The Office of the National Coordinator for Health Information Technology

Meeting Notes

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC)

May 13, 2020, 9:30 a.m. – 12:00 p.m. ET

VIRTUAL

EXECUTIVE SUMMARY

Donald Rucker welcomed members and gave an overview of some of ONC's COVID-19 response efforts. He noted that ONC has used their enforcement discretion on the timelines for the Cures Act Final Rule and that they have received public comments on the federal health IT strategic plan for 2020 to 2025. **Carolyn Petersen** and **Robert Wah** reviewed the meeting agenda, and the minutes of the April 15, 2020, meeting of the HITAC were approved by voice vote. **Elise Anthony** provided an overview of ONC policy updates, including information on new resources and tools ONC has made available on their website. ONC's **Teresa Zayas-Cabán** and **Kevin Chaney** presented the national health IT priorities for research. Co-chairs **Sheryl Turney** and **Alix Goss** gave an overview of the recent activities of the Intersection of Clinical and Administrative Data task force. HITAC members submitted comments and questions to both groups of presenters. There was one public comment submitted by phone, and 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 April 15, 2020 Meeting Minutes
09:45 a.m.	ONC Policy Updates
09:55 a.m.	National Health IT Priorities for Research
10:35 a.m.	Intersection of Clinical and Administrative Data Task Force Update
11:30 a.m.	Public Comment
11:45 a.m.	Wrap Up and Final Remarks
12:00 p.m.	Adjourn

CALL TO ORDER/ ROLL CALL

Lauren Richie, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC), called the May 13, 2020, meeting to order at 9:00 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 Kansky, Indiana Health Information Exchange
Ken Kawamoto, University of Utah Health
Steven Lane, Sutter Health
Leslie Lenert, Medical University of South Carolina
Arien Malec, Change Healthcare
Clem McDonald, National Library of Medicine
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
Michelle Schreiber, Centers for Medicare and Medicaid Services
Steve Ready, Norton Healthcare

FEDERAL REPRESENTATIVES

Jonathan Nebeker, Department of Veterans Health Affairs
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
Seth Pazinski, Director, Division of Strategic Planning and Coordination
Elise Anthony, Executive Director, Office of Policy
Avinash Shanbhag, Acting Executive Director, Office of Technology
Lauren Richie, Branch Chief, Coordination, Designated Federal Officer

WELCOME REMARKS

Donald Rucker welcomed members to the virtual meeting of the HITAC. He acknowledged that all of the members had been affected by COVID-19 and sent a special thanks to all front-line workers. He explained that the Office of the National Coordinator for Health Information Technology (ONC) staff and HITAC members have been busy working on solutions to aid in the COVID-19 response effort, and some of the health information exchanges (HIEs), in particular, have generated additional response opportunities.

He noted that ONC has used its enforcement discretion on the timelines for the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule (ONC Cures Act Final Rule). He stated that, as a result, the certification components of the program have been delayed by roughly four and a half months.

He gave a brief update on work that has been completed as a part of the COVID-19 response, including updates to the COVID-19 information on the healthit.gov website. He noted that many informative meetings were held following the April 15, 2020 HITAC COVID-19 hearing.

He noted that ONC had received public comments on the federal health IT strategic plan for 2020 to 2025. Finally, he thanked everybody for their hard work over the past two years, and he directed them to an infographic depicting the HITAC's work over that time period.

REVIEW OF AGENDA AND APPROVAL OF MEETING MINUTES

Carolyn Petersen, HITAC co-chair, welcomed all the participants and thanked them for attending the meeting.

Robert Wah, HITAC co-chair, welcomed the members of the HITAC and noted that the committee would be returning to the regularly scheduled activities with the current meeting, following a number of meetings focused on COVID-19 response efforts. He reviewed the agenda for the meeting and noted that there would be two presentations held at the meeting; one is on the National Health IT Priorities for Research, and the other is an update from the Intersection of Clinical and Administrative Data task force. He welcomed members of the public to the meeting and reminded them of the period for public comment.

He invited members to examine the minutes from the April 15, 2020, meeting of the HITAC. There were no comments or corrections, so he called for a vote. The HITAC approved the April 15, 2020, meeting minutes by voice vote. No members opposed, and no members abstained.

