

ONC Update

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AMDIS Annual Physician-Computer
Connection Symposium 2024

June 20, 2024



Office of the National Coordinator for Health IT





ONC is charged with formulating the federal government's health IT strategy to advance national goals
for better and safer health care through an interoperable nationwide health IT infrastructure



Laying the foundation of EHRs across the industry

- \$40B CMS investment to subsidize EHRs for hospitals and ambulatory providers
- ONC certification of EHR systems to support CMS and CDC programs
- ONC certification now covers EHRs used by 97% of hospitals and 86% of ambulatory providers

Leveraging EHRs to drive value

- <u>Information blocking</u>: Prohibits providers, technology developers, and health information networks from interfering with access, exchange, and use of electronic health information
- <u>Standards</u>: Requires access to information through APIs "without special effort"
- <u>TEFCA</u>: Requires nationwide governance for health information exchange networks – Trusted Exchange Framework and Common Agreement

About ONC



Our Vision

Better health enabled by data.



Our Mission

To create systemic improvements in health and care through the access, exchange, and use of data.

PRIORITIES

% Build the digital foundation

- Data standards
- Health IT gaps
- HHS Health IT Alignment Policy

Make interoperability easy

- TEFCA
- APIs
- Expand education and outreach

Promote information sharing

- Information blocking rules
- HHS Health IT Alignment Policy

Ensure proper use of digital information and tools

- Health equity by design (data capture and use)
- Transparency in areas such as algorithm use and safety

"What we do"

ONC Activities



ONC Objectives

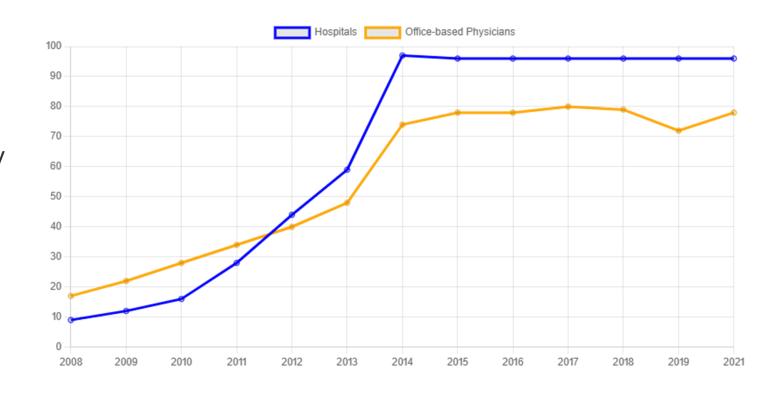




ONC's Health IT Certification Program

- ONC-certified Health IT is the foundation of the US' digital health infrastructure.
 - 400+ health IT products
 - Used by >96% of hospitals and ~80% of clinical offices.

- Sets industry-baseline for data, standards, and interoperability
- Certified capabilities are "baked-in" to the technology that providers use daily
- Also applies to health IT developers' business practices
- Referenced by more than 20 federal programs, including Medicare and Medicaid programs



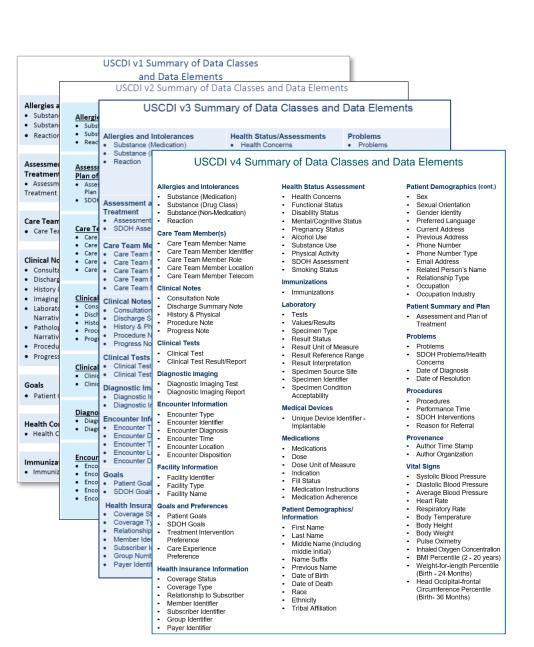
US Core Data for Interoperability (USCDI) Background

- Standard established by ONC in the 2020 21st Century Cures Act Final Rule
- Minimum dataset required for interoperability
 - Defines required data elements and vocabulary standards
 - Focuses on patient access/care coordination use cases
- Updated on an annual cycle with federal agency and industry input
 - Updates based on multiple criteria including standards maturity and public/industry priority



