Meeting Notes

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC)



EXECUTIVE SUMMARY

Micky Tripathi, the National Coordinator for Health IT, welcomed everyone to the January 19, 2022, virtual meeting of the HITAC and welcomed the HITAC members. He provided an update on ONC's recent achievements and announced the rollout of a new task force and a new workgroup. The co-chairs of the HITAC, Denise Webb and Aaron Miri, welcomed members, reviewed the meeting agenda, and the minutes from the November 10, 2021, HITAC meeting, which were approved by voice vote. Mike Berry provided an overview of the Calendar Year 2022 (CY22) HITAC Work Plan and next steps.

Mariann Yeager and Alan Swenson presented an update on TEFCA. Elizabeth Holland presented an update on the CMS Promoting Interoperability Program, including a Promoting Interoperability Performance Category Overview, and gave an update on the program under Medicare. Aaron Miri presented an update from the HITAC Annual Report Workgroup and provided an overview of the draft FY21 Annual Report. HITAC members discussed each of the presentations and submitted feedback and questions to the presenters. One public comment was submitted by phone during the meeting, and there was a robust discussion in the public meeting chat via Zoom.

AGENDA

| 11:00 a.m. 11:05 a.m. | Call to Order/Roll Call Welcome Remarks, Interoperability Standards Workgroup, and e-Prior |
|--------------------------|--|
| 11.00 a.m. | Authorization RFI Task Force |
| 11:25 a.m. | Opening Remarks, Review of Agenda and Approval of November 10, 2021 |
| | Meeting Minutes |
| 11:30 a.m. | HITAC CY22 Final Work Plan |
| 11:45 a.m. | TEFCA Update |
| 12:45 p.m. | Break |
| 01:00 p.m. | Promoting Interoperability Program Update |
| 01:30 p.m. | HITAC Annual Report Workgroup Update |
| 02:15 p.m. | Public Comment |
| 02:30 p.m. | Final Remarks and Adjourn |
| | |

CALL TO ORDER/ ROLL CALL

Mike Berry, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC), called the January 19, 2022, meeting to order at 11:00 a.m.

Mike asked HITAC members to state any potential conflicts of interest during the roll call. John Kansky and Steven Lane disclosed that they do not have any conflicts of interest but that they serve on the board of The Sequoia Project. Ken Kawamoto disclosed that he reports honoraria consulting, sponsored research, licensing, or co-development in the past year with Hitachi, Pfizer, RTI, UCSF, Indiana University, Cosme, MD Aware, and ONC (through Security Risk Solutions). He developed a number of health IT tools, which have been commercialized to enable a wider impact. Aaron Neinstein reported consulting fees over the past year with Eli Lilly, Roche, Medtronic, and Intuity Medical. Eliel Oliveira disclosed that he is the tech lead on two ONC-funded projects at the Dell Medical School. Raj Ratwani disclosed that MedStar Health is a recipient of the ONC LEAP award. Abby Sears disclosed that one of the members of the OCHIN team is on the board of The Sequoia Project.

ROLL CALL

Aaron Miri, Baptist Health, Co-Chair
Denise Webb, Individual
Medell Briggs-Malonson, UCLA Health
Hans Buitendijk, Cerner
Steven Eichner, Texas Department of State Health Services
Cynthia A. Fisher, PatientRightsAdvocate.org



Lisa Frey, St. Elizabeth Healthcare Raiesh Godavarthi, MCG Health, part of the Hearst Health network Valerie Grey, New York eHealth Collaborative Steven Hester, Norton Healthcare Jim Jiriis. HCA Healthcare John Kansky, Indiana Health Information Exchange Ken Kawamoto, University of Utah Health Steven Lane, Sutter Health Leslie Lenert, Medical University of South Carolina Hung S. Luu, Children's Health Arien Malec, Change Healthcare Clem McDonald, National Library of Medicine Aaron Neinstein, UCSF Health Eliel Oliveira, Dell Medical School, University of Texas at Austin Brett Oliver, Baptist Health James Pantelas, Individual Raj Ratwani, MedStar Health Abby Sears, OCHIN Alexis Snyder, Individual Fillipe Southerland, Yardi Systems, Inc. Sheryl Turney, Anthem, Inc.

FEDERAL REPRESENTATIVES

Thomas Cantilina, Military Health System, Department of Defense (Absent)
Adi V. Gundlapalli, Centers for Disease Control and Prevention
Ram Iyer, Food and Drug Administration (FDA) (Absent)
Jonathan Nebeker, Department of Veterans Health Affairs
Alex Mugge (alternate for Michelle Schreiber), Centers for Medicare and Medicaid Services
Ram Sriram, National Institute of Standards and Technology

ONC STAFF

Micky Tripathi, National Coordinator for Health Information Technology Steve Posnack, Deputy National Coordinator for Health Information Technology Elise Sweeney Anthony, Executive Director, Office of Policy Avinash Shanbhag, Executive Director, Office of Technology Mike Berry, Designated Federal Officer

PRESENTERS

Mariann Yeager, The Sequoia Project Alan Swenson, Carequality Elizabeth Holland, Centers for Medicare and Medicaid Services (CMS)

WELCOME REMARKS, INTEROPERABILITY STANDARDS WORKGROUP, AND E-PRIOR AUTHORIZATION RFI TASK FORCE

Micky Tripathi, the National Coordinator for Health IT, welcomed everyone to the first virtual meeting of the HITAC in 2022 and welcomed the eight newly appointed members who will serve three-year terms on the HITAC: **Medell Briggs-Malonson**, **Hans Buitendijk**, **Steve Eichner**, **Raj Godavarthi**, **Hung Luu**, **Aaron Neinstein**, **Eliel Oliveira**, and **Fil Southerland**. Additionally, he welcomed **Tom Cantilina**, who will represent the DoD on the HITAC, and he thanked **James Ellzy** for his two years of service.



