Health Information Technology Advisory Committee (HITAC)

VIRTUAL

Meeting Notes | April 12, 2023, 11 AM – 2 PM ET

EXECUTIVE SUMMARY

Micky Tripathi, the National Coordinator for Health IT, Office of the National Coordinator (ONC), welcomed attendees to the meeting and provided a summary of the newly released ONC proposed rule. The Co-Chairs of the HITAC, **Medell Briggs-Malonson** and **Aaron Miri**, welcomed members, reviewed the meeting agenda, and presented the minutes from the March 9, 2023, HITAC meeting, which were approved by voice vote. **Elise Sweeney Anthony**, Executive Director, Office of Policy, ONC, provided a high-level overview of the new ONC proposed rule on Health Data, Technology, and Interoperability. **Kathryn Marchesini**, Chief Privacy Officer, ONC, reviewed the decision support interventions (DSI) and algorithm section of the new proposed rule, including DSI proposals, the benefits of DSI, and the impact of DSI proposals on health IT. **Mike Lipinski**, Director, Division of Regulatory and Policy Affairs, ONC, reviewed the certification standards and functionality updates in the new proposed rule. **Sarah DeSilvey** and **Naresh Sundar Rajan**, Interoperability Standards Workgroup (IS WG) Co-Chairs, presented the Interoperability Standards Workgroup 2023 Recommendations Report which included recommendations for draft USCDI version 4. **Avinash Shanbhag**, Executive Director, Office of Technology, ONC, presented an ONC Office of Technology update on health IT innovation. There was a robust discussion in the public meeting chat via Zoom.

AGENDA

11:00 AM	Call to Order/Roll Call
11:05 AM	Welcome Remarks
11:25 AM	Opening Remarks, Review of the Agenda and March 9, 2023, Meeting Notes – HITAC Vote
11:30 AM	ONC Proposed Rule: Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing
12:45 PM	Interoperability Standards Workgroup Recommendations on Draft USCDI Version 4 – HITAC Vote
1:30 PM	ONC Office of Technology Updates – Health IT Innovation
1:50 PM	Public Comment
2:00 PM	Final Remarks and Adjourn

CALL TO ORDER/ROLL CALL

Mike Berry, Designated Federal Officer, ONC, called the April 12, 2023, meeting to order at 11:01 AM and welcomed ONC's executive leadership team.

ROLL CALL

Medell Briggs-Malonson, UCLA Health, Co-Chair
Aaron Miri, Baptist Health, Co-Chair
Shila Blend, North Dakota Health Information Network
Hans Buitendijk, Oracle Health
Sarah DeSilvey, Larner College of Medicine, University of Vermont
Steven (Ike) Eichner, Texas Department of State Health Services
Cynthia A. Fisher, PatientRightsAdvocate.org
Hannah Galvin, Cambridge Health Alliance
Rajesh Godavarthi, MCG Health, part of the Hearst Health network
Jim Jirjis, HCA Healthcare
Bryant Thomas Karras, Washington State Department of Health
Kensaku (Ken) Kawamoto, University of Utah Health
Steven Lane, Health Gorilla
Hung S. Luu, Children's Health
Arien Malec, Change Healthcare
Anna McCollister, Individual
Clem McDonald, National Library of Medicine
Deven McGraw, Invitae Corporation
Aaron Neinstein, UCSF Health
Eliel Oliveira, Dell Medical School, University of Texas at Austin
Kikelomo Adedayo Oshunkentan, Pegasystems
Naresh Sundar Rajan, CyncHealth
Alexis Snyder, Individual
Fillipe Southerland, Yardi Systems, Inc.
Sheryl Turney, Elevance Health

HITAC MEMBERS NOT IN ATTENDANCE

Lisa Frey, St. Elizabeth Healthcare
Steven Hester, Norton Healthcare
Valerie Grey, State University of New York

FEDERAL REPRESENTATIVES

Thomas Cantilina, Military Health System, Department of Defense (DoD) *(Absent)*
Adi V. Gundlapalli, Centers for Disease Control and Prevention (CDC)
Ram Iyer, Food and Drug Administration (FDA) *(Absent)*
Meg Marshall, Department of Veterans Affairs
Michelle Schreiber, Centers for Medicare and Medicaid Services
Ram Sriram, National Institute of Standards and Technology
Nara Um, Federal Electronic Health Record Modernization (FEHRM) Office *(Absent)*