ONC POLICY UPDATES

Elise Anthony thanked members of the HITAC for all of the work members have done since the inception of the committee, including the COVID-19 response efforts and the hearing, and she summarized a number of their activities. She noted that their next steps included working with federal partners to determine where a potential HITAC charge could exist, and ONC has been working with the Centers for Disease Control (CDC) to explore specific activities for the HITAC.

She provided details on resources that ONC has made available on their website, which included:

- COVID-19: Tools & Resources for the Health IT & Clinical Community
- Health IT Feedback & Inquiry Portal
- New Blogs (e.g., Strategic Planning, Rule Provisions, Clinical Genomics Data for Precision Medicine)
- ONC Cures Act Final Rule Resources (e.g., webinars, fact sheets, PowerPoints, audio)

She noted that questions and feedback could be submitted through the Health IT Feedback portal anonymously or with the stakeholder's name attached, should they care to receive a response.

She gave a summary of enforcement discretion for the ONC Cures Act Final Rule, and she stated that ONC will exercise its discretion in enforcing all new requirements under 45 CFR Part 170 that have compliance dates and timeframes until three months after each initial compliance date or timeline identified in the ONC Cures Act Final Rule. She directed HITAC members to the following website for more information: https://www.healthit.gov/curesrule/resources/enforcement-discretion

She shared a list of ONC Cures Act Final Rule webinars, and she included both upcoming webinars and past recordings and slides that have been made available online. She noted that the Health and Human Services (HHS) Office for Civil Rights (OCR) hosted a webinar for health IT stakeholders on the Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy and security issues related to COVID-19 and recent OCR actions connected to the pandemic. She shared the link to the recording of the April 24, 2020, public webinar.

Carolyn Petersen thanked Elise Anthony for the information and introduced the presenters from ONC.

NATIONAL HEALTH IT PRIORITIES FOR RESEARCH

Teresa Zayas-Cabán, Chief Scientist for the Office of the National Coordinator for Health Information Technology, introduced herself and her colleague, **Kevin Chaney**, Senior Program Manager with the Chief Scientist division. She noted that they would present the policy and development agenda, and she provided background information on the Chief Scientist Division and some recent updates. She noted that their work is at the intersection between research and care delivery and, though ONC does not fund research, they leverage health IT to support the biomedical and health services research enterprise. She gave an overview of their activities, which included:

- Developing and evaluating ONC's scientific efforts and activities.
- Recommending scientific policy to the National Coordinator.
- Promoting and leading activities that spur innovation, support patient-centered outcomes research, and advance precision medicine.

She noted that the 21st Century Cures Act prioritized interoperability, which, she stated, will be critical for the research, policies, regulations, and technology that ONC is advancing. Then, she described some of the recent activities of ONC's Chief Scientist Division, which included:

- LEAP in Health IT Special Emphasis Notice
    - Cutting Edge Health IT Tools for Scaling Health Research
- Precision Medicine Initiative
    - Sync for Genes Project Phase 2 Final Report
    - Blog post series
- Patient-Centered Outcomes Research
    - Patient-Reported Outcomes through Health IT final report
    - Web page refresh

She noted that their work and collaborations with federal agencies, as well as private stakeholders, has demonstrated that health IT is foundational for research. She emphasized that the large array of data will require new thinking and pathways for storing, accessing, and analyzing the information. She stated that success will require portable electronic health information that is actively exchanged among health care providers, researchers, and individuals. In particular, she noted that the increased availability of electronic health data has created an opportunity for biomedical clinical health services and public health research. She explained that ONC has examined gaps and challenges in order to leverage those data and the health IT infrastructure for research and discovery.

Kevin Chaney presented the National Health IT Priorities for Research, a policy and development agenda which articulated a vision of a health information ecosystem supporting research and advancing scientific discovery. He gave an overview of the methodology used, including key inputs like background reports, key informant interviews, in-person workshops, coding and analysis, and validation with experts. He described how this process lead to the identification of the initial six gap areas. Next, he noted that these areas were validated by some of the key informants, who helped synthesize the major challenges. He explained that nine priority areas were generated and were then presented to the American Medical Informatics Association (AMIA) conference at two panels, after which feedback and further information from informants were incorporated. He noted that these nine priority areas would be discussed in greater detail later in the presentation.