Micky provided an overview of ONC's recent program updates, including:

- On January 18, 2022, The Sequoia Project, ONC's Recognized Coordinating Entity
 (RCE), released the Trusted Exchange Framework and Common Agreement (TEFCA)
 Common Agreement for Nationwide Health Information Interoperability Version 1 and
 Qualified Health Information Network (QHIN) Technical Framework for
 Operationalization. A nationwide health information network has been part of ONC's
 vision since its foundation in 2004, and ONC looks forward to continuing to work with
 The Sequoia Project to achieve these aims.
- ONC released the <u>Draft Version 3 of the United States Core Data for Interoperability</u>
 (draft USCDI v3), which is <u>open for public comment</u> through April 30, 2022. The HITAC will be charged with reviewing the document and providing recommendations.
- On January 10, 2022, ONC released the <u>2022 Interoperability Standards Advisory</u> <u>Reference Edition</u>, and the HITAC will be invited to review and comment on that document, as well.
- On January 7, 2022, ONC released <u>Project US@ ("Project USA") Technical Specification Final Version 1.0</u> and completed a one-year goal to coordinate the creation of a healthcare specification for use across the industry for representing patient home and mailing addresses. This will support more efficient patient matching and record linkage.
- The format of the ONC Annual Meeting has been adjusted to address ongoing needs related to the pandemic. It will be held in two parts, with education sessions on February 2 and 3, 2022, and a variety of dynamic and engaging panel sessions and exhibits on April 13 and 14, 2022. Related information will be released on the healthit.gov website.
- Information Blocking provisions of the 21st Century Cures Act (the Cures Act) went into
 effect on April 5, 2021. Micky described the myriad factors that will come together in
 2022 to make information sharing across the healthcare industry and encouraged
 members to visit healthit.gov for FAQs, educational materials, and other details.

Micky provided an overview of ONC's work on the Electronic Prior Authorization (ePA) Request for Information (RFI) and explained that, once the RFI is released, ONC will solicit public comments, including HITAC feedback, on how the ONC Health IT Certification program can incorporate standards and certification criteria related to ePA. Two subcommittees of the HITAC, the <u>Interoperability Standards Workgroup (IS WG)</u> and the <u>e-Prior Authorization RFI Task Force 2022 (ePA RFI TF 2022)</u>, will be launched to support the rollouts related to emerging/new standards. **Micky** described the charges, rosters, and timeframes/next steps for the IS WG and the ePA RFI TF 2022, which were detailed in <u>the presentation materials</u>.

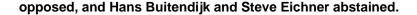
OPENING REMARKS, REVIEW OF AGENDA, AND APPROVAL OF NOVEMBER 10, 2021, MEETING MINUTES

Aaron Miri and **Denise Webb**, HITAC co-chairs, welcomed all members and presenters, and they extended a special congratulations to the new members of the HITAC. **Aaron** shared his gratitude for the work of Project US@, while **Denise** expressed her excitement about the release of TEFCA. **Denise** reviewed the agenda for the meeting and the list of planned presentations.

Aaron invited members to examine the minutes from the November 10, 2021, meeting of the HITAC and called for a motion to approve the minutes. The motion was made by **Ken Kawamoto** and was seconded by **James Pantelas.**

The HITAC approved the November 10, 2021, meeting minutes by voice vote. No members





HITAC CY22 FINAL WORK PLAN

Mike Berry presented an overview of the HITAC Calendar Year 2022 (CY22) Work Plan. This information was detailed in presentation materials posted at https://www.healthit.gov/sites/default/files/facas/2022-01-19-HITAC 2022 Work Plan with HITAC Recommendations 508.pdf.

Mike explained that members shared comments following the presentation of the CY22 Work Plan at the November 2021 HITAC meeting, and these were incorporated into the current document. Updates and changes were denoted by orange text in the CY22 Work Plan, and **Mike** briefly described each item. He invited members to share feedback on the updated document.

Discussion:

- Steven Eichner asked if information would be forthcoming on the timeline for future work by Public Health Task Force/Feedback Sessions (noted as "timing TBD" on the work plan at a glance page).
 - Mike responded that this (or a related task force) and/or feedback sessions will be scheduled in 2022, but the dates are not set.
 - **Steven** emphasized the need to support public health efforts, especially those related to social determinants of health (SDOH), health equity, and components that were the focus of the Public Health Data Systems Task Force 2021 (PHDS TF 2021) and its recommendations.
- Steven Lane commented that the HITAC should revisit and provide feedback on the topic of Closed Loop Referrals, as some members have expertise in this field (360S Standard Protocol).
- Clem McDonald asked for additional details on the potential topic of "Information Sharing under ONC Cures Act Final Rule - Supporting Industry Transition from USCDI to Full Scope of EHI Definition."
 - Denise responded that this is a transition where providers have shared the USCDI data elements up until October 5, 2022, under the Content and Manner Exception where the definition of electronic health information (EHI) is constrained to the USCDI data elements. On October 6, 2022, that definition is restored to the full scope EHI, as defined in the regulation in the Final Rule. At that point, providers will need to respond to requests for all EHI.
 - Elise Sweeney Anthony added that the transition from the data represented by the USCDI, to the full scope of EHI, is part of the Information Blocking Regulations. Therefore, it applies to all actors that are covered, including health information networks (HINs) and health information exchanges (HIEs), healthcare providers, developers, and certified health IT.
 - Clem asked if all the work around the USCDI will be carried over or if it will go away after the October 6 transition.