USCDI: Transparent, Predictable, Collaborative

- USCDI v1 is required by Cures Act Final Rule and added data classes clinical notes and provenance, and data elements pediatric vital signs and address
- USCDI v2 added three data classes and 22 data elements in support of advancing health equity (SOGI and SDOH)
- USCDI v3 added 24 data elements focused on factors promoting equity, reducing disparities and supporting public health data interoperability.
 - Finalized as new required version in Health Data,
 Technology, and Interoperability 1, with a compliance date of January 1, 2026
- USCDI v4 added Alcohol and Substance Use Assessments, Physical Activity, Treatment Intervention and Care Experience Preferences, and Medication Adherence data elements





USCDI Version 1

Allergies and Intolerances *NEW

- •••
- Substance (Medication)
- Substance (Drug Class) *NEW
- Reaction

*NEW

Assessment and Plan of Treatment



Care Team Members





Clinical Notes *NEW

- Consultation Note
- Discharge Summary Note
- History & Physical
- Imaging Narrative
- Laboratory Report Narrative
- Pathology Report Narrative
- Procedure Note
- Progress Note

Goals



Health Concerns



Immunizations



Laboratory

- Tests
- Values/Results



Medications



Patient Demographics

- First Name
- Last Name
- Previous Name
- Middle Name (incl. middle initial)
- Suffix
- Birth Sex
- Date of Birth
- Race
- Ethnicity
- Preferred Language
- Current Address
- Previous Address
- Phone Number
- Phone Number Type
- Email Address

Problems



*NEW

*NEW

*NEW

*NEW

*NEW

Procedures



Provenance *NEW

- Author Time Stamp
- Author Organization

Smoking Status



Unique Device Identifier(s) for a Patient's Implantable Device(s)

Vital Signs



- Diastolic Blood Pressure
- Systolic Blood Pressure
- Body Height
- Body Weight
- Heart Rate
- Respiratory Rate
- Body Temperature
- Pulse Oximetry
- Inhaled Oxygen Concentration
- BMI Percentile (2-20 Years) *NEW
- Weight-for-length Percentile (Birth - 36 Months) *NEW
- Occipital-frontal Head Circumference Percentile (Birth - 36 Months) *NEW

8





USCDI Version 3

Allergies and IntolerancesSubstance (Medication)Substance (Drug Class)Reaction	Clinical Tests Clinical Test Clinical Test Result/Report	Assessments ★★ In Health Concerns → Functional Status ★	Patient Demographics/ Information ★ ★ • First Name • Last Name	Procedures • Procedures • SDOH Interventions • Reason for Referral ★
Assessment and Plan of Treatment • Assessment and Plan of Treatment • SDOH Assessment	Diagnostic ImagingDiagnostic Imaging TestDiagnostic Imaging Report	◆ Pregnancy Status		ProvenanceAuthor OrganizationAuthor Time Stamp
Care Team Member(s) Care Team Member Name Care Team Member Identifier Care Team Member Role Care Team Member Location Care Team Member Telecom	Encounter Information	Immunizations • Immunizations	 Ethnicity Tribal Affiliation ★ Sex ★★ Sexual Orientation Gender Identity Preferred Language Current Address 	Unique Device Identifier(s) for a Patient's Implantable Device(s) • Unique Device Identifier(s) for a patient's implantable device(s)
Clinical Notes Consultation Note Discharge Summary Note History & Physical Procedure Note Progress Note	Goals • Patient Goals • SDOH Goals	Laboratory • Test • Values/Results • Specimen Type ★ • Result Status ★	 Previous Address Phone Number Phone Number Type Email Address Related Person's Name Related Person's Relationship Occupation Occupation Industry 	Vital Signs Systolic blood pressure Diastolic blood pressure Heart Rate Respiratory rate Body temperature Body height Body weight
	Health Insurance Information ★ • Coverage Status ★ • Coverage Type ★ • Relationship to Subscriber ★ • Member Identifier ★ • Subscriber Identifier ★ • Group Number ★ • Payer Identifier ★	Medications • Medications • Dose ★ • Dose Units of Measure ★ • Indication ★ • Fill Status ★	Problems Problems SDOH Problems/Health Concerns Date of Diagnosis Date of Resolution	 Pulse oximetry Inhaled oxygen concentration BMI Percentile (2 - 20 years) Weight-for-length Percentile (Birth - 24 Months) ★★ Head Occipital-frontal Circumference Percentile (Birth - 36 Months)



Allergies and Intolerances

- Substance (Medication)
- Substance (Drug Class)
- Substance (Non-Medication)
- Reaction

