITAC Activities (Proposed): Charge a HITAC subcommittee to review and provide recommendations regarding metadata standards and potential additions to the USCDI.

Aaron Miri described the gaps and recommended HITAC activities for the topics under the target area of privacy and security.





Target Area: Privacy and Security

- Topic: Beyond HIPAA: Rules for Sharing
 - Gap: Clear rules are lacking for data not subject to HIPAA protections
 - Recommended HITAC Activities (Proposed):
 - Hold listening sessions to learn more about HHS and FTC activities, as well as approaches of third-party app developers.
 - Explore patient and clinician experiences with the sharing of health data with third-party technology companies to continue to identify best practices and gaps.
 - Review government and industry activities already underway protecting the privacy and security of health data shared with third-party technology companies.
- Topic: Beyond HIPAA: Consent
 - Gap: A lack of clarity exists about the parameters of data sharing and disclosure, and their implications for consent
 - Recommended HITAC Activities (Proposed):
 - Identify educational approaches and potential regulatory solutions that offer improved transparency of privacy protections outside the purview of HIPAA.
 - Suggest steps toward a consistent technical and operational approach to capturing and managing consent.
 - Explore ways clinicians can educate patients about the benefits and potential risks of using third-party apps as contemplated by the ONC Cures Act Final Rule and about the need to review and comprehend the apps' privacy policies.
- Topic: Beyond HIPAA: Internet of Things (IoT)
 - Gap: Security risks and concerns about informed consent increase as IoT objects become more integrated with health IT systems
 - Recommended HITAC Activities (Proposed):
 - Identify best practices for increasing the privacy and security of connected devices.
 - Identify educational approaches that increase awareness of the privacy and security issues related to the IoT and ways to reduce them.
- Topic: Privacy and security of synthetic data
 - Gap: HIPAA constraints limit the ability to conduct research and train machine learning models using large-scale datasets
 - Recommended HITAC Activities (Proposed): Hold listening sessions to determine whether the use of synthetic data raises any unintended privacy risks, such as the ability to use artificial intelligence (AI) to re-identify the actual patients on which the synthetic health data are based.

Aaron Miri described the gaps and recommended HITAC activities for the topics under the target area of patient access to information.

Target Area: Patient Access to Information

- Topic: Safety and impact of mobile health apps
 - Gap: There is increasing concern about the clinical accuracy of consumer-facing mobile health apps and the potential for patient harm.
 - Recommended HITAC Activities (Proposed):





- Support the existing efforts of consortia that are working to vet apps based on their safety and accessibility and educate patients about the findings of the consortia. In particular, investigate if frameworks or scorecards for assessing apps exist or are being developed; if so, raise awareness of these efforts.
 - Explore ways the safety of mobile health applications could be enhanced.
 - Hold a listening session on the impact of the use of apps (as opposed to the current portal systems) on patient challenges in collecting, accessing, using, and sharing their health data. Areas to consider include the efficacy, patient experience, and remaining challenges of the use of apps.
- Topic: Correction of incorrect clinical data and the ramifications of exchange of this data
 - Gap: Transparency about the accuracy of patient data and consent to share it are lacking for patients
 - Recommended HITAC Activities (Proposed): Hold a listening session to:
 - Identify approaches that clinicians and HIEs are taking to correct incorrect data, including incentives for widespread correction.
 - Discuss liability considerations related to exchanging and correcting incorrect data.
 - Learn about organizational policies and mechanisms for patients to document change requests, and how data provenance of patient corrections is being tracked.

Aaron Miri and **Carolyn Petersen** encouraged HITAC members to submit comments and questions on all sections in the crosswalk of topics and explained that all feedback would be incorporated during the ARWG's November and December meetings.

Discussion:

- **Steven Lane** submitted several comments on the overall crosswalk of topics, which included:
 - The major challenge will be to prioritize the issues by the greatest, immediate opportunity for ONC and HITAC to be engaged and to provide value within the industry.
 - There is an appropriate focus on moving information from providers (clinicians, laboratories, etc.) into public health.
 - There should be more focus on "closing the loop." There are no standardized processes for returning important information from public health back to providers, nor the ability for providers to pull data from public health for specific patients. The ARWG should add the public health provider exchange as a bidirectional process to the crosswalk.
 - **Carolyn Petersen** responded that these were great observations and that the ARWG would adjust the crosswalk to reflect them.
- **Anil Jain** voiced his support for **Steven Lane's** statements and submitted several comments, which included:
 - Encouraging the HITAC to think about the exchange of both clinical and administrative data to avoid creating another silo.
 - As a recommended HITAC activity, include feedback from the downstream users/consumers of the accumulated data and consider how to make the data more transparent and useable for them.