- Elise responded that the USCDI is a standard that is developed by ONC that continues to be extremely important in many different aspects of ONC's work, including under the Health IT Certification Program and TEFCA. Under the Information Blocking rule, the definition of EHI starts with the data represented in the USCDI. ONC recognizes that the additional information needs to be supported under the Information Blocking Regulations, so, giving the initial timeframe of the USCDI, the use of the data represented in the USCDI allows for transition from those who are stakeholders as well as covered actors as we move towards the full scope of the EHI definition (after October 6).
- Jim Jirjis stated that the USCDI will continue to be used with national EHI exchanges and Fast Healthcare Interoperability Resources (FHIR) APIs, where the full EHI requested and exchanged is much larger. Also, he commented on endorsing the suggestion to consider patient-generated health data and the ability to make that data available by looking at FHIR Write Access to the EHR or View Access from the EHR (out to another app), which under the potential topic of FHIR Standards Advancements.
- **Aaron** voiced his agreement and added that any patient-generated health apps should also be included.
- Ken Kawamoto voiced his support for getting the electronic data extract and using FHIR to align with US Core. He stated that there are gaps in terms of data that are not supported, like orders. Also, there are EHR vendors that do not support the mapping of supposedly "supported aspects," like value sets, query parameters, and performance. When patient profiles are not fully supported, clinicians deal with the burden of extra time needed at the point of care to pull and review patient data from the EHR.
 - **Aaron** agreed, adding that this could negatively affect a provider's "bedside manner" from a patient perspective.
- Steven Eichner submitted several comments:
 - Policy levers/laws should be added to the framework around the bidirectional exchange of data with public health (not just focusing on HIEs and HINs).
 - The Patient Access and Data Sharing topic should include exploring how to regulate/control access to patient data. This will become more important as the technological frameworks of patient health profiles in the EHR get more sophisticated. Patients should be aware of with whom their data is shared and to have a voice in where and when their data is shared.
 - Aaron supported this notion of more granular patient consent.
- Raj Godavarthi supported further improvements in the Intersection of Clinical and Administrative Data (ICAD) and highlighted the need to reduce the burden of time for ePA.
 - Denise commented that the ICAD Task Force (ICAD TF) held many discussions on PA and added that HITAC member Sheryl Turney was the co-chair of the ICAD TF. She will also be a co-chair of the new ePA RFI TF, so the recommendations from the ICAD TF on ePA/PA should be carried over to any new TF work.
- Medell Briggs-Malonson suggested that SDOH data are clearly defined, underscoring how understanding the various forms of SDOH data is critical to moving toward health equity by design.
 - Aaron encouraged the new HITAC members to review prior discussions, work, and recommendations on SDOH data by the HITAC and the USCDI TF.

- HITAC
- Hung Luu suggested clarifying the implications for IRB permissions in terms of how data from the EHR are used in research across institutions.
- Clem McDonald raised the issue of a lack of standards for distinguishing time in deidentified research data that has been converted to FHIR.
- Aaron Miri encouraged members to share feedback on potential upcoming topics with the Annual Report Workgroup (AR WG) as they create an annual crosswalk with gaps, opportunities, and potential HITAC opportunities. Once this report is finalized by the HITAC, it is transmitted to the National Coordinator and then on to Congress.

TEFCA UPDATE

Mariann Yeager, CEO, The Sequoia Project; Recognized Coordinating Entity (RCE) Lead, and **Alan Swenson**, Executive Director, Carequality, presented an update on TEFCA. The presentation included an overview of TEFCA and its components, the Exchange Purposes under TEFCA and how they work, the privacy and security requirements included in TEFCA, and information on how to become a Qualified Health Information Network (QHIN) and how TEFCA will be operationalized. All these topics were detailed in the meeting materials.

Mariann thanked the HITAC for the opportunity to present on behalf of The Sequoia Project, which is the RCE, and introduced herself and **Alan**. She explained the RCE is working with ONC to implement an aspect of the Cures Act in which Congress directed ONC to develop or support a trusted exchange framework for trust policies and practices and for a common agreement for exchange between health information networks. She shared overviews of the goals for and benefits of TEFCA (including nationwide sources), and she explained how interoperability and data exchange work under TEFCA, including ONC's role in setting policy direction and governance requirements. She defined QHINs and their role in the process.

Mariann and **Alan** highlighted and discussed the components of TEFCA, including the Trusted Exchange Framework (TEF) and its seven principles and

the Common Agreement and the framework agreement for flow-down provisions that participants sign—binding them to the applicable terms of the Common Agreement, the seven Standard Operating Procedures (SOPs) that have been developed and released (more will be made available in the future), the QHIN Technical Framework (QTF), and the Governing Approach, all of which were newly released. Alan explained that the QTF looks similar to what has been proven in Carequality for implementers to production today (QTF defines the technical requirements). The QHIN Onboarding and Metrics components have not been released.

Alan provided an overview of the exchange modalities that were in the draft version of the TEFCA, released in the summer of 2021. These included QHIN query ("push") and QHIN message delivery ("pull"). He described how they are used to move patient data and explained that one of the newly released documents has example scenarios of query and message delivery. This information has been detailed in user guides. He presented the three-year FHIR Roadmap for TEFCA (for work between 2022 and 2025), which was included in the presentation materials, and he discussed the three planned stages of FHIR availability/functionality via the exchange among QHINs through TEFCA. Then, he discussed the QHIN eligibility criteria, onboarding processes, and designation (only the RCE designates QHINs).

Mariann explained that the Common Agreement puts forward how governance will be structured between QHINs, participants, and subparticipants, and this approach was detailed on slide #19 of the presentation materials. She added that the role of a cybersecurity council was not fully reflected in the slides and described how it would examine the security of the TEFCA itself and would be chaired by the RCE cybersecurity officers. Their role will be to have oversight as information begins to be exchanged during the first year.



Mariann described and defined the six permitted Exchange Purposes identified in the Common Agreement under TEFCA, which included Treatment, Payment, Health Care Operations, Public Health, Government Benefits Determination, and Individual Access Services. Stakeholders indicated to the RCE that four of the six exchange purposes were not as mature, though they are in the Common Agreement. Alan described the ways in which the Carequality community has focused on exchange purposes, noting that the definitions in TEFCA mirror those from Carequality. Also, he explained how stakeholder feedback and lessons learned during the pandemic have and will continue to shape TEFCA implementation guides (IGs). Mariann explained that individuals will be able to access their own information from all connected entities through an Individual Access Services (IAS) Provider, which was defined in the presentation on slide #23. Alan provided additional clarification around the terms IAS and IAS provider, adding that, in general, entities are required to respond to requests for information for the purpose of IAS. Each QHIN, participant, and subparticipant that offers IAS is an IAS Provider, though it is optional to be an IAS Provider.