Care Team Member(s)

- Care Team Member Name
- Care Team Member Identifier
- Care Team Member Role
- Care Team Member Location
- Care Team Member Telecom

Clinical Notes

- Consultation Note
- Discharge Summary Note
- History & Physical
- Procedure Note
- Progress Note

Clinical Tests

- Clinical Test
- Clinical Test Result/Report

Diagnostic Imaging

- Diagnostic Imaging Test
- Diagnostic Imaging Report

Encounter Information

- Encounter Type
- Encounter Identifier +
- Encounter Diagnosis
- Encounter Time
- Encounter Location
- Encounter Disposition

Facility Information +

- Facility Identifier +
- Facility Type
- Facility Name

Goals and Preferences

- Patient Goals
- SDOH Goals
- Treatment Intervention Preference -
- Care Experience Preference

Health Insurance Information

- Coverage Status
- Coverage Type
- Relationship to Subscriber
- Member Identifier
- Subscriber Identifier
- Group Number
- Payer Identifier

Health Status Assessments

- Health Concerns
- Functional Status
- Disability Status
- Mental/Cognitive Status
- Pregnancy Status
- Alcohol Use
- Substance Use
- Physical Activity
- SDOH Assessment →
- Smoking Status

Immunizations

Immunizations

Laboratory

- Tests
- Values/Results
- Specimen Type
- Result Status
- Result Unit of Measure
- Result Reference Range +
- Result Interpretation
- Specimen Source Site
- Specimen Identifier
- Specimen Condition Acceptability #

Medical Devices A

• Unique Device Identifier -Implantable 🔼

Medications

- Medications
- Dose
- Dose Unit of Measure
- Indication
- Fill Status
- Medication Instructions
- Medication Adherence

Patient Demographics/ Information

- First Name
- Last Name
- Middle Name (Including middle initial)
- Name Suffix
- Previous Name
- Date of Birth
- Date of Death
- Race
- Ethnicity
- Tribal Affiliation
- Sex
- Sexual Orientation
- Gender Identity
- Preferred Language
- Current Address
- Previous Address
- Phone Number
- Phone Number Type
- Email Address
- Related Person's Name
- Relationship Type
- Occupation
- Occupation Industry

Patient Summary and Plan 🔼

 Assessment and Plan of Treatment

Problems

- Problems
- SDOH Problems/Health Concerns
- Date of Diagnosis
- Date of Resolution

Procedures

- Procedures
- Performance Time
- SDOH Interventions
- Reason for Referral

Provenance

- Author Organization
- Author Time Stamp

Vital Signs

- Systolic Blood Pressure
- Diastolic Blood Pressure
- Average Blood Pressure
- Heart Rate
- Respiratory Rate
- Body Temperature
- Body Height
- Body Weight
- Pulse Oximetry
- Inhaled Oxygen Concentration
- BMI Percentile (2 20 years)
- Weight-for-length Percentile (Birth - 24 Months)
- Head Occipital-frontal Circumference Percentile (Birth
 - 36 Months)



Draft USCDI Version 5

Allergies and Intolerances

- Substance (Medication)
- · Substance (Drug Class)
- Substance (Non-Medication)
- Reaction

Care Team Members

- Care Team Member Name
- Care Team Member Identifier
- Care Team Member Role
- Care Team Member Location
- Care Team Member Telecom

Clinical Notes

- Consultation Note
- Discharge Summary Note
- Emergency Department Note
- · History & Physical
- Operative Note
- Procedure Note
- Progress Note

Clinical Tests

- Clinical Test
- Clinical Test Result/Report

Diagnostic Imaging

- Diagnostic Imaging Test
- Diagnostic Imaging Report

Encounter Information

- Encounter Type
- · Encounter Identifier
- Encounter Diagnosis
- Encounter Time

[ADVENTISTHEALTH: INTERNAL] Encounter Disposition

Facility Information

- · Facility Identifier
- Facility TypeFacility Name

Goals and Preferences

- Patient Goals
- SDOH Goals
- Treatment Intervention Preference
- Care Experience Preference

Health Insurance Information

- Coverage Status
- Coverage Type
- · Relationship to Subscriber
- Member Identifier
- · Subscriber Identifier
- Group Identifier
- Payer Identifier

Health Status Assessment

- Health Concerns
- · Functional Status
- Disability Status
- · Mental/Cognitive Status
- Pregnancy Status
- Alcohol Use
- Substance Use
- Physical Activity
- SDOH Assessment
- Smoking Status