- **Aaron Miri** responded that these were good points and described unforeseen obstacles related to sharing larger volumes of public health data from contact tracing.
- **Les Lenert** submitted several comments, which included:
 - The main tasks for public health are vaccine distribution and targeting populations with health disparities.
 - Focusing on creating a practical set of recommendations to rapidly facilitate the tracking of vaccines is important and is related to the national patient identifier issue.
 - There is a tension between information blocking statutes and the pull-based and FHIR-based (Fast Healthcare Interoperability Resources) infrastructure created to access electronic health records (EHRs).
 - Public health is pursuing strategies via Digital Bridge, a broad healthcare interoperability project, to automatically report on cases when triggered by lab tests.
 - The HITAC should delve into the process of how public health gets data/reports from the healthcare system to find a meeting place between the push operations of Digital Bridge's work and the pull operations happening under FHIR for ongoing case investigation. This will provide a full picture to public health officials.
- **Jonathan Nebeker** voiced his agreement with the previous comments and submitted several points, which included:
 - Tie the Annual Report topics to the Federal Health IT Strategic Plan and reference the recent the VA and DoD's recent initiative and metric mapping work.
 - Reinforce the Annual Report by highlighting levers available to the HITAC and ONC related to information gathering/analysis/awareness, standards development/promotion/enforcement, regulations, private-public partnerships for demonstrations, and monetary incentives.
 - There is a great deal of focus in the Annual Report agenda on exploring issues and not enough explicitly focused activity on levers that the HITAC and ONC can use to complete work.
 - **Carolyn Petersen** voiced her agreement with his comments and explained that some ARWG members noted that listening sessions were over-proposed as HITAC activities. She looks forward to discussing levers with ONC leadership.
 - **Aaron Miri** noted his agreement with **Carolyn's** points and discussed how prior year's Annual Reports have been used to inform the general public on issues, many of which were eventually included in levers, proposed rules, and final rules. He discussed the merits of listening sessions, as well as levers to move work forward faster.
- **Sheryl Turney** submitted several comments, which included:
 - Bidirectional data sharing between clinical and administrative settings, as well as patients/consumers in the public health setting, is important.
 - There are differences in interactions patients experience with public health with regard to COVID-19 diagnoses.
 - COVID-19 provides a good use case for creating ideal state recommendations for how to manage a pandemic from a public health perspective, including the use of automated systems to share data bidirectionally, from patients to providers to public health and back.





- The Intersection of Clinical and Administrative Data Task Force (ICAD TF) has examined some of these issues, and some of the TF's recommendations will support the recommendations being discussed.
- **Denise Webb** submitted a question and a comment, which included:
 - What is the difference between a hearing and a listening session, as stated in the proposed HITAC recommendations section of the Annual Report?
 - There should be more focus on the bidirectional exchange of information. She discussed her experiences working in public health at the state level in Wisconsin, noting that funding is siloed and often comes via federal grants, and stated that issues related to underfunded public health departments create challenges around the exchange of information and data. A recommendation could focus on shoring up public health IT infrastructure.
 - **Carolyn Petersen** asked **Michelle Murray** to comment on the difference between hearings and listening sessions. **Michelle** explained that a hearing would entail an all-day session with the HITAC or a task force, while a listening session would be part of a meeting and less resource-intensive.
 - **Aaron Miri** thanked everyone for the feedback.
- **Jim Jirjis** thanked the ARWG and echoed previous comments that the HITAC should focus on tangible action items to move issues forward in a meaningful way. He discussed how the lack of standards at a federal level has created numerous interpretations and variations in public health responses to the COVID-19 crisis, often leading to unnecessary costs and confusion. **Jim** suggested that the HITAC could focus on several topics and recommended activities related to interoperability to empower public health departments in the near, mid, and longer-term.
- **Steven Lane** referenced **Les Lenert's** comments about supporting public health departments in their ability to pull data and submitted several comments, which included:
 - He discussed public health issues related to returning and pulling data using FHIR and CDA.
 - Carequality has published a policy that allows public health entities to query other organizations across the Carequality framework for information for treatment purposes, even though both parties understand that the data will be used for non-treatment public health purposes. Because health IT vendors cannot currently manage this public health information at a discrete level, the HITAC should push health IT vendors to do so appropriately.
 - Though it is required under HIPAA, providers need to receive an assertion from public health departments that they are querying for the minimum necessary data for the purpose at hand; in this way, providers can remain protected under HIPAA.
 - If the Office of Civil Rights (OCR) provides an assertion applicable nationwide, public health entities would be able to pull clinical data from providers instead of waiting for that data to arrive as an information push.
- **John Kansky** complimented the thoroughness and breadth of the crosswalk of topics and thanked the ARWG for including the topics around HIEs. He stated that he would support an expanded role for HIEs in public health and explained that, where they exist and have data flowing, HIEs already support providers with public health information. He discussed interoperability-related challenges specific to HIEs, noting that different approaches are necessary to make them effective in different states/regions.





