Office of the National Coordinator for Health Information Technology

Algorithms, Certified Health IT, and ONC's Health Data, Technology, and Interoperability (HTI-1) Proposed Rule

NCVHS Full Committee Meeting
Conversational AI Panel

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- 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.

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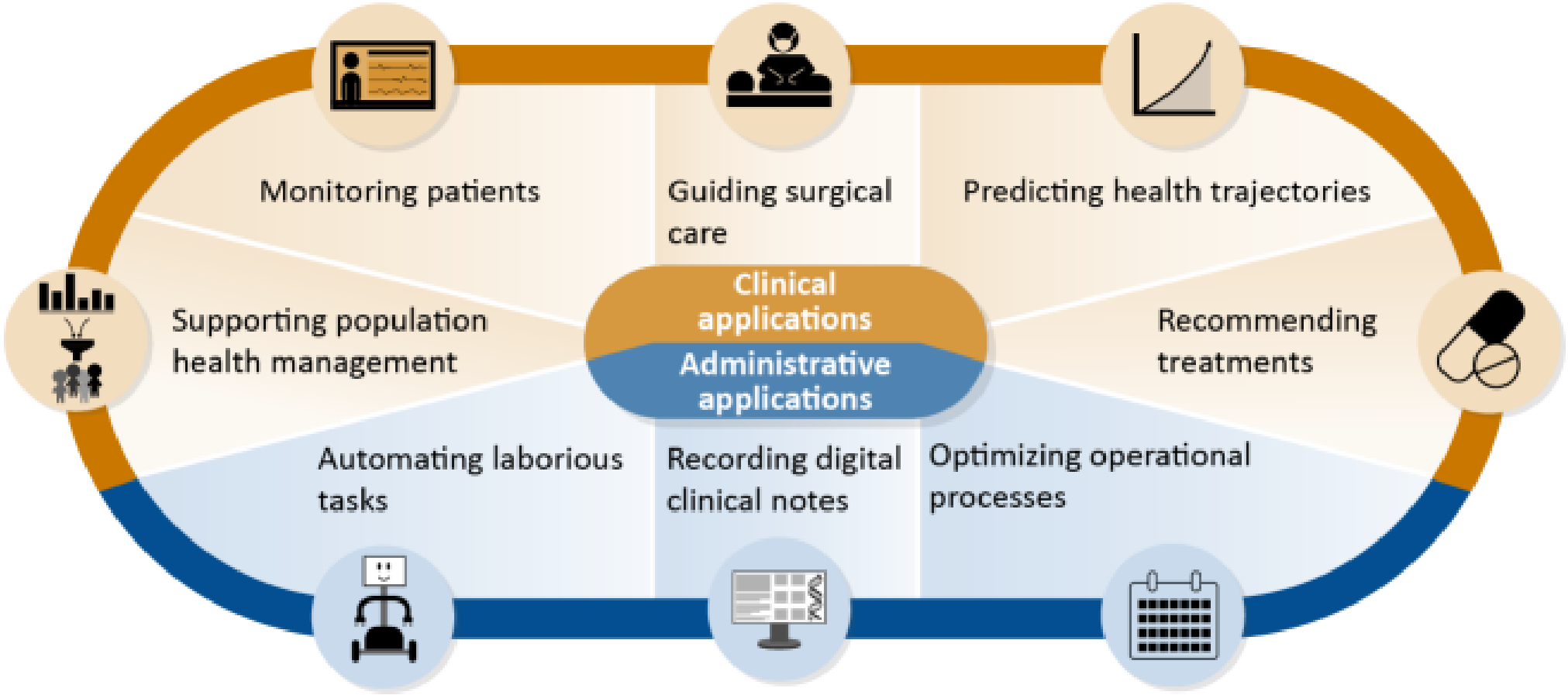
AI in Health Care



Source: GAO. | GAO-21-7SP https://www.gao.gov/assets/gao-21-7sp.pdf

The Promise and the Peril of AI

To optimize the use of AI in health care, we must address fundamental and far-reaching challenges associated with predictive algorithms that:

