Health Information Technology Advisory Committee

HTI-1 Proposed Rule Task Force 2023 Virtual Meeting

Group 2: ONC Health IT Certification Updates – New and Revised Certification Criteria

Meeting Notes | May 3, 2023, 10:30 AM – 12 PM ET

Executive Summary

The focus of the Group 2 Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule Task Force session on May 3 was to recap the HTI-1 Proposed Rule Task Force Charge; review Decision Support Interventions (DSI) and Predictive Models source attributes, intervention risk management, and oversight and implementation metrics; and discuss the patient and carepartner perspective on DSI.

Agenda

10:30 AM	Call to Order/Roll Call
10:35 AM	HTI-1 Proposed Rule Task Force Charge
10:40 AM	Decision Support Interventions (DSI) and Predictive Models
11:30 AM	DSI Proposals: Patient & Carepartner Perspective
11:35 AM	Discussion
11:50 AM	Public Comment
12:00 PM	Adjourn

Call to Order

Seth Pazinski, Acting Designated Federal Officer, Office of the National Coordinator for Health IT (ONC), called the meeting to order at 10:32 AM.

Roll Call

Members in Attendance

Steven Eichner, Texas Department of State Health Services, Co-Chair, Group 2 Lead
Steven Lane, Health Gorilla, Co-Chair
Medell Briggs-Malonson, UCLA Health
Hans Buitendijk, Oracle Health
Jim Jirjis, HCA Healthcare
Anna McCollister, Individual
Aaron Miri, Baptist Health
Kikelomo Oshunkentan, Pegasystems
Naresh Sundar Rajan, CyncHealth
Fillipe Southerland, Yardi Systems, Inc
Sheryl Turney, Elevance Health

ONC Staff

Seth Pazinski, Acting Designated Federal Officer, ONC
Jordan Everson, ONC
Kathryn Marchesini, ONC
Dustin Charles, ONC
Sara McGhee, ONC
Michael Wittie, ONC

Key Points of Discussion

HTI-1 Proposed Rule Task Force Charge

Steven Eichner and Steven Lane welcomed the attendees to the HTI-1 Proposed Rule Task Force (Task Force) meeting. Group 2 lead, Steven Eichner, reviewed the agenda and charge outlined in the May 3 meeting presentation materials.

DSI and Predictive Models

Jordan Everson, ONC, reviewed the DSI and Predictive Model portion of the agenda, which included overviews of source attributes, intervention risk management, and oversight and implementation. Additionally, Jordan reviewed intellectual property, intervention details and development, and availability and access of source attributes. Kathryn Marchesini, ONC, walked through intervention risk management and provided snapshots of proposals that aim to promote transparency and trustworthiness. Lastly, Kathryn moved into an overview of the risk management framework, pillars of the intervention risk management proposal, risk analysis categories, and governance.

DSI Proposals: Patient & Carepartner Perspective

Grace Cordovano, Enlightening Results, thanked ONC for bringing so many important aspects to the surface for this discussion and then provided an overview of DSI from the patient and carepartner perspective. She noted there needs to be diverse patient representation for DSI to succeed and to include predictive DSI from the patient perspective. Grace also indicated it will be important to be transparent with patients when DSI is used, reviewed common patient and carepartner concerns, and provided recommendations.

Discussion

- Steven Eichner agreed with Grace's points. Patient engagement will be very important when creating and utilizing DSI.
    - Kathryn Marchesini noted that ONC solicits comments on whether existing requirements are sufficient for DSI.
- Aaron Miri mentioned ONC and the Task Force should consider the origin of the DSI. Increasing trustworthiness with the public is critical. There is also the notion of private and public algorithms. A public agent that can derive an algorithm, such as ChatGPT, is vulnerable to being hacked. Some organizations are experimenting with private algorithms to reduce that risk. The Task Force should also consider HIPAA in DSI.
    - Jordan Everson noted there are bibliographical citations, funding, and revision dates included in current regulation. That may help alleviate some concerns.