He summarized the gaps in health IT infrastructure that were identified in the process, which included:

- Adaptability of the health IT infrastructure
- Ability to produce data for research

- Functionality needed for research
- Data aggregation across multiple platforms
- Advancement of patient engagement in research
- Realizing a transparent and scalable architecture

He explained that these six gap areas were synthesized to create a series of challenges that cut across the gap areas, which created the foundation for their priority areas. He gave an overview of the challenges that were identified, which included:

- Transparent and interoperable health-related data
- Tools that allow use, interaction with, and sharing of standardized electronic health record (EHR) data
- Solutions to enable aggregation across multiple, non-EHR-based data sources
- Functional solutions for patient matching and identity management
- Consent management necessary for data sharing in research
- Research opportunities for those traditionally underserved or underutilized in research participation
- Opportunities to encourage dialogue and education on the use of the health IT infrastructure for research

He stated that the vision that was defined as a result of the work on the gap areas and challenges was for a health IT infrastructure that supports alignment between the clinical and research ecosystems so research can happen more quickly and effectively. He explained that the agenda to reach this vision was supported by two goals and a series of associated nine priority areas, and he provided a deeper overview each of the goals, priority areas, and supporting strategies, which included:

- Goal 1: Leverage high-quality electronic health data for research.
    - Priority 1: Improve data quality at the point of capture
        - Identify and develop metadata standards that capture more information about a given data point at the time of capture
        - Promote the adoption and use of current and emerging data and metadata standards to improve data quality for care and research
    - Priority 2: Increase data harmonization to enable research uses
        - Increase support for the development and use of existing common data models to transform and analyze data for research purposes
        - Identify collaborative opportunities to improve understanding regarding research data use and reuse in accordance with established privacy and security safeguards
    - Priority 3: Improve access to interoperable electronic health data
        - Ensure health IT systems provide sufficient documentation about their data models and technical specifications to develop shared tools for acquiring clinical data from those systems
- Goal 2: Advance a health IT infrastructure to support research.
    - Priority 4: Improve services for efficient data storage and discovery
        - Realize efficiencies by making advanced computational capacity and storage available to researchers to reduce redundant data collection efforts
    - Priority 5: Integrate emerging health and health-related data sources
        - Support functionality within the health IT architecture to link research-relevant data sources outside the patient care setting with EHR data
        - Provide support for accelerating the process of standardizing new data

concepts while working to update current standards
- Priority 6: Improve methods and tools to support data aggregation
  - Improve the ability to match individuals to different sources of data
  - Develop tools to efficiently manage data use agreements across organizations
  - Develop functionalities needed to manage data across distributed sources, including to identify redundancy; account for updates to data and metadata; and analyze data in different formats
- Priority 7: Develop tools and functions to support research
  - Support easier consent management for research
  - Develop additional tools to support research processes such as recruitment, enrollment, randomization, and HIPAA-compliant de-identification
  - Investigate and expand tools that index, search, and query systems to identify and recruit possible patient cohorts for a given study as well as easily extract data about participants
- Priority 8: Leverage health IT systems to increase education and participation
  - Develop health IT tools that deliver value for providers and patients to participate in research
  - Pursue infrastructure improvements that enable participation from a diverse patient population
  - Expand research opportunities beyond large health systems
- Priority 9: Accelerate integration of knowledge at the point of care
  - Advance new methods to accelerate the digitization of evidence into computable knowledge
  - Develop tools, like Clinical Decision Hooks or API tools, to support the translation of computable knowledge at the point of care supporting providers and patients

Teresa Zayas-Cabán stated that achieving the agenda's vision would support the pursuit of more complex research questions, the development of more rapid and reliable discoveries about health and healthcare to improve outcomes, and the engagement of a broader, more representative population in research participation. She described work that ONC will do or will continue to do to be able to advance the agenda, and she noted that ONC will collaborate with federal colleagues. ONC has been collaborating with the National Institutes of Health's (NIH), including their *All of Us* research program and standards development organizations to pilot and advanced standardized data-sharing. She stated that alignment is needed between priorities and other agencies' data and infrastructure, and she explained how ONC collaborated with the Food and Drug Administration (FDA), which has been undergoing an IT modernization project. Also, she noted that ONC has also worked the Veteran's Health Administration and described their research enterprise and research initiatives.

Discussion:

- **Arien Malec** thanked the presenters and submitted two questions:
  - He inquired about the legal framework for research and how to address the use of real-world evidence pulled from EHRs, especially data related to COVID-19, and with regard to its use by institutional review boards (IRBs).

