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 19, 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 19 was to discuss Electronic Case Reporting Certification Criteria. John Loonsk, Johns Hopkins University, presented the steps involved with Electronic Case Reporting and a robust discussion followed.

Agenda

10:30 AM	Call to Order/Roll Call
10:35 AM	HTI-1 Proposed Rule Task Force Charge
10:40 AM	Electronic Case Reporting Certification Criteria
11:10 AM	Steps Involved in Electronic Case Reporting
11:20 AM	Discussion
11:50 AM	Public Comment
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 10:32 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
Hans Buitendijk, Oracle Health
Jim Jirjis, HCA Healthcare
Anna McCollister, Individual

Members Not in Attendance

Medell Briggs-Malonson, UCLA Health
Aaron Miri, Baptist Health
Kikelomo Oshunkentan, Pegasystems
Naresh Sundar Rajan, CyncHealth

Fillipe (Fil) Southerland, Yardi Systems, Inc
Sheryl Turney, Elevance Health

ONC Staff

Mike Berry, Designated Federal Officer, ONC
Johnny Bender, ONC
Sara McGhee, ONC
Jeffery Smith, ONC

Key Points of Discussion

HTI-1 Proposed Rule Task Force Charge

HTI-1 Proposed Rule Task Force (Task Force) co-chairs, Steven Eichner and Steven Lane, welcomed Group 2 attendees. Group 2 lead, Steven Eichner, reviewed the meeting agenda and charge detailed in the May 19 meeting presentation materials.

Electronic Case Reporting (eCR) Certification Criteria

Jeffery Smith, ONC, reviewed the Electronic Case Reporting proposal and benefits. Jeffery also walked through the Fast Healthcare Interoperability Resources (FHIR)-based approach for referencing specific profiles within eCR FHIR Implementation Guides (IG), as well as the Clinical Document Architecture (CDA)-based approach that would reference specific CDA IGs and the Electronic Reporting and Surveillance Distribution (eRSD) profile of the eCR FHIR IG. He noted ONC seeks feedback on the option to use either CDA or FHIR, or both, if the eRSD profile is appropriate for health IT modules, and if the eRSD profile is adequately defined.

Steps Involved in Electronic Case Reporting

John Loonsk, Johns Hopkins University, reviewed the "Steps Involved in Electronic Case Reporting" workflow slide and stated the movement to eCR specific standards is critical. CDA and FHIR were developed with specific eCR implementations, and both standards can send data to public health agencies. eCR is built on a "hub-and-spoke" model, so there is a need for decision support logic to get the right data sent to the proper agencies. Extensive work between CDA and FHIR standards is underway. This would enable public health agencies to support eCR in the way they want, regardless of the format it was submitted. John noted there is a set-up step that involves eRSD, and then data is made available for download. The goal is to have the eRSD profile be easily consumed by certified health IT modules so that it can be implemented as quickly as possible in an emergency use case. The ability to electronically consume specifications is crucial in completing surveillance. John added that the current eRSD content is managed by the Center for Disease Control and Prevention (CDC), the Council of State and Territorial Epidemiologists (CSTE), and the Association of Public Health Labs. When that data is shared, there is a manual sign-off. It is not automated. Additionally, John explained multiple electronic initial case reports (eICRs) can be sent at once. Subsequent eICRs represent the updates made after the initial eICR that was sent. He emphasized the need for decision logic support to ensure data is reportable.

Discussion

- Steven Eichner said John Loonsk brought up a vital point. Looking at how public health agencies

receive data is important. It is crucial not to breed an environment where providers run into challenges exchanging information with public health agencies in their jurisdiction.