    - Aaron said current regulation is missing some geographical location data, and more needs to be done to ensure public trust. If the public's trust is violated, it will be difficult to come back from.
- Anna McCollister anecdotally spoke about her experience with emergency room physicians referencing clinical guidelines to administer her insulin. She noted her specialists understand better how to treat her condition, and the emergency room clinicians are not as prepared. It is not appropriate for the regulation to hide behind a guise of intellectual property, and it will be important to understand how the DSI is developed.
- Hans Buitendijk noted that the proposed rule focuses on health information technology (HIT). How do we engage developers? They provide HIT capabilities, but it is not indicated that they need to certify their HIT.
    - Jordan said ONC has included the need to clearly indicate when information from the developers is missing. There is an intention to deter folks from using technology that is not certified. This work intersects with other parts of the US Department of Health and Human Services, such as the FDA.
- Medell Briggs-Malonson noted some health systems are developing their own DSI. There have been movements to develop predictive DSIs, but there is caution in how it is developed. How will this rule be applied to provider organizations? Additionally, when there are elements that aren't available, has ONC considered defining what a strong DSI is? She is concerned that providers may see the DSI is available but may be ill-equipped to evaluate if that DSI is relevant or not.
    - Kathryn clarified the proposal requirements are focused on certified health IT developers. However, there is some language about other parties in the rule. If a healthcare provider organization created the health IT, the developer would need to request the necessary information from the other party (in this case, the healthcare organization). In the preamble, there are more requests for information. The requests are located towards the end of the risk management section and mention users of health IT, particularly healthcare provider organizations. ONC also has two other requests for comments on the social and legal implications of data sections.
    - Jordan added ONC is promoting transparency around DSI.
- Steven Lane asked when discussing users of certified health IT, are patients and caregivers included?
    - Jordan said ONC has intentionally not defined the users of health IT.
    - Steven Lane asked what components of DSI may be considered electronic health information (EHI) for information sharing?
        - Kathryn encouraged looking into the HIPAA interpretation in the proposed rule. There are links she can share in the chat related to more information.
- Sheryl Turney stated that her focus is ensuring the certification fulfills the requirements to supply sufficient data. There is a concern about data interpretation being cumbersome. If there were a sandbox that had a minimum amount of data required, it would provide more validity around the depth and scope of testing. This is a rapidly developing field, and without strict requirements, it may do more harm than good.

PUBLIC COMMENT

Seth Pazinski opened the meeting for public comments.

QUESTIONS AND COMMENTS RECEIVED VERBALLY

No comments were received verbally.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Steven Lane: Welcome, members of the public, who are joining us today.

Steven Lane: Thanks to ONC for the recent publication of Word version of the proposed rule and a public comment template: https://click.connect.hhs.gov/?qs=c81997b7cd13e7ae6be16f7d54bf3f059623ee0c5e08612cc5af20df571913418249a0661312a363eefb2cec66e123c17cca62d5b62daf29bf56d11e4f80fe45 https://click.connect.hhs.gov/?qs=c81997b7cd13e7aef40c66150bf0c650644400c03b466dc4063c78dbb3d98051c152873a96b3ea4d18864db6fdb3bb271fcfc982fcb8c78af665ad56a24f6d17

Steven Lane: We will need to hold questions and comments this morning until after the presentations due to the volume of material that we hope to present.

Grace Cordovano: Incredibly helpful to have the Word version and the public comment template. Thank you!

Steven Lane: Feel free to raise hands to get into queue. If there is a pressing question feel free to highlight this in the chat.

Grace Cordovano: In the same way that physicians and clinicians may have a bio featured on their organization's or provider's website, it would be helpful for patients and their carepartners to have a similar set up of a "bio" for a predictive DSI that illustrates, in this case, the source attributes.

Hans Buitendijk: As many DSI services/capabilities is expected to be developed outside the HIT that is typically certified (e.g., EHRs) yet enables its use in context, how can we encourage those making DSI services/capabilities to provide the necessary documents if not being certified? How is ONC collaborating with FDA to further align those DSI service/capabilities suppliers?

Grace Cordovano: +1 Hans

Steven Lane: As we anticipate a broad uptake of Predictive DSI across healthcare, for a broad range of use cases and workflows, this would likely end up being a "directory" of DSI used in/by an organization, similar to the directory of providers.

Hans Buitendijk: Can you clarify whether providers who develop and deploy their own DSI need to provide this documentation, or whether the intent is for the certified HIT supplier is expected to include this? Or is the certified HIT supplier only obligated to do so for DSI it ships with model?

Medell K. Briggs-Malonson: +1 Hans

Hans Buitendijk: @Steven: As such a library would evolve, having that documented once for DSI services/capabilities that are re-used would be very helpful, which goes back to the earlier comment on having the source make this available for all their users to have available.