- He asked for information about addressing the 90/10 split with regard to clinical trials data. He clarified that the common data (lab, demographic, adverse event reporting, etc.) is usually in the EHR and makes up 90% of the data, while the other 10% is typically unstructured and is likely contained in case notes.
- **Teresa Zayas-Cabán** responded that the focus has been on advancing infrastructure to enable data sharing with attention to informed consent, and she noted that the necessary privacy and security provisions are in place. She discussed some of the awards ONC has granted to groups to further this work. She stated that ONC is collaborating with other agencies to advance relevant standards, to identify high-priority use cases, and to integrate relevant data from sources outside of the EHR.

- **Ken Kawamoto** noted that research committees and the clinical domain often use different or competing data models. He inquired if this issue could be solved by converging on a common United States Core Data for Interoperability (USCDI) based set of Fast Healthcare Interoperability Resource (FHIR) profiles for both clinical and research.
  - **Teresa Zayas-Cabán** responded that she is on a temporary reassignment to NIH to coordinate their FHIR-related activities. They are examining how to either harmonize common data models with FHIR or to converge the models with FHIR as the data model to use.
  - **Ken Kawamoto** advised her to keep the work convergent at the profile level, and he noted that, though the use of FHIR is becoming more common, systems often do not communicate. He advised her to focus on creating profiles that apply to research and clinical situations, not just research-specific cases.

- **Sheryl Turney** thanked the presenters and noted that her family had participated in several research trials. She responded to **Arien Malec's** comment about privacy, and she noted her concern about data that has not been fully deidentified. She discussed a report on the state of all-payer claims data (APCD), and she noted that data, in combination with public information, can be used to reidentify individuals. She asked the presenters to discuss their thoughts on this issue.
  - **Teresa Zayas-Cabán** responded that this is an issue that has increased recognition recently, and she noted that work on it is being done in collaboration with Sage Bionetworks. The collaborators are communicating with individuals and keep them more informed.
  - **Kevin Chaney** responded that the *All of Us* research program has targeted a specific workgroup of interest and has encouraged them to prioritize concerns of privacy and security, especially for certain sectors of the population.
- **Les Lenert** submitted two comments, which included:

- He discussed the tension between maintaining privacy and getting high quality data. He explained that, as patients have more control over the disclosure of their data, there should be a mechanism to mark that the data are not missing, but, rather, that the data have been intentionally suppressed. He stated that the standards should reflect the difference between missing and intentionally withheld data.
- He recognized the success of the All of Us program and the patient-driven approaches to research through Sync for Science. He discussed the importance of patient-oriented approaches for research through personal health records.
- **Elise Anthony** responded that a new blog post about work ONC has done with Sync for Science would be released within a week. She voiced her agreement with his comment and noted that it is in line with ONC's priorities. Also, she noted the relevance of his comment about the issue of what the standards could support with regard to privacy and security, and she explained that work would be done on this topic.

INTERSECTION OF CLINICAL AND ADMINISTRATIVE DATA TASK FORCE (ICAD TF) UPDATE

Alix Goss and **Sheryl Turney**, co-chairs of the ICAD TF, presented an update on the TF's recent work to the HITAC.

Sheryl Turney gave an overview of the makeup of the ICAD TF's membership and thanked all TF members for their efforts. Then, she presented their vision, which 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." She stated that the ICAD TF will produce recommendations and related roadmap considerations for submission to the HITAC no later than September 2020, and she noted that these deliverables will also be shared with the National Committee on Vital and Health Statistics (NCVHS). The overarching charge of the ICAD TF 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 (ePA) to support work underway, or yet to be initiated, to achieve the vision.