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
Kathryn Marchesini, Chief Privacy Officer
Mike Lipinski, Director, Division of Regulatory and Policy Affairs

Mike Berry, Designated Federal Officer

WELCOME REMARKS

Micky Tripathi welcomed the attendees on the call. He highlighted the newly released ONC proposed rule and noted there have been a lot of market developments with respect to implementation. Highlights from the rule include:

- A shift from United States Core Data for Interoperability (USCDI) version 1 (v1) to USCDI version 3 (v3), which includes social determinants of health (SDOH) data, gender and sexual orientation data, and insurance information,
- Exploration of the ability to automate the discovery of endpoints,
- Further context into the Trusted Exchange Framework and Common Agreement's (TEFCA) newly introduced exception that allows actors to comply with information blocking rules,
- Technical standards for electronic case reporting,
- Requests for information (RFIs) for Fast Healthcare Interoperability Resources (FHIR) and smart health links,
- Context into information blocking requirements, and
- Information related to predictive decisions support interventions

Sarah DeSilvey disclosed she is now affiliated with Yale Center for Outcome Research and Evaluation, assisting with CMS health equity measurement.

Opening Remarks, Review of Agenda and March 9, 2023, Meeting Notes – HITAC Vote

Medell Briggs-Malonson and **Aaron Miri**, HITAC Co-Chairs, welcomed attendees.

Aaron reviewed the agenda. **Medell** called for a motion to approve the March 9, 2023, HITAC meeting notes. **Hans Buitendijk** motioned to approve the meeting notes. This motion was seconded by **Kikelomo Adedayo Oshunkentan**.

The HITAC approved the March 9, 2023, meeting notes by voice vote. No members abstained and no members opposed.

ONC Proposed Rule – Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing

Elise Sweeney Anthony, Executive Director, Office of Policy, ONC, provided a high-level overview of the new ONC Proposed Rule on Health Data, Technology, and Interoperability (HTI-1). The ONC Proposed Rule was released on April 11, 2023. **Elise** provided an overview of ONC's new naming convention, presented what is in HTI-1, and why updates were proposed. **Elise** noted ONC is discontinuing year-themed "editions" and is establishing applicability and expiration timelines for certification criteria and standards. **Elise** also reviewed Assurances Condition and Maintenance of Certification Requirements compliance.

Mike Lipinski, Director, Division of Regulatory and Policy Affairs, Office of Policy, ONC, reviewed the certification standards and functionality updates in the new proposed rule. He also highlighted that the rule is

proposing USCDI version 3 as the new standard baseline for certification. **Mike** noted there are proposed updates to Standardized API Revisions and Related API Conditions, Electronic Case Reporting, Patient Requested Restrictions Criterion, and Requests for Information. **Mike** provided an overview of the Insights Condition and Maintenance of Certification Requirements, how the measures were developed, and who will be reporting on the measures. **Mike** also presented on the Information Blocking section of the proposed rule, including sections on defining what it means to offer health IT, and creating new conditions under current exceptions such as the infeasibility and manner exceptions.

Kathryn Marchesini, Chief Privacy Officer, ONC, reviewed the Decision Support Interventions (DSI) and algorithm section of the proposed rule, including DSI proposals, the benefits of DSI, and the impact of DSI proposals on health IT. Kathryn also highlighted data transparency, predictive DSI transparency, and organizational transparency as it relates to health IT.

Elise reviewed how to register for ONC's listserv and how to submit a comment on the proposed rule. **Elise** walked through the HTI-1 Proposed Rule Task Force charge and topics by group.

Discussion:

- **Jim Jirjis** noted the proposed rule incorporates much of the feedback from the past few years. He commended ONC for their cross-agency work.
- **Medell Briggs-Malonson** asked if there is a sub-task force for DSI. She recommended having a separate sub-group for that component.
    - **Elise** said DSI is included in the task force review, but there is not a specific sub-group for it. ONC is happy to consider a specific DSI task force group if the HITAC finds it appropriate.
- **Anna McCollister** seconded Medell's comments and noted that the algorithm section will garner lots of public interest.
- **Steven Eichner** agreed with Anna and Medell. He asked for more information about how algorithms are addressed in the proposed rule.
    - **Kathryn** noted there is a section on source attributes with categories specific to the intended use and the algorithm itself. ONC has requested comments on the social and legal implications of using algorithms. The proposal is not prescriptive on the methodology used. The proposed rule focuses on what information should be provided when DSI is used.
- **Steven Lane** asked if there is time in the agenda to review the new rulemaking and FAQs released this morning.
    - **Kathryn** noted the information blocking regulations accommodate new rulings. If new policy is passed, the proposed rule will adapt with it.
    - **Rachel Nelson** said there are three FAQs that mention intersection with other privacy laws.