- **Terrence O'Malley** thanked the ARWG for their work on the crosswalk of topics and commented that there might be an opportunity to create a minimum standard dataset for public health. The HITAC could be involved in assembling a basic communications packet for public health on this topic.
 - **Carolyn Petersen** suggested that this would be an opportunity for the HITAC to work with other organizations and dedicated public health experts. This suggestion will be incorporated into the crosswalk.
- **Aaron Miri** encouraged the HITAC to provide feedback at the meeting or in writing afterward.
- **Terrence O'Malley** highlighted the importance of work on interoperability connected to transitions of care under the exchange of health data across the care continuum section. He suggested that the HITAC set up a process to develop a standardized dataset for information required to be shared, including supporting national standards, to be shared when a patient moves/transitions between different care teams and settings.
- **Raj Ratwani** thanked the ARWG for its work on the crosswalk and submitted two comments, which included:
 - The HITAC should think about the two components of EHRs and safety:
 - The safe use of health IT, including identifying unintended consequences of the technology that could lead to patient safety issues, and
 - The use of health IT to make care safer, including the leveraging of health IT to tackle current and future patient safety issues.
 - ONC and its sub-organizations have done a lot of work in the past on patient safety, including the creation of a safety roadmap and proposals for a health IT safety center. This work could be leveraged by the HITAC and ONC in a public-private partnership or other mechanism, or it could be evaluated to see where previous roadblocks impeded work from continuing.
- **Les Lenert** discussed the IoT topic and the need for supporting standards, referencing his previous work on the use of IoT technologies for search capacity for intensive care units (ICUs), which has led to the creation of systems of care that can rapidly expand to supervise patients in remote settings. These systems are supported by standards, safety protocols, and the ability to identify medical devices that are also integrated in the cloud, and he discussed how using and understanding these links has been critical to supporting ICUs during the COVID-19 pandemic. **Les** asked the ARWG to align the IoT topic more closely with the needs related to COVID-19 and ICU search capability.
 - **Carolyn Petersen** responded that the crosswalk would be updated to reflect his comment.
- **Robert Wah** submitted several comments, which included:
 - He highlighted the international exchange of clinical data topic and provided an update on the *Commons Project*, which he is involved with as a board member.
 - The pilot project of *CommonPass*, which pulls data from Apple Health and *CommonHealth* and displays the status of a traveler, was used successfully twice for international flights. He described how *CommonPass* works now to smoothly facilitate travel and border crossings and suggested that vaccine status could be included in the future.
 - The work the *CommonsProject* has done in conjunction with the World Economic Forum and other governments to harmonize regulations has raised questions about data veracity. He suggested that a token should be included with clinical results to prove that they are authentic and are linked to the traveler.



- **Sheryl Turney** commented that the ICAD TF report includes recommendations related to enabling patients to receive identity verification, as well as consent, and to share this information bidirectionally. She linked these recommendations with Robert's comments on the creation of a token for identity verification and credentialing.

Carolyn Petersen thanked the ONC Annual Report team, contractors, and support staff for their assistance in developing the Annual Report and capturing/aligning feedback from the HITAC. She invited HITAC members to send feedback on the list of topics by email to herself, **Aaron Miri**, or **Lauren Richie**. **Aaron** thanked everyone at ONC, especially **Michelle Murray**, for their work. Both co-chairs thanked the members of HITAC for their feedback on the draft Annual Report crosswalk of topics.

Robert Wah thanked the ARWG co-chairs.

INTERSECTION OF CLINICAL AND ADMINISTRATIVE DATA TASK FORCE FINAL RECOMMENDATIONS AND REPORT VOTE

Introductions and Overview

Sheryl Turney and **Alix Goss**, co-chairs of the Intersection of Clinical and Administrative Data Task Force (ICAD TF), presented an update on the TF's recent work. **Sheryl** began by thanking the HITAC for the opportunity to present and provided a brief overview of the ICAD TF's agenda, charge, and a list of TF members. All of these items were included in the first few slides in the TF's presentation. She briefly described the TF's process of crafting the draft report and thanked the many stakeholders who shared their expertise with the TF.

