Health Information Technology Advisory Committee
Office of the National Coordinator for Health Information Technology

Meeting Notes

Health Information Technology Advisory Committee
May 22, 2019, 10:30 a.m. – 1:45p.m. ET
Virtual

The May 22, 2019, meeting of the Health IT Advisory Committee (HITAC) was called to order at 10:30 a.m. ET by Seth Pazinski, Acting Designated Federal Officer (DFO), Office of the National Coordinator for Health IT (ONC) and conducted roll call.

Roll Call

MEMBERS IN ATTENDANCE

Carolyn Petersen, Individual, Co-Chair
Robert Wah, Individual, Co-Chair
Terry Adirim, Department of Defense
Christina Caraballo, Audacious Inquiry
Tina Esposito, Advocate Aurora Health
Cynthia A. Fisher, WaterRev, LLC
Valerie Grey, New York eHealth Collaborative
Anil Jain, IBM Watson Health
John Kansky, Indiana Health Information Exchange
Kensaku Kawamoto, University of Utah Health
Steven Lane, Sutter Health
Leslie Lenert, Medical University of South Carolina
Arien Malec, Change Healthcare
Denni McColm, Citizens Memorial Healthcare
Clement McDonald, National Library of Medicine
Aaron Miri, The University of Texas at Austin, Dell Medical School,and UT Health Austin
Brett Oliver, Baptist Health
Terrence O’Malley, Massachusetts General Hospital
Raj Ratwani, MedStar Health
Sasha TerMaat, Epic
Andrew Truscott, Accenture
Sheryl Turney, Anthem BCBS

MEMBERS NOT IN ATTENDANCE

Michael Adcock, Individual
Kate Goodrich, Centers for Medicare and Medicaid Services (CMS)
Steve L. Ready, Norton Healthcare
Mark Roche, Centers for Medicare and Medicaid Services (CMS)
Patrick Soon-Shiong, NantHealth
Ram Sriram, National Institute of Standards and Technology
Denise Webb, Individual

FEDERAL REPRESENTATIVES

Laura Conn, Centers for Disease Control and Prevention
Terry Adirim, Federal Representative, Department of Defense

ONC STAFF

Seth Pazinski, Acting Designated Federal Officer (DFO), ONC
Jon White, Deputy National Coordinator

Call to Order

Seth Pazinski called the meeting to order and turned the meeting over to Jon White, Deputy National Coordinator.

Welcome Remarks

Jon White, Deputy National Coordinator

Jon White thanked the HITAC members for agreeing to meet again and noted this would be the last meeting to review recommendations on ONC's proposed rule. He noted that their input has been tremendously valuable and represents a huge amount of effort. ONC's comment period closes on June 3, 2019, and The Trusted Exchange Framework and Common Agreement (TEFCA) comment period closes on June 17, 2019.

He turned it over to Carolyn Petersen, co-chair for opening remarks.

Carolyn Petersen reviewed the agenda and noted that the purpose of today's meeting would be to finalize the review of recommendations for transmittal to the National Coordinator.

Robert Wah thanked the group for all of their hard work and mentioned that the 5/13 HITAC meeting notes were still being pulled together and would be reviewed/approved at the next meeting of the HITAC in June. He then transitioned the discussion to Christina Caraballo, co-chair of the U.S. Core Data for Interoperability Task Force (USCDI TF) to review an update to the recommendations.

U.S. Core Data for Interoperability Task Force Draft Recommendations and Vote

Christina Caraballo, Co-Chair

Terry O'Malley, Co-Chair

Christina Carballo noted that the U.S. Core Data for Interoperability Task Force (USCDI TF) only made a small change made to Recommendation 28.

Recommendation 28: Missing Data Elements

- **Recommendation 28:** Add provider demographic data elements to the Care Team Members Data Class in USCDI v1

  - **Recommendation 28c:** Include Identifier (e.g., NPI, certification, state license). The use of an identifier is mandatory if the identifier is defined/provided/managed by a national or regional professional body [replaces “accreditation”]. If there is no identifier provided by a national or regional professional body [replaces “accreditation”], then the user shall indicate that no such identifier exists.

