Health Information Technology Advisory Committee

HTI-1 Proposed Rule Task Force 2023 Virtual Meeting

Meeting Notes | April 25, 2023, 10:30 AM – 12 PM ET

Executive Summary

The focus of the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule Task Force session on April 25 was to review the HTI-1 Proposed Rule Task Force Charge and Timelines and walk through the Decision Support Interventions (DSI) and Predictive Models.

Agenda

10:30 AM	Call to Order/Roll Call
10:35 AM	Opening Remarks/Task Force Instructions
10:50 AM	HTI-1 Proposed Rule Task Force Charge and Timelines
11:00 AM	Decision Support Interventions (DSI) and Predictive Models
11:50 AM	Public Comment
11:55 AM	Task Force Work Planning
12:00 PM	Adjourn

Call to Order

Mike Berry, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC), called the meeting to order at 10:31 AM.

Roll Call
Members in Attendance

Steven Eichner, Texas Department of State Health Services, Co-Chair
Steven Lane, Health Gorilla, Co-Chair
Medell Briggs-Malonson, UCLA Health
Hans Buitendijk, Oracle Health
Hannah Galvin, Cambridge Health Alliance
Jim Jirjis, HCA Healthcare
Hung Luu, Children's Health
Anna McCollister, Individual
Deven McGraw, Invitae Corporation
Clem McDonald, National Library of Medicine
Eliel Oliveira, Dell Medical School, University of Texas at Austin
Kikelomo Oshunkentan, Pegasystems
Naresh Sundar Rajan, CyncHealth
Fillipe (Fil) Southerland, Yardi Systems, Inc.
Sheryl Turney, Elevance Health

Members Not in Attendance

Rajesh Godavarthi, MCG Health, part of the Hearst Health Network
Adi Gundlapalli, CDC
Elaine Johanson, FDA
Meg Marshall, Department of Veterans Affairs (VA)
Aaron Miri, Baptist Health

ONC Staff

Mike Berry, Designated Federal Officer, ONC
Kathryn Marchesini, ONC
Jeff Smith, ONC
Jordan Everson, ONC
Dustin Charles, ONC
Dan Healy, ONC
Sara McGhee, ONC
Michael Wittie, ONC

Key Points of Discussion

Opening Remarks/Task Force Introductions

HTI-1 Proposed Rule Task Force (Task Force) co-chairs, Steven Eichner and Steven Lane, welcomed attendees. Steven Lane reviewed the meeting agenda detailed in the April 25 meeting presentation materials. Task Force members can join the other HTI-1 Task Force sessions than which they have been assigned. All meetings will be open to the public. Steven Lane facilitated Task Force introductions.

HTI-1 Proposed Rule Task Force Charge and Timelines

Steven Eichner reviewed the HTI-1 Proposed Rule Task Force Charge and associated timelines. The overarching charge is to evaluate and provide draft recommendations to the Health Information Technology Advisory Committee (HITAC) on the HTI-1 Proposed Rule. Steven Eichner reviewed the Task Force topics by group.

- Group 1: Information Blocking
- Group 2: ONC Health IT Certification Updates- New and Revised Certification Criteria
- Group 3: ONC Health IT Certification Program Updates- Insights Condition, Standards Updates, and Request for Information (RFIs)

Steven Lane reviewed the individual group assignments, and Mike Berry recapped the proposed week-by-week timeline. All the work culminates in a presentation to the HITAC on June 15. Mike noted the HITAC is proposing an in-person June HITAC meeting in Washington, DC.

Discussion:

- Hans Buitendijk asked how feedback will be collected throughout the process.
  - o Steven Lane said all Task Force members will add their input to the spreadsheet. The spreadsheet was sent in the "homework" email by ONC.
- Eliel Oliveira said he reviewed the slide deck sent via email and does not see his name on the group assignments.
  - o Steven Lane said Eliel will be in group 1.

- Fil Southerland asked if guest speakers are allowed.
  - Steven Lane said yes, subject matter experts (SMEs) will be invited to meetings. Task Force members are encouraged to contact the co-chairs to recommended SMEs for invitation to the calls as they see fit.
- Clem McDonald asked if there will be information packages sent out to Task Force members.
  - Steven Lane said yes.
  - Mike said ONC is separating the Proposed Rule into smaller sections for the Task Force members. It will be hyperlinked in the recommendations spreadsheet.
  - Clem noted some of the United States Core for Data Interoperability (USCDI) topics have been reviewed before. He asked if they would be reviewed again.
    - Steven Lane said no, USCDI will not be reviewed again.

DSI and Predictive Models

Kathryn Marchesini opened the presentation and reviewed the agenda. Kathryn reviewed DSI Proposals, revisions, intended benefits, the proposed definition for "Predictive Decision Support Intervention," data and organizational transparency, predictive DSI transparency, and trustworthy algorithms. Jeffery Smith recapped "Decision Support and Certified Health IT." Jeffery reviewed the background of the ONC Health IT Certification Program, recapped the landscape from 2012 to the present, and Clinical Decision Support vs. DSI definitions.