Grace Cordovano: @Steven @Hans…make source available to all users, including patients

Medell K. Briggs-Malonson: Understanding the application of the proposed rule in terms of source attribute findings for provider developed DSI is important.

Grace Cordovano: 100%

Aaron Miri: idea for consideration: Could the ONC CHPL be modified to list out so that we could capture some of the DSI heuristics (algorithm origin ,etc) e.g.: What Grace said up above, so that everyone can see that DSI algorithm X comes from a "reputable" source?

Steven Lane: In the same manner that providers are expected by an organization to maintain their profile in a directory, DSI developers should be required, by contract, to maintain their profiles for display to both internal users and patients/the public.

Grace Cordovano: +100 Steven!

Hans Buitendijk: As the 21st CC Act focuses on clinical decision support while the proposal is focusing on DSI. not including the term "clinical", and having various examples that seem to fall in non-treatment purposes (e.g., healthcare operations), unclear what the boundary of decision support included is.

Anna McCollister: How do we actively protect against the use of poorly defined measures that may not reflect what patients think are important or may have been developed before the use of newer forms of data/measurement? It's been v difficult to get medical associations/CMS to incorporate new measures into clinical guidelines when the guidelines are created in "analog" form. How do we keep inadequate guidelines from becoming "calcified" within AI?

Hans Buitendijk: Agreed with Steven that the source (the DSI developer rather than the user) should provide this information that can then be linked to. Kinda like a capability statement in FHIR speak.

Aaron Miri: @Anna +1 . We can't even all get to agreement across health systems on the measures that go into common predictive models such as sepsis, risk of falls, adult deterioration index and risk of readmission.

Sheryl Turney: Should we recommend that HHS create a sandbox that DSI developers are able to use to validate models that would include enough base and outlier data/conditions to ensure that a minimum standard of validation is met?

Sheryl Turney: how do we ensure models are framed sufficiently to address rare/orphan conditions so understanding the scope of the model and the scope of the data set is crucial

Steven (Ike) Eichner: Are there requirements regarding utilizing a patient's individual data, compared with paramaters related to the DSI module, to evaluate the applicability of the module to that specific patient and advise the care team an patient if there is a contraindication indicated regarding use of the tool? There are likely to be some situations where the tool may produce a recommendation that is in conflict with what is best for the patient.

Medell K. Briggs-Malonson: Has there been any discussions regarding appropriate display of source attributes to patients? This material should be clearly interpretable and presented at grade level 6 or lower.

Sheryl Turney: Patients especially those whose procedure decisions or services are based on this data is crucial for ensuring the prevention of harm or the impact of added burden they would face with adverse decision

Grace Cordovano: Thank you @Medell; also critical displays are accessible to those with disabilities.

Medell K. Briggs-Malonson: Absolutely @Grace!

Medell K. Briggs-Malonson: Also agree, @Steven!

Grace Cordovano: +1 Steven

Sheryl Turney: Steven agree

Steven (Ike) Eichner: +1, Sheryl

Steven Lane: Inadvertently sent to a limited group earlier: We should offer patients/public information regarding DSI using BOTH 6th grade level language AND with the full detail that is provided to CHIT users so as to meet the needs of the full range of readers.

Hans Buitendijk: Do you foresee that export of DSI is for the DSI developer? Or of the HIT using the DSI how they used the DSI? Or both? As the proposal is to follow the EHI Export approach, which has no standards, how do you envision consistent sharing to the variety of potential interested parties in the absence of such standards? What is the primary audience for this export?

Medell K. Briggs-Malonson: Will RWT be required on am annual basis?

Julie Maas: +1 to sandbox Sheryl; was just making notes about that...For lack of a sandbox provided by ONC, reference sandboxes used by developers in their testing might be specifically required to contain (or at least transparently communicate more specific information from training and sandbox data they did use such as) a minimum population size, time frame of health data collected (in years), demographic diversity & % occurrence of conditions the provider is most likely to diagnose (if DSI designed for a specialty) or transparent communication of a few key conditions' rate of occurrence in the training attributes along with comparison to that of the general population. This might provide a more standard table of information compared to the more narrative style information Kathryn is mentioning.

Anna McCollister: Is “real world testing” defined?

Hans Buitendijk: There is much CDS, already available, that represent simple algorithms, growth charts, etc. that are not in the AI/ML space (although AI/ML learning over time, as other research, could be "enshrined" into simple, agreed to algorithms). Where do we draw the line on the need for this documentation?

