Health Information Technology Advisory Committee

The Office of the National Coordinator for Health Information Technology

Meeting Notes

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC)

July 14, 2021, 10:00 a.m. – 2:30 p.m. ET

VIRTUAL

EXECUTIVE SUMMARY

Micky Tripathi, the National Coordinator for Health IT, welcomed everyone to the July 14, 2021, virtual meeting of the HITAC and highlighted several ONC program items. The co-chairs of the HITAC, **Denise Webb** and **Aaron Miri**, welcomed members, reviewed the meeting agenda, and the minutes from the June 9, 2021, HITAC meeting, which were approved by voice vote, pending a small revision. **Carolyn Petersen** and **Janet Hamilton**, co-chairs of the Public Health Data Systems Task Force 2021 (PHDS TF 2021), presented the TF's recommendations to the HITAC, which was followed by the HITAC voting on two motions. **Arien Malec** and **David McCallie** presented the updated Interoperability Standards Priorities Task Force 2021 (ISP TF 2021) recommendations, which was followed by HITAC voting on several motions. **Carolyn Petersen** and **Aaron Miri,** the co-chairs of the Annual Report Work Group (AR WG), presented an update on the work of the AR WG and reviewed a list of potential topics developed for the HITAC Annual Report for Fiscal Year 2021. **Michael Wittie, Gary Ozanich,** and **Fred Blavin** provided an overview of the Electronic Health Record (EHR) Reporting Program (EHRRP) work and draft developer measures. **Michael** announced the kick-off of a new task force, the EHR Reporting Program Task Force 2021 (EHRRP TF 2021). Three public comments were submitted by phone during the meeting, several comments were submitted in writing/via email following the meeting, and there was a robust discussion in the public meeting chat via Adobe.

AGENDA

10:00 a.m.	Call to Order/Roll Call
10:05 a.m.	Welcome Remarks
10:15 a.m.	Remarks, Review of Agenda and Approval of June 9, 2021, Meeting Minutes
10:20 a.m.	Public Health Data Systems (PHDS) Task Force Recommendations – HITAC Vote
11:30 a.m.	Interoperability Standards Priorities Task Force (ISP TF) Recommendations – HITAC Vote
12:00 p.m.	Break
12:15 p.m.	Annual Report Workgroup (AR WG) Update
12:45 p.m.	Electronic Health Record Reporting Program Draft Developer Measures
2:15 p.m.	Public Comment
2:30 p.m.	Final Remarks & Adjourn

CALL TO ORDER/ ROLL CALL

Mike Berry, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC), called the July 14, 2021, meeting to order at 10:00 a.m.

ROLL CALL

Aaron Miri, The University of Texas at Austin, Dell Medical School and UT Health Austin, Co-Chair
Denise Webb, Indiana Hemophilia and Thrombosis Center, Co-Chair
Michael Adcock, Magnolia Health
Lisa Frey, St. Elizabeth Healthcare
Valerie Grey, New York eHealth Collaborative
Steven Hester, Norton Healthcare
John Kansky, Indiana Health Information Exchange
Leslie Lenert, Medical University of South Carolina
Arien Malec, Change Healthcare
Clem McDonald, National Library of Medicine
Brett Oliver, Baptist Health
Terrence O'Malley, Individual
James Pantelas, Individual
Carolyn Petersen, Individual

Raj Ratwani, MedStar Health
Abby Sears, OCHIN
Alexis Snyder, Individual
Sasha TerMaat, Epic
Andrew Truscott, Accenture
Sheryl Turney, Anthem, Inc.
Robert Wah, Individual

HITAC MEMBERS NOT IN ATTENDANCE

Cynthia A. Fisher, PatientRightsAdvocate.org
Jim Jirjis, HCA Healthcare
Ken Kawamoto, University of Utah Health
Steven Lane, Sutter Health

FEDERAL REPRESENTATIVES

James Ellzy, Defense Health Agency, Department of Defense (Absent)
Adi V. Gundlapalli, Centers for Disease Control and Prevention (CDC)
Ram Iyer, Food and Drug Administration (FDA)
Jonathan Nebeker, Department of Veterans Health Affairs
Michelle Schreiber, Centers for Medicare and Medicaid Services
Ram Sriram, National Institute of Standards and Technology

ONC STAFF

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, Acting Executive Director, Office of Technology
Mike Berry, Designated Federal Officer

PRESENTERS

Janet Hamilton, Council of State and Territorial Epidemiologists (CSTE), PHDS TF 2021 Co-Chair
David McCallie, Individual, ISP TF 2021 Co-Chair
Michael Wittie, ONC
Fred Blavin, Urban Institute
Gary Ozanich, HealthTech Solutions

WELCOME REMARKS

Micky Tripathi, the National Coordinator for Health IT, welcomed everyone to the July 14, 2021, virtual meeting of the HITAC, reviewed the meeting agenda, and highlighted the following ONC programs:

- The rescheduled Advancing Social Determinants of Health (SDOH) Data Use and Interoperability for Achieving Health Equity Workshop was held on July 13 and had great engagement and turnout. **Micky** thanked everyone who set up the event and all participants and provided a brief overview of events that occurred.
- Version 2 of the USCDI (USCDI v2) was released on July 9, 2021, and it included many data elements and data classes because of HITAC feedback. Health equity needs were reflected by the addition of Sexual Orientation and Gender Identity (SOGI) and SDOH data elements.