Christina Carballo noted that the USCDI TF added professional (as noted above in red text) to ensure that care team members were not inadvertently excluded.

The HITAC approved Recommendation 28 by voice vote. No members opposed. None abstained.

Health IT for the Care Continuum Task Force Draft Recommendations and Vote

Carolyn Petersen, Co-Chair

Christoph Lehmann, Co-Chair

Carolyn Petersen provided an overview of the Health IT for the Care Continuum Task Force (HITCC TF) membership, charge, and recommendations around data segmentation for privacy (DS4P).

She reviewed what ONC included in the proposed rule to remove the current 2015 Edition DS4Psend and receive certification criteria and replace with three new DS4P criteria.

She reminded the HITAC members that there was interest in changing the language in the transmittal letter around DS4P. The HITCC TF reviewed the comments received from the May 13, 2019 HITAC meeting and updated the recommendations as follows.

- The HITCC TF acknowledges barriers to optimal implementation of DS4P such as: safety implications; medicolegal recordkeeping requirements; “leakage” or the concern that segmentation will not meet user expectations (particularly regarding narrative content); and, the significant scope of development efforts to implement DS4P in health information technology systems
  - The HITCC TF recognizes that governance will be necessary to prioritize use cases for industry consideration, address barriers, and facilitate consistent implementation
  - However, the HITCC TF agrees that it is crucial to initiate future work to advance DS4P now including efforts on both technical and policy components
    - Failure to do so at this junction would be a great opportunity loss and hamper future interoperability efforts. The work could be accomplished in part through multi-stakeholder collaborative work and testing of the DS4P standard to enable priority use cases.

Discussion

- **Arien Malec** commented that there are standards that allow for privacy or sensitivity preferences. Electronic health record (EHR) functional expectations do not go along with this data, and there is no additional guidance. This is concerning because an EHR may get certified for the DS4P standard, but there isn’t clear policy guidance around what is expected around the EHR. He explained that he doesn’t know if data received from behavioral health is tagged with DS4P, and there is equivalent information in the chart and asked if this is acceptable. He asked if it is okay to redisclose if the patient shares information in a DS4P report. He was concerned about when data can or cannot be shared. He suggested that ONC and wider HHS policy recommendations may be needed for functional requirements for DS4P.

- **Sasha TerMaat** commented that she shared Arien's concerns and appreciated the HITCC TF's work to update the language. EHR developers fear the proposed update will have a significant impact and require extensive development (20,000 hours per product). Ultimately, if there isn't confidence in governance, there is a fear of leakage around narrative information. It is important to understand the policy implications, but not appropriate to recommend for certification without policy consensus.
    - **Arien Malec** noted that standards developers point towards the policy as the enablement. DS4P does not solve the policy problem. Policy guidance is needed.
- **Carolyn Petersen** commented that the HITCC TF members understood that there are technical challenges, and even though it is hard, there is a need to continue to push it forward.
- **Chris Lehmann** commented that he appreciates the developer concerns and noted they were discussed with the HITCC TF. The HITCC TF unanimously agreed that this needs to be pushed forward.
- **Arien Malec** suggested adding that there are policy and functional guidance added to address the policy and privacy needs.
- **Clem McDonald** commented that he didn't know what the "it" is. He hasn't seen any enumeration of what is subject to redaction. He wondered if the redacted data would be shared with public health and if providers would have protections against malpractice. He felt that more clarity is needed before moving forward.
    - **Chris Lehmann** noted his appreciation for Clem McDonald's concern but felt that it was a paternalistic view of the patient/provider relationship.
- **Steven Lane** suggested specific modifications to the recommendation. He suggested developing stakeholder consensus regarding the data that may be restricted by the patient and what data must be transmitted to support safe, coordinated care. He commented that the current language was murkier than it could be. He supports the right of the patient to restrict data, but it needs to be balanced by the caregiver.
- **Clem McDonald** commented that the consequences are not explained thoroughly. He asked how this can be accomplished with narrative in the notes as it is not possible with today's technology.
- **Carolyn Petersen** commented that ONC is looking for direction, not specifics about design principles or how developers should implement. She suggested there should be a group organized to work together on the policy specifics and concerns that Clem McDonald mentioned.

