



# HTI-1 Proposed Rule Task Force 2023

## Group 2: ONC Health IT Certification Updates – New and Revised Certification Criteria Meeting #5

Steven Eichner, Co-Chair/Group 2 Lead

Steven Lane, Co-Chair

May 3, 2023





# Call to Order/Roll Call

Seth Pazinski, Acting Designated Federal Officer, ONC

# HTI-1 Proposed Rule Task Force 2023 – Group 2 Roster



Name	Organization
<b>Steven Eichner* (Co-Chair/Group 2 Lead)</b>	Texas Department of State Health Services
<b>Steven Lane*(Co-Chair)</b>	Health Gorilla
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

\* HITAC Member

\*\* HITAC Federal Representative

# Agenda

## 10:30 AM Call to Order/Roll Call

- Seth Pazinski, Acting Designated Federal Officer, ONC

## 10:35 AM HTI-1 Proposed Rule Task Force Charge

- Steven Eichner, Co-Chair/Group 2 Lead
- Steven Lane, Co-Chair

## 10:40 AM Decision Support Interventions (DSI) and Predictive Models

- Kathryn Marchesini, ONC
- Jordan Everson, ONC

## 11:30 AM DSI Proposals: Patient & Carepartner Perspective

- Grace Cordovano, Enlightening Results

## 11:35 AM Discussion

- Steven Eichner, Co-Chair/Group 2 Lead
- Steven Lane, Co-Chair

## 11:50 AM Public Comment

- Seth Pazinski, Acting Designated Federal Officer, ONC

## 12:00 PM Adjourn



# HTI-1 Proposed Rule Task Force Charge

Steven Eichner, Co-Chair/Group 2 Lead

Steven Lane, Co-Chair



# HTI-1 Proposed Rule Task Force 2023

## Overarching Charge:

The HTI-1 Proposed Rule Task Force 2023 will evaluate and provide draft recommendations to the HITAC on the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule.

**Specific Charge:** Provide recommendations on ONC's proposals that would:

- Rename all certification criteria within the ONC Health IT Certification Program (Program) as “ONC Certification Criteria for Health IT” and discontinue year themed “Editions”
- Establish a new baseline version of the United States Core Data for Interoperability (USCDI) from Version 1 to Version 3
- Implement the Electronic Health Record (EHR) Reporting Program as a new Insights Condition and Maintenance of Certification for health information technology (health IT) developers under the Program
- Enhance information sharing under the information blocking regulations



# HTI-1 Proposed Rule Task Force 2023 (continued)

**Specific Charge:** Provide recommendations on ONC's proposals that would:

- Adopt new and revised standards and certification criteria, including:
  - Electronic case reporting certification criterion;
  - Clinical decision support (CDS) and decision support interventions (DSI) certification criteria;
  - Application programming interfaces (APIs) for patient and population services;
  - FHIR US Core Implementation Guide STU version 5.0.
  - HL7 CDA® R2 IG: C–CDA Templates for Clinical Notes STUR2.1 Companion Guide, Release 3 US Realm;
  - A new patient requested restrictions certification criterion; and
  - Requirements for health IT developers to update their previously certified health IT.
- Establish additional Assurances Condition and Maintenance of Certification requirements
- Solicit requests for information (RFIs) on Program standards, certification criteria, and information blocking to inform potential future rulemaking

**Recommendations are due to the HITAC by the end of the 60 day public comment period.**



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

- Decision Support Interventions (DSI) and Predictive Models
- Electronic Case Reporting
- “The ONC Certification Criteria for Health IT” and Discontinuing Year Themed “Editions”
- Assurances Condition and Maintenance of Certification Requirements
- Requirement for Health IT Developers to Update their Previously Certified Health IT
- Patient Requested Restrictions Certification Criterion