- ONC published a Buzz Blog post, "TEFCA will be live in 2022," about the new timeline and milestones for the Trusted Exchange Framework and Common Agreement (TEFCA), which will be released in the coming months. **Micky** thanked The Sequoia Project, the Recognized Coordinating Entity (RCE) for its work on TEFCA. The RCE will be convening the Common Agreement Work Group to gather additional feedback, and a special HITAC meeting will be added on October 13, 2021, to focus on key elements of the Common Agreement and the TEFCA framework. HITAC members were invited to participate in RCE-led stakeholder engagement activities and TF members and the public were directed to the RCE's website for more information: https://rce.sequoiaproject.org/
- ONC and the Urban Institute (an ONC contractor) have been working together to create a draft set of initial developer measures for the Electronic Health Record (EHR) Reporting Program (EHRRP), which is a requirement of the 21st Century Cures Act.. The scope of the draft interoperability-focused measures includes patient access, public health and clinical care information exchange, and standards adoption and conformance. The Urban Institute is now accepting feedback on the draft measures during a 60-day public comment period that will end on September 14, 2021 . Micky explained that he will ask the HITAC to kick off a new task force to review the draft measures and provide recommendations by the September 9, 2021, HITAC meeting.
- Public Health Informatics & Technology (PHIT) Workforce Development Program: ONC has received $80 million to implement or expand training, certification and degree programs in public health informatics and data science at minority-serving institutions and other colleges and universities. The funding will help to address the need for more public health professionals trained in informatics and technology, a need that has been highlighted during the COVID-19 pandemic. Applications are due by August 11, and the anticipated start date for the program is September 14, 2021.
- The ONC Tech Forum will be held on September 10 and September 17, 2021. The meeting will be held virtually, and more information will be released shortly.
- ONC's Health Interoperability Outcomes 2030 project has received many great submissions, including video clips. Outcomes received will be published later in the year, and all listeners were invited to submit ideas and videos.
- The U.S. Government Accountability Office (GAO) plans to publish a notice in the Federal Register in mid-July announcing that the Comptroller General of the United States will appoint five new HITAC members to replace those whose terms are expiring at the end of this year.

REMARKS, REVIEW OF AGENDA, AND APPROVAL OF JUNE 9, 2021, MEETING MINUTES

Aaron Miri and **Denise Webb**, HITAC co-chairs, welcomed members, and **Aaron** congratulated ONC on all their recent achievements. **Denise** reviewed the agenda and list of planned presentations and reminded attendees that a break is scheduled at the mid-point of the meeting.

Aaron invited members to examine the minutes from the June 9, 2021, meeting of the HITAC. **Robert Wah** asked that the text be updated on page 7 to read, "Some countries do not have procedural codes, and others have developed their own code sets." **Aaron** called for a motion to approve the minutes with the minor modification, which was made by **Arien Malec** and seconded.

The HITAC approved the June 9, 2021, meeting minutes with the minor modification by voice vote. No members opposed, and no members abstained.

PUBLIC HEALTH DATA SYSTEMS TASK FORCE 2021 (PHDS TF 2021) RECOMMENDATIONS – HITAC VOTE

Carolyn Petersen and **Janet Hamilton**, co-chairs of the PHDS TF 2021, presented the TF's recommendations to the HITAC. **Carolyn** provided an overview of the TF's charge, updated TF scope and roster, all of which were included in the PHDS TF's presentation slides. She explained that all of the TF's work from its considerable charge has occurred in seven weeks and described the recent efforts of the TF members and co-chairs. The PHDS TF 2021 presented 52 recommendations to the HITAC, and **Carolyn** explained that six of these recommendations were cross-cutting and addressed the overall ecosystem, while the others were more specific. All of the TF's recommendations were detailed in the presentation materials.

Janet thanked the HITAC for the opportunity to present and discussed the PHDS TF 2021's work to recognize that public health is part of the healthcare ecosystem, despite currently being in a situation with inadequate funding and support. The co-chairs took turns presenting the TF's 52 recommendations, which were detailed in the presentation slides and PHDS TF 2021 Report to the HITAC. They were grouped into the following categories:

- Cross-Cutting
- Laboratory Reporting
- Case Reporting
- Immunizations
- Syndromic Surveillance
- Situational Awareness Data
- Infrastructure
- Funding Mechanisms
- Policy
- Health Equity
- Individual Engagement

Janet discussed the ordering of the recommendations, which was meant to emphasize topical pairings, and **Carolyn** requested feedback from HITAC members.