Alan provided an overview of the privacy and security requirements included in TEFCA and stated that TEFCA will provide strong privacy protections, as most connected entities will likely be HIPAA Covered Entities or Business Associates of Covered Entities. Thus, they are already required to comply with HIPAA privacy and security requirements. He explained that the Common Agreement requires each Non-HIPAA Entity to protect individually identifiable information that it reasonably believes is TEFCA Information in substantially the same manner as HIPAA Covered Entities protect Protected Health Information (PHI), including most provisions of the HIPAA Privacy Rule. He stated that TEFCA will also provide strong security protections, all of which were detailed on slide #26, and explained how the newly published SOPs apply at different levels and have flow downs to ensure the complete privacy and security of the information being exchanged across all the levels in the chain.

Alan described the QHIN education, application, and onboarding processes, which were detailed on slides #28 and #29. He added that the processes are, again, like those used by Carequality. He explained that there is ongoing monitoring of production metrics.

Mariann described how and when TEFCA will be operationalized and described the timeline, which covered 2021 through 2023 and was included on slide #31 in the presentation. She explained that while they have the initial time periods where applications will be open, they will accept applications on a rolling basis thereafter. She invited members to review the list of educational resources at the end of the presentation for additional resources and a list of upcoming educational events.

Alan added that the RCE has held informational webinars, and more will be offered in the coming months. All resources and documents developed by the RCE are located at https://rce.sequoiaproject.org/ and invited HITAC members to review them.

Denise thanked the presenters and invited HITAC members to share comments and questions. She also acknowledged the comments that were submitted in the public chat in Zoom during the presentation.

Discussion:

 Jim Jirjis thanked the presenters and described the process of connecting to HIEs/national exchanges, which has involved a great deal of redlining. He asked if there will be a standard paper that people can be expected to use and how to balance liability indemnification for the various participants versus exchanges. Also, he asked how to monitor whether participants are claiming permitted use but might be in violation.



- Mariann responded that the standard paper is a QHIN-to-QHIN agreement that the RCE signs (Common Agreement) and should not involve redlining, though there are flow-down provisions with language provided in the Common Agreement. The RCE opted not to provide a template because there are existing network and participation agreements that already include these provisions. The issue of liability is addressed in the Common Agreement, where there is some discretion in the participation agreement between a QHIN and its participants. This could be expanded in the future. Monitoring typically takes place through the submission of issues and concerns or through large shifts in end-user behavior/requests, for example. The RCE is interested in exploring this topic further and invited feedback.
- Jim stated that new QHINs will be yielded from the TEFCA infrastructure, so QHINs will have more power. Should they address the QHIN-toprovider protections to give each protective language? Otherwise, situations arise from the asymmetric power, like pushing liability down to providers.
- Mariann responded that they are aware of this issue, which will require work in the future.
- Aaron Miri thanked the presenters and asked if they had worked through the
 challenge of appropriate and precise patient identification so that data is validated. He
 described his recent struggles with the issue of data entries looking different,
 depending on the state where data was entered, for patients receiving care in both
 Florida and southern Georgia. They also encounter patients from other countries with
 different General Data Protection Regulation (GDPR) provisions.
 - Alan responded that this is a complicated issue that Carequality has been working to address through demographic-based patient matching. However, there is no industry standard for how vendors manage demographic-based matching algorithms. Also, there is hesitancy to share this information and to make improvements. The QTF calls out the need for future work within the QHIN community to improve patient matching recommendations and requirements. The Project US@ standard that was recently released by ONC will be helpful, and the QTF points participants to it. This should improve the consistency of some of the data that are shared. Participants and subparticipants will now have the TEFCA infrastructure in place to leverage for improvements.
 - Mariann responded that the Common Agreement treats the information of people from other countries (seeking treatment in the US) as subject to the local body of laws (privacy and security) once it is incorporated into the patient record in the US.
- Sheryl Turney highlighted the comments she entered in the public chat. They included
 concerns around patient access and the lack of a standard consent model. She asked
 what assurances patients have that their data will be protected and secure if HIEs do
 not provide an opportunity for patients to provide specific consent to the use/sharing of
 their data by third parties and researchers.
 - Mariann responded that further discussions will be held on this topic (obligations for consent and future use by IAS providers), and she invited members to participate in the January 26, 2022, webinar that will provide an overview of the Common Agreement.
 - Alan responded that privacy and security requirements to protect individuals will be compliant with HIPAA (whether a covered entity/IAS provider is or not). There is more information in the Common Agreement (Section 10).

- Mariann added that the RCE received a lot of feedback in this area about the need to bridge gaps in policy and existing laws.
- Sheryl stated that unanticipated events could occur to make this more
 challenging and shared her experiences as a payer. She stated that
 incorrect data could lead to inappropriate sharing with the wrong
 individuals, and there are further aspects to be considered than what has
 been included in the framework.
- Eliel Oliveira asked what happens when someone arrives at an ER/EMS truck without identification and/or unconscious. How do they get linked to their data and treated appropriately? What if they are homeless? He suggested that the next generation of TEFCA address these issues.
 - Alan responded that these are important questions and described work
 Carequality has done, along with guidance from HEMA that was released
 with the Project US@ specifications. Demographic-based matching
 algorithms could be used for a homeless patient, for example, though he
 stated that improvements need to be made across the board in data entry
 across systems. Additional work is needed on how to document patients.
- Steven Eichner asked how the advisory groups/panels would be configured and what
 the focus areas would be initially. Also, he asked how a provider will directly determine
 how participants can/cannot receive messages as data are pushed across the
 network.
 - Mariann responded that QHINs must be in production with real-world
 activities occurring before advisory panels are set up. Subject matter
 experts will be engaged to inform this work and to maximize transparency
 for stakeholders. The RCE and ONC will have flexibility with regard to the
 governance process.
 - Alan explained that the intention is that this will be in the directory, and this will include information about QHINs, their participants and subparticipants, methods of exchange, whether someone receives a push message, appropriate exchange purposes, and more. The RCE will point to specifications with C-CDA and the USCDI for coding the content that is exchanged, though there will be allowances for other forms of consent. QTF providers will have agreements with QHINs/participants for data conversion and receipt.