Sheryl Turney: + Julie I agree

Steven Lane: @Hans - Wouldn’t we ideally want rule-based CDS held to a similar requirement of transparency as we do algorithmic DSI?

Steven Lane: My understanding is that we are updating the name of the term/CHIT requirement from CDS to DSI, which would then be inclusive of interventions based on both rule-based and AI/ML logic.

Aaron Miri: +1 Grace

Medell K. Briggs-Malonson: Thank you Grace! Those were all critical recommendations!

Anna McCollister: Excellent points Grace!!!

Aaron Miri: https://securityintelligence.com/articles/chatgpt-confirms-data-breach/

Steven (Ike) Eichner: And how does DSI address data not distinctly codified in CEHRT? Foor example, many drugs in clinical trials do not appear in medication lists (there may not be a code). Physicians note these in patient notes, but how does that data get to the DSI for evaluation?

Grace Cordovano: Thank you @Kathryn!

Kathryn Marchesini: Here is information about ONC's existing Real World Testing Program: https://www.healthit.gov/topic/certification-ehrs/real-world-testing#:~:text=Real%20World%20Testing%20verifies%20that,as%20Real%20World%20Testing%20results.

Steven Lane: @Ike - There are workflows for adding new and blinded trial drugs to the medication list and allowing these to trigger appropriate decision support alerts, e.g., stating that it is not possible to thoroughly evaluate, e.g., drug-drug interactions.

Grace Cordovano: Thank you @Aaron!

11:30:52 Aaron Miri: You're correct @anna, attribution is to you for the comment of codification of an algorithm into workflow and it becomes 'stale '. :-)

Steven (Ike) Eichner: @Steven- the difficulty is that for a number of drugs in trial there is no NDC code available, so they aren't coded in medication lists where ONLY NDC codes are accepted.

Grace Cordovano: Doesn't the urgency of the conversation change if DSI outputs that are used to make decisions about an individual's care or care coordination are recognized as EHI then access and export are necessary as per the Information Blocking Rules?

Steven Lane: EHRs can utilize dummy medication entries, that may even be specified based on therapeutic an/or pharmacological class.

Steven Lane: 10 minutes until public comment @ xx:50.

Hans Buitendijk: @Grace - an interesting perspective as there are two parts, the patient agnostic aspect of the capabilities and the patient specific suggestions provided. The first one seems to be the focus of the NPRM, thus not yet EHI.

Hans Buitendijk: The export aspect (which may need the DSI source to contribute) might be considered EHI (others would be able to clarify that) as it is patient specific.

Grace Cordovano: @Hans, I'm in agreement that 2 parts have crystallized: patient agnostic capabilities and patient specific. If we prioritize patient specific as the North Star, won't we be more comprehensive as opposed to restrictive, in our efforts?

Hans Buitendijk: @Grace: For purposes of how to engage DSI developers to provide the necessary data I believe we have to address the two parts separately as the first is a "one time" capability statement, while the second is the feedback loop / export proposal where patient specific data comes into play, although still likely would be de-identified when exported depending on the requester/target audience.

Steven Lane: Members of the public, please get your hands up if you have any comments that you would like to share orally.

Kathryn Marchesini: Here are the links to some of the mentioned discussion in the proposed rule: https://www.federalregister.gov/d/2023-07229/p-717 https://www.federalregister.gov/d/2023-07229/p-862

Anna McCollister: Completely agree @Sheryl!

Kathryn Marchesini: Here are the mentioned RFCs: https://www.federalregister.gov/d/2023-07229/p-857 https://www.federalregister.gov/d/2023-07229/p-862 https://www.federalregister.gov/d/2023-07229/p-898

Kathryn Marchesini: Here is some of the discussion about "users" in the proposed rule: https://www.federalregister.gov/d/2023-07229/p-547

Grace Cordovano: "We further anticipate that a long-term outcome of such transparency would be increased public trust and confidence in predictive DSIs, so that users, including healthcare systems, clinicians, and PATIENTS, can expand the use of these technologies in safer, more appropriate, and more equitable ways. " Thank you for the reference Kathryn!

Sheryl Turney: great info today. Thank you presenters and all

Grace Cordovano: Thank you everyone!

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 – May 3, 2023 Meeting Webpage
HITAC Calendar Webpage

Adjournment

The meeting adjourned at 12 PM.