- Hans Buitendijk highlighted FHIR is the long-term direction, but having a choice is beneficial. He noted there can be a standards choice given there are mapping opportunities. The recommendation should clarify that the reporting source has the option to decide which standard to use.
    - Jim Jirjis agreed and added the AIMS platform needs to be added into the slide on "Steps Involved in Electronic Case Reporting". Are there public health agencies and EHRs that do not use the AIMS platform?
        - Jeffery said yes, there are some not connected to AIMS.
    - Steven Eichner said it is important there is good availability and exchange between providers and public health agencies, either directly or with an intermediary. He is concerned that if both standards can be utilized, there may be a scenario where the technology the provider adopted is not compatible with a public health agency's receiving choice.
- John Loonsk explained the eRSD is available to immediately download or to be pulled and then downloaded. Subscription methodology has been developed, but there have been technical issues on the recipient side. Currently, there is an email list of who has registered for the site, and they receive notice on updated versions. Some health IT modules have implemented automatic polling to retrieve them as well. It is exportable as XML or JSON.
- Johnny Bender noted clarification on the "consumer process" definition is in the preamble.
- Jim asked if the documents are consumable so the automated processes can occur.
    - Johnny Bender said ONC was not looking to preclude that and leave it to health IT modules. ONC is not expecting health IT modules to do anything beyond what is proposed, such as acting on reportability response or required follow-up.
    - John Loonsk added it is important data is triggered from the health IT module to obtain accurate case reports.
    - Steven Eichner said on the AIMS platform, there are multiple paths providers can use to connect. There is not one single pathway.
- John Loonsk clarified whenever the eICR is received, a report ability response is pushed to the healthcare organization in the same format it came in.
- Jim said there is a requirement to send case reports, but it does not require that the technology distribute it in a way that can be read by the receiving entity. Who is this directed at? This could cause provider burden.
    - Jeffery said ONC did not want to only require the transmission of case reports through AIMS.
- Jim said ONC wants content and transport standards. There is an opportunity to clarify that either FHIR or CDA standards need to be used, but there is no platform vendor requirement.
- John Loonsk stated it is important to note what is triggered out of clinical care does not meet reportability laws in each state. Additional decision logic is needed regardless of the platform.
- Hans said the Task Force should consider standards-based diversity, such as having choices. However, it is critical that knowledge is shared on how and when to share data.

PUBLIC COMMENT

Mike Berry opened the meeting for public comments.

QUESTIONS AND COMMENTS RECEIVED VERBALLY

No questions or comments were received verbally.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Steven Lane: Meeting materials are available at: https://www.healthit.gov/hitac/events/hti-1-proposed-rule-task-force-2023-group-2-2

Steven Lane: The HITAC has recommended this change repeatedly in the past.

Jim Jirjis: A nice step forward in improving the complexity, burden and timeliness of public health reporting

Noam Arzt: So remind me: is it BOTH or EITHER. I heard him say both if these things I thought. Remember, PH is not really ready to receive FHIR-based eICRs, nor is RCKMS (which is not mentioned on these slides at all).

Jim Jirjis: I think it is both or either except the RR, where they are saying both Or asking if it should be both

Steven Lane: Also standardizing the reporting process from certified HIT will encourage public health agencies to engage in receiving and utilizing eCR in lieu of existing burdensome disease reporting workflows.

Hans Buitendijk: There is no clear preference for CDA vs. FHIR based at this time, although FHIR will enable consistency with strategic direction. A choice is helpful, as long as it is not required that the reporting HIT ends up having to certify to both as PHAs could require "the other". In those situations, "the other" could be mapped to by tools outside the reporting HIT and should not yield a certification requirement.

Johnny Bender (ONC): Here is the link to the reg text for the eCR section: https://www.federalregister.gov/d/2023-07229/p-2299 The language reads, "(B) Create a case report consistent with at least one of the following standards:" and references FHIR and CDA IGs

Hans Buitendijk: The requirement should be a choice and paired, i.e., certification to either CDA based eICR plus RR, or FHIR based eICR plus RR. Not both CDA and FHIR. Instead, accept reliance on mapping capabilities, e.g., APHL/AIMS providing the conversion, or eCR Now open source supporting either output.

Jim Jirjis: I thought the ability to receive the RR was the only place they were asking if there should be both CDA and FHIR? I am guessing this is because of variation in public health entity's ability to do one versus the other

Hans Buitendijk: Are there plans to expand eRSD to cover full RCKMS knowledge on when, what, how to report to the variety of PHAs?

Noam Arzt: But if the EHR can pick which one they could pick the WRONG one from a PH agency's point of view. I don't think eCR now actually can OUTPUT a FHIR-based eICR but I am checking now.

Hans Buitendijk: Note that eRSD sharing needs further guidance on how it can be shared (email, notifications, API endpoint).

Jim Jirjis: The last bullet confuses me a little. Who are we thinking this is

Hans Buitendijk: @Noam: We should get confirmation in next discussion on whether eCR Now and APHL/AIMS can already map back-and-forth so the reporting source only need to support one certified capability, while PHAs can receive it in their desired format.

Laura Conn: @noam the eCR FHIR app can output either CDA or FHIR eICRs. There is also the ability to transform to/from CDA and FHIR to meet PHA format needs - recognizing it will take some time for PHAs to transition to newer standards such as FHIR.