# Decision Support Interventions (DSI) and Predictive Models

Kathryn Marchesini, ONC

Jordan Everson, ONC



# Health Data, Technology, and Interoperability: Decision Support Intervention

## HTI-1 Proposed Rule Subgroup 2

Presented by Kathryn Marchesini and Jordan Everson

May 3, 2023





## Disclaimer and Public Comment Guidance

- The materials contained in this presentation are based on the proposals in the "Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing" proposed rule. While every effort has been made to ensure the accuracy of this restatement of those proposals, this presentation is not a legal document. The official proposals are contained in the proposed rule.
- ONC must protect the rulemaking process and comply with the Administrative Procedure Act. During the rulemaking process, ONC can only present the information that is in the proposed rule as it is contained in the proposed rule. ONC cannot interpret that information, nor clarify or provide any further guidance.
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# Agenda

## HITAC TF Meeting #3 – May 3, 2023

- Source Attributes
- Intervention Risk Management
- Oversight & Implementation





# Source Attributes Continued

# Sources of Source Attributes

We emphasized source attribute information that

1. Were most commonly included in existing, reviewed reporting guidelines
2. Would be most meaningful and interpretable in the context of health IT users and developers
3. Were focused on health equity, fairness, and identifying issues of bias
4. Were intended to show that the model would perform effectively outside of the specific context in which it was developed

## Goals

- Identify minimum necessary attributes
- Based on existing model reporting guidelines
- Balance prescriptiveness and flexibility to accommodate varied applications, contexts, and use cases
- Align with existing reference material (e.g., NIST AI RMF, WH Blueprint, WH E.O.s)
- Support emerging industry-led efforts (e.g., CHAI and Health AI Partnership)

# DSI - Health IT Modules are not required to enable or interface with predictive DSIs, but...

If a Health IT Module enables or interfaces with predictive DSIs, we are proposing that the module must make information about additional Source Attributes available to provide users transparency on how the predictive DSI was designed, developed, trained, evaluated, and should be employed.

- **Intervention Details**

1. Output of the intervention
2. Intended use of the intervention
3. Cautioned out-of-scope use of the intervention

- **Intervention Development**

1. Input features of the intervention including description of training and test data
2. Process used to ensure fairness in development of the intervention
3. External validation process, if available

- **Quantitative Measures of Intervention Performance**

1. Validity of prediction in test data
2. Fairness of prediction in test data
3. Validity of prediction in external data, if available
4. Fairness of prediction in external data, if available
5. References to evaluation of use of the model on outcomes, if available

- **Ongoing Maintenance and Use**

1. Update and continued validation/fairness assessment schedule
2. Validity of prediction in local data, if available
3. Fairness of prediction in local data, if available

# Intellectual Property

- The proposals in § 170.315(b)(11)(vi)(C) would not require disclosing or sharing intellectual property (IP) existing in the developer's health IT (including other parties' IP)
- The proposed requirement would not provide information about or report any details of the specific code, pipeline, statistical processes, or algorithms used to generate model predictions, which might be considered the developer's intellectual property



# Source Attributes Prescriptiveness

- We request comment on whether there are items contained within the proposed source attributes that we should explicitly require as elements of source attributes information.
  - Specific attention to three Source Attributes with multiple “should” components:
    - “Intended use of the intervention,”
    - “Input features of the intervention including description of training and test data”
    - “External validation process, if available”



# Intervention Details

**Output of the intervention** is a description of the value that the model produces as an output, including whether the output is a prediction, classification, or other type of output

- Users evaluating the model or deciding whether to use it should know what the model is predicting to ensure that the output is directly relevant to the way in which the users intend to use it

**Intended use of the intervention** is a description of the intent of the model developers in how the model is meant to be deployed and used, including its intended role in the identified use case. This information should clarify:

- Whether the model is intended for specific or general tasks and what those tasks are;
- Who the intended patient population is;
- Who the intended users of the model are, as well as the intended action of the user;
- The role of the model (e.g., whether it informs, augments, or replaces clinical management), which may be most clearly conveyed through use of a taxonomy such as those described by the International Medical Device Regulators Forum (IMDRF), American Medical Association, Consumer Technology Association, and others; and
- The logic underlying the model; for instance, the exact question the algorithm is supposed to answer, how it fits into specific clinical decision-making, and in what ways the inputs are appropriate to answer that question and, if appropriate, how that logic is associated with how the model should be used.