She described the scope and approach of work completed thus far by the ICAD TF. She noted that a compendium of industry artifacts and prior ONC Federal Advisory Committee Act (FACA) work products and source documents was created and used by the TF to inform and enrich discussions. A small subgroup created a basic clinical workflow demonstrating the prior authorization (PA) of durable medical equipment (wheelchair) as an example, and she explained that an ICAD TF workgroup transformed this workflow into a workbook that highlighted the data classes required to support the clinical workflow for durable medical equipment, medical admittance and procedures, pharmacy, and specialty. She explained that both of these efforts allowed the ICAD TF to begin outlining the following:

- Data classes aligned to current standards group adoption efforts
- Guiding principles and a description of a re-imagined "ideal" state
- Other considerations (includes considerations recommended to the HITAC from third parties)
- Recommendations (includes recommendations made to the HITAC from third parties)

She summarized the ICAD TF's progress to date. She noted that the TF began their weekly meetings on March 3, 2020; the ICAD TF meets on Tuesdays at 3:00 p.m. ET, and the meetings are open to the public. She shared a list of demonstrations by third parties held for the ICAD TF as of May 13, 2020:

- March 28th: Surescripts and CoverMyMeds
- May 5th: Regence and Humana
- May 12th: American Medical Association

Alix Goss noted that the ICAD TF has made substantial progress and summarized their next steps, which included:

- Continue weekly meetings and workbook elaboration
- Elaborate on guiding principles and considerations with a focus on privacy and security
- Fully defined Ideal State
- Review the recommendations submitted to the HITAC by third parties
- Extrapolate PA deliberations to larger intersection of clinical and administrative data
- Draft Recommendations Concepts for HITAC's feedback by mid-summer 2020
- Target Final Recommendations to the HITAC in September 2020

She noted that the ICAD TF has created a framework of four questions to solicit input from the HITAC, and those included:

- As we move from PA focus to broader intersection of clinical and administrative data, what specific goal areas should be covered, or questions should be answered?
- What are key considerations for the task force to keep in mind?
    - Coordination of benefits
    - Cost transparency
    - Attachment requirements
    - Request response and pended response timeliness
- What piloting activities are needed to explore the barriers and challenges of electronic medical record (EMR) systems related to PA and the intersection of clinical and administrative data?
- Is there a way to standardize the data requirements across payers which clinical decisions are based upon even if the PA decisions differ by payer, plan, and product? And how would the United States Core Data for Interoperability (USCDI) fit into this model?

Discussion:

- **Ken Kawamoto** thanked the presenters and asked them to comment on how administrative data or claims data could be available through USCDI. He noted that procedures sometimes do not have standardized coding associated with them in the procedure interfaces.
    - **Alix Goss** thanked him for his question and noted that it was helpful, as ICAD TF has been more closely focused on PA. She noted that work on claims data would broaden the TF's scope of consideration, which is in line with their next steps.
    - **Sheryl Turney** noted his point that claims data is often put into a separate database, and she stated that the ICAD TF would examine how to make that data available in the EMR.
- **Clem McDonald** discussed status codes and medical record codes. He noted that systems are able to deliver test results through a messaging system, but he raised the issue that the test results are not available or stored within large systems. He suggested requiring that the primary codes in USCDI be stored in the records, and he suggested that everything in the condition record would carry similar codes.
    - **Alix Goss** clarified that the recommendation was that the test results and those indicators and codes be stored with the test results.
    - **Clem McDonald** discussed the examples of having the standard code stored in the primary field in a prescription record or test result. He noted that the researchers have a

difficult time finding these codes in complex systems. **Alix Goss** responded that she understood.