Updated ICAD TF Report Outline

Sheryl presented the updated report outline, highlighting the organizational structure, and explained that there were no material changes to the outline but that clarifications were added based on the feedback the ICAD TF received previously from the HITAC. The updated report outline included:

FRONT MATTER:

- Foreword by Co-Chairs
- Vision and Charge
- Task Force Member List
- List of Tables

EXECUTIVE SUMMARY

- I. Introduction
- II. Analysis of the Current Prior Authorization Landscape
- III. ICAD Task Force Findings and Recommendations
- IV. Summary and Conclusion: Toward Further Integration of Clinical and Administrative Data

LIST OF APPENDICES

- List of Acronyms
- Glossary
- Presentation Summaries and Key Points
- Compendium of Landscape Artifacts



Final Report Updates

Sheryl explained that the ICAD TF received feedback from many members of the industry, including:

- American Hospital Association (AHA)
- American Health Information Management Association (AHIMA)
- American Medical Association (AMA)
- American Psychiatric Association (APA)
- California Public Employees' Retirement System (CalPERS)
- Council for Affordable Quality Healthcare (CAQH)
- CoverMyMeds
- Health Innovation Alliance
- Medical Group Management Association (MGMA)
- National Council for Prescription Drug Programs (NCPDP)

Sheryl provided an overview of the material revisions made to the ICAD TF's Report since it was last presented to the HITAC and summarized some of the overarching themes of the feedback received, which included:

- The Report's patient-centered focus and providing more clarity around how the TF's recommendations and the ideal state would look for the patient,
- Attachment standards and making standards open to implement without licensing costs,
- The adoption of FHIR and FHIR's current progress and potential for the future,
- The need to clarify some of the TF's guiding principles and recommendations related to testing,
- The addition of new items to the Report,
- Clarifying the Report's focus, both in the Introduction and Summary sections,

Sheryl stated that **Alix Goss** would review the material updates to the Report and that a list of material changes made to the Report was included on slide #8 in the TF's presentation. **Sheryl** explained that HITAC members received the list of material changes and a redlined version of the Final Report before the meeting.

Alix Goss noted that the ICAD TF has heard from various stakeholders on improving the prior authorization (PA) process, which was used as an exemplar for the TF's work. The ICAD TF has reimagined an ideal state for the PA process that:

- Is an end-to-end, closed-loop process,
- Reduces the burden across all stakeholders,
- Accounts for the vast majority of situations,
- Leverages existing investments and efforts, where appropriate, acknowledging the existing gaps
- Enables innovation and continuous improvement

Guiding Principles and Ideal State - Updates

Alix explained that the ICAD TF developed a series of Guiding Principles to frame and guide the TF's work toward their Ideal State and Recommendations. Two of these Guiding Principles were updated since the TF's previous presentation to the HITAC, and the Guiding Principles included:

- Patient-Centered Design and Focus (revised)



- This Guiding Principle was previously called “Patient at the Center” and was retitled, following feedback provided by the HITAC, to better reflect the TF’s intent that the patient should be at the center of focus in workflow designs, not that they should be put into the middle of administrative processes, unnecessarily.
- Measurable and Meaningful
- Aligned to National Standards
- Transparency
- Continuous Improvement
- Design for the Future While Solving Today’s Needs (**revised**)
 - The wording of the title of this Guiding Principle was updated.
- Real-Time Data Capture and Workflow Automation
- Information Security and Privacy
- Reduce Burden on All Stakeholders

Alix stated that as a result of the feedback, additional work was done to strengthen the lead-in to the Recommendations section of the TF’s Report. The new language was highlighted on slide #11 in the TF’s presentation, and **Alix** explained that the TF’s Recommendations, which are not listed in priority order, outline necessary steps on the path toward clinical and administrative data integration. She said that the Recommendations focus on “the what,” not “the how,” and clarify the areas in which resources and energies must be focused to solidify the details needed to fulfill them. Using the recommendations as a basis for initiating follow-on activities, industry partners and other stakeholders now need to get involved in translating the “whats” into “hows” and moving forward toward the Ideal State. **Alix** emphasized that federal leadership is essential to ensure that this process includes robust interagency coordination, industry, and Federal Advisory Committee engagement, and alignment with other relevant initiatives.

Updates to Draft ICAD TF Recommendations

Alix Goss shared a list of the ICAD TF’s Recommendations for the HITAC, which was included on slide #12 of the presentation materials, and she explained that she would highlight the updated Recommendations that have been added since the TF’s previous presentation to the HITAC. She provided a brief recap of the key material and non-material changes made to the TF’s Recommendations, which included:

- **Recommendation 1:** Prioritize Administrative Efficiency in Relevant Federal Programs
- **Recommendation 2:** Establish a Government-wide Common Standards Advancement Process
- **Recommendation 3:** Converge Health Care Standards
- **Recommendation 4:** Provide a Clear Roadmap and Timeline for Harmonized Standards
- **Recommendation 5:** Harmonize Code and Value Sets
- **Recommendation 6:** Make Standards (Code Sets, Content, Services) Open to Implement Without Licensing Costs
 - **Non-material Change:** As a result of feedback received by the TF, a sentence was added to the conclusion of this Recommendation as a point of clarification.
- **Recommendation 7:** Develop Patient-centered Workflows and Standards – **New Material Change**