# Intervention Development

**Cautioned out-of-scope use of the intervention** is a description of tasks, situations, or populations to which the model developer cautions a user against applying the predictive model. This description should include:

- Known risks, inappropriate settings, inappropriate uses, or known limitations of the model
- Description should inform users about tasks, situations or populations related to the intended use of the model in which the model may not perform as expected

**Input features of the intervention** including description of training and test data should include:

- Exclusion and inclusion criteria that influenced who was included in data sets;
- Statistical characteristics—including sample size—of the demographic and other key variables in these data to assess representativeness;
- The source and clinical setting from which the data was generated
- The extent of missing values in the training and testing data sets; and
- Other attributes related to data quality, such as the comprehensiveness of the data and the process of collecting the data should be included as the developer determines what is relevant while examining the data during pre-processing, creation, and testing of the model.

# Intervention Development

**Process used to ensure fairness in development of the intervention** is a description of the approach the model developer has taken to ensure that the model output is fair. This should include:

- Approaches to manage, reduce, or eliminate bias in models and could be similar to a brief synopsis of risk mitigation practices and outcomes related to fairness for this DSI
- Many such approaches exist; however, there is no universal best process to ensure fairness
- For example, this attribute might state that in pre-processing the data before training the model, the developers employed a “disparate impact remover” transformation across race or ethnicity groups based on a well-known approach

**External validation process, if available** is a description of how and in what source, clinical setting, or environment a model’s validity and fairness has been assessed other than the source training and testing data. This should include:

- Who conducted the external testing (e.g., the model developer, developer of certified health IT, or an independent third party);
- The setting from which the external data was derived;
- The demographics of patients in external data; and
- A brief description of how external validation was carried out.



# Quantitative Measures of Intervention Performance

- **Validity of prediction**

- In test data and, if available, external data and local data is the presentation of the measure or set of measures related to the model's validity (often referred to as performance) tested, respectively, in data derived from the same source as the initial training data, in data from an external source, and in data local relative to its current use.
  - This proposal would not prescribe the specific performance or validation measures to be used or included as part of the source attributes requirements but would require that some performance or validation measure(s) be used and included in the source attribute.

- **Fairness of prediction**

- In test data and, if available, external data and local data is the presentation of the measure or set of measures related to the model's fairness (evaluation of fairness in a model) in terms of the accuracy of its output across certain groups in data derived from the same source as the initial training data, in data from an external source, and in data local relative to its current use.
  - Numerous approaches and related measures exist to measure the fairness of model outputs. Examples of potential fairness measures include positive predictive parity, false positive error rate balance and false negative error rate balance, equivalent calibration within groups, and mean residual difference

- **References to evaluation of use of the model on outcomes, if available** are bibliographic citations or links to evaluations of how well the intervention, or model on which it is based accomplished specific objectives such as reduced morbidity, mortality, length of stay or other important outcomes



# Ongoing Maintenance and Use

- **Update and continued validation or fairness assessment schedule** is a description of the process and frequency by which the model's performance is measured and monitored in the local environment and corrected when risks related to validity and fairness are identified
  - Information should also include how often performance is evaluated and how often the model is updated to provide users with insight into the likelihood that the model may have degraded (i.e., no longer provides valid or accurate predictions) since it was last updated
- **Validity and Fairness in Local Data**
  - As previously described



# Additional Considered Source Attributes Example

- Intervention Details
  - Information on explainability and interpretability
  - Whether a DSI meets the definition of a medical device under the FDA definition
- Intervention Development
  - Details on how model prediction and classification cut-points were selected
  - Security and privacy-preserving approaches included in model development
- Quantitative Measures of Intervention Performance
  - Model calibration or calibration curve
  - Confidence or prediction intervals or other measures of uncertainty
- Ongoing Maintenance of Intervention Implementation and Use
  - Whether the model is 'online' or 'unlocked'
    - Any additional organizational or technical controls in place to evaluate the impact of the online or unlocked updating and results of that evaluation.
    - The controls in place to update the descriptions of source data to reflect the changing composition of the data.