- **Christina Caraballo** thanked the presenters and inquired about how their work would fit into the USCDI model. She noted that there is a defined process, and she suggested looking at the criteria ONC put in place. She discussed using the promotion model as a template, which would help to identify data elements and data classes. Also, she suggested submitting data through the submission form that will soon be available and asked them to continue to monitor the submission process between USCDI levels.
    - **Alix Goss** responded that USCDI is foundational to the TF's work, and the TF will leverage work other committees have done. She noted that Sheryl Turney and the small ICAD TF workgroup have worked to harmonize their work on data flows, data classes, and data elements within the context of the USCDI.
    - **Sheryl Turney** noted **Christina Caraballo's** request and voiced her support for the maturity process that was adopted through the work that she discussed. She explained that data claims had been separated from clinical data and that their work will bring them together. She noted that data claims are already exchanged electronically, so, even if they are not a part of the EMR, they will be ready for consideration in the USCDI model. She referenced pilot programs by the Da Vinci Project.
- **Ken Kawamoto** gave background information related to his question, and he noted that he had been involved with reviewing work on standards (Da Vinci and HL7). He noted that the overall frameworks are good, but there are issues when granular data need to be exchanged. He discussed some examples of how data might not be available in the standard form or interface. He asked the presenters to comment on situations in which the framework is available, but discrete data in the standard form is not being mapped or made available.
    - **Alix Goss** clarified that it is one thing to have a framework, but another thing to be able to know that there is discrete data available at the intersection with the policies of the payers that can be pulled back into the PA process, and whether that data is actually within the EMR or an ancillary application so that we make sure that the specific elements needed for whatever medical necessity determination is being performed are available.
    - **Ken Kawamoto** affirmed her summary and discussed the example of home oxygen requirements and how these requirements are processed by the payer in the models. He noted that there could be issues with how the EMR systems handle the data.
    - **Alix Goss** noted that his question and examples about data capture dynamics presented an interesting dynamic on top of the workflows the ICAD TF has considered. She noted that the second aspect, related to the use case and burden reduction, involves the coverage requirements discovery, document templates, and then PA. She explained that the ICAD TF considered the ability of the Authorization and Referral Request 278 PA transaction and its scope of content. However, she noted the challenges of how the existing application programming interfaces (API) that leverage content in the EHRs to create more automation often create the need for new types of data elements. She recognized the complex challenge presented when the new data elements need to be supported in the foundational standards, USCDI frameworks, and the EMR certifications.
    - **Sheryl Turney** agreed with Alix Goss's points and explained that the ICAD TF is examining data requirements for different types of PA and whether the data are available in the EMR. She explained that a possible solution is to put a framework like the USCDI put in place and to have it mature over time; it would apply to one data group at a time. She discussed the ideal state and how it could apply not only to PA but also to claims data. She noted that the ICAD TF's recommendations would have to allow integration, and she emphasized the complexity of the issue.
    - **Alix Goss** tied the concept of the maturity framework to the payer-related processes the ICAD TF has discussed, including that PA requirements are reviewed and refreshed

periodically. She noted that this work is multifaceted that includes discrete data captures, storage access, and downstream use within the USCDI.
    - **Ken Kawamoto** shared his experience with this issue. He noted that it has often been deemed as too daunting to be solved. He encouraged the ICAD TF to keep it in scope.
    - **Sheryl Turney** agreed that recommendations were needed relating to how to provide more than the data exchange. She identified the opportunity for the EMR system to open up certain aspects to open-source solutions to allow for the greater integration of payer and provider data. She noted that the ICAD TF would add this to their recommended list of pilot programs.
- **John Kansky** described the state and community-based health information exchanges (HIE) that have participation from both payers and providers, and he noted that, in some cases, both clinical data and claims data are matched around patients and populations for constructive purposes. He stated that HIEs can be used as a source for completing or providing PA data, but he noted that this is not yet a common occurrence.
    - **Alix Goss** responded that this was a good assessment from the perspective of an HIE.
- **Arien Malec** shared two comments:
    - He voiced his agreement with **Ken Kawamoto's** comment, and he emphasized that the current state of PA (paper, fax, portal) is unacceptable. He stated that advancing the current state, even without full automation, is beneficial, but a model that leads to a real-time system is necessary. He noted that a multiphase process will be required to get to the "ideal state."
    - He observed that the process of collecting data upstream in the EHR could be complex and suggested that it would be better to burden clinicians at the time of PA than at the time of data entry.
- **Clem McDonald** supported **Ken Kawamoto's** comments about home oxygen measurements and encouraged the ICAD TF to push forward a fix to the vital sign specification.

Robert Wah thanked **Alix Goss** and **Sheryl Turney** for their presentation and noted that the ICAD TF is a joint task force between NCVHS and that the HITAC.

He thanked **Elise Anthony** for the update on ONC policies, and he gave the opportunity to HITAC members to submit any follow-up questions to her, especially any follow-up to the HITAC's COVID-19 response hearing.

Elise Anthony encouraged all interested parties to sign up for the listserv to get updates on current activities and information in real-time, including blogs, updates to the inquiry portal, and more.

PUBLIC COMMENT

Lauren Richie opened the meeting for public comment, and there was one public comment submitted by phone:

Lauren Riplinger, Vice President of Policy and Government Affairs at the American Health Information Management Association (AHIMA): Thank you. Good morning, everyone. My name is Lauren Riplinger. I'm the vice president of policy and government affairs for the American Health Information Management Association. AHIMA represents health information professionals that work with health data for more than 1 billion patients a year, and we recently brought together a group of our members who are actively focused on this important topic of integrating clinical and administrative data. The committee and the task force's current focus on prior authorization is incredibly important, but we believe that it's just as important to focus on additional administrative processes that require data exchange between clinicians and payers, such as inpatient authorization and medical necessity reviews.