- The Task Force discussed the critical importance of transparency to the patient of key administrative workflows. These workflows define access to and reimbursement for care, and delays in these workflows are a key source of care delays and sub-optimal outcomes within the health care system. Accordingly, “patient-centered design and focus” must be a system-design philosophy and built in from the ground up. Engagement in the workflow should be available to patients at their discretion, and not a requirement of the process. The Task Force believes that administrative workflow information is part of the Designated Record Set (DRS) (as it is patient-specific information used for decision making). If there is uncertainty on the inclusion of administrative workflows in the DRS, the Task Force recommends that ONC work with OCR to clarify the status of administrative workflows under the access provisions of HIPAA and ensure that patients have visibility into bi-directional workflows and exchanges of such data.
- The Task Force recommends that ONC work with other Federal actors and standards development organizations to prioritize and develop administrative standards that are designed for patients’ bi-directional digital data exchange. Even “workhorse” administrative standards like eligibility, claiming, and electronic EOB/remittance that are traditionally considered provider-to-payer should allow access through the same API frameworks already supporting API access. Converged clinical and administrative workflows, including prior authorization, should be designed to support API access and patient engagement as a matter of course. As an example, benefits information provided to the provider via eligibility transactions should also be available to the patient via APIs; the content and status of claiming/remittance should be available to the patient not only at the end of the process through the current EOB API, but throughout the process of claiming and adjudication. As another example, the patient should have the ability to bi-directionally share health data (including patient generated data) with providers and other third parties from their applications of choice without special effort.
- **Recommendation 8: Adopt a Member ID Card Standard – New Material Change**
 - The Task Force recommends that ONC work with CMS (for Medicare, Medicaid, Medicare Advantage and MAPDs), OPM/FEBP, and DOD/Tricare to adopt a standard for member ID cards (following on INCITS 284-2011; reaffirmed as INCITS 284-2011 [R2016]). Alternatively, a virtual ID card could be permissible provided it complies with the INCITS ID card capability requirements and HIPAA privacy/security requirements. Standard ID cards would reduce burden by supporting patient access, clinical and administrative automation, and transparency between member/patient, provider, and plan. Member ID should be sufficient, along with HIPAA-appropriate levels of assurance, to reference patient-specific plan and product requirements like drug formularies and prior authorization.
- **Recommendation 9: Name an Attachment Standard**
- **Recommendation 10: Establish Regular Review of Prior Authorization Rules**
- **Recommendation 11: Establish Standards for Prior Authorization Workflows**
- **Recommendation 12: Create Extension and Renewal Mechanism for Authorizations**
- **Recommendation 13: Include the Patient in Prior Authorization**
 - **Non-material Change:** The language was edited for clarity.
- **Recommendation 14: Establish Patient Authentication and Authorization to Support Consent**
- **Recommendation 15: Establish Test Data Capability to Support Interoperability – New Recommendation**



- The Task Force recommends that HHS lead development of a national approach to have test data beds to drive innovation and ensure real-world functionality and interoperability. To accomplish this, the following actions are needed:
 - Review the current administrative transactions and associated value/code sets to ensure that USCDI supports data concepts and elements needed downstream to support clinical and administrative functions.
 - Establish (illustrative) information models, in stages, to align clinical and administrative data for secondary use in stages, based on the highest societal priorities.
 - Establish a sufficient data set for transactions at the intersection of clinical and administrative data that adheres to “minimum necessary” requirements.
 - Advance an appropriately constrained implementation guide as a standard.
 - Offer incentives for stakeholders to pilot and test innovative solutions.

Alix invited HITAC members to submit questions and/or feedback on the final version of the Report. She explained that the timeline for the ICAD TF’s work was extended from an end date in September through to the current meeting due to the extensive nature of the process. She suggested that there is synergy between the TF and the strategic focus areas of the National Committee on Vital Health Statistics (NCVHS), and all ongoing partnerships will be critical to ensuring that healthy, effective workflows and data standards are built, going forward, to underscore the objectives of 21st Century Cures Act and a modern healthcare delivery system.

Carolyn Petersen recognized the large time commitment of the ICAD TF members and thanked them all for their accomplishments. On behalf of the HITAC, she expressed gratitude for the work the TF completed. She reminded HITAC members that a final vote on whether to accept the TF’s Report would be conducted and encouraged members to submit any additional feedback.

Discussion:

- **Terrence O’Malley** congratulated the ICAD TF on its comprehensive Report and, in reference to **Aaron Miri’s** earlier comments about metadata that he made during the ARWG’s presentation, asked if there is a broader role for standardizing metadata in the TF’s process.
 - **Alix Goss** responded that the FHIR at Scale Taskforce (FAST) has been looking at aspects of metadata exchange and asked **Terrence** if he was referring to the metadata for routing.
 - **Terrence** explained that he meant metadata for administrative tasks and provenance, as well as routing. There are several issues around metadata that the HITAC could address.
 - **Alix** discussed how the ICAD TF built the Report based on the frameworks of intersecting national standards like the USCDI and HIPAA standards. She acknowledged that the conversation around metadata goes beyond routing information and could be another point of coordination between NCVHS and HITAC that would be addressed as part of the next steps.