- Reproduce or amplify implicit and structural biases
- Magnify existing ethical, legal, and social concerns related to data collection and use
- Repeat the ills of history by reinforcing common, non-evidence-based practices or baking-in existing inexplicable differences in health outcomes
- Perpetuate fundamental information asymmetries regarding an algorithm's quality, performance (including its fairness and validity)
- Lead to outputs or recommendations that are ineffective or are unsafe

Health IT as a Delivery Mechanism

ONC-Certified health IT serves as the *wellspring* for algorithms in health care…

…ONC-Certified health IT is also a primary *delivery mechanism* of algorithmic results and outputs into clinical and administrative decision-making

Source: https://www.uchicagomedicine.org/-/media/images/ucmc/forefront/general/universal/doctor-software-laptop-universal.jpg?sc_lang=en&h=385&as=1&hash=09D5CF1C3A92FE2CF0A1F0BA727A75C0

HTI-1 Proposals for Predictive Decision Support Interventions

Objective: Enable improved information transparency on the trustworthiness of predictive DSIs to support their widespread use in health care.

Improve Transparency 	Regarding how a predictive DSI is designed, developed, trained, evaluated, and should be used
Enhance Trustworthiness 	Through transparency on how certified health IT developers manage potential risks and govern predictive DSIs that their certified Health IT Modules enable or interface with
Support Consistency 	In the availability of predictive DSI information to users, so that users may determine the DSI's quality and whether its recommendations are fair, appropriate, valid, effective, and safe (FAVES)
Advance Health Equity by Design 	By addressing bias and health disparities, potentially propagated by predictive DSIs, to expand the use of these technologies in safer, more appropriate, and more equitable ways

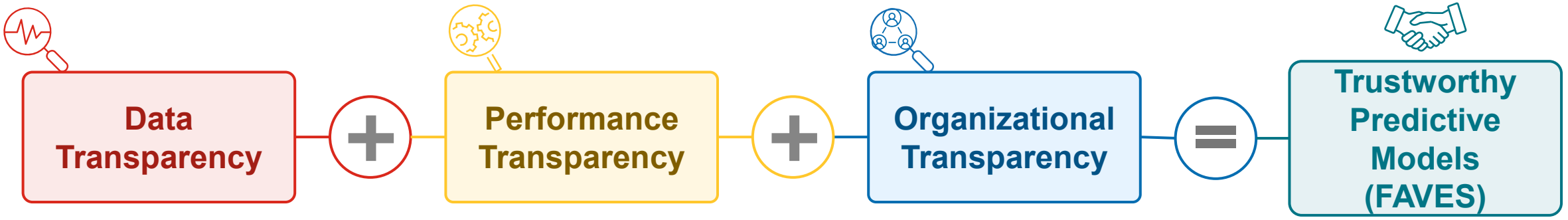
Proposed Definition: "Predictive Decision Support Intervention"

Predictive Decision Support Intervention Means:

"Technology intended to support decision-making based on algorithms or models that derive relationships from training or example data and then are used to produce an output or outputs related to, but not limited to, prediction, classification, recommendation, evaluation, or analysis."

- Technology estimates a value based on relationships 'learned' in prior data
  - Contrast with "evidence-based DSI" which supports decision-making by relying on pre-defined rules based on expert consensus or from expert recommendation (e.g., computable clinical guidelines).
- Predictive DSIs include those based on:
  - Simple statistics or regression model → risk calculator
  - Machine learning models (e.g., predicting healthcare costs; sepsis onset; no-show)
  - From widely used ASCVD and APACHE IV models, to bespoke machine learning models used to predict opioid overdose, hospital bed capacity, and other emerging use cases
  - Natural language processing (NLP) and large language models (LLMs) (sometimes referred to as generative AI)
- DSI may be presented in a broad array of forms (e.g., alerts, order sets, flowsheets)
- Proposed definition is
  - **Not** tied to a specific purpose or intended use.
  - **Not** dependent on who developed the algorithm or model (can be someone other than a developer of certified health IT).
  - **Not** based on a level of risk associated with the technology's purpose.