## Availability of Source Attributes to the Public

- We solicit comment on whether we should require developers of certified health IT with Health IT Modules certified to proposed § 170.315(b)(11) to make all source attributes information publicly available or accessible, for example, on a website, similar to the existing API documentation requirement in § 170.315(g)(10)(viii)(B).
- We solicit comment on whether having this information publicly available would be beneficial for potential users that purchase models or associated technology or software, and would help inform them prior to procurement of certified health IT and procurement of predictive DSIs integrated with certified health IT.
- We also solicit comment on whether having this information publicly available would improve public confidence in predictive DSIs by enabling research on source attribute information.

## Patient Access to Source Attributes

- Patients want to know if AI is being used in their care, and understand how and why it is being used in their care. We understand an emerging trend is for health care providers to inform patients about the use of these technologies, including predictive DSIs, in making decisions about their care.
- We solicit comment on whether existing Program requirements in the Communications condition and maintenance of certification requirements in § 170.403 are sufficient to ensure open and transparent discussion regarding the use of predictive DSIs in patient care – including discussion between users of certified health IT and patients. We are especially interested in whether we should require developers of certified health IT to provide the technical capability for users to support patients electronically accessing underlying source attribute information (e.g., through a patient portal) for predictive DSIs or otherwise indicate to a patient when a predictive DSI was used to make decisions about the patient in the course of the patient's care.





# Consensus Metrics and Standards

- We also solicit comment on testing or assessment tools that might further support transparency and trustworthiness including
  - Consensus metrics and technical standards for evaluating fairness (assessing for bias) and validating performance (including testing performance in different populations and evaluating applicability or generalizability) of predictive models that are enabled by or interface with Health IT Module(s) prior to and during deployment
  - Development and engineering of algorithmic impact assessments (AIAs)
  - Development of documentation of datasets used, such as datasheets for datasets and data cards as well as tools that could be useful in these areas so that Health IT Modules certified to §170.315(b)(11) can demonstrate it meets a given requirement on an ongoing basis



# Authoring and Revising Source Attributes

- We propose in § 170.315(b)(11)(vi)(E) that Health IT Modules enable users to author attributes and revise attributes beyond what is proposed in to support the ongoing evolution of what source attributes are important to users to make informed decisions regarding the DSI's recommendation(s).
  - Pertains to both evidence-based DSIs and predictive DSIs
  - Means that a Health IT Module would need to support the technical ability for a limited set of identified users to create new or revised attribute information alongside other source attribute information proposed
  - Example: a hospital that develops its own predictive DSI that is interfaced with a certified Health IT Module would be able to create new or revise existing source attributes information related to that predictive DSI that is made available through the certified Health IT Module without the developer of certified health IT's direct involvement.



## DSI Feedback Loops

- In the 2015 Edition Proposed Rule, we proposed to adopt new functionality that would require a Health IT Module to be able to record at least one action taken, and by whom it was taken, when a CDS intervention is provided to a user
  - For example, whether the user viewed, accepted, declined, ignored, overrode, provided a rationale or explanation for the action taken, took some other type of action not listed here, or otherwise commented on the CDS intervention) (80 FR 16821).
  - We also proposed that a Health IT Module certified to § 170.315(a)(9) be able to generate either a human readable display or human readable report of the responses and actions taken and by whom when a CDS intervention is provided (80 FR 16821).
- In the 2015 Edition Final Rule, we noted that many commenters stated that current systems already provide a wide range of functionality to enable providers to document decisions concerning CDS interventions and that such functionality is unnecessary to support providers participating in the EHR Incentive Programs (80 FR 62622).



## DSI Feedback Loop Proposal

- We propose that a Health IT Module certified to § 170.315(b)(11) must be able to export such feedback data, including but not limited to the intervention, action taken, user feedback provided (if applicable), user, date, and location, so that the exported data can be associated with other relevant data.
- We propose that such feedback data be available for export by users for analysis in a computable format, so that it can be associated with other relevant data, such as diagnosis, other inputs into the DSI, and the outputs of the DSI for a particular patient, to evaluate and improve DSI performance.
- In addition to quality improvement of the DSI, such an export would facilitate research, associating feedback data with other relevant data, and linking the DSI to patient health outcomes, including assisting in identifying and reducing health disparities and possible discriminatory outcomes.