Noam Arzt: Thanks, Laura.

Hans Buitendijk: @Laura: That is the same for the return RR as well, right? PHA sends RR in CDA and it can be converted into FHIR and vice versa by APHL/AIMS and/or eCR Now?

Steven Lane: Thank you Laura @CDC for providing this detail.

Laura Conn: @Hans yes, transforms are available for the RR too

Hans Buitendijk: With this direction, the interim criterion should adjust scope from USCDI to the standard defined in the proposed standards.

Jim Jirjis: @Hans. What do you mean?

Annie Fine: And also the hub reduces the burden on reporters to have to know what is reportable where and to route reports to the right jurisdiction.

Jim Jirjis: agree

Hans Buitendijk: Currently the scope of eCR is to include USCDI. However, there is subregulatory guidance that the eICR content (which does not necessarily cover all of USCDI) is appropriate. There is a proposal for an interim criterion to go into effect sooner, thus that statement of appropriateness could be elevated to the regulation to be clear.

Annie Fine: Agree we need shared services to translate back and forth from cda to FHIR to accommodate both health care and public health.

Steven Lane: http://build.fhir.org/ig/HL7/case-reporting/eicr_data_elements.html

Annie Fine: It is very important not to reduce or stop current reporters from being able to report (eg those using cda or FHIR now and might have to switch if there were only one option - that would be bad)

Sara Mader: Will the recording of this session be on this website with the other meeting materials? https://www.healthit.gov/hitac/events/hti-1-proposed-rule-task-force-2023-group-2-2

Hans Buitendijk: What are plans to expand availability of eCR "knowledge" from eRSD to RCKMS scope? What methods of obtaining eRSD are currently available?

Melanie Epstein-Corbin: I'm interested in learning more about the certification of the HIT modules. Is there any language in the HTI-1 that discusses real-world testing which would measure the quality of the coded data coming out of the HIT modules to meet certification in either format (CDA or FHIR)?

Annie Fine: The content for ersd and for the criteria used by PHA's to adjudicate reports to determine reportability is developed primarily by CSTE (in collaboration with APHL and CDC) with input from the public health epidemiology and surveillance/informatics community.

Steven Lane: https://build.fhir.org/ig/HL7/case-reporting/electronic_reporting_and_surveillance_distribution_ersd_transaction_and_profiles.html

Johnny Bender (ONC): @Melanie, ONC did not include anything specifically related to "quality of coded data coming out of the HIT modules" for case reporting, but the (f)(5) Certification criterion is in-scope for Real World Testing. The Real World Testing Resource Guide may be useful to review: https://www.healthit.gov/sites/default/files/page/2021-08/ONC-Real%20World%20Testing%20Resource%20Guide_Aug%202021.pdf

Melanie Epstein-Corbin: Thanks, Johnny. I'll review that resource.

Steven Lane: It is great to see so many STLT public health officials here to be a part of this discussion.

This is an uniquely innovative and valuable use case that instantiates both the need for flexibility to address highly variable state and local requirements and the value of bidirectional exchange between providers and public health.

Annie Fine: Implementation or consumption of the ERSD in EHRs is also a topic of some concern for public health. We do ideally want a) use of the most recent version of the ERSD to ensure that no case reports are

missed/not sent and b) accurate mapping of local codes to all the standard codes in the ERSD - both of these are critical to ensure complete reporting. Also use of standard codes within EHRs would also be preferable!

Hans Buitendijk: What does ONC mean with consuming/process in this context?

Melanie Epstein-Corbin: +1 to Annie. So important!!

Marisa Hopper: I agree too

Johnny Bender (ONC): @Hans, RE: "What does ONC mean with consuming/process in this context?" - the preamble for the proposal at § 170.315(f)(5)(ii)(A) provides some context for "consuming/processing" eRSD: https://www.federalregister.gov/d/2023-07229/p-443

Jim Jirjis: Doesn't this also all depend on whether ALL PHA's and EMR's are using the hub? Would like to know if anyone is not

Yes I agree we should add the AIMS platform to this diagram

Annie Fine: Maybe add the concept of a hub or decision support tool rather than specifically saying aphl aims?

Yes there are a few I think

Laura Conn: Those alternate approaches are not likely using this approach/architecture for case reporting.

Jim Jirjis: I would love to know a few specific examples of PHA's who do not use AIMS so that I can learn what is driving it

Annie Fine: The centralized hub also reduces the burden on PHA's since they Can author and update their reporting requirements in ONE place rather than many

Noam Arzt: And I wonder whether the "alternative approaches" are even using *electronic* reporting, or standards-based electronic reporting. I'd also love to know the examples.