BREAK

The HITAC took a short break. **Mike Berry** reconvened the meeting at 1:02 p.m., and **Aaron** and **Denise** welcomed HITAC members, presenters, and the public back to the meeting.

PROMOTING INTEROPERABILITY PROGRAM UPDATE

Elizabeth Holland, Senior Technical Advisor, CMS, presented an update on the Promoting Interoperability Program, including a Promoting Interoperability Performance Category Overview, and gave an update on the program under Medicare. **Elizabeth** shared some background information on Medicare & Medicaid EHR Incentive Programs from 2011-2018, which was detailed in the CMS presentation slides and materials. These programs advanced in three stages, and she shared the dates the incentive programs were active/ended.

Elizabeth described the Quality Payment Program, which provides two participations tracks: Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (Advanced APMs). She provided an overview of MIPS performance categories and scoring in 2022, and this information was detailed in the presentation slides. Then, she described the 2022 Promoting Interoperability Performance





categories for eligible clinicians for the 2022 performance year, including a breakdown of scoring and requirements. She discussed the category objectives (Electronic Prescribing, HIE, Provider to Patient Exchange, Public Health and Clinical Data Exchange) and the various corresponding measures, which were laid out in the presentation slides and included scoring information.

Elizabeth explained the requirements for reporting for the 2022 Promoting Interoperability performance categories, including the submission of collected data for all required measures from each of the objectives and providing the EHR's CMS Certification ID/attesting "yes" to a list of attestations and measures. Then she described the weighting (weighted at 25% of the MIPS Final Score) and scoring, including maximums and bonus points. Finally, she gave an overview of electronic clinical quality measures (eCQMs) and requirements for Calendar Year (CY) 2022, CY 2023, and CY 2024. Then, she shared a list of the eCQMs for eligible hospitals and CAHs for CY 2022, which was included in the slide deck.

In closing, **Elizabeth** directed HITAC members to the additional resources in the appendix of the presentation slides and invited them to comment and submit feedback.

Discussion:

- Denise Webb submitted several comments:
 - Do the clinicians have four categories, including the eCQMs?
 - Elizabeth confirmed this.
 - Is there a specific set of measures and number of those that must be selected and sent as eCQMs for clinicians?
 - Elizabeth responded that electronic quality measures are not required for clinicians, though they can choose from electronic options when submitting their quality measures. This area is moving toward digital measures in the future.
 - For what number of quarters do clinicians have to submit?
 - Elizabeth responded that they must submit for a whole year (four quarters) for quality and cost categories. However, improvement activities and promoting interoperability performance categories are 90 days currently.
- Clem McDonald described his experiences at the early meetings setting up the quality
 measures and stated that some big hospital systems asked to have every tiny detail in
 the rules so they could get the highest scores possible. He asked for more clarification
 around CMS's goals of moving toward digital.
 - Elizabeth responded that, for hospitals, the requirement for the Promoting Interoperability Program is that the measures must be computed in the certified EHR technology. CMS is limited to those eCQMs because that was included in the HITECH Act, but there is no similar restriction on the clinician side. In the quality category, there are many kinds of CQMs, and under the Hospital Inpatient Quality Reporting (IQR) program, there are many kinds of eCQMs available.
 - Clem asked if these are just fixed measures about easy-to-measure things that do not require a great deal of extra data collection. He asked if he was characterizing the IQR set correctly.
 - Elizabeth stated that there are many choices in the IQR set, including chart-ups, active measures, hybrid measures that get data from multiple sources. There are over 100 choices in the Promoting Interoperability Performance category.

- Les Lenert asked what is required for certification in the electronic case reporting (eCR) category and if this is only for eCR for COVID-19 or beyond. Are comprehensive eCR data required for all notifiable conditions for the state where the health facility is located?
 - Elizabeth stated that this has not yet been specified because some EHRs are not certified for the function of eCR (can claim an exclusion in CY 2022 if your EHR is not certified).
- Steven Eichner asked what standards providers should use to exchange information for eCR?
 - Elizabeth responded that this is specified and, as they work closely together, she invited ONC to provide the information on the standards and certification requirements.
 - Avinash Shanbhag responded that there are over 35 certification requirements for eCR and that this is a functional requirement in terms of exchange. In terms of data, there is a requirement to have them coded with ICD-10 codes.
 - Steven asked what can be done to accelerate current work on this so that
 providers can take advantage of the move toward digital/evolve paper
 reporting. He was concerned with improving the quality and timeliness of
 data received by public health.
 - Avinash explained that the Centers for Disease Control and Prevention (CDC) have promoted requirements for exchange, which could be useful in focusing the industry on making it easier for both senders and receivers. There is flexibility in terms of allowing newer technologies that use FHIR-based standards (allowing them to be eligible for certification).
 - **Steven** stated that public health would support any means that help providers move electronic reporting more quickly.
- Les Lenert asked if the presentation only covered eCR and not also electronic lab
 reporting (eLR). He stated that eCR has a specific architecture (CCD document
 structure and submission process) and asked if CMS will require that the entire
 production chain is in place for certification. He highlighted the role of vendors in this
 process and stated that some of the standards from ONC do not reflect the full
 process.
 - Elizabeth responded that CMS only requires vendors to be certified and
 to get the particular eCR module certified (if there were not certified
 previously). She explained that the number of certified vendors increased
 greatly after CMS proposed this at the time of the Final Rule.
 - Les stated that, from the time CMS made the proposal to the Final Rule, the number of vendors supporting eCR for COVID-19 increased, which is different than them broadly supporting the architecture proposed under eCR along with a subscription to different definitions of triggers. He emphasized that additional investigation and HITAC discussion is needed to move the innovative eCR work forward.
- Steven Lane echoed the previous comments in support of the rapid advancement of eCR to a named standard that is required of all EHR vendors. There is a path in place, though it might take a few more years. He stated that the HITAC should look for opportunities to require collaboration with public health entities that will now receive data electronically. They will need support to integrate the data into their systems and to guide providers to stop reporting using parallel systems.