Some key areas of interest that we've acquired from our members include the need to improve processes for both patients and clinicians, thereby removing barriers and delays to care for patients, as well as reducing administrative burden for clinicians. We're also very focused on addressing factors beyond automation, including more standardization of business processes and other factors that will help facilitate trust between clinicians and payers. It's also important to consider on-the-ground operations, including how information flows throughout the healthcare system and really, the crucial role health information professionals play in translating that clinical information for administrative purposes, including, obviously, the revenue cycle.

Another key area of interest we believe is important is addressing the coding accuracy and ensuring that there's a clear understanding of how those code sets are used for both clinical and administrative purposes, and of course, the need to prioritize privacy and security, including assurances that only the minimum necessary information is shared and used for the specific transaction in question. We just really want to thank the committee and the task force for their work on this important topic thus far and, of course, welcome the opportunity to serve as a resource for the committee and the task force going forward. So, thank you for the opportunity to allow me to comment this morning.

Questions and Comments Received via Adobe Connect

Jim Jirjis: Jim Jirjis joined

Ram D. Sriram: Lauren: I am in listen mode

Lauren Richie: hi Jim and Ram, noted

Leslie Lenert: Leslie Lenert here

Michael Adcock: Michael Adcock is here

Lauren Richie: GM Les and Michael

clem mcDonald: I am now on please note

Lauren Richie: Hello Clem, noted

Steven Lane: https://www.healthit.gov/sites/default/files/facas/2020-05-13_ONC_Research_Policy_and_Development_Agenda_HITAC.pdf

Ken Kawamoto: We should consider using a data model spanning clinical and research -- e.g., a common FHIR profile based on USCDI

Steven Lane: It will be important to align these evolving research priorities with the work being done to support the advancement of the USCDI.

Ken Kawamoto: Data mapping will also be important -- e.g., if the model specifies that hemoglobin A1cs use LOINC codes X, Y, and Z -- there must be accompanying processes to ensure that all such lab data are in fact mappe *[sic]* to these LOINC codes

Steven Lane: Now is the time for the Research group to prepare a prioritized list of specific data and metadata classes and elements that would be most beneficial to support the Research community.

Ken Kawamoto: +1

Arien Malec: Clinical trials are very much a 90/10 issue -- 90% of the data (safety, lab, demographics) are the same every damn time, but 10% are very TA/endpoint specific

Ken Kawamoto: COVID-19 could be used as a common focal point to identify this. E.g., for the relevant labs, comorbidities, diagnoses, location, etc.

Arien Malec: I also don't see anything about managing the logistics of clinical trials -- I worked for a company using a model-based view of a clinical trials to automate visit scheduling, flow sheets, etc.

Arien Malec: Actually managing a clinical trial at an investigational site is hard -- really easy to miss required data.

Steven Lane: MAy *[sic]* be beneficial to add a Priority to focus on advancing/moderninzing *[sic]* the Privacy and Security rules, regs and tools to optimally manage eHI used for research.

Aaron Miri: Steven - agree on the specific data / metadata classes. This would also help inform common IRB data submission standards so that we can accelerate study requests and the data classes / privacy and security considerations / etc. across the country.

Tammy Banks: COVID-19 includes request for staffing, supplies not tied to patient record in EMR.

Ken Kawamoto: Great point -- similar to things like availability of on-site procedure capabilities

Steven Lane: Work is being done now within the national interoperability *[sic]* networks and framework to support the Research purpose of data access and use. ONC could catalog, engage in and support these efforts now.

Aaron Miri: Ken - problem we have had with things like onsite lab availability, etc. is that it's not enough to do a raw count of tests available but you literally have to inventory everything specifically to ensure the kits are intact and then there's a distinct difference if the labs are done on-site or have to be sent off-site. We have found for offsite lab processing, putting an upper limit bounds is important. So (example not real): 800 / 5000 labs sent today, 400/5000 returned - from the local testing company. Helps you spot the backlogs etc. and other items.

Ken Kawamoto: These issues seem quite challenging. But in context of COVID, perhaps they can be overcome given the clear need.