Interoperability Standards Workgroup Recommendations on Draft USCDI Version 4 – HITAC Vote

Sarah DeSilvey and **Naresh Sundar Rajan**, Workgroup Co-Chairs, reviewed the IS WG agenda, roster, and charge, then provided an overview of the WG meetings and areas of focus, and presented recommendations for Draft USCDI version 4 and high-level recommendations for future consideration within the presentation slides.

Discussion:

- **Steven Lane** thanked Sarah and Naresh for their hard work and dedication to the IS WG. He expressed his full support of the recommendations.
- **Hannah Galvin** asked if the IS WG should clarify the meaning of sex and gender in the recommendations.
    - **Sarah** noted the IS WG recommendations align with the Gender Harmony recommendations.
    - **Medell** mentioned she wants to ensure there is a clear definition of when providers should use "sex for clinical use" versus "recorded sex or gender."
- **Eliel Oliveira** said the University of Texas at Austin created a platform through an ONC Leading Edge Acceleration Project (LEAP). He noted his team had trouble mapping terminology during their project. It needs to be clear what gender and sex data elements need to be collected.
- **Arien Malec** mentioned the HITAC should strive for "sex for clinical use" as the primary clinical marker.
- **Medell** noted that the Level 2 recommendations on care planning with advanced directives are critical.

Medell called for a motion to adopt the IS WG 2022 Recommendations. **Steven Lane** motioned to approve the recommendations. **Naresh** seconded the motion.

The HITAC approved the IS WG Recommendations on Draft USCDI v4 by voice vote. No members abstained and no members opposed.

ONC Office of Technology Updates – Health IT Innovation

Avinash Shanbhag, Executive Director, Office of Technology, ONC, presented an ONC Office of Technology update on health IT innovation. Avinash reviewed ONC's role in health IT innovation, the Office of Technology's investments in innovation (including LEAP projects), LEAP areas of interest from 2018-2022, and areas of interest for 2023.

Discussion:

- **Steven Lane** asked for further explanation of what ONC is looking for regarding data quality in their areas of interest for 2023.
    - **Avinash** said the LEAP scope is kept broad purposefully to garner ideas from industry. It is an open-ended funding request.

PUBLIC COMMENT

Mike Berry opened the meeting for public comments.

QUESTIONS AND COMMENTS RECEIVED VERBALLY

- **Adele Stewart** asked if the manner exception would apply to any data exchanged within the required purposes or if it is limited to what is defined in the TEFCA SOPs.
    - **Mike Lipinski** said the exception can be the extent of the definition of electronic health information (EHI) and it can also include the permitted purposes. It will be limited to the connectivity agreements in place. It is meant to encourage the broader use of TEFCA beyond the required purposes.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Mike Berry (ONC): Thank you for joining the HITAC meeting. We will be starting soon.

Mike Berry (ONC): Please remember to tag "Everyone" when using Zoom chat so that everyone can see your message. Thank you!

Henry Cobb: IS-WG-2023_ Recommendation 10 "Specimen Condition and Disposition data element to Specimen Exception Annotation", what happens to collection procedure results that are not exceptional? Is no record kept of the checks that were made in case the testing procedure is later found to be suboptimal?

Mark Savage: Thank you, Micky!

Grace Cordovano: Thanks for that great overview Micky!

Hung S. Luu: All laboratories have processes to ensure specimens that do not meet specimen acceptability criteria (i.e., known interfering substance, or outside of acceptable stability) are rejected and testing is not peformed. This information is recorded. This data element is intended to address situations where testing is performed at the request of a clinician despite the specimen not meeting acceptability criteria. This information such as knowing ammonia was performed on a hemolyzed specimen is important so the results can be interpreted within that context. This is also required by CLIA and this recommendation has been made to harmonize the USCDI with CLIArequirements. If a specimen is later found to be unacceptable, the results would either be removed or the results edited to include information on the fact the specimen has been found to not be acceptable for testing.