HITAC ANNUAL REPORT WORKGROUP UPDATE

Aaron Miri, Annual Report Workgroup (AR WG) chair, presented an update on the draft HITAC Annual Report, and the information was detailed in the <u>AR WG presentation slides</u>. He explained that **Carolyn** Petersen had previously served as the other AR WG co-chair, but her term on the HITAC ended in December 2021. He invited additional HITAC members to join the WG and to review the report and submit written comments to the WG.

Aaron presented the AR WG scope, membership, schedule, and next steps to the HITAC. The timeframe for the report is to present the final version to the HITAC for a vote of approval at the February meeting. Then, the document will be transmitted to the National Coordinator for review and consideration.

Aaron guided members through the <u>draft Annual Report for FY21 document</u> and focused on the crosswalk of topics, key gaps, key opportunities, and recommended HITAC activities, which were detailed in the draft document. The crosswalk was divided by the HITAC Target Areas of: Use of Technologies that Support Public Health, Interoperability, Privacy and Security, Patient Access to Information, and Federal Activities Across Target Areas. He highlighted some of the immediate opportunities and elaborated on several topics with real-world examples.

Following the discussion period, **Aaron** thanked HITAC members for their input, reviewed the next steps, and invited everyone to contribute additional feedback to him via email.

Discussion:

HITAC

- Steven Eichner thanked Aaron for the presentation and suggested adding the need for policy changes to the list of discussion components. He described issues that public health faces around data collection and disclosures, which impact the ability for public health to reshare the information for different purposes/reshared externally. He also emphasized the need for the patient to have privileges to access their own information and rules of responsibility for sharing data with other providers (patient privacy and patient rights). He asked how technology will be leveraged to achieve these aims. The HITAC should also focus on retaining the public health workforce (beyond training).
- John Kansky stated that he would submit written feedback on the Public Health Data Systems – Infrastructure (first row). He discussed how public health reporting infrastructure was lacking/non-existent, as demonstrated by the pandemic response, and there were challenges with quality and completeness. Linkages between providers, EHRs, and public health systems should be made part of the infrastructure. He also asked the HITAC to consider using statewide health data utilities as the infrastructure.
- Clem McDonald supported John's comments and highlighted two other issues. Long
 COVID is not a technical issue, and it is difficult to define it in Medicare. He would
 encourage the HITAC (or a more appropriate body) to get assistance from infectious
 disease specialists and clinical experts on the subject. Also, he commented that
 excessive emphasis on the Minimum Necessary in the document could impede the
 public health needs from being met.
- Arien Malec commented on the topic of Patient Matching that a core standard set of
 data elements already exists for this area within the USCDI and Project US@
 (standard for address information). He suggested that the recommendation be tailored
 toward governance for data collection at registration and more adequately matching in
 other workflows where patient information is collected. He described possibilities for
 algorithmically tuning optimizing patient matching, but he noted that the limitations
 occur around the quality and provenance of the data. Hone in on the standards for
 governance, provenance, and workflows associated with the collection of quality
 patient information at the source.

• Aaron thanked him and encouraged everyone to submit their comments in writing to Michelle Murry (ONC). He encouraged HITAC members to be creative with their comments and suggestions in terms of recommending new technologies for a future roadmap, but he also urged pragmatism.

PUBLIC COMMENT

Mike Berry opened the meeting for public comment and reminded attendees that written comments could be submitted at ONC-HITAC@accelsolutionsllc.com.

Questions and Comments Received via Telephone

There was one public comment received via telephone:

Bob Brown: Thank you very much. My name is Bob Brown, and I wanted to highlight a submission to the committee concerning how IT supports healthcare and interoperability. Our submission is via the meeting's public chat function and includes our contact information. Thank you.

Questions and Comments Received via Zoom Webinar

Adi Gundlapalli: Good morning! Adi from CDC

Aaron Miri: ditto here. honored to be serving alongside a legend like clem

Steven Lane: And Clem is an absolute pleasure to work with and learn from.

Steven Lane: Amazing representation on the committee from across the health IT industry.

Aaron Miri: ** note for all of the new members ** You get out of HITAC what you put into it. So please volunteer for sub-committees, etc. That's truly where the magic happens.

Hans Buitendijk: Are panelist and private chats public as well? Or only Everyone?

Aaron Miri: https://www.healthit.gov/hitac/committees/health-information-technology-advisory-committee-hitac

Steven Lane: Note that some organizations limit the opportunity for users to copy links or other content from Zoom chat. These individuals may need to get such content from meeting notes, which we have heard will only include the content of chat messages sent to "Everyone".

Albert Taylor: Draft United States Core Data for Interoperability (USCDI) Version 3 Website https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi#draft-uscdi-v3

Albert Taylor: ONC Standards Bulletin Issue 2022-1 https://www.healthit.gov/sites/default/files/page/2022-01/Standards Bulletin 2022-1.pdf

Aaron Miri: re: TEFCA - Outstanding job ONC team !!!!! Congratulations.

Albert Taylor to Everyone: Project US@

https://oncprojectracking.healthit.gov/wiki/pages/viewpage.action?pageId=180486153

 $\label{lem:albert} \textbf{Albert Taylor: TEFCA} \ \underline{\text{https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement-tefca}$



Seth Pazinski: ePrior Auth RFI listed in the Unified Agenda https://www.reginfo.gov/public/do/eAgenda/viewRule?publd=202110&RIN=0955-AA04

Andrew Hayden: 2022 ISA Reference Edition https://www.healthit.gov/isa/sites/isa/files/inline-files/2022-ISA-Reference-Edition.pdf

Eliel Oliveira: Very exciting year ahead indeed!

Clem McDonald: Lots of good work and MUCH progress!! Have question about how to get a copy of the work on standard addresses for linking-called, I think project USAA

Seth Pazinski: Project US@ info is available here...

https://oncprojectracking.healthit.gov/wiki/pages/viewpage.action?pageId=180486153

Seth Pazinski: Project US@'s goal is to issue a unified, cross-SDO, healthcare industry-wide specification for representing patient address

Albert Taylor: @Clem, the new final specification of US@ is available at that link.