Transparency Is a Prerequisite for Trustworthy AI



Data Transparency

Proposed requirements would enable users to know when a DSI uses specific data elements relevant to health equity, including:

- Sexual Orientation
- Race, Ethnicity, & Language
- Gender Identity
- Social Determinants of Health
- Disability
- Date of Birth

Performance Transparency

Proposed source attributes would enable users to have consistent and routine electronic access to technical and performance information on predictive DSIs

- Intended use, training data descriptions, measures of fairness, maintenance, etc.
- Establishes baseline ingredients for a model “nutrition label”
- Information available to users in plain language and via “direct display,” “drill down” or “link out” functionality

Organizational Transparency

Proposed requirement for certified health IT developers to employ or engage in risk management of predictive DSIs

- Analyze risks; mitigate risks; and establish governance for predictive DSIs spanning 8 socio-technical characteristics including Validity, Reliability, Robustness, Fairness, Intelligibility, Safety, Security, & Privacy
- Report summary information publicly

Resources Available on HealthIT.gov

Visit https://healthIT.gov/proposedrule for additional information.

Fact Sheets

- General Overview
- At-a-Glance
- Decision Support Interventions and Predictive Models
- Insights Condition
- Information Blocking

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April 2023

AT-A-GLANCE

Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule

Standards and Certification Criteria Proposals

- To adopt United States Core Data for Interoperability (USCDI) v3 as the new data set baseline across applicable certification criteria.
- To revise electronic case reporting certification criterion to be based on consensus-based, industry developed standards by HL7.
- To revise existing clinical decision support (CDS) certification criterion as the decision support interventions (DSI) certification criterion.
- To add new requirements for revoking access privileges.
- To add new data elements, and rename the demographics certification criterion.
- To update the transitions of care certification criterion to USCDI v3.
- To adopt a new patient requested restrictions certification criterion and to revise an existing criterion to support additional tools for implementing patient requested restrictions.

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DECISION SUPPORT INTERVENTIONS AND PREDICTIVE MODELS FACT SHEET

Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule

April 2023

For important background on the proposals made in the HTI-1 proposed rule, please first visit the ONC Health IT Buzz Blog **Increasing the Transparency and Trustworthiness of AI in Health Care.**

What Proposals Are Included?

The HTI-1 proposed rule would revise the existing "clinical decision support" (CDS) certification criterion[1] for the first time since 2012 to reflect an array of contemporary and emerging functionalities, data elements, and software applications that aid decision-making in health care. The current criterion for CDS would be renamed as the "Decision Support Interventions" (DSI) certification criterion and be recategorized as part of the care coordination criteria in § 170.315(b). The proposal expands on existing requirements related to "source attributes" and configuration requirements for linked referential and evidence-based decision support intervention types.

The DSI proposal also includes several new requirements for Health IT Modules that enable or interface with technology intended to support decision-making based on predictive algorithms or models. This proposal would not require Health IT Modules to support predictive DSIs. However, there are additional requirements for those Health IT Modules and those developers of certified health IT that support predictive DSIs. We propose to define predictive DSIs as technology that is "intended to support decision-making based on algorithms or models that derive relationships from training or example data and then are used to produce an output or outputs related to, but not limited to, prediction, classification, recommendation, evaluation, or analysis."

Why Is ONC Proposing These Changes?

ONC proposes these revisions to optimize the use of predictive and other DSI types in health care. Our primary proposals would:

- Improve transparency on how a predictive DSI was designed, developed, trained, evaluated, and should be used, addressing fundamental information asymmetries in the marketplace for predictive DSIs.
- Enhance trustworthiness through transparency on how certified health IT developers manage potential risks and govern predictive DSIs that their certified Health IT Modules enable or interface with.
- Support consistency in the availability of predictive DSI information, so that users may determine the DSI's quality and whether its recommendations are fair, appropriate, valid, effective, and safe (FAVES).
- Advance health equity by addressing bias and health disparities that may be propagated by predictive DSIs to expand the use of these technologies in safe, appropriate, and more equitable ways.

What Are the Details?

Updated source attributes requirements – The HTI-1 proposed rule would expand the number of source attributes and the kinds of information that must be available to users "via direct display, drill down, or link out from a Health IT Module." These updates focus on ensuring that users know when race, ethnicity, social determinants of health, and other data salient to health equity are used by a DSI, including predictive DSIs.

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