# **Intervention Risk Management**

# Snapshot of Proposals to Promote Transparent & Trustworthy DSIs through the ONC Health IT Certification Program

## Technical & Performance

- Information about how the predictive DSI “works” made available to users, in plain language and via direct display, drill down, or link out:
  - Output and intended use, out of scope use(s), description of training data, external validation, update schedule, etc.
  - Like a “nutrition label”; leverage existing “source attributes” certification requirement
- Supportive of health equity by design:
  - Identification of REL, SOGI, SDOH, & Health Status data elements used
  - Information on validity and fairness of prediction in test and local data (if available)
- Additional enhancements that enable:
  - Authoring and revision capability for users
  - User feedback capabilities and feedback exports for quality improvement of DSIs

## Governance

- Public disclosure regarding how certified health IT developer manages risks and govern predictive DSIs:
  - Risk analysis (8 risk types): validity, reliability, robustness, fairness, intelligibility, safety, security, and privacy
  - Risk mitigation of those risks
  - Governance processes, including data management
- Summary documentation must be:
  - Publicly accessible through hyperlink without precondition
  - Reviewed annually for updates
- Detailed documentation must be:
  - Available to ONC upon request from ONC for each predictive DSI the certified health IT enables or interfaces with
  - Reviewed annually for updates

## Oversight

- Conformance to proposed new requirements through Real World Testing (RWT) Program:
  - RWT for all DSI types (predictive, evidence-based, and linked referential) beginning for 2024 plans
  - Annual cycle of RWT plans and results publicly available via the Certified Health IT Product List (CHPL)
  - Measures demonstrating conformance to requirements, self-identified by developer
- Summary of intervention risk management practices made publicly available
- Detailed risk management practices made available to ONC upon request from ONC

# Snapshot of Proposals to Promote Transparent & Trustworthy DSIs through the ONC Health IT Certification Program

## Governance & Risk Management

- Public disclosure regarding how certified health IT developer manages risks and govern predictive DSIs:
  - Risk analysis (8 risk types): validity, reliability, robustness, fairness, intelligibility, safety, security, and privacy
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# NIST Risk Management Framework

“ AI risk management can drive responsible uses and practices by prompting organizations and their internal teams who design, develop, and deploy AI to think more critically about context and potential or unexpected negative and positive impacts. Understanding and managing the risks of AI systems will help to enhance trustworthiness, and in turn, cultivate public trust.

- Govern 6 – Policies and procedures are in place to address AI risks and benefits arising from third-party software and data and other supply chain issues.
- Map 4 – Risks and benefits are mapped for all components of the AI system including third-party software and data.
- Measure 2 – AI systems are evaluated for trustworthy characteristics.
- Manage 1 – AI risks based on assessments and other analytical output from the MAP and MEASURE functions are prioritized, responded to, and managed.



## Background on IRM

- Given a lack of healthcare sector-specific guidance and the nascency of several emerging efforts for risk management of predictive software, our proposals would not require a specific framework, guideline, or approach that such developers of certified health IT must use – only that they employ or engage in IRM practices in accordance with proposed requirements in § 170.315(b)(11)(vii)(A) through (D)
- We view our proposals for risk management of predictive DSIs in § 170.315(b)(11)(vii) as complementary to our proposals for predictive DSI source attributes in § 170.315(b)(11)(vi)(C)
- The proposed source attributes information requirement is meant to provide users and implementers with sufficient information to understand how the model was designed, developed, and tested, including the model’s purpose, known limitations, and intended use(s)
- Correspondingly, the proposals for intervention risk management would provide users, implementers, and the wider public, including patients, with information to understand how developers of certified health IT with Health IT Modules that enable or interface with predictive DSIs analyze, mitigate, and govern risks throughout the technology’s life cycle



# Pillars of Intervention Risk Management Proposal

## Risk Analysis

- Should estimate the likelihood and magnitude of the negative impact (harm), or consequences, of each risk characteristic; to whom each risk applies (including, for example, individual, group, and societal harm); and the source of each risk