Discussion:

- **Alexis Snyder** thanked the presenters and the PHDS TF 2021 for their hard work and suggested that the wording in Recommendations 48 and 49 be changed to include lay language/terminology for readers that are not in the healthcare field and/or those who may not understand reporting system language.
  - **Carolyn Petersen** asked **Alexis** to propose language for Recommendations 48 and 49 at the time of the vote.
  - **Denise Webb** reminded HITAC members that the vote on the recommendations would be a majority vote, given the time constraints on the deliverables at the federal level, so any changes to the text would need to be made immediately.
- **Andy Truscott** submitted several comments, including:
  - He emphasized the eventual need for bidirectional exchange of data for public health but suggested that the TF and the HITAC not insist on it now, given the state of public health infrastructure.
  - The TF should have recommended that HL7 incorporate and expand its work to include syndromic surveillance.
  - He was surprised that the TF did not suggest payers sharing more voluminously or using claims data as a rich source of information with preexisting routes.

  - When the TF has mentioned developing new standards as a solution in several recommendations, he cautioned that standards development work is complex and slow. The TF should consider investigating existing standards to see if they could be used before developing new ones.
  - **Janet Hamilton** thanked him for his comments and inquired where his feedback regarding bidirectionality could be incorporated.
  - **Carolyn Petersen** explained that bidirectionality was mentioned throughout the recommendations because that was part of the TF's charge from ONC. Also, payers were mentioned more often within the report than the presentation slides.
  - **Andy** inquired if the HITAC was voting on the report or the presentation. Carolyn responded that the HITAC would vote on the report. The presentation was an abstraction of the 25-page report due to the TF's limited time to present and discuss.
- **Les Lenert** commented that, though bidirectionality is aspirational for some areas of public health, it is the spirit of the TF's recommendations and one goal for the future state.
  - **Janet Hamilton** replied that this was the consensus during TF deliberations.
- **Alexis Snyder** commented that, from her perspective as an engagement specialist, there is no true or authentic engagement without bidirectional communication and transparency. She suggested that the TF use the text regarding Plan Language from a previous recommendation to carry through to Recommendations 48 and 49 to give them greater clarity.
- **Andy Truscott** responded that he agreed with the importance of bidirectionality but was concerned about the timeframe for getting all public health to be bidirectional. He asked if the scope for work on bidirectionality was passed down from ONC or a revision of the TF's charge.
  - **Carolyn Petersen** responded that the TF co-chairs negotiated with ONC prior to the beginning of the TF's work and bidirectionality is a key piece that ONC wanted to better understand for the future ideal state.
  - **Andy** responded that he agreed with their aspirations but was concerned about the associated costs and timeframe.
  - **Carolyn** described how the TF originally created a list of ideas about easier items the TF could achieve but noted that it would basically replicate previous task force work on the subject.
- **Arien Malec** thanked the TF co-chairs and expressed his pleasure at being included as a member of the TF. He explained that one of their key goals was to integrate public health into the United States healthcare ecosystem instead of leaving it in its own silo. He described the situation in which work on orders and results was left undone in Meaningful Use because the burden of pushing in electronic orders and standardizing electronic results seemed like it was too large. This led to significant gaps in demographic and contact tracing for public health during the pandemic response. He asked the TF to "finish the job" for nationwide interoperability and to include public health in that work. He added that while public health having a certain state/local/territorial/tribal focus is important, everything must be incorporated to some extent to build up national standards and interoperability.
  - **Denise Webb** agreed with Arien's comments that the umbrella of a national/federal framework of standards for public health is important for states and referenced her work in the Division of Public Health in Wisconsin.
- The TF read and discussed the suggested updates to the text for Recommendation 10a, which included:

- From **Andy Truscott**: He suggested that the words "where possible" be inserted in front of "bidirectional" on Recommendation 10a, which, as currently drafted, says, "ONC should require the eICR and eCR specification standards, including bidirectional communications between providers, other entities (e.g., payors), and PH within Health IT certification programs."
- **Alexis Snyder** cautioned against adding wording like "where possible," as it can dilute the recommendation.
- **Andy** responded that, without the wording added, the recommendation could be taken as an implied mandate. He also suggested removing "bidirectionality" and saying "including communications between providers."
- **John Kansky** agreed with **Andy's** suggestion and stated that, as a federal advisory committee, the HITAC could add wording to make the recommendation better.
- **Sheryl Turney** stated that there is no implied timeframe or legislation being recommended and urged the HITAC to keep language similar to the original. She suggested using the wording "where it makes the most sense."
- **Aaron Miri** discussed his experiences with Texas' limits on file size for uploaded data and likened the current discussion to discussions held during work on Meaningful Use. He supported the wording suggestions submitted by **Andy** and **John.**
- **Denise** responded that the TF was not creating a mandate but a recommended direction. The execution and plan still have to be worked out.
- **Carolyn Petersen** compared the issue to a chicken and egg problem and suggested that there are two pathways forward: figure out the funding first and then make suggestions or define high consequence issues for public health (from learnings from the pandemic) and bring them to legislators to show how funding would be used.
- **Janet Hamilton** suggested "where appropriate," and **Arien Malec** supported this suggestion, stating that it is the job of the TF and the HITAC to advocate for policy goals and not to negotiate them down.
- TF members discussed wordsmithing options in the public comments in the chat and verbally. They made sure to note that they were not recommending the creation of a mandate.

The co-chairs thanked TF members and HITAC members for all their diligent work and useful feedback. **Denise Webb** made a motion to amend Recommendation 10a to add the text "where appropriate". **Arien Malec** seconded it. **Denise** called for a vote.