Carolyn Petersen suggested adding the following based on the discussion:
HITAC recognizes that while patients do have the right to choose, clinicians have the right to know that they are practicing with specific restrictions to their access to data. At this time stakeholder consensus regarding what data may be restricted by the patient and what data must be transmitted to support safe, coordinated care is lacking. HITAC is concerned that the health IT community currently lacks the policy recommendations to move forward with DS4P. HITAC recommends that ONC urgently drive a

policymaker, developer, and provider workgroup to define and address policy needs and functional requirements to address policy and privacy needs.

- **Andy Truscott** noted that he was concerned with the initial language, but agrees with the new language.
- **Steven Lane** commented that he is concerned about constricting the data.
- There was a lot of discussion about the recommended language. Carolyn Petersen volunteered to rework the language for discussion later in the meeting.

Carolyn Petersen provided updated language which removed the original last paragraph and inserted the following language:
The HITCC TF recognizes patients do have the right to choose and restrict information. At this time stakeholder consensus regarding what data may be restricted by the patient and what data must be transmitted to support safe coordinate care is lacking. The HITCC TF is concerned that the health IT community currently lacks the policy recommendations to move forward with the DS4P.

Recommendation: ONC should stand up a multi-stakeholder workgroup to identify and define policies and functional requirements to address patient privacy and provider needs.

- **Sasha TerMaat** proposed amending the language in the first paragraph to remove "supports this proposal and."
    - **Carolyn Petersen** agreed to this change.
    - **The HITAC approved the removal of "supports this proposal and" by voice vote. No members opposed. None abstained.**

The HITAC approved the recommendation to stand up a multi-stakeholder workgroup by voice vote. No members opposed. None abstained.

Information Blocking Task Force Draft Recommendations and Vote

Andrew Truscott, Co-Chair

Andy Truscott reviewed the remaining Information Blocking Task Force (IB TF) recommendations.

Recommendation 1

Health Information Network or _HIN_ means an individual or entity that satisfies one or several of the following—

- (1) Determines, oversees, administers, controls, or sets policies or makes agreements that define business, operational, technical, or other conditions or requirements for Health Information Exchange between or among two or more individuals or entities,
- or (2) Provides, manages, or controls any technology or service that enables or facilitates Health Information Exchange between or among two or more individuals or entities.

Recommendation 2

- Health Information Exchange or HIE means: Any entity performing the access, exchange, transmittal, processing, handling, or other such use of Electronic Health Information who is not considered a Provider, Health Information Network, or Health IT Developer.

Recommendation 3

- The TF recommends making the following revisions to the definition of “electronic health information”: Electronic Health Information (EHI) means— (1) Electronic protected health information (as defined in 45 CFR § 160.103); and (2) Electronic Individual Health Information: (i) Any other information that identifies the individual, or with respect to which there is a reasonable basis to believe the information can be used to identify the individual and is transmitted by or maintained in electronic media, as defined in 45 CFR 160.103, that relates to the past, present, or future health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment(s) for the provision of health care to an individual. (ii) On the two-year anniversary of the effective date of the final rule, an individual’s consent directives including privacy, medical treatment, research, and advanced care. (3) Electronic information which can reasonably be used to inform care decisions, by a provider or patient, including pricing information which can be attributable to an individual patient.
- **Minority Opinion**: the definition should be open, and the information should be completely unblocked.