## Risk Mitigation

- Should describe:
  - Practices used to prioritize or establish different levels of risk;
  - Practices to mitigate or minimize identified risks;
  - Change control plans or ongoing validation/updating processes
  - Processes to supersede, disengage, or deactivate deviations from intended use
  - Approaches to include SMEs in measuring / validating performance

## Governance

- Should set an effective framework for risk management, with defined roles and responsibilities for clear communication of predictive DSI limitations and assumptions
- Should include setting and enforcing priorities for managing and using data as a strategic asset

## Risk Analysis Categories - Validity

- NIST's AI RMF describes seven characteristics of trustworthy AI, and we propose to adapt these concepts and require that developers of health IT with certified Health IT Modules that enable or interface with predictive DSIs employ or engage in risk management practices related to the following characteristics:
  - Validity - Assessment of risk related to validity should include and consider the following areas:
    - Validation of the accuracy and completeness of data used in development and testing of the predictive DSI
    - Evaluation plans and results for validation in testing environments and ongoing evaluation in deployment;
    - Both technical validity and clinical validity, which is closely related to measurement of effectiveness such as those discussed in the proposed source attribute "References to evaluation of use of the model on outcomes" in § 170.315(b)(11)(vi)(C)(3)(v).



# Risks to Reliability and Robustness

- “Reliability” indicates whether a model used in a predictive DSI consistently performs as required, without failure, for a given time interval, under given conditions. Assessment of reliability should include
  - Defining what range of behaviors is considered reliable for a model
  - The error rate considered acceptable
  - The results of evaluations that demonstrate reliability in both testing and deployed environments
- “Robustness” or generalizability is the ability of a model used in a predictive DSI to maintain its level of performance under a variety of circumstances. Assessment of robustness should
  - Evaluate limitations of the model based on the source of the training and testing data used and how features of that data and its source might relate to performance outside of the training and testing environment, which are likely to relate to information discussed in the proposed source attribute “input features of the intervention including description of training and test data”



## Risks to Fairness and Intelligibility

- “Fairness,” as noted above in this section, is defined by a lack of bias against certain groups, and fairness enhancing (or bias managing) processes seek to ensure that models are fair. NIST has identified three major categories of AI bias that should be addressed and managed to enhance fairness of models:
  - Systemic
  - Computational and statistical
  - Human-cognitive
- “Intelligibility” refers to the extent to which the predictive DSI can be understood, often through a representation of the mechanisms underlying an algorithm’s operation and through the meaning of AI systems’ output in the context of its designed functional purpose. In assessing intelligibility, developers of certified health IT should
  - Delineate the expected and acceptable context of use, including the intended users and operational setting.
  - Assess whether the predictive DSI provides intelligible information as an output that will allow for its intended users to make effective interpretation of relevant predictive DSI behavior when applied or used in the expected operational setting.



# Risks to Safety and Security

- “Safety” as a concept is highly correlated with risk and generally denotes that the product is free from any unacceptable risks and the probable benefits outweigh any probable risk. Developers should assess
  - Who could be injured,
  - when injury could arise and how injury could arise, engaging external parties in this assessment when such risks are not obvious
  - Implement procedures for regularly evaluating safety
- “Security” (and relatedly resilience) is a predictive DSI's and model's ability to withstand adversarial attacks, or more generally, unexpected changes in its environment or use. In assessing security, developers should consider
  - Common IT security concerns related to the exfiltration of models, training data, or other intellectual property through the technology's endpoints
  - Potential weaknesses in the controls for the access, transmission, and storage of sensitive information

# Risks to Privacy

- “Privacy” refers generally to the norms and practices that help to safeguard human autonomy, identity, and dignity, as well as data autonomy and intrusions on information about an individual. Analysis of privacy should
  - Consider the NIST Privacy Framework and application of NIST Privacy Risk Assessment Tool
  - Like safety and security, specific technical features of AI or ML-enabled technologies may promote or reduce privacy, and assessors can identify how the processing of data could create privacy-related problems