The HITAC approved the amendment to Recommendation 10a of the PHDS TF 2021 recommendations report by voice vote. James Pantelas opposed, and no members abstained.

The co-chairs called for a vote to approve the entire report with the amendment to 10a and amendment to 48 and 49 to carry the language of 45 and 46 (related to Plain Language). **Arien Malec** made the motion, which was seconded. **Denise** called for a vote. NOTE: The Plain Language discussed by the HITAC is actually in Recommendation 47 (not 45 and 46), which was confirmed by **Alexis Snyder** who initiated the comment.

The HITAC approved the amendments to the PHDS TF 2021 recommendations report by voice vote. No members opposed, and no members abstained.

Aaron thanked everyone for their participation and for raising detailed points.

INTEROPERABILITY STANDARDS PRIORITIES TASK FORCE (ISP TF) RECOMMENDATIONS – HITAC VOTE

Arien Malec and **David McCallie**, the Interoperability Standards Priorities Task Force 2021 (ISP TF 2021) co-chairs, thanked the HITAC for the opportunity to present and referred to ISP TF 2021's timeline, roster, mission, and charge, which is grounded in the 21st Century Cures Act. Details of these items were included in the ISP TF 2021 presentation slide deck.

Arien explained that the focus of the ISP TF 2021 was to identify opportunities to update the ONC Interoperability Standards Advisory (ISA). He explained that the TF previously presented its recommendations to the HITAC. However, the HITAC asked the TF to review its third recommendation, Foundational Standards – Terminology, and to present an amended version. He explained that in the interim period, the ISP TF 2021 held a hearing with the American Medical Association (AMA) and the National Committee on Vital Health Statistics (NCVHS), which had made parallel recommendations on vocabulary standards. The TF's revised recommendation reflects the feedback from the hearing. Additionally, the TF had a meeting with the National Council for Prescription Drug Programs (NCPDP), which led to an edit and an amendment to the recommendation.

The co-chairs provided detailed background and context information on the TF's updated recommendation, which is accessible within the TF's supporting documents and within the transcript for the HITAC meeting. Arien highlighted key changes within the redline version of the ISP TF 2021's original recommendation and shared a new document, the ISP TF 2021 Addendum Report to the HITAC. It contained all of the updated portions of the TF's recommendations, which he discussed and for which he shared additional context and insight into TF discussions.

Arien also explained the other work that served as a basis for the TF's new suggestions, including the 2019 NCVHS Vocabulary Recommendations and the OMB Circular A-119. He described how recommendations were streamlined to align with federal policy and discussed Clem McDonald's input on updating the detailed recommendations for Laboratory Results. TF co-chair, **David McCallie,** added that the inclusion of wording around the use of LOINC, UCUM, and SNOMED is not a change in any way. Rather, it is to reiterate the best practice currently in use. **Clem McDonald** commented that RxNorm does not have all of the codes that are in NDS, and **Arien** responded that the intent is to harmonize between the FDA and NLM to ensure that the coding system is not split nationally. **Aaron** invited HITAC members to provide feedback on the updated recommendations.

Discussion:

- **Clem McDonald** commented that RxNorm does not have all of the codes that are in NDC and suggested a change in the wording of the recommendation.
  - **Arien Malec** responded that the intent was to harmonize between the Food and Drug Administration (FDA) and the National Library of Medicine (NLM) so the coding systems are not split. He suggested that **Clem's** comment could be addressed by a future task force.
  - **Clem** requested that the wording of the recommendation be updated to mention NLM, because RxNorm, a national initiative, was created by the National Library of Medicine.
  - **Robert Wah** voiced his support of this suggestion.
- HITAC members clarified that they were first being asked to vote on the change in the ISP TF 2021 Recommendation F and then on the entire Recommendation 3.
- **Robert Wah** submitted several comments:
  - He thanked the ISP TF 2021 co-chairs and members for their hard work and for their willingness to reconsider and redraft the recommendations in question.

  - He recognized the addition of terminology curators as key stakeholders, which he stated improved the recommendation. He emphasized that everyone was focused on reducing the friction across data collection and data classification. He emphasized the key process of minimizing workflow disruption.
  - He disclosed his past relationship to the AMA as the past Chair of the Board of Trustees and past President. He described his previous experience with the AMA during the creation of the CPT coding process and emphasized that the AMA wants to reduce the friction in the collection and use of this data. Keeping workflows intact is also a key goal for the AMA, so because many of the coding systems are ingrained in provider workflows, changes can be impactful.
  - The AMA submitted a final letter to the ISP TF 2021 and the HITAC. He warned that the recommendations should be clear in the language used when referencing other documents.
  - **Arien Malec** responded that the formal transmittal included footnotes and specific references to the appropriate documents.
- **Clem McDonald** commented on existing issues with requirements for payment and research survey instruments.

As a result of the discussion period, **Arien** made a motion to proceed with amending the recommendations and include "NLM" in the list of partners with the FDA. **Robert Wah** seconded the motion. **Aaron** called for a vote on the redline text and the inclusion of "the FDA, NLM, and CMS."