Recommendation 4

- Within the definition of Electronic Health Information, the term “information” shall be read as applying to both “Human Readable” information that can be readily understood by a real person actor without specialized reference (e.g., narrative clinical notes), and also “Machine Readable” information that is interpreted by a computerized actor for use either by computerized processes or a real person actor (e.g., data codified using a terminology or classification).

Discussion regarding recommendation 1-4

- **John Kansky** commented that what he likes about the health information exchange definition is that it clarifies for a provider or provider network that they will not end up being an HIE. The unintended consequences are that HIE is the last definition if an organization doesn’t apply to the others.
    - **Andy Truscott** commented that the definitions are not mutually exclusive.
    - **John Kansky** suggested adding text to Recommendation 2 to ensure that if there is an organization that could meet more than one definition, they could be considered more than one thing (e.g., health information network, health information exchange).
- Suggested language change: Any entity who is considered a provider, health information network, or health IT developer performing the access, exchange, transmittal, processing, handling, or other such use of electronic health information for care.
    - **Les Lenert** expressed concern that this could apply to research organizations.
    - **Andy Truscott** asked if they would want these types of organizations to fall under information blocking.
    - **Les Lenert** noted that those organizations would not want to fall under information blocking.
    - **Sasha TerMaat** suggested addressing the research use case with a separate exception.

- **It was moved to amend Recommendation 2** with this language to follow after "...HIE means: Any entity who is not considered a provider, health information network, or health IT developer performing the access, exchange, transmittal, processing, handling, or other such use of electronic health information.
    - **The HITAC approved the amendment to Recommendation 2 by voice vote. No members opposed. Valerie Grey abstained.**
- **The HITAC approved Recommendations 1-4 by voice vote. No members opposed. Valerie Grey abstained.**

After much discussion, the HITAC worked to create the following recommendation to be included in the exception recommendation:

- **Recommendation XXX** (to be inserted in the recommendation concerning exceptions).
    - The following activities are specifically excluded from being implicated under the rule.
        - Non-direct clinical care activities being conducted by public health authorities;
        - Research as defined by 45 CFR 164.501
    - **The HITAC approved this Recommendation by voice vote. No members opposed. Valerie Grey abstained.**

Recommendation 5: Price Transparency

- The IB TF agreed that price transparency is important, which is why the definition of health information network was crafted carefully to include price transparency.
- The IB TF recognized the complexities of price transparency and recommended that ONC create a task force to work on this area with suggested considerations for discussion.
- **The HITAC approved Recommendation 5 by voice vote. No members opposed. None abstained.**

Recommendation 6: Health IT Developer of Certified Health IT

- The IB TF felt that the regulations should apply to self-developers. They did not want to inadvertently create a two-track system. The IB TF wants to be sure that the regulations are applied equally to everyone.
- **Ken Kawamoto** asked for clarity around the fact that ONC can't do anything based on the definition.
    - **Andy Truscott** comment that there is no enforcement for those without certified health IT.
- **The HITAC approved Recommendation 6 by voice vote. No members opposed. None abstained.**

Recommendations 7-13: Practices That May Implicate the Information Blocking Provision

- **Recommendation 7** – Removed
- **Recommendation 8**
    - Patient Access - The IB TF believes that "open" patient access to EHI about them is likely to have implications that relate to the information blocking provision.
- **Recommendation 9** – Removed
- **Recommendation 10**
    - The IB TF recommended that the preamble be updated to give greater specificity as to the real-world organizational types who could fall into the various categories of Actors.
- **Recommendation 11**

  - The IB TF recommended that the preamble should also be updated to give greater specificity as to the real-world organizational types who would not fall into these categories and would not, therefore, implicate the information blocking provision.
- **Recommendation 12**
  - This is looking at how organizations are impacted. The IB TFis hoping to capture the broad definition of access so that there are not unintended consequences. The IB TF is concerned about electronic health information being prevented from being accessed, exchanged, or used.
- **Recommendation 13**
  - The IB TF suggested adding text to the preamble noting that healthcare is undergoing change.
- **The HITAC approved Recommendations 7-13 by voice vote. No members opposed. None abstained.**

Recommendations 30-38: Recovering Costs Reasonably Incurred

Andy Truscott noted that these recommendations were reviewed previously, but were not voted on; therefore, he reviewed the recommendations at a high-level.