# Risk Mitigation

- We propose in § 170.315(b)(11)(vii)(A)(2) “Risk Mitigation” to require implementation of practices to mitigate risks associated with predictive DSIs. Risk mitigation practices implemented by developers of certified health IT should cover the following:
  - Practices to prioritize (establish different levels of) risks based on their impact and likelihood
  - Practices to mitigate or minimize identified potential risks
  - Change control plans, including schedule of validation and updating processes
  - Processes to supersede, disengage, or deactivate an existing predictive decision support intervention that demonstrate performance or outcomes that are inconsistent with their intended use
  - Approaches to including subject matter experts in measuring and validating whether the system is performing consistently with their intended use and as expected in the specific deployment setting



# Governance

- We propose to require health IT developers to establish policies and implement controls for predictive decision support intervention governance, including how data are acquired, managed, and used in a predictive decision support intervention
  - Governance should encompass models, software and data developed or provided by other parties as well as internally developed interventions
  - We expect developers of health IT to consider how the policies and controls they implement for data governance ensure the responsible acquisition, management, and use of data, including how the developer of certified health IT factors in and addresses ethical, legal, and social implications (ELSI) underlying data collection (acquisition) and use
- Our use of the term “policies” means statements of management intent regarding the objectives and required components of intervention risk management.
- Our use of the term “controls” means a system of internal controls that the developer has in place to implement the associated risk management policies, including those at the organizational and technology level
  - For example, processes for controlling the quality of the data inputs; internal and external audits; process to escalate conflicting views between the model development and validation groups



# Source Attributes and IRM Information Help Users Determine the FAVES of a Predictive DSI

Fair	<ul style="list-style-type: none"> <li>• <i>Process used to ensure fairness in development of the intervention</i></li> <li>• <i>Fairness of prediction in test data</i></li> <li>• <i>Fairness of prediction in external data, if available</i></li> <li>• <i>Fairness of prediction in local data, if available</i></li> <li>• <u>Risks to fairness are managed</u></li> </ul>
Appropriate	<ul style="list-style-type: none"> <li>• <i>Output of the intervention</i></li> <li>• <i>Intended use of the intervention</i></li> <li>• <i>Cautioned out-of-scope use of the intervention</i></li> <li>• <u>Risks to intelligibility are managed</u></li> </ul>
Valid	<ul style="list-style-type: none"> <li>• <i>Input features of the intervention including description of training and test data</i></li> <li>• <i>External validation process, if available</i></li> <li>• <i>Validity of prediction in test data</i></li> <li>• <i>Validity of prediction in external data, if available</i></li> <li>• <i>Validity of prediction in local data, if available</i></li> <li>• <u>Risks to Validity, Robustness, and Reliability are managed</u></li> </ul>
Effective	<ul style="list-style-type: none"> <li>• <i>References to evaluation of use of the model on outcomes, if available</i></li> <li>• <i>Update and continued validation/fairness schedule</i></li> </ul>
Safe	<ul style="list-style-type: none"> <li>• <u>Risks to safety are managed</u></li> <li>• <u>Risk to security are managed</u></li> <li>• <u>Risks to privacy are managed</u></li> </ul>



# Oversight & Implementation

# Snapshot of Proposals to Promote Transparent & Trustworthy DSIs through the ONC Health IT Certification Program

## Technical & Performance

- Information about how the predictive DSI “works” made available to users, in plain language and via direct display, drill down, or link out:
  - Output and intended use, out of scope use(s), description of training data, external validation, update schedule, etc.
  - Like a “nutrition label”; leverage existing “source attributes” certification requirement
- Supportive of health equity by design:
  - Identification of REL, SOGI, SDOH, & Health Status data elements used
  - Information on validity and fairness of prediction in test and local data (if available)
- Additional enhancements that enable:
  - Authoring and revision capability for users
  - User feedback capabilities and feedback exports for quality improvement of DSIs

## Governance

- Public disclosure regarding how certified health IT developer manages risks and govern predictive DSIs:
  - Risk analysis (8 risk types): validity, reliability, robustness, fairness, intelligibility, safety, security, and privacy
  - Risk mitigation of those risks
  - Governance processes, including data management
- Summary documentation must be:
  - Publicly accessible through hyperlink without precondition
  - Reviewed annually for updates
- Detailed documentation must be:
  - Available to ONC upon request from ONC for each predictive DSI the certified health IT enables or interfaces with
  - Reviewed annually for updates