The HITAC approved the motion to approve the redline text and the inclusion of "NLM" by voice vote. No members opposed, and no members abstained.

Aaron Miri called for a motion for the HITAC to accept the ISP TF 2021's remaining recommendation. **Arien Malec** moved to support the motion, and **Robert Wah** seconded it.

The HITAC approved the motion to approve the ISP TF 2021 Recommendation #3 by voice vote. No members opposed, and no members abstained.

Arien Malec thanked the HITAC for the opportunity to craft a stronger recommendation.

BREAK

The HITAC took a short break. **Mike Berry** reconvened the meeting at 12:15 p.m., and **Aaron** and **Denise** welcomed HITAC members, presenters, and the public back to the meeting.

ANNUAL REPORT WORKGROUP (AR WG) UPDATE

Carolyn Petersen and **Aaron Miri,** the co-chairs of the AR WG, introduced themselves and presented an update on the work of the WG. **Carolyn** reviewed a list of potential topics developed by the AR WG for the HITAC Annual Report for Fiscal Year 2021 (FY21), which was included in the AR WG Presentation Slides. Following her review of the topics, **Aaron** invited HITAC members to submit additional topics for consideration and explained that submissions could be shared verbally or in the public chat during the meeting or via email after the conclusion of the meeting.

No additional feedback was given during the meeting.

ELECTRONIC HEALTH RECORD (EHR) REPORTING

PROGRAM DRAFT DEVELOPER MEASURES

Michael Wittie provided an overview of the ONC program implementation for the EHR Reporting Program. He described the background and timeline of the program and discussed the 21st Century Cures Act requirements for the EHR Reporting Program, ONC's implementation of the EHR Reporting Program, ONC's approach to establishing user-reported and developer-reported measures and the health IT Advisory Committee Charge. He explained the ONC approach to measure selection criteria, the scope of draft interoperability-focused measures, and other considerations. He explained how ONC's approach was connected to efforts by the Urban Institute who was contracted by ONC to support the program's implementation starting in 2018. The Urban Institute is developing a draft set of developer-reported measures for ONC, and **Michael** reminded everyone that all measurements are linked back to certification criteria. The public feedback period is open on the Urban Institute's website until September 14, 2021. All of these topics were presented in detail in the ONC EHR Reporting Program slide deck.

Michael discussed the vision, overarching charge, and specific charges of the new EHR Reporting Program Task Force 2021 (EHRRP TF 2021) that will kick off shortly to create a set of draft recommendations to the HITAC. He provided the roster and schedule for the EHRRP TF 2021. He explained that the TF's work will be very focused because they are expected to provide draft recommendations to the HITAC at the September 9, 2021 meeting. He introduced the co-chairs of the TF, **Raj Ratwani** (MedStar Health) and **Jill Shuemaker** (American Board of Family Medicine's Center for Professionalism & Value in Health Care),and invited everyone to the upcoming public kick-off meeting of the TF.

Fred Blavin of the Urban Institute recognized his team and introduced himself before presenting the key domains and measures they developed. These were detailed in the Urban Institute's presentation slide deck that also included a timeline and a list of other measures to be considered in the future (in the Appendix). He reiterated the public comment period on the draft developer-reported measures is open until September 14, 2021, and is accessible via the Urban Institute website at https://www.urban.org/policy-centers/health-policy-center/projects/ehr-reporting-program.

Gary Ozanich of HealthTech Solutions presented the four draft measurement domains and measure concepts that were identified in the first pass of work, all of which are linked to interoperability. These were detailed in the Urban Institute's presentation slide deck on slide #4 and included:

- Patient Access
  - Use of different methods for access to electronic health information
  - Use of 3rd party patient-facing apps
  - Collection of app privacy policy
- Public Health Information Exchange
  - Sending vaccination data to Immunization Information Systems (IIS)
  - Querying of IIS by health care providers using certified health IT
- Clinical Care Information Exchange
  - Viewing summary of care records
  - Use of 3rd party clinician-facing apps
- Standards Adoption and Conformance
  - Use of Fast Healthcare Interoperability Resources (FHIR) profiles by clinician-facing apps (adjusted by #patients and #apps)
  - Use of FHIR profiles by patient-facing apps (adjusted by #patients and #apps)
  - Use of FHIR bulk data

Fred discussed the cross-cutting issues identified for discussion by the EHRRP TF 2021, which were included in full in the presentation on slide #10. He also provided an example of one of the public health

information measures, which was included in the slides and depicted the measures along with the numerator and denominator specifications.

Aaron Miri invited HITAC members to submit comments and feedback on the presentation. He also asked that any HITAC member interested in participating in the new EHRRP TF 2021 reach out to **Mike Berry** and the ONC team immediately.

Discussion:

- **Michael Wittie** responded to a question from the public comment chat in Adobe that inquired about the real-world testing program and stated that they were designed to be complementary. He discussed the differences between the two programs.
- **Denise Webb** commented on the TF's compressed work schedule and noted that she is looking forward to their presentation to the HITAC in September.