Mike Berry (ONC): Meeting materials can be found at: https://www.healthit.gov/hitac/events/health-it-advisory-committee-55

Mike Berry (ONC): A recording to today's meeting will be available later today at the same link.

Vaishali Mittal: thank you!

Steven Lane: Does this mean that we are sunsetting the SVAP process?

Hans Buitendijk: Do you have a summary table with effective dates for each criterion being new, updated/replaced, etc. to understand until when what is proposed to be in effect and when it is supposed to start to be valid (with or without SVAP) or in effect?

Steve Posnack: Steven L -- no change to SVAP process

Avinash Shanbhag: Hans - Thanks for note. We can certainly provide that as a resource

Hans Buitendijk: @Avinash - Thank you! That would be great.

Linda Michaelsen: Isn't US Core 5.0.1 USCDI v2? This guide and the US Core profiles have become the foundation for US Realm FHIR implementation guides. This release is the first of yearly US Core updates to reflect changes to U.S. Core Data for Interoperability (USCDI) v2 and requests from the US Realm FHIR community. from http://hl7.org/fhir/us/core/STU5.0.1/

Matthew Rahn: @Linda - Yes, US Core 5.0.1 aligns with USCDI v2. We expect that US Core 6.0.0 that aligns with USCDI v3 will be published during the comment period and if it is we plan on requiring US Core 6.0.0 in the final.

Avinash Shanbhag: Linda - Yes, the US Core 6.0.0 maps to USCDI v3 and has not been published (planned for May). Our proposal does note that ONC will consider the US Core 6.0.0 as part of the notice and comment period

Annie Fine: CDC has just proposed a new race/ethnicity code set. Wouldn't it be advisable to use that code set rather than the 2021 one? Thank you!

Hans Buitendijk: As ONC shifted from certifying EHRs to HIT, what types of HIT does ONC aim to have certified to improve on access, particularly FHIR based APIs as described in (g)(10) and using documents as described in (g)(6)? Having consistent, reliable access to EHI from the relevant source HIT by patients and providers, which is not always the typical EHR one thinks of, is quite valuable. However, it is not clear how this rule intends to advance that goal. Can you clarify that?

Medell K. Briggs-Malonson: Annie +1 to using updated ethnoracial categories proposed

Jordan Jones: Looking over timelines - I know it was mentioned 24 months from Final Rule publication as typical timeline for implementation. In contrast, I'm seeing targets throughout the Proposed Rule of Dec 31st, 2024 (~20 months from today). Would we expect the Final Rule to shift the dates to align with the 24 month post-publication timeframe? Or is the thought that this instance would stick to that shorter timeframe (Final Rule publication to 12/31/2024)?

Annie Fine: Also important that patient preference/consent is not required for transmission of information to public health in accordance with state/local law or regulation

Pooja Babbrah: Great to see an RFI on pharmacy interoperability and RTPB capabilities!

Fil Southerland: +1 Hans regarding scope of HIT data sharing and access. We need to move to additional settings certification beyond acute and ambulatory to capture the entire patient longitudinal record. e.g. LTPAC, Behavioral, HCBS settings.

Mike Berry (ONC): Meeting materials can be found at: https://www.healthit.gov/hitac/events/health-it-advisory-committee-55

Hans Buitendijk: @Fil - and as we are expanding into images, lab, etc. where the access is to subsets of USCDI, do so with the same access capabilities/performance/standards/etc. While non-clinical data in USCDI is not necessarily kept by all EHRs but other HIT.

Robert Anthony: Hans and Fil, we appreciate those thoughts and would encourage you and others to submit those as part of the public comment process

Hans Buitendijk: @Rob - Certainly will, but curious about how you see this NPRM enabling such focus so we can provide our comments in that context of proposed content as well.

Susan Clark: +1 Fil to additional care settings having certified technology.

Mark Savage: @Rob, +1 Hans comment. Hearing ONC's thoughts now to extent possible will greatly help frame and improve the quality of public comment on this in the next months.

Leigh Burchell: @Rob +2 both of Hans' comments

Wendy Noboa: ONC is hosting a series of information sessions to explain the proposed rule. You can register on HealthIT.gov: https://www.healthit.gov/topic/laws-regulation-and-policy/health-data-technology-and-interoperability-certification-program

Robert Anthony: @Hans @Mark Certainly understand, and we'll look at how we discuss this in the preamble to see how we can help. But obviously we can't add to the information or framing of what we have proposed in this regulation

Elisabeth Myers: @Hannah - there is a primary proposal that is standards agnostic and several alternate proposals exploring application of standards in different ways. We expect the TF may look at that in more detail and welcome public comment on all of the various alternatives and RFI questions included in that section.