- **Sheryl Turney** agreed that going forward, there should be a focus on metadata, blockchain, and AI because they will all support different aspects of bidirectional data sharing, but she explained that this work gets into the “how” aspects of work that the ICAD TF tried to avoid. She expressed hope that ONC would work with industry and federal stakeholders to create plans for how data will work and noted that, while the TF initially discussed including a federal data model, the Recommendation was put aside. She discussed how the TF’s recommendations would support interoperability.

Vote to Adopt the ICAD TF’s Report and Recommendations

Carolyn Petersen thanked **Alix** and **Sheryl** for their responses and confirmed no further comments or feedback from HITAC members. **Sheryl Turney** moved to adopt the final version of the Report and Recommendations from the Intersection of Clinical and Administrative Data Task Force, and **Robert Wah** seconded the motion. **Carolyn** called for a voice vote.

The HITAC approved the ICAD TF’s Report by voice vote. No members opposed. No members abstained.

HITAC 2021 DRAFT WORK PLAN

Lauren Richie presented the HITAC 2021 draft work plan and encouraged HITAC members to submit feedback in anticipation of presenting the final work plan at the January 2021 meeting. She explained that the full calendar of meeting dates for 2021 would be published in the federal register and on the [healthit.gov](https://www.healthit.gov) website shortly.

Lauren gave an overview of the three Priority Target Areas in the Cures Act for the HITAC, which include:

- Patient Access: The facilitation of secure access by an individual and their caregiver(s) to such individual’s protected health information
- Interoperability: Achieving a health information technology infrastructure that allows for the electronic access, exchange, and use of health information
- Privacy and Security: The promotion and protection of privacy and security of health information in health IT

In addition to the priority target areas, **Lauren** explained that the HITAC is considering adding an additional target area: “Use of Technologies that Support Public Health.”

Lauren summarized the agenda for discussion, which included:

- Review planned topics and timing for HITAC discussion
- Acknowledge current commitments
- Discuss opportunities for other HITAC work in 2021 and beyond

Lauren asked HITAC members to focus on the following discussion questions:

- What topics would you add, remove, or change?
- How would you frame HITAC and/or ONC focus within a topic?
- What topics should be addressed in 2021 vs. later?
- Which topics are more suitable for a subcommittee, panel hearing, or full committee discussion?

Lauren recapped the 2021 HITAC planning process, of which the following steps were undertaken:

- Reviewed transcripts and meeting notes from prior HITAC discussions



- Reviewed HITAC recommendations, including the HITAC Annual Report for FY19
- Considered legislative requirements, existing work plans, and emerging issues
- Obtained input from the HITAC co-chairs

A snapshot of current HITAC activities included:

- Completed in Calendar Year 2020 (CY20):
 - COVID-19 Panel Hearing
 - EHR Reporting Program (User Criteria)
 - FY19 HITAC Annual Report
 - Overview of ONC Cures Act Final Rule
 - 2020-2025 Federal Health IT Strategic Plan
- In Progress:
 - COVID-19 Follow-Up (As Needed)
 - HITAC Annual Report for FY20
 - Intersection of Clinical and Administrative Data Task Force Report
- Not Started:
 - Interoperability Standards Priorities Task Force – Annual Review and Publication
 - Trusted Exchange Framework and Common Agreement
 - USCDI v2
 - EHR Reporting Program (Developer Criteria)

Lauren presented the abbreviated HITAC 2021 Work Plan at a Glance for calendar year 2021, which was depicted on slide #6 in the presentation materials. She described the HITAC's confirmed activities for 2021, which will include:

- An administrative meeting
- Several HITAC Annual Report Workgroup meetings
- A public health and HIE hearing
- Several task forces:
 - USCDI TF
 - EHR Reporting Program TF
 - ISP TF
 - ICAD TF

Lauren explained that several additional potential topics have come up in prior HITAC discussions and asked HITAC members to weigh in on the following topics:

- Data Privacy/Secondary Uses of Data
- Data Segmentation for Privacy
- Improving Interoperability of Lab Data
- Integrating and Using Imaging Data
- Patient Generated and Reported Data
- Payer-to-Provider Health Information Exchange
- Telehealth Delivery



Discussion:

- **Sheryl Turney** asked if the HITAC could do more than a public hearing on public health and HIE and suggested that a task force could be created to focus on recommendations that could support the bidirectional sharing of data for public health.
- **John Kansky** responded to **Sheryl's** comment about a new task force and offered to join it, if started. He asked ONC to comment on the triggers for reigniting the TEFCA Task Force and when it would begin.
 - **Elise Anthony** responded that ONC is evaluating timing considerations based on the Recognized Coordinating Entity's (RCE) feedback on the Common Agreement. Once the feedback has been reviewed, ONC will schedule a presentation for the HITAC and announce the task force's launch, which will happen in 2021.
 - **John** asked if the Common Agreement will be put out for public comment and if the task force would be restarted at that time.
 - **Elise** explained that what has been released is the minimum required terms and conditions and confirmed that the release of a draft version of the Common Agreement for public comment would be the next step.
 - **John** thanked her.
- **Les Lenert** suggested that the public health activities were scheduled too late in 2021 and that the HITAC should have a discussion about how vaccine administration tracking systems and adverse event reporting systems integrate with EHRs. He emphasized that this process should begin right away in January or February 2021 with the creation of a task force or similar group that would review current processes and the CDC's standards to determine how to improve population health-related outcomes.
- **Jim Jirjis** asked for clarification around ONC and the HITAC's roles concerning TEFCA, the RCE, and the public comment period on the Common Agreement.
 - **Elise Anthony** responded that ONC identified the RCE through a cooperative agreement to work directly with ONC and noted that, once the TEFCA framework and Common Agreement are in place, the RCE will help ONC operationalize the framework. The RCE has also worked on identifying the minimum required terms and conditions and additional required terms and conditions to operationalize the TEFCA framework. The RCE's work will be shared with the HITAC for feedback, which ONC will consider, along with the public comment period feedback, to create the Common Agreement's final draft.
- **Steven Lane** asked the ONC team to comment on the USCDI advancement process for next year and how the HITAC and the USCDI Task Force will be involved.
 - **Avinash Shanbhag** described ONC's work on choosing an initial set of data elements (from over 600 submissions) to be part of the draft USCDI v2. This will be published for public comment, along with a HITAC review and discussion period in early 2021. There will be a USCDI Task Force similar to the one convened previously that will review those data elements and complete work on an analysis, along with a period for feedback. He anticipated that USCDI v2 would be released in March or April of 2021, and then it would be formally adopted into the Cures Act Final Rule.
 - **Lauren Richie** explained that the specific charge for the USCDI TF would come from the HITAC and differ from the previous iteration of the task force.





- **Ken Kawamoto** noted that he submitted several proposed elements to the USCDI and thought that ONC's response to his submission was handled in a timely and thorough fashion. He suggested that the scope for tasking and timeline for the 2021 version of the USCDI Task Force include a review of the many submissions that are not level two that might be beneficial for public health. This would extend the TF's work through the end of 2021 and allow the TF to focus on supporting and accelerating these additional submissions that are not level two.
- **Lauren Richie** thanked the HITAC members who submitted verbal feedback and comments in the meeting chat. She asked if the topics' specificity was correct and if other topics should be included or prioritized.
- **Carolyn Petersen** commented that, during the planning process for the HITAC's 2020 work, privacy in relation to patient and person-generated health data was a topic of discussion, and it was not included in the previous work plan. She suggested that additional types of data and issues related to secondary uses will become topics of note due to the public health data being generated in relation to COVID-19 relief efforts and vaccine tracking. She asked to include data privacy as an issue.

Lauren encouraged HITAC members to submit feedback to her, **Robert Wah**, or **Carolyn Petersen** following the current meeting. All input will be considered, topics will be prioritized, and the Work Plan will be adjusted as needed. **Lauren** noted that the final Work Plan will be presented at the January 2021 HITAC meeting.

Carolyn thanked everyone for contributing to the discussion and congratulated the ICAD TF on its excellent work to advance the field and help to improve the current situation on the ground.

PUBLIC COMMENT

Lauren Richie opened the meeting for public comment. There were no public comments submitted by phone.

Questions and Comments Received via Adobe Connect

Andy Truscott: Hey - I'm here. Sat in the Lobby.

Leslie Lenert MD: This is Leslie Lenert--I am here

Jim Jirjis: Jim Jirjis

Andy Truscott: And in.

Anne Burns: Anne Burns from the American Pharmacists Association

Abby Sears: This is Abby. I am here.

Lauren Richie: Hello Abby

Anil Jain: That was Anil Jain not Ken

Aaron Miri: Yep thank you Anil! Sorry!

Anil Jain: Yes, by consumers I meant patients, future patients, caregivers, etc.

Alexis Snyder: Consumers are more than patients, such as caregivers. Anyone "consuming" healthcare and healthcare data





Hazel Chappell: Hazel Chappell - Past Digital Health Advisor - UK NHS, now living in Austin

Sheryl Turney: thank you fr [sic] clarifying

Aaron Miri: (for learning purposes) he's a great 2 pager that the CDC put out about their Data Modernization Initiative that the CARES act funding helped get the ball rolling on:
<https://www.cdc.gov/budget/documents/covid-19/COVID-19-Data-Modernization-Initiative-Fact-Sheet.pdf>

Sheryl Turney: thank you!