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

Matt Kerschner with AHIMA:
Great. Good afternoon, everyone. My name is Matt Kerschner, and I'm the director of regulatory affairs for the American Health Information Management Association or AHIMA. AHIMA represents health information professionals that work with health data for more than one billion patients a year. We appreciate the opportunity to provide comments on the work of the Public Health Data Systems Task Force. We are highly supportive of the work of this task force and applaud the task force on all of their work thus far to provide a data-driven response to COVID-19 and future at-consequence public health threats. We understand the urgent need for these recommendations, so it's necessary to narrow the scope of any additional important topics related to this critical work beyond the scope of these recommendations.

AHIMA would like to, specifically, note an area that we believe warrants additional consideration, that being the linkage between workforce readiness and data equality. Our members have reported significant challenges within their organizations related to identifying, hiring, and retaining qualified persons throughout the pandemic to maintain data quality in public health reporting. Even under normal circumstances, our members have reported struggles at their institutions relating to complex public health data reporting. Doing this work requires a high degree of specialized expertise and cross-functional analysis, and there is a limited available talent pool. We urge the HITAC to consider the need for sufficient workforce education and training to make sure that data quality is being maintained and to ensure that reporting is being done accurately. AHIMA believes that this could be incorporated as a critical element in the recommended public health data workforce staffing and execution plan in Recommendation 33. Data standards are incredibly important, but the key will be ensuring data quality to make sure that the reported data is accurate, complete, timely, and meaningful.

Furthermore, we encourage ONC to work with CMS and others to ensure the workforce development needs are met in advance of future high consequence events. I want to thank the HITAC for the opportunity to provide this public comment and for all of your work on this important issue**.**

Debbie Condrey with The Sequoia Project:
Thank you. Good afternoon and thank you for the opportunity to comment. My name is Debbie Condrey. I'm the chief information officer for The Sequoia Project. And as you all may know, we're a nonprofit

public/private collaborative whose mission is to advance secure health IT interoperability for the public good. Prior to joining Sequoia, I worked within the Virginia state government for 32 years, the past 12 years spent in leadership roles at the Virginia Department of Health.

The Sequoia Project has supported the Patient Unified Look-Up System for Emergencies, or PULSE, since 2018 by facilitating an advisory council. They've recently expanded that work group and convened the Emergency Preparedness Information Work Group. The membership includes public health experts from around the country, as well as others who are subject matter experts in emergency preparedness and response. The group's main focus is to discuss insights pertaining to a response as a country to the pandemic and make recommendations based on the collective experiences of our members. And these members are boots on the ground experts.

During our work group meetings, we've discussed data and access to data needed in order to respond to an emergency or a typical public health response. Bidirectional flow of data is key to ensuring the data is where it needs to be in order to respond appropriately to an emergency, whether that's a pandemic or weather emergency or a typical public health response in terms of syndromic surveillance. Three areas that seem key to freeing up the data so that the bidirectional exchange could take place include a focus on accuracy, quality, and clarity of data, policy law and regulatory constraints within states that must be addressed. This includes the need to support state and local policy staff to identify their specific policy constraints and explore ways to better align their policies to support national data-sharing goals and interoperability, appropriate sustainability funding, in addition to the initial grants available to public health. We congratulate you and the public health task force on their work and welcome the opportunity to provide a resource to the full HITAC as you work on resolving these complex issues. Thank you so much.

Shelly Spiro with Pharmacy HIT Collaborative:
Good afternoon. My name is Shelly Spiro. I'm the executive director of the Pharmacy HIT Collaborative representing over 250,000 members of the Majority National Pharmacy Associations, including pharmacy education and accreditation and 11 associate members. Pharmacy HIT Collaborative submitted written comments to the ISP task force 2021 recommendations 3F regarding adopting RxNorm as the single source of data and terminology, noting that it would pose issues to systems and databases, especially those coded to use NDC as an identifier in pharmacy transactions. Relying solely on RxNorm terminology would not only directly impact pharmacy but also a substantial segment of the healthcare industry, payers, drug manufacturers, drug distributors, and other healthcare providers.

We believe that the Pharmacy HIT Collaborative's written comment letter emphasizes the need to map NDC to RxNorm for clinical data exchange. For example, medication orders, allergies, and more. If NDC is used, it should be standardized with product specific codifications need. For example, for prescription recalls, adverse drug events, reporting related to specific products such as dyes and fillers and more. For these specific examples, if NDC is replaced with RxNorm then, RxNorm must be linked to the product specific code. We're asking ONC to clearly identify when it is appropriate to use RxNorm coding and when to use product specific coding such as NDC. Thank you very much.

Questions and Comments Received via Adobe Connect

Mike Berry (ONC) 2: Good morning, and welcome to the July HITAC meeting. We will be getting started soon!

Steve Eichner: Good morning!

Adi Gundlapalli (CDC): Adi Gundlapalli from CDC -- waiting to join by phone.. Thank you and Good morning!

Bob Brown: Anyone know the title of the sprightly hold music?

Bryant Thomas Karras MD: Good morning

Dan Jernigan: Dan Jernigan joining from CDC

michelle schreiber 2: hi. its michelle schreiber from cms - sorry to be a few minutes late but I am on the meeting also

Jill Shuemaker: Jill Shuemaker joining from ABFM

Clement McDonald: I am here also Clem McDonald

Robert Wah: correction to meeting notes... Thanks have a small

Ram D. Sriram: I have joined the meeting Ram D. Sriram: This is Ram Sriram here.