Immunizations

- Immunizations
- · Lot Number

Laboratory

- Tests
- Values/Results
- Specimen Type
- Result Status
- Result Unit of Measure
- Result Reference Range
- Test Kite Unique Device Identifier
- Result Interpretation
- Specimen Source Site
- Specimen Identifier
- · Specimen Condition Acceptability

Medical Devices

 Unique Device Identifier -Implantable

Medications

- Medications
- Dose
- Dose Unit of Measure
- Route
- Indication
- Fill Status
- Medication Instructions
- Medication Adherence

Observations

- Advance Directive Observation
- · Sex Parameter for Clinical Use

Orders

Orders

Patient Demographics/Information Problems

- First Name
- Last Name
- Middle Name (Including middle initial)•
- Name Suffix
- Previous Name
- · Name to Use
- Pronoun
- Date of Birth
- Date of Death
- Race
- Ethnicity
- Tribal Affiliation
- Sex
- Sexual Orientation
- · Gender Identity
- Preferred Language
- Interpreter Needed
- Current AddressPrevious Address
- Phone Number
- Phone Number Type
- Email Address
- Related Person's Name
- Relationship Type
- Occupation
- Occupation Industry

Patient Summary and Plan

· Assessment and Plan of Treatment

- Problems
- SDOH Problems/Health Concerns
- Date of Diagnosis
- Date of Resolution

Procedures

- Procedures
- Performance Time
- SDOH Interventions
- · Reason for Referral

Provenance

- Author
- Author Role
- Author Time Stamp
- Author Organization

Vital Signs

- Systolic Blood Pressure
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- Head Occipital-frontal Circumference Percentile (Birth-36 Months)

Health IT and the 21st Century Cures Act

21st Century Cures Act



Trusted Exchange Framework & Common Agreement (TEFCA)

21st Century Cures Act - Section 4003(b)

"[T]he National Coordinator shall convene appropriate public and private stakeholders to develop or support a trusted exchange framework for trust policies and practices and for a common agreement for exchange between health information networks." [emphasis added]









Establish a universal policy and technical floor for nationwide interoperability



Simplify connectivity for organizations to securely exchange information to improve patient care, enhance the welfare of populations, and generate health care value





Enable individuals to gather their health care information

Benefits of TEFCA

Relevant, trusted information from nationwide sources for:



Individuals

Use an app to access their own records from TEFCA-connected sources located across the nation.



Providers and Health Systems

Improve care, coordination and population health by obtaining a more informed picture of care across settings through fewer connection points.



Public Health

Improve quality, reduce costs, and expand public health interoperability.

For more detail on the benefits of TEFCA for stakeholders, see factsheets at: https://rce.sequoiaproject.org/tefca-and-rce-resources/



Payers

Get and share data needed for care management, value-based care, payer-to-payer exchange, etc.



Health Information Networks

Enhance the value of network participation and lower the cost of connecting with other networks.



Technology Developers

Provide a scalable policy and technical ecosystem for innovation.



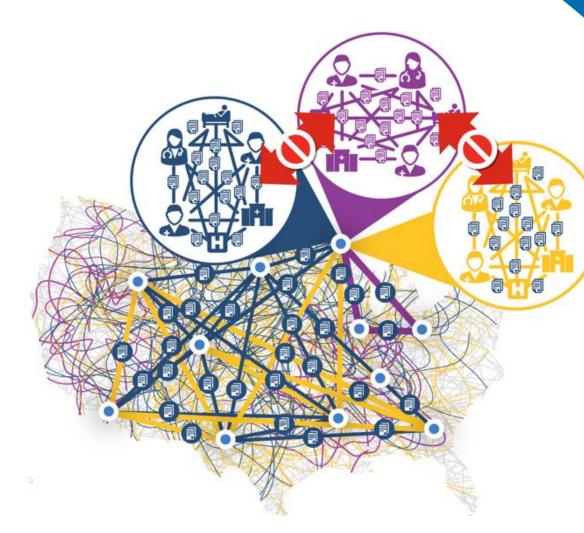
Researchers (Future)

Improve quality, reduce costs, and expand participation in clinical research.