Discussion:

- Steven Eichner asked what controls are built into the system to identify when DSI should not be used in making a recommendation?
  - Kathryn said in the proposal, under source attributes, there is an element that indicates out of scope.
  - Steven Eichner said from a regulatory standpoint that there should also be a rule noting when these tools should not be used.
- Hans asked what ONC intends to certify capabilities beyond electronic health records (EHR).
  - Jeffery explained more time will be spent on that information, but the short answer is to note that ONC regulates health IT modules and health IT modules are certified with certain criteria. The certification program would include health DSI so ONC would regulate specific DSI related to health IT modules.
- Sheryl Turney noted she wants to flag that predictive models should have the capacity to address rare conditions.
- Clem noted decision support should not be put too high on a pedestal and that it is not perfect.
- Deven McGraw asked what incentives there are to purchase DSI from a vendor with a Health IT Certification.
  - Jeffery said developers are currently not required to incorporate DSI. Developers must adhere to these standards to meet base EHR certification requirements. There are financial incentives to use a baseline EHR.
- Hannah Galvin suggested thinking about how to be transparent with implementers versus the providers. It will be important to keep provider burden in mind.

PUBLIC COMMENT

Mike Berry opened the meeting for public comments.

QUESTIONS AND COMMENTS RECEIVED VERBALLY

No comments were received verbally.

Task Force Work Planning

Steven Lane thanked all attendees and noted the conversation will pick up again on 4/26.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Mike Berry (ONC): Welcome to the HTI-1 Proposed Rule Task Force! Please remember to tag "Everyone" when using Zoom chat so that we can all see your message. Thanks!

Hans Buitendijk: Those links are extremely helpful, and learned they were actually available from the Fed Reg. Already being re-used.

Steven Lane: Special welcome to and appreciation for the members of the public who are joining us today. Feel free to use the Chat to contribute to the discussion and avail yourself of the public comment period that we will have at 11:50 EDT.

Hans Buitendijk: Given scope and use of DSI in HIT, what is ONC's intended/desired focus on/scope of HIT for certification beyond EHRs?

Jim Jirjis: Hans, agree. That is my question as well. Perhaps the FDA guidance and authority covers non-EMR DSI?

Jim Jirjis: What. Is Plain language definition

Steven Lane: For the public, all of our task force meetings are now listed on the web at https://www.healthit.gov/topic/federal-advisory-committees/hitac-calendar-type/7066 where they can be readily downloaded to your calendar.

Mark Savage: On this point--race and ethnicity as part of predictive DSI, as well as, say, gender identity and sexual orientation--will also be important to know the source of value. Was it the individual's self-reported value? Clinician's (perhaps erroneous) "observation"? An overwritten value from a batch file? Can really affect the reliability of the result!

Steven Lane: Meeting materials will be posted and can be access via the HITAC calendar at https://www.healthit.gov/topic/federal-advisory-committees/hitac-calendar

Steven Lane: Today's meeting materials are posted at: https://www.healthit.gov/hitac/events/hti-1-proposed-rule-task-force-2023

Deven McGraw, Invitae: Are there already financial incentives to using certified DSI vs. DSI that wouldn't be subject to these criteria?

Steven Lane: These specific slides are at: https://www.healthit.gov/sites/default/files/facas/2023-04-25_Decision_Support_Interventions_%28DSI%29_and_Predictive_Models.pdf

Steven Lane: All of the ONC blog posts related to AI & ML are organized on a single page at: https://www.healthit.gov/buzz-blog/category/blog-series-artificial-intelligence-machine-learning

Steven Lane: Oral public comment will begin at 11:50 EDT.

Hannah K. Galvin: How does ONC (or does ONC) see this certification applying to more sophisticated neural networks, e.g. generative AI, much of which is subject to the black box problem?

Steven Lane: Taskforce discussion on this topic will continue at tomorrow's TF Group 2 meeting at 10:30 ET: https://www.healthit.gov/hitac/events/hti-1-proposed-rule-task-force-2023-group-2

Steven Lane: To make a comment please Use the Hand Raise Function. If you are on the phone only, press "*9" to raise your hand. (Once called upon, press "*6" to mute/unmute your line). All public comments will be

limited to three minutes. You may also email your public comment to onc-hitac@accelsolutionsllc.com. Written comments will not be read at this time, but they will be delivered to members of the task force and made part of the public record.

Hans Buitendijk: @Deven: Agreed with your question above on what would incent HIT, which is not EHRT, to certify as certification is voluntary from an ONC perspective for any HIT that wishes to be certified, while the boundary of "HIT" is unclear. Any IT holding EHI? Other?

Hans Buitendijk: So beyond EHRs, other HIT providing DSI as defined would not have to certify and do not have incentives to get certify, correct?

Deven McGraw, Invitae: Hans, I think that's right - the incentives may be market ones. If these criteria end up setting best practice or good practice expectations, it could have an impact on the non-certified marketplace.

Deven McGraw, Invitae: As I understand it, certified developers have to adhere to these standards to meet Base EHR certification requirements. There are financial incentives to use a Base EHR, but no "sub-incentives" (so to speak) for providers to specifically use certified DSI.

Hans Buitendijk: Deven - agreed that only market interest would be a driver for non-EHR HIT to certify to certain modules (such as DSI) to state a difference. For a (g)(10) that would not work (APIs) as that is too coarse to give that an opportunity.

Deven McGraw, Invitae: Great meeting - thanks to the co-chairs and ONC staff ☺

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL
No comments were received via email.

Resources
HTI-1 Proposed Rule Task Force 2023 Webpage
HTI-1 Proposed Rule Task Force 2023 – April 25, 2023 Meeting Webpage
HITAC Calendar Webpage

Adjournment
The meeting was adjourned at 12:00 PM.