Steve Eichner: Can the speaker increase her volume?

Mike Berry (ONC) 2: Materials for today's HITAC meeting can be found here: https://www.healthit.gov/hitac/events/health-it-advisory-committee-36

Thompson Boyd MD: Agree: A bidirectional feed is critical. It is time to bring interoperability to the next level.

Debbie Condrey: Debbie Condrey from the Sequoia Project here. The Sequoia Project's Emergency Preparedness Information Workgroup has some recommendations regarding bidirectional data flows for public health. We will send those in written form.

Carolyn Petersen: Thanks, Debbie

Andy Truscott: Carolyn: I have a proposed amendment for consideration: Recommendation 10a "ONC should require the eICR and eCR specific standards, including bi-directional communications between providers, other entities (e.g., payors), and PH within Health IT certification programs" to "ONC should require the eICR and eCR specific standards, including where possible bi-directional communications between providers, other entities (e.g., payors), and PH within Health IT certification programs"

Noam Arzt (HLN): Is there a process for written public comments on this material? Up until now it has been difficult making public comments since we have not had access to draft materials before task force meetings. Thanks.

Carolyn Petersen: Comments in this public chat space are included along with the TF materials that the ONC uses in consideration of the work.

Julie Maas: What is the intention of "where possible"? Can we be more specific?

Brett Oliver, MD: I agree with the recommended change as written. It is a recognition of the reality of the present state and the direction we recommend

Noam Arzt (HLN): Well, we have a 25 page report to review. What is the process for making comments outside of the context of this chat? Just send unsolicited to ONC?

Arien Malec: For what it's worth, I support "bidirectional" as the policy goal.

Arien Malec: We don't need to microspecify the how or pre-negotiate failure in advance.

Alexis Snyder: Agree with Arien fully

Aaron Miri: @Arien - Agree

Andy Truscott: Agree with Arien on the policy goal.

Brett Oliver, MD: No one is "pre-negotiating failure" but living in reality. If it is only aspirational, it runs the risk of being ignored

Brett Oliver, MD: But, do agree on the policy goal

Andy Truscott: "where appropriate and feasible" ?

Alexis Snyder: I like that better then where possible

Sheryl Turney: i like appropriate and feasible

John Kansky: +1 for appropriate and feasible

Aaron Miri: +1 appropriate and feasible

Steve Posnack (ONC): Since these are all ultimately recommendations that come to ONC, that ONC will ultimately have to review and compare to what's happening on the ground, investment availability, available policy actions, I would suggest that HITAC focus on the outcomes. You can leave the appropriate and feasibility assessment to ONC and HHS sister agencies.

Andy Truscott: Thanks Steve.

Sheryl Turney: Thanks Steve

Brett Oliver, MD: Appreciate the comment Steve

Michael Adcock: I believe everyone believes in it as a goal, but I do think it needs appropriate and feasible to avoid stopping action until there are funds available to implement future state

Jim Pantelas: This is a recommendation - but it should set forth optimal guidance. Using words that negate the optimal should be avoided. As such, I would avoid using terms like when possible or where appropriate.

Thompson Boyd MD: I agree with Steve and agree with Jim.

Aaron Miri: Congrats Carolyn and Janet!!!! Great leadership

Arien Malec: Likewise - fantastic leadership!

Andy Truscott: Yep - good job. Thanks colleagues for listening.

Janet Hamilton: Thank you to the entire Public Health Data Systems TF

Micky Tripathi: Thank you Carolyn and Janet and the entire TF! And to the HITAC for a great discussion!

Steve Posnack (ONC): @Noam and for public in general.... any member of the public can submit comments to the HITAC before and after meetings with respect to materials that have been discussed.

Written comments can be sent to: onc-hitac@accelsolutionsllc.com They will be added to the meeting minutes.

Carolyn Petersen: Yes, kudos to the PHDS Task Force members for all their hard work and dedication to advancing America's public health capabilities and interoperability with clinical care environments. Tremendous vison for a better future!

Thompson Boyd MD: Regarding the ISO-TF-2021 Recommendations - For the ICD-11 Transition, agree with working with CMS (procedure codes); would however include working with the CDC (e.g. diagnosis codes).

Cathy Graeff: My concern is the term administrative workflows being part of the last sentence.

Micky Tripathi: Thank you David and Arien and ISP TF!

Grace Cordovano, PhD, BCPA: An excellent list with topics that are incredibly important to patients. Correction of errors in medical records are an ever growing unmet need, especially now as greater access to records is acheived. *[sic]*

Grace Cordovano, PhD, BCPA: The acceleration of APIs in health care goes hand in hand with patients seeking more personalized privacy controls and data segmentation technologies and tools.

Bryant Thomas Karras MD: if key new PH measures (identified in the PHDS taskforce) are identified can those be added now?