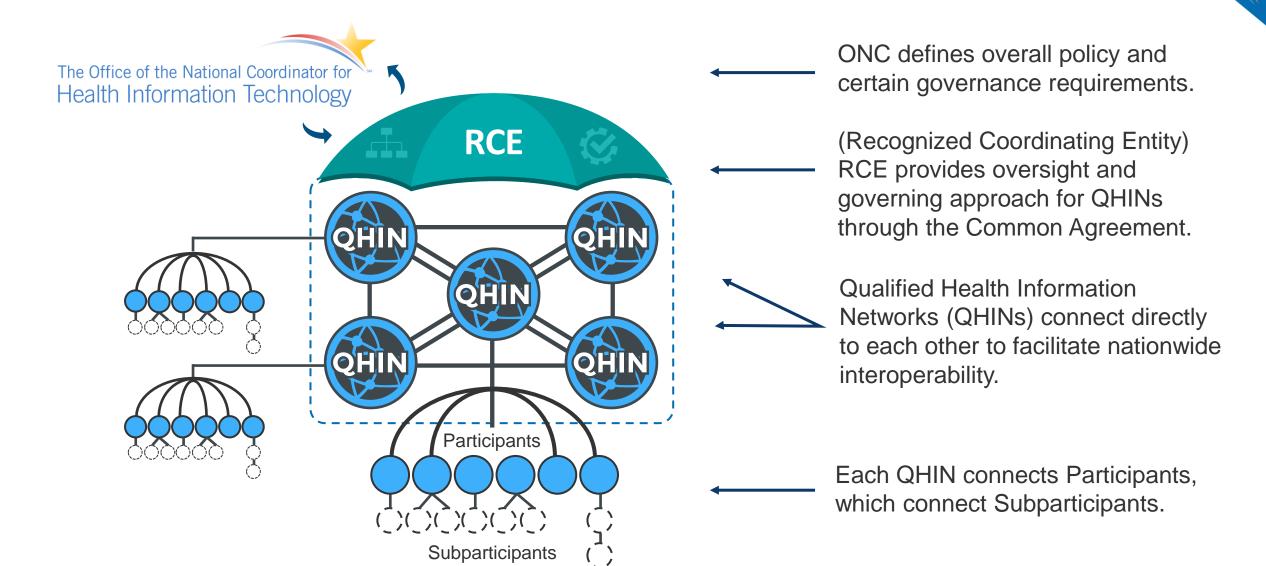
TEFCA Will Simplify Health Data Exchange

While there has been growth in national networks, there is much unfinished business

- Less well-resourced providers, rural, behavioral health, LTPAC
- Payers (government and commercial)
- Public health
- Social services
- Research
- Federal government involvement required to spur the further evolution of nationwide network interoperability



What is the structure of TEFCA?



TEFCA is Operational!

The following organizations have officially been designated as Qualified Health Information Networks[™] (QHINs[™]) after completing the rigorous TEFCA onboarding process:















Once designated, these QHINs were able to immediately begin supporting the exchange of data under TEFCA's policies and technical requirements.





Permitted Exchange Purposes

Treatment



Payment



Health Care Operations



Public Health



Government Benefits Determination



Individual Access Services



(FUTURE) Research

Individuals, health care providers, health plans, public health authorities, and government agencies routinely need to query HINs for these purposes.

For example:

- Patients with multiple health care providers want to manage their own health information through consumer-facing applications without visiting each patient portal across all their health care providers
- Primary care physicians and specialists need to have their patient's health information available to coordinate care
- Public health authorities performing case investigations need to understand previous care provided to a particular patient

2024-2030

Federal Health IT Strategic Plan

Draft for Public Comment

Prepared by:

The Office of the National Coordinator for Health Information Technology, Office of the Secretary, United States Department of Health and Human Services

HealthIT.gov

MARCH 2024

2024-2030

Federal Health IT Strategic Plan

Federal Health IT Mission and Vision



Federal Health IT Mission

Improve the health and well-being of individuals and communities using technology and health information that is accessible when and where it matters most.



Federal Health IT Vision

A health system that uses information to engage individuals, lower costs, deliver high-quality care, and improve individual and population health.



Federal Health IT Strategic Plan Framework

Federal Health IT Strategic Plan

2024-2030

GOALS AND OBJECTIVES

GOAL 1: OBJECTIVES

- Individuals are empowered to manage their health
- Individuals and populations experience modern and equitable health care
- **c** Communities are healthier and safer

GOAL 2: OBJECTIVES

- Providers deliver safe, equitable, high-quality, and improved care
- Patients experience expanded access to quality care and reduced or eliminated health disparities
- Health care is improved through greater competition and transparency
- Providers experience reduced regulatory and administrative burden
- The health care workforce uses health IT with confidence

GOAL 3: OBJECTIVES

- Researchers and other health IT users have appropriate access to health data to drive individual and population health improvement
- Individual and population-level research and analysis are enhanced by health IT
- Sesearchers advance health equity by using health data that includes underrepresented groups

GOAL 4: OBJECTIVES

- A Development and use of health IT capabilities continues to advance
- B Health IT