Seth Pazinski: Information Blocking timeline...

https://www.healthit.gov/cures/sites/default/files/cures/2020-10/Highlighted Regulatory Dates Information Blocking.pdf

Mike Lipinski: https://www.healthit.gov/buzz-blog/information-blocking/say-hi-to-ehi

Mike Lipinski: https://www.healthit.gov/cures/sites/default/files/cures/2021-12/Understanding_EHI.pdf

Mike Lipinski: https://www.healthit.gov/cures/sites/default/files/cures/2021-12/Understanding_EHI-Scope-Diagram.pdf

Mike Lipinski: EHI resources just posted

Hans Buitendijk: Having USCDI/EHI discussion as part of Interoperability Standards might be a helpful topic to consider as we need to address closing the standards gaps/alignment across all EHI if not ePHI, the role of USCDI. USCDI+ and other efforts.

Julie Maas: Sorry I had to step away briefly but in case it was not mentioned, with respect to Patient Identity/Universal Patient Identifier, I would also remind of the ONC FAST Identity work taking place in HL7 presently and on track for May 2022 balloting: https://build.fhir.org/ig/HL7/fhir-identity-matching-ig/hoping we can share notes

Aaron Neinstein, UCSF (he, him): Agree with Jim Jirjis' comment about the critical importance of writing to EHR as enabler of a digital health ecosystem, where patients can receive virtual care from a wide variety of providers.

Clem McDonald: Trying to look at US@ ,the presentation is horribly slow. Minutes between slides. It does not behave like a typical snappy PDF. Maybe some one could see if there is a technical problem

Steven Lane: It would be helpful to include an update on the work of the Gravity Project this year in our discussion of SDOH data standards and their role in supporting health equity.

Mark Savage: Happy to help!

Medell Briggs-Malonson: That would be helpful. It is important to have a deep understanding of the various forms of SDOH data and how they are appropriately captured in our EHRs to drive equitable care and outcomes. It would be great to see the work from Gravity Project.

Mark Savage: I can be reached at MarkSavage.eHealth@pacbell.net. Am the Gravity Project's policy lead.

Clem McDonald: More on US@ spec. When I content finally showed up, I see pages of comment and lable [sic] for the final spec but no version of the final specification. The comments were numerous and critical. Is there really an agreed upon final spec?

Steve Posnack: Clem, the final version of the spec is available on the Project page and also here is a direct link:

https://oncprojectracking.healthit.gov/wiki/pages/viewpage.action?pageId=180486153&preview=/180486153/237306191/Project%20US%40%20FINAL%20Technical%20Specification%20Version%201.0.pdf

Aaron Miri: @steve P - I am happy to provide real world feedback as we try to adhere to the US@ standard in our major EHR switch. There's lots of interfacing systems that have to adopt / be modified which leads to interesting lessons learned that may be beneficial for future specification

Dawn VanDyke: All TEFCA documents and resources discussed can be found here: https://rce.sequoiaproject.org/tefca-and-rce-resources/

Dawn VanDyke: The User's Guide Alan mentioned can be found directly here: https://rce.sequoiaproject.org/wp-content/uploads/2022/01/Common-Agreement-Users-Guide.pdf

Jim Jirjis: Will "healthcare operations" be more explicitly defined

Sheryl Turney: Without having a standard consent model for individual access there are concerns related to privacy and security raised by many stakeholders.

Jim Jirjis: Will a standard data use and ISA be issued? We typically experience a lot of contract relining and we are starting to see HIE's use language limiting their liability to breaches, bad actors etc. Will there be similar protections for providers when they connect to a QHIN and the QHIN experiences a breach or other privacy/security issue that causes harm due to QHIN actions?

Jim Jirjis: Also would be good to know what the plan for monitoring misuse or misrepresentation of a participant about their permitted use

Brett Oliver: Agree with Sheryl - a standard consent when individuals request is important

Aaron Miri: Agree :jim . Specifically for me, It would be helpful to understand if a qhin can take data that traverses their "hop", de-identifies it (removing any hipaa defined identifiers), and then tries to monetize it - what is the path of investigation.

Deven McGraw: Patient-facing apps have experience with getting consent from individuals to collect their data and must be part of any effort to find standard approaches. Suggest CARIN Alliance could be helpful here.

Jim Jirjis: If non HIPAA convered [sic] entities violate the requirement what is the enforcement or sanction? Simply not being allowed to participate? Or are their other OIG consequences

Sheryl Turney: Patients should be very concerned about their data being shared in these networks without their specific permissions and awareness of how their data could be used by all participants especially if their data becomes de-identified.

Dawn VanDyke: Upcoming RCE webinars: https://rce.sequoiaproject.org/community-engagement/

Julie Maas: Another topic we are contemplating in the HL7 Identity/Matching work group is: what degree of probabilistic matching may occur in an Individual Access request? Stakeholder feedback presently indicates: none; responders want to be certain they have authenticated the actual requester, i.e. through federated, strong assurance patient credentials.

Aaron Miri: @sheryl - it'll be interesting to see what type of consent is required or notification, especially in states that have rightfully locally doubled down on strengthening patient privacy

Eliel Oliveira: Besides allowing individuals to access their data under the IAS, has TEFCA addressed the ability of individuals to share their data with third-parties (app developers, researchers, etc.)? In either case, it would be important to limit risk to covered entities for actions taken by individuals further sharing their data. Standard legal artifacts to support such data sharing would be valuable for all.

Deven McGraw: OCR has already issued an FAQ or two regarding whether covered entities are legally responsible (at least under HIPAA) for individual data sharing with third parties. The short answer is that covered entities are not responsible for what individuals subsequently do with the data they receive through exercising their right of individual access.

Steven Lane: We will want to build the monitoring of compliance with permitted purposes and use into the standard metrics that QHINs will be required to share.

Jim Jirjis: Steven: agree

Jim Jirjis: Congrats to Marilyn with sequoia and ONC for getting this moving!