Steven Lane: Should the diagram also reflect the alternative intermediaries where HIEs or registries serve this role?

Jim Jirjis: Who can provide examples of such PHA's Steven, are there instances where HIE is currently being used for this?

Laura Conn: There are some HIEs that are an intermediary between healthcare and AIMS and PHAs. One example is KHIE in Kentucky.

Steven Lane: Someone mentioned that earlier. I know that HIEs WANT to be a part of this data flow.

Jim Jirjis: Got it. So the rule should not PREVENT other players from getting in this space May be a good opportunity to comment that consume and process is too loose

Hans Buitendijk: @steve: That raises the question of enabling access to the full RCKMS knowledge, not just eRSD. That would ensure consistency of interpretation for any hub to provide that ability (QHIN?).

Jim Jirjis: Data completness and quality may be an issue with current HIE's

Hans Buitendijk: @Jim: If they are the source of the date, not only the intermediary to route and map.

Jim Jirjis: True but HCa is involved with twenty HIE's and the information they request/get from us is very limited

Hans Buitendijk: @Jim: Yes, no argument on content.

Annie Fine: Yes in my experience hies don't always have enough data to actually a) trigger and or b) populate the ecr completely - there could also be issues with timeliness if they are the source. If they are the conduit that may be different and of course this can vary across hies.

Johnny Bender (ONC): The HTI-1 preamble discusses "receipt, consumption, and processing of reportability responses" here: https://www.federalregister.gov/d/2023-07229/p-439 -- an excerpt that seems relevant: "It is critical for the health IT industry to support clinicians or other appropriate personnel (e.g., infection preventionists) in receiving reportable response information in a usable format from public health, in order to enhance communication between the public health community and the healthcare community. Processing the reportability response will help clinicians access responses from public health, including where the PHA has deemed a case reportable."

Hans Buitendijk: @Donna: Do you mean the NHSN surveillance, of operational reporting that went from NHSN to HHS and back?

Steven Lane: While it is great that so many entities want to help support this data exchange, we should be cautious about inadvertently encouraging unnecessary complexity. The simpler and more standardized this is made the better for our citizens.

Jim Jirjis: Thanks. Rich discussion

Hans Buitendijk: @Johnny: Thank you! That is indeed the language that is not clear on what consuming and processing actually means. View by the right party? Ingestion of data trigger (C)DS? Other? RRs are not necessarily as structured for what may be considered "consume and process" beyond viewing be the right party (which would be a reasonable starting point).

Noam Arzt: More than "routing." There is CDS to consider as well.

Jim Jirjis: Yes it is the format we are talking about Hans.. here, here

Johnny Bender (ONC): @Hans - Fantastic, we would love that feedback submitted as comment(s) to the NPRM!

Annie Fine: Agree it is important for PHAs to have a centralized place to indicate their reportability rulea

Rules There is a very high signal to noise ratio in the data

Jim Jirjis: Steven. I agree. We had 22 different interfaces for covid reporting (one for each state) all of them different and nuanced Standards improve burden and timeliness of data

Annie Fine: The centralized hub facilitates reporting with standards while allowing jurisdictions to get what they need

Jim Jirjis: A central hub would have been heavenly

Steven Lane: Driving toward standards may force some stakeholders to evolve their business model.

Jim Jirjis: @ Steven…AMEN and improve burden, timeliness and effectiveness

Steven Lane: Members of the public are encouraged to take advantage of the ability to comment verbally. We can still accept public comment if you want to raise your hand.

Jim Jirjis: ITs fun to be part of the choir…preaching to each other!!! ☺. if only the IT "heathen" would agree

Donna Doneski: @Jim - Agree 100%... bringing states along with federal standards would be fantastic.

Steven Lane: And bringing locals along with states!

Jim Jirjis: Yes. We had more than 22 states worth of variation in what data was requested during covid. In fact local health departments had additional variability…Santa Clara county is one example

Donna Doneski: @Steven - Exactly.

Jim Jirjis: Have to log off. What a fun discussion

Annie Fine: Thank you all. Very excited about these changes and the conversation!

Steven Lane: While local needs are special, they are rarely unique.

Jim Jirjis: Their data definitions are uniques (include patients who life in the area versus those who got care int he area for exmaple

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 19, 2023 Meeting Webpage
HITAC Calendar Webpage

Adjournment

The meeting adjourned at 11:55 AM.