Hans Buitendijk: @Rob: Thank you! That would be helpful as the initial read indicates "all USCDI must be supported by certified HIT" while there may have been an intent to enable "certified HIT must support the USCDI they manage" that could be clarified. That would help frame feedback accordingly to achieve the intended goals of interop without special effort to EHI in HIT (where not all HIT captures/manages all EHI yet is a valid primary source for EHI available).

Hannah K. Galvin: Thanks @Elisabeth - for clarification, I had asked a question to panelists/hosts. I'm interested in understanding more about what was intended by the standards agnostic criterion for patient requested restrictions (i.e. how this was intended to work without standards). Sounds like we'll discuss this more as part of the TF.

Mark Savage: @Rob and All: And, for example, Gravity Project has been working to build ecosystems for health equity and better care & health using FHIR API exchange of SDOH data elements among individuals/family caregivers, community-based orgs, social service agencies, etc. who do not have/use FHIR servers and certified HIT proper, working with providers and payers with certified HIT.

Elisabeth Myers: @Jordan - to your comment above, adding for everyone - the timeline approach as relates to a final rule is discussed in the NPRM, and we welcome public comment on that proposed approach.

Jordan Jones: Thank you Elisabeth!

Steve Posnack: @Hans to your reply to Rob. The capabilities required in certification for the exchange of USCDI is the capability to do 100% of USCDI, not some of the USCDI. In instances where a particular data element is not available to the certified tech, then it can't exchange that data, but that doesn't change the requirement to be able to do so if/when the data is present.

Adele Stewart: Is the manner exception as it relates to TEFCA limited to the use cases described in a given SOP?

Elisabeth Myers: @Annie and others to comments above, adding response for everyone - We are aware of the draft modifications CDC has out for public comment and are/will continue working with them so that any future updated final version of the demographics standard, when ready, can be aligned across health IT for public health and beyond.

Fil Southerland: @Hans - completely agree with your last statement and like the valid primary source approach. The current all or nothing approach to USCDI is a major barrier to EHRs that fall outside the strict definitions of Acute/Ambulatory. For example, LTPAC provider EHRs servicing senior populations needing to provide pediatric observations and measures to achieve certification. Inferno doesn't allow null or data-absent values in cases like this. This becomes an access equity issue as HIT providers opt-out of certification due to non-applicable requirements. Hope ONC can look at this @steve

Hans Buitendijk: @Steve: That helps clarify the intent and can frame further comments as various HIT being the source of EHI would never have all of USCDI, thus never be able to share it. Does that mean they still can be certified because they only have to share it if ever they expand into supporting such data? I.e., CHIT need not expand their scope of data management to be able to be certified? Clarity on that intent and interpretation would be helpful.

Hannah K. Galvin: Does this align with the FDA's recent guidance on CDS software (9/2022)?

Jim Jirjis: @Hannah. I had the same question. It is important that this aligns with the (somewhat murky) FDA guidance

Jeffery Smith: @Hannah - Yes, we worked extensively with FDA to ensure alignment.

Hannah K. Galvin: Great - thanks, @Jeffery

Sheryl Turney: Wouldn't it make sense related to supporting providers and HC stakeholders that do not have FHIR capability for TEFCA and QHIEs have the ability to support participants with this capability?

Jim Jirjis: This is so important and timely because EMR's would need to do some development to ensure that the FDA guidance document is realizable by providers

Jim Jirjis: The ability to provide links to such information is not ubiquitous in important places within the EMR

Jim Jirjis: It is so refreshing to see such collaboration across HHS entities

Mark Savage: Really appreciate ONC's efforts to consider alignment with FDA's work on CDS software (and perhaps other FDA efforts such as SAMD).

Jeffery Smith: Thanks @Jim and @Mark. And yes, @Shelly we are also cognizant of the FDA's PCCP guidance and worked with the team at FDA to ensure alignment. There will be a dedicated DSI webinar and a focus on DSI provisions as part of the HITAC TF workstreams.