John Kansky: Ugh -- I just accidentally diconnected [sic] myself. Calling back in.

Hazel Chappell: Thank you Aaron

Jonathan R. Nebeker: About safety, I would hope that ONC would really look to promoting the AAMI standards for safety. In VA, we think this is a critical vehicle for making real change.

Raj Ratwani: Agree, using AAMI standards will be impotant. [sic]

Carolyn Petersen: HITAC members, please raise your hand in Adobe if you have other questions or feedback. Thanks!

Hazel Chappell: Agree with Jonathan, a dedicated resource for this.

Jim Pantelas: I wonder if we might not be better served by switchable considerations as regard standards for data sharing? By creating standards that do not allow for unexpected conditions we tend to hamstring public health. Might we think about defining a capability that might be available under extreme circumstances, and allow Congress or some administrative body to be able to authorize that extreme sharing depending on conditions?

Jocelyn Keegan: Thanks to Alix, Sheryl, Lauren and company for all of their hard work and leadership.

Don Rucker: Ditto on the thanks for this extremely important activity. Don

Sheryl Turney: Thank you for all your support, input and guidance. It has truly been the culmination [sic] of a very meaningful experience. I am honored that I was able to participate

Alix Goss: Thank you HITAC! Thank you ONC for your leadership and support of his important work!

Sheryl Turney: Thank you ALix [sic] for your partnership. It has been an honor working with you

Denise Webb: Congrats Alix, Sheryl and and [sic] ONC team!

Rebecca Hines: Fantastic work, well done all!

Denise Webb: What about our 2020 report and the activities we discussed today related to public health?

Sheryl Turney: I agree Denise

Robert Wah: For the Public Comment period today, we are likely ahead of schedule so please be prepared to make your Public comments early. Thank you.

Sheryl Turney: i agree with Les on this - adverse event and vaccine tracking





Jonathan R. Nebeker: Regarding Les' comments on role of HITAC in COVID work: Is HITAC the right place for this or should this be in the agencies and task forces that are already chartered *[sic]* for this work. This may *[sic]* be better framed as a collaboration with *[sic]* HITAC.

Lauren Richie: To members of the public, To make a comment please call:1-877-407-7192 (once connected, press "1" to speak

Brett Oliver: Organizations are already gearing up for vaccine tracking and distribution. Please consider any "direction" from a new committee may lead to additional *[sic]* work that organizations *[sic]* are ill prepared to do

Sheryl Turney: I want to thank Carolyn and Robert for their leadership over the last 3 years.

Denise Webb: I ditto Sheryl's *[sic]* comment--appreciate all you have done to guide the committee Carolyn and Robert

Brett Oliver: Thanks Carolyn and Robert!

Aaron Miri: Agree - Giant thank you to Carolyn and Robert for their wonderful leadership! Can't wait until we are all able to see each other in person next so that we can thank them both with a cheers.

Jonathan R. Nebeker: !

Sheryl Turney: I raise my glass to that! Cheers!

Carolyn Petersen: Thank you for the kind words! It's been great to be a part of such important work.

Terrence O'Malley: Wonderful job. Thank you both.

Anil Jain: Thanks Carolyn and Robert for your leadership!

Aaron Miri: Happy Holidays everyone! Enjoy and please be safe.

FINAL REMARKS

Sheryl Turney thanked **Carolyn Petersen** and **Robert Wah** for their hard work and dedication as co-chairs of the HITAC.

Avinash Shanbhag thanked **Ken Kawamoto** for his feedback on the USCDI process and noted that the ONC team would review and identify the level one data elements of potential value to support the HITAC's work in the coming year. **Elise Anthony** thanked the members of the HITAC for the work completed around issues and topics in health IT over the past year, noting its importance to ONC's work. **Steve Posnack** thanked **Carolyn** and **Robert** for their masterful leadership and service to the HITAC. **Lauren Richie** also thanked the departing co-chairs.

Robert thanked **Carolyn** for being a supportive co-chair and expressed his gratitude and congratulations to ONC staff and all members of the HITAC for the work completed over his term as co-chair. He thanked everyone for their hard work, support, and patience as the agenda of the HITAC has shifted due to external factors. **Carolyn** echoed **Robert's** remarks and thanked everyone who helped facilitate a meaningful, effective committee process.





ADJOURN

Lauren Richie reminded members that all meeting materials, including the ICAD TF's Final Report, would be posted on the HITAC's website. The Final Report will be formally transmitted to Dr. Rucker in the next several days.

There will not be a December 2020 meeting, so the next meeting of the HITAC will take place in January 2021.

The meeting was adjourned at 11:42 a.m. ET.