Eliel Oliveira: Biometrics standards possibly.

Medell Briggs-Malonson: Agree with biometrics. But we also have to consider that some populations may not trust biometric data collection for numerous reasons.

Aaron Miri: (for learning) GAO report on patient matching: https://www.gao.gov/assets/gao-19-197.pdf Aaron Miri: @eliel - we have biometrics at our hospitals for registration purposes. pediatric staff (especially neonates) and challenges with explaining integrity of that biometric data to concerned patients. So perhaps biometric plus something else to achieve a fidelity necessary [sic]

Jim Jirjis: And congrats, Marilyn

Julie Maas: Regarding biometrics, the FAST Identity work including SME feedback was able to get behind the idea of a verified facial photo, that is consistent with the identity proofing event, being used to help with matching.

Jim Jirjis: mariann

Eliel Oliveira: @Aaron Miri - thank you for that insight. It seems standards for biometrics may still be valuable although not all individuals will be able or want to comply. But, for the ones that do, they may benefit with more accurate linkage and during emergency situations.



Julie Maas: At least on the FAST Identity/Matching side I can say that the sharing of biometrics, other than a verified facial photo, for cross-organizational matching purposes is not in the recommendations we are publishing.

Medell Briggs-Malonson: @Eliel, biometrics would be very advantageous in emergent clinical situations, to identify patients that have variations in their names, and in populations that often access multiple health systems for care. It seems like the key is to design the biometric system in a manner that is accessible, high value, and culturally respectful.

Bryant thomas Karras MD: i can hear DW

Allison Viola: Can hear you.....

Steven Lane: It would be most helpful if ONC could support the CMS requirement for eCR with the identification of a standard/implementation guide as part of the HIT Certification Program. This would support consistency in eCR methodologies, data and utility.

Eliel Oliveira: @Medell, indeed. With our focus on health equity I believe such standard and solution could be quite impactful for the ones most in need.

Steven Lane: The CMS MU/PI programs have been invaluable in moving forward nationwide interoperability. This is a critical tool that HHS has and clearly uses to support the priorities identified by the HITAC and promoted by ONC. The collaboration across HHS agencies is invaluable.

Steven Lane: Can anyone from CMS and/or ONC share the planned direction for USCDI+ as it will support the advancement of eCQMs and other CMS data priorities?

Aaron Neinstein, UCSF (he, him): As there are more and more non-traditional healthcare delivery organizations, eg venture capital-funded digital clinics, it will be interesting and useful to watch for their participation in these programs to ensure that as patients choose different types of care and care settings, their health information transmits along with them.

Steve Posnack: Here is more information on eCR certification criterion. https://www.healthit.gov/test-method/transmission-public-health-agencies-electronic-case-reporting as Avinash mentioned, the certification criterion focuses on functionality to support case reporting, including trigger codes and being able to create a case report that includes USCDI data, the criterion does not prescribe a specific implementation guide, which allows for local/state flexibility in terms of sending and receiving

Chris Baumgartner: APHL for eCR Now Requests - The state (or locality) uses the HL7 electronic initial case report (elCR) standards (R1.1 and R3) for electronic case reporting (eCR) and to support the new CMS Promoting Interoperability regulations for eCR. It is these standards that we will use to eventually eliminate manual reporting requirements. We also require the use of APHL AIMS and the Reportable Condition Knowledge Management System (RCKMS) to ensure appropriate reporting.

Hans Buitendijk: The current standards-based capabilities for eCR being deployed are based on a CDA based document (eICR, which is not a C-CDA document type, but still CDA based). The creation and delivery can be done in alternative ways, using a FHIR based SMART App approach (eCR Now) or "self-generated" using the XDR or Direct standard to deliver through APHL. It includes the variety of triggers that are being implemented where COVID had a clear focus as this began to roll out in earnest last year.

Leslie Lenert: Hans and Chris: appreciate your clarifications of eCR and eiCR standard.

Michelle Murray: Reminder for HITAC members: Written comments on the HITAC Annual Report for FY21 can be sent by 1/26 to onc-hitac@accelsolutionsllc.com. Thanks!



Chris Baumgartner: For patient matching would min requirements for a MPI also be important?

Steven Eichner: There needs to be communications about WHEN patient matching has occurred upstream, and what methodology has been used, to help donstream [sic] users resolve hat they may see as a mis-match.

Steven Lane: Encourage additional HITAC members to join the Annual Report Workgroup. This is a tremendous opportunity to inform the future ONC and HITAC work plans. Asron [sic] needs a co-chair. Great opportunity to dig way into the work and impact the future direction of health IT.

Julie Maas: And how the information collected is verified, perhaps...

Robert Gergely MD: Blockchain technology?

Chris Baumgartner: For the API i suggest you explore the use of Smart Health Cards. Several PHAs are

using them for Vaccine

Robert Gergely MD: Patient Mediated Interoperability?

Bob Brown: To: HITAC From: Steven Waldren, MD and Bob Brown

Bob Brown: Based on our independent research project, we've developed a framework and adoption approach to improve how information technology supports health care delivery. Given the potential impact to our nation's health information infrastructure, and given HITAC's unique role and responsibility, we are advising the committee of this development. We intend to contribute our suggested framework and approach to the health care community and to assist in establishing or designating an organization to coordinate adoption by the community. A video of our introductory presentation is available at https://bit.ly/improveHIT. Our contact email: framework@mosaicapartners.com

FINAL REMARKS

Mike Berry reminded members that the next meeting of the HITAC will be held on February 17, 2022. All materials from the current meeting would be made available at https://www.healthit.gov/hitac/events/health-it-advisory-committee-41.

Denise and **Aaron** thanked everyone for their participation and robust discussion. They welcomed all the new HITAC members, who were invited to sign up for workgroups and task forces. **Denise** reminded everyone to provide written comments on the draft HITAC Annual Report, and **Aaron** thanked ONC for empowering the HITAC to tackle bold issues and to create solutions.

ADJOURN

The meeting was adjourned at 2:00 p.m. ET.