Carolyn Petersen: +1 to Bryant Karras's comment

Grace Cordovano, PhD, BCPA: Respectfully need to point out that patients are not the only individuals accessing their medical records. Primary carepartners play a significant role in managing medical records and care coordination, especially in life-altering, life-limiting conditions, disabilities, and in cases of limited English proficiency and low health literacy.

Fred Blavin: That's a good point. For the patient acces *[sic]* measures, we propose collecting subgroup data from patients vs. caregivers.

Julie Maas: Apologies if this has been answered in an FAQ already (but I took a quick look and did not see): another topic to discuss may be how this program complements Real World Testing?

Krystal Collier: +Julie Mass's comment

Genevieve Morris: How will these measures help a user/potential customer evaluate the EHR products? It seems like the measures are pretty focus on usage of the EHR by users (i.e. how many C-CDAs did they view) versus the product performance/usability. I thought the EHR reporting program was primariliy *[sic]* about usability and performance of the product not the users.

Aaron Miri: recommendation: When evaluating various dimensions, it would be helpful to categorize note items that (for example: potentially directly affect patient safety vs feature identification vs phys. burden increase/reduction, etc.)

Linda VanHorn: With regard to setting: it could be helpful to tie back to a standard such as CMS Place of Service codes.

Meryl Bloomrosen: Wondering to what extent the proposed measures and reporting proesses *[sic]* been pilot tested.

Julie Maas: Thank you!

Krystal Collier: Thank You Michael!

David McCallie: +1 for Smart Heath Cards

Robert Wah: Here is more detail on the progress being made with SMART Health Cards and clinical information and specifically vaccination status. Key components in the ecosystem are the Issuers, the Trust Network of issuers, and the Verifier network including this new verifier app. It had been great to see how this all has come together with VCI.org and the Commons Project Foundation.
https://www.businesswire.com/news/home/20210708005512/en/The-Commons-Project-Releases-Free-App-to-Scan-SMART%C2%AE-Health-Cards-and-Quickly-Verify-Vaccination-Status

Aaron Miri: +1 for data quality needs and the amazing professionals that do heroic work on this

Robert Wah: For transparency, as most folks know, I am Chair of the Board at The Commons Project and am on the Steering Committee of VCI.org Amey Hugg - ASHP: Recommendation from ASHP: ASHP encourages the supplementation or replacement of the NDC coding structure to support unique drug (or combination of drugs), strength, route and dose form in a unified standard coding scheme. It calls on the Food and Drug Administration, the pharmaceutical industry, pharmacy and medical software providers, Centers for Medicaid and Medicare Services, and purveyors of clinical data repositories and drug databases to support a common, standard and non-proprietary coding structure for the representation of medications.

Janet Hamilton: Thank you all! Janet

Questions and Comments Received via Email

The following public comments were received via email.
HLN Public Comments Letter
AMA Public Comments Letter
NCPDP Public Comments Letter
PHIT Public Comments Letter
CoverMyMeds Public Comments Letter

Arien Malec, response to CoverMyMeds Public Comment:

Thanks, Kristina –

I am having similar conversations with NCPDP and I believe there is a fundamental misunderstanding of our recommendations. The intent is to have a single set of terminology that is inclusive of the level that NDC currently provides (which is specific to labeler/manufacturer and package) *and* the level that RxNorm currently provides.

While I see a cogent argument in the CoverMyMeds comments on the need for labeler/manufacturer and package-specific information in specific cases, I do not see a reflection that using that level of terminology as the only level of specificity is problematic. As an example, when a provider sends a script through to a pharmacy, she does not intend to dispense, by way of example, atorvastatin 10mg tablets manufactured by Lannett Company in 90 tablet bottles (NDC 62175-890-46); she intends to prescribe a 30 days supply of atorvastatin 10mg qid; when we have a split language, we either over-specify in some cases, or underspecify in others.

Thank you again for your comments,
Arien

FINAL REMARKS

Robert Wah shared information with the HITAC on work being done at the VCI, which is a coalition of several hundred participants working together to harmonize the standards and produce the implementation guides needed to support the issuance of verifiable health credentials. As a result of this work, California and Louisiana have opened up their immunization information systems (IIS) to allow their citizens to get a smart health care envelope with their vaccine information inserted into it. Over a million citizens in California have already opted to do so and have been provided with a QR code depiction of the card, which is secure and verifiable. This is an example of clinical information being used in a patient-controlled way that still maintains their privacy.

Additionally, **Robert** explained that the CommonsProject has established the Common Trust Network, which provides a list of the trusted issuers of the smart health care envelopes and has released a common verifier app to scan the QR codes and establish their veracity. Aaron thanked him for the information but asked all participants to be mindful of their own states' laws related to prohibitions on vaccine tracking or other uses of technology.

Mike reminded members that the next meeting of the HITAC will take place on September 9, 2021, and added that all materials from the current meeting would be made available at https://www.healthit.gov/hitac/events/health-it-advisory-committee-36.

Denise and **Aaron** thanked the presenters and HITAC members for their thoughtful comments and discussions during the meeting. **Denise** briefly summarized the timeline for upcoming HITAC and task force work, and **Aaron** asked everyone to be safe and take care in light of the spread of the new COVID-19 variants.

ADJOURN

The meeting was adjourned at 2:30 p.m. ET.