Deven McGraw: Just because FDA has set terms for when it will consider DSI to be a "medical device" and/or subject to pre-market approval doesn't necessarily mean there aren't other issues to consider in terms of regulation. FDA doesn't regulate for privacy, for example.

Mark Savage: +1 Deven!

Rachel Nelson: DSI Proposals Information Session -- Thursday, May 4, 2023 at 1pm ET

Registration URL: https://kauffmaninc.zoom.us/webinar/register/WN_V8v4H5P6SXiI9NE73WJiZw

Grace Cordovano: Love this —> "Supports patient access to underlying information about use of a predictive DSI as part of the patient's care"

Jim Jirjis: Needs to have grade reading level standards so that it is understandable to non-analysts

Grace Cordovano: Patients need to have access to any DSI generated outputs, such as reports, scores, etc, that may be used to inform decisions about an individual's care or coordination of care.

Steven Lane: Assume that all webinars will be recorded and posted as well.

Kathryn Marchesini: @Grace - Check out the proposed rule preamble language related to patients and having access to information.

Jeffery Smith: Yes, good assumption @Steve. Webinar recordings and slides will be posted publicly.

Grace Cordovano: Will do thank you @Kathryn!

Kathryn Marchesini: @Jim J. Check out the proposal that includes a "plain language" requirement.

Jim Jirjis: @Kathryn. Thank you. Is plain language defined there?

Deven McGraw: Thanks @Jordan - just wanted to make sure to stress the point that ONC's proposals could - and should - go beyond the FDA guidance (while not necessarily conflicting, of course).

Deven McGraw: Terrific, @Kathryn!

Deven McGraw: (Still reading the proposed rule ;)

Kim Boyd: Great to see additional focus on Real-time prescription benefit in the NPRM

Zhan Caplan: For those attending HIMSS next week, there will be a proposed rule overview session on Wed, 4/19 at 4pm CST: https://www.himss.org/global-conference/session-overview-oncs-health-data-technology-and-interoperability-certification

Kathryn Marchesini: Here is HHS Press Release that includes reference to some of the federal partners ONC collaborated around the DSI proposal: https://www.hhs.gov/about/news/2023/04/11/hhs-propose-new-rule-to-further-implement-the-21st-century-cures-act.html

Deven McGraw: Still digesting! Looking forward to the working group discussions

Rachel Nelson: The IB blog URL: https://www.healthit.gov/buzz-blog/information-blocking/information-blocking-regulations-work-in-concert-with-hipaa-rules-and-other-privacy-laws-to-support-health-information-privacy

Rachel Nelson: The blog mentions, and links to, three new information blocking FAQs.

Deven McGraw: It might be helpful to have someone from OCR address the ONC proposed rule working group when the matter of technologies to restrict transmission of certain types of information is discussed.

Rachel Nelson: These three FAQs walk through the intersection with other laws: https://www.healthit.gov/faq/would-it-be-information-blocking-if-actor-does-not-fulfill-request-access-exchange-or-use-ehi

https://www.healthit.gov/faq/if-actor-such-health-care-provider-operates-more-one-state-it-consistent-information-blocking

https://www.healthit.gov/faq/if-individual-requests-their-ehi-not-be-disclosed-it-information-blocking-if-actor-does-not

Mark Savage: Website only lists two FAQs, I think.

Mark Savage: https://www.healthit.gov/topic/laws-regulation-and-policy/health-data-technology-and-interoperability-certification-program

Zhan Caplan: Mark all 3 faqs are up on the site - you can find links directly to them in the blog: https://www.healthit.gov/buzz-blog/information-blocking/information-blocking-regulations-work-in-concert-with-hipaa-rules-and-other-privacy-laws-to-support-health-information-privacy

Mike Lipinski: all 4 FAQs are flagged as "NEW"

Sam Godwin: any updates to clinical research and trials ?

Grace Cordovano: Thanks @Elise, @Michael, @Kathryn!

Mark Savage: Thanks! Transposed "fact sheets" and "FAQs". Sorry.

Rachel Nelson: We are having some technical issues with the FAQs' behind-the-scenes machinery today. These links have been working pretty consistently: https://www.healthit.gov/faq/would-it-be-information-blocking-if-actor-does-not-fulfill-request-access-exchange-or-use-ehi

https://www.healthit.gov/faq/if-actor-such-health-care-provider-operates-more-one-state-it-consistent-information-blocking

https://www.healthit.gov/faq/if-individual-requests-their-ehi-not-be-disclosed-it-information-blocking-if-actor-does-not

Mike Berry (ONC): The Interoperability Standards Workgroup's full Recommendations Report and accompanying slides can be found at: https://www.healthit.gov/hitac/events/health-it-advisory-committee-55

Hannah K. Galvin: Question: will there be a difference between sex recorded at birth and legal sex?