Tammy Banks: Inclusion of atypical EMR data request like on-site procedures, staffing and supplies in US CORE to standardize the requests would be valuable, versus request for multiple data to meet same research need.

Steven Lane: As we build new capabilities to support research and data exchange tools for COVID-19 we should think holistically to implement permanent advances that will also support other research needs.

Steven Lane: Need standard data elements to capture individual and study-specific consent/authorization that can be tied to and travel with patient data. This should be included as a part of the ongoing analysis of Data Segmentation for Privacy.

Sasha TerMaat: Clem, your suggestion about requiring certain record storage seems to me overly prescriptive as to system design. The goal of interoperability standards is to provide an abstraction layer that mean that regardless of how the underlying system would be designed, the data (including codes) are accessible.

Lauren Richie: Public Audience: If you would like to make a comment please call 1-877-407-7192(once connected, press "*1" to speak)

clem mcDonald: Sasha it *[sic]* you raise a good point, but it *[sic]* present researchers at many (not all) sites can't find the codes for aggregation across multiple sites. so they should be emade *[sic]* much mmore *[sic]* visible. . *[sic]* Big medical record sytems *[sic]* may carry 20,000 tables m

Sasha TerMaat: I think the better solution to address that problem is to align on a standard (such as FHIR) that includes the codes necessary for the research purpose.

Jonathan Nebeker: @the points that Ken raises about getting the right data (and somewhat to Clem's point) VA is doing a lot of work in this area with standards organizations and federal partners. examles *[sic]* of some initiatives *[sic]* that can help are Solor (which Clem hadinput *[sic]* to naming *[sic]*) and Analysis Normal Format.

clem mcDonald: More. What is the barrier to keeping *[sic]* standard codes with the records to which they apply. All of the message standards- V2, FHIR, CDA require that. How painful would it be to add 10 more (Or less) bytes to each result record, each drug order, each condition record t be sure the standard code is there. ?

Jonathan Nebeker: Steve Brown is on your workgroup and cn *[sic]* provide details.

Jonathan Nebeker: We are also working with Mike Waters and FDA and instustry *[sic]* to ensure that observations from lab and other devices are returened *[sic]* with proper codees *[sic]* from the get go

Sasha TerMaat: Clem, I think you are proposing a dangerous precdent *[sic]* of dictating national system design in a committee *[sic]*. That is extremely limiting--for one thing, it sidesteps the usual processes of user centered design and continual improvmeent *[sic]* of systems. I think this committee needs to focus on interoperbility *[sic]* standards, which are clearly in scope, not internal system design.

clem mcDonald: Don't want to dicate *[sic]* anything, just pointing out that researchers have a problem findg *[sic]* the stanadard *[sic]* codes in the medcial *[sic]* record systems that their institutions paid for. Leaving out who required ist *[sic]* would like to understand the problems that having standard codes with the records would cause. Having developed some big systes *[sic]*, it seems like an eassy *[sic]* fix. What am I missing?

Sasha TerMaat: I agree that making standard codes more accessible is worthy goal and one we should focus on. The committee should do that by prioritizing key interoperability areas and identifying and promoting interoperability standards, not being overly prescriptive as to system architecture. You may think that a system architecture change is obvious, but suggesting changes to system architecture is a hazardous slippery slope in precedent, which is why I think we need to focus on interoperabiliy *[sic]* standards.

Toni Hebda: thank you - great information

Lauren Richie: Public Audience: If you would like to make a comment please call 1-877-407-7192(once connected, press "*1" to speak)

Jim Pantelas: Thanks to all presenters. This was a good meeting.

WRAP-UP AND FINAL REMARKS

Carolyn Petersen thanked the presenters for their time.

Robert Wah thanked everyone for participating. He stressed the importance of the monthly HITAC meetings and recommended that members review the infographic of the HITAC's accomplishments, which, he noted, have been impressive. He requested that any additional comments, suggestions, or feedback be submitted to himself or **Carolyn Petersen.**

ADJOURN

Lauren Richie reminded members that the next meeting of the HITAC will take place on June 17, 2020. Also, she noted that ICAD TF meetings take place weekly on Tuesdays, and the next one will occur on May 19, 2020.

Donald Rucker thanked everyone for their comments and wished them safety and good health.

The meeting was adjourned at 11:24 a.m. ET.