## Oversight

- Conformance to proposed new requirements through Real World Testing (RWT) Program:
  - RWT for all DSI types (predictive, evidence-based, and linked referential) beginning for 2024 plans
  - Annual cycle of RWT plans and results publicly available via the Certified Health IT Product List (CHPL)
  - Measures demonstrating conformance to requirements, self-identified by developer
- Summary of intervention risk management practices made publicly available
- Detailed risk management practices made available to ONC upon request from ONC

## Snapshot of Proposals to Promote Transparent & Trustworthy DSIs through the ONC Health IT Certification Program

### Oversight & Implementation

- Conformance to proposed new requirements through Real World Testing (RWT) Program:
  - RWT for all DSI types (predictive, evidence-based, and linked referential) beginning for 2024 plans
  - Annual cycle of RWT plans and results publicly available via the Certified Health IT Product List (CHPL)
  - Measures demonstrating conformance to requirements, self-identified by developer
- Summary of intervention risk management practices made publicly available
- Detailed risk management practices made available to ONC upon request from ONC

# Oversight through Transparency & Real World Testing

- Summary information for intervention risk management practices should be publicly available via a publicly accessible hyperlink that allows any person to directly access the information without any preconditions or additional steps.
  - Clinicians, patients, health systems, and the public could use this information to bolster their trust in the developers of certified health IT and those certified Health IT Modules that enable or interface with predictive DSIs.
- Developers of certified health IT with Health IT Module(s) certified to § 170.315(b)(11) would be required to submit real world testing plans and corresponding real world testing results, consistent with other “(b)-criteria” in § 170.405(a)
  - RWT for all DSI types (predictive, evidence-based, and linked referential) beginning for 2024 plans
  - Measures demonstrating conformance to requirements, self-identified by developer
  - Annual cycle of RWT plans and results publicly available via CHPL
- Propose to add (a)(9) to the list of applicable criteria for Real World Testing, effective as of a final rule until it expires



## Contact ONC



**Phone:** 202-690-7151



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# DSI Proposals: Patient & Carepartner Perspective

Grace Cordovano, Enlightening Results



# Discussion

Steven Eichner, Co-Chair/Group 2 Lead

Steven Lane, Co-Chair



# Task Force Topics Worksheet

Steven Eichner, Co-Chair/Group 2 Lead

Steven Lane, Co-Chair

# Public Comment

To make a comment please  
**Use the Hand Raise Function**

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*(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](mailto: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*

# Upcoming Meetings

Month	Task Force/HITAC Meeting Dates	Task Force Topics
May	5/10	<ul style="list-style-type: none"> <li>• “The ONC Certification Criteria for Health IT” and Discontinuing Year Themed “Editions”</li> <li>• Requirement for Health IT Developers to Update their Previously Certified Health IT</li> <li>• Assurances Condition and Maintenance of Certification Requirements</li> </ul>
	<b>5/17 (HITAC)</b>	<ul style="list-style-type: none"> <li>• <b>TF Update</b></li> </ul>
	5/19	<ul style="list-style-type: none"> <li>• Electronic Case Reporting</li> </ul>
	5/24	<ul style="list-style-type: none"> <li>• Patient Requested Restrictions Certification Criterion</li> </ul>
	5/31	<ul style="list-style-type: none"> <li>• TBD</li> </ul>
June	6/6 (Full TF)	<ul style="list-style-type: none"> <li>• Develop transmittal report/slides</li> </ul>
	6/7 (Full TF)	<ul style="list-style-type: none"> <li>• Develop transmittal report/slides</li> </ul>
	6/8 (Full TF)	<ul style="list-style-type: none"> <li>• Develop transmittal report/slides</li> </ul>
	6/13 (Full TF)	<ul style="list-style-type: none"> <li>• Develop transmittal report/slides</li> </ul>
	<b>6/15 (HITAC)</b>	<ul style="list-style-type: none"> <li>• <b>Final Recommendation and Vote</b></li> </ul>



**Adjourn**