Steven Lane: https://confluence.hl7.org/display/VOC/The+Gender+Harmony+Project

Mark Savage: @Hannah, "Recorded Sex and Gender" enables capturing the sex or gender in various contexts. Not just sex recorded at birth.

Hannah K. Galvin: Thanks @Mark - I thought I heard that the group to was specifying "sex at birth", but perhaps I misunderstood.

Eliel Oliveira: What considerations have been made on the Gender/Sex standards as it relates to matching/record linkage given its importance of Gender for that purpose. As an example self-reported gender is highly important for individual identity but if individuals are able to change their Gender we would face challenges with linkage.

Pooja Babbrah: +1 Steven - kudos to the co-chairs!

Mark Savage: @Ellel, working to identify a specific link, but the use case you mentioned is well known and the Gender Harmony Project did work that in. Will post a link.

Sarah DeSilvey: Thank you, Steven and thank you to all our ISWG peers

Mark Savage: +1 Steven to appreciations for the co-chairs.

Eliel Oliveira: @mark, Thanks!

Dayo Oshunkentan: +1 Steven

Naresh Sundar Rajan: Thank you, Steven and ISWG members for all your support.

Mark Savage: How to talk?

Mark Savage: Refer to my comment above. GHP recognized that there is more than "Recorded Sex at Birth" across so many circumstances, so developed "Recorded Sex or Gender" to cover more broadly the reality.

Sarah DeSilvey: https://confluence.hl7.org/display/VOC/Recorded+Sex+or+Gender

Mark Savage: @Medell, IMO, the distinct "Recorded Sex or Gender" data element and the "Sex for Clinical Use" in different situations (labs, imaging, medications, etc.) capture the distinctions you mention. And FAQs to explain how would be great.

Sarah DeSilvey: https://confluence.hl7.org/display/VOC/Sex+For+Clinical+Use

Sarah DeSilvey: I have tried to add the descriptions from the elements here from Gender Harmony

Sarah DeSilvey: Thank you, Carmela

Mark Savage: +1 Arien. As Arien suggests, there is so much more than sex assigned/observed at birth, and today's recommendation and the Gender Harmony Project's work make it possible to capture that for far better health equity.

Sarah DeSilvey: In addition sex for clinical use is critical from a health equity perspective to enable studies that may be denied based on alternate recorded sex or gender.

Mark Savage: +1 @Medell on care plan and advance directive recommendations! So needed!

Grace Cordovano: Thank you for recognizing that @Medell!

Sarah DeSilvey: Agreed, Medell!

Steven Lane: The workgroup recommendations contribute substantially to the additions that ONC included in the Draft V4/

Pooja Babbrah: It's great to see the ONC proposed rule looking to name USCDI v3. Helps put in perspective how important this work is around new versions

Steven Lane: +1 Pooja!

Sarah DeSilvey: Excellent work, colleagues. Thank you, all!

Hung S. Luu: Thank you, Sarah and Naresh!

Medell K. Briggs-Malonson: Thank you again Sarah and Naresh for your leadership! Thank you ISWG for your time and work!

Bryant Thomas Karras: BRB

Sam Godwin: 👍

Adele Stewart: Thanks so much for the clarification!

Rachel Nelson: The preamble discussion to which Mike is speaking begins on page 409 of the PDF available here: https://public-inspection.federalregister.gov/2023-07229.pdf

Adele Stewart: @Rachel thank you

Mark Savage: So grateful!

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

There were no public comments received via email.

FINAL REMARKS

Mike Berry reminded members that the next meeting of the HITAC will be held on May 17, 2023. All materials and testimony from today's meeting will be made available at https://www.healthit.gov/hitac/events/health-it-advisory-committee-55.

Aaron Miri and **Medell Briggs-Malonson** thanked attendees for their participation, the ONC team for their work on the new Proposed Rule, the IS WG's work on the draft recommendations for USCDI v4, and for everyone's discussion.

ADJOURN

The meeting adjourned at 1:54 PM.