- **Recommendation 30:** An entity not considered a provider, or health IT developer is considered an HIE.
- **Recommendation 31:** The preamble should address that there is an expectation that many organizations will meet the definition of HIN.
- **Recommendation 32:** Where cost-based pricing mechanism are required, the IB TF recommended that the method for assessing the cost basis be reasonably associated with the complexity or cost of providing capabilities.
- **Recommendation 33:** ONC should distinguish between basic access and value-added access, Exchange, and Use. Within this recommendation references to Designated Record Set and Covered Entity are interpreted in line with 45 CFR 164.501.
- **Recommendation 34:** There should be a distinction between basic and value-added capabilities.
- **Recommendation 35:** ONC should distinguish between intellectual property rights (IPR) that are essential for access and IPR that is allowed for value-added services.
- **Recommendation 36:** Cost recovery should be pure and direct. This ties the fees that will be incurred to what the access will entail.
- **Recommendation 37:** Fees would not be reasonable if they materially discourage access, exchange or use, or impede the development of competitive markets for value-added exchange and use services.
- **Recommendation 38:** No further restrictions should be made on permitted fees.

Discussion of Recommendations 30-38

- **Sasha TerMaat** asked for clarity around her understanding of Recommendation 33, providing a scenario of a technology that collects data. In the scenario she provided, this recommendation would divide the data collected. Vitals could fall into a core standards list, but other elements like the innovative ways data are collected would fall into value-added access.
- **Arien Malec** commented that the output and capabilities would never be a part of basic access.

  - **Sasha TerMaat** commented that the patient is entitled to have the output of the data in the record.
- **Sasha TerMaat** also asked what the core standards list is.
  - **Arien Malec** responded that once a standard becomes part of something maintained by ONC, it would become part of basic access. The intent is to create incentives to adopt and implement certified standards.
- **Sasha TerMaat** moved to amend Recommendation 33, changing the word from 'core' to 'certified.'
  - **The HITAC approved the amendment to Recommendation 33revising core to certified by voice vote. No members opposed. None abstained.**
- **The HITAC approved Recommendations 30-38 by voice vote. No members opposed. None abstained.**

Assurances Request for Information

Andy Truscott noted that Recommendation 48 was removed.

Communications

Andy Truscott reviewed changes to Recommendation 52 (as noted in red below).

- The IB TF recommends the following revisions to the regulatory text: (2) A health IT developer does not prohibit the fair use communication of screenshots of the developer's health IT, subject to the limited restrictions described in paragraph (a)(2)(ii)(D) of this section, and with the understanding that any actor disclosing the screenshots is responsible for communicating that each use is to be put to "fair use."
- **The HITAC approved Recommendation 52 by voice vote. No members opposed. Raj Ratwani abstained.**

Seth Pazinski opened the lines for public comment.

Public Comment

There were no public comments.

Comments in the Public Chat feature of Adobe

Steven Lane: Suggested text: ...stakeholder consensus regarding what data may be restricted by the patient and what data must be transmitted to support safe coordinated care."

Carolyn Petersen: Incorporating that into additional language to propose

Steven Lane: While patients do have the right to choose, clinicians have the right to know that they are practicing with specific restrictions to their access to data.

Brett Oliver: Agree, Steven

Carolyn Petersen: Yes, just passing some language to ONC to display

Chris Lehmann: Unless knowing that there is a restriction would allow a clinician to deduct the content.

Al Taylor: Is it not a safe assumption that the provider is ALWAYS practicing with possibly incomplete information, whether because patients refuse to disclose or information is not completely shared.

Brett Oliver: Sure - yet I trust the record I receive is complete and has not been "hidden" selectively. Segmenting data as suggested is clinically dangerous

Denni McColm: Is there also something that could be included about informing patients about the risks of withholding information? I don't think patients understand those risks as Clem as described.

Steven Lane: As discussed, knowing that information has been willfully withheld is itself useful/meaningful information. While, in rare cases, knowing that data is missing may allow some deduction of the missing content, this would seem a small minority of cases. Simply telling a provider that a diagnosis, med, allergy, result, etc. has been withheld gives the provider the opportunity to have a focused discussion with the patient about this. If patients decline to divulge that is fine. Based on 30 years of clinical experience I believe that most patients would share information appropriately with their clinician when presented with an explanation regarding why it is relevant to their current care.

Andy Truscott: There has been much debate on similar functionality in other jurisdictions (e.g. "Sealed Envelopes" in the UK, for both patients and providers to put special access controls on segments of data). Should we potentially look to previous thinking to inform our debate here?

Andy Truscott: If I recall - the Patient Sealed Envelope came down to a Provider being alerted that one existed, and it was part of their engagement with the patient to gain permission to access, or to have a highly audited override.

Steven Lane: The patient may not remember what data they have restricted in the past. I believe that the provider needs to know, for example, that allergy checking is incomplete because an allergy has been restricted, or drug interaction checking is incomplete because medication information has been restricted.

Andy Truscott: If a clinical is aware that data has been restricted, can they not then engage in a discussion with the patient as to whether that information is relevant to the care decisions being made?

Andy Truscott: *clinician

Elisabeth Myers: For reference, it seems part of what is missing here is context on the proposal in the rule. The criteria being proposed in the rule is a tool, it is not the rules by which the provider would implement the tool. The proposal in the rule is to support a method by which existing privacy policies can begin to be supported by technology in a manner other than what is often happening now, where providers simply do not send the document at all. The DS4P standard allows for a tool to tag data at the data element level as private. This can be tagged based on wide range of laws. At present, those rules are applied by state, federal, and other laws and requirements.

Laura Conn: Based on the new definitions of HIN and HIE, if an organization meets both definitions it would only be called a HIN?

Laura Conn: Can we see the HIE slide again?

John Kansky: For some reason you can't hear me

Katherine Campanale: John- you are not muted on our end. Please make sure you are not muted

John Kansky: I'll dial back in

Laura Conn: "Who is not considered a ..." appears you can't be both.

Laura Conn: Can you clarify why the definition of HIE purposely leaves out "between organizations"?

Val Grey: Can someone clarify - would new definition of HIE cover health plans?

Laura Conn: Is it adding public health and clinical research to the not considered list

John Kansky: I sent Andy and Robert a first attempt at an "actors' exception"

Cassandra Hadley: Thanks. I let them know.

Laura Conn: Activities carried out by public health authorities....but not public health activities carried out by clinical care

Sasha TerMaat: Andy I think we still want to get rid of the part of bullet 2 after "103"

MorrisLandau: Research is 45 CFR 164.501 under the HIPAA Privacy Rule

Halley Simpson: Just having public health authorities excludes other organizations engaged in research

Closing Remarks and Adjourn

Carolyn Petersen thanked the HITAC members for the significant time and work put forth to provide feedback on the proposed rule. She emphasized how important it is to share different perspectives and noted her appreciation.

Seth Pazinski reminded the HITAC that the Trusted Exchange Framework and Common Agreement Task Force's (TEFCA TF) next meeting will be on May 23, 2019. The TEFCA TF will share updates at the next HITAC meeting on June 13, 2019 (the June 13, 2019 HITAC meeting was canceled after this meeting, and the next HITAC meeting will be on June 19, 2019).

Seth Pazinski adjourned the meeting at 1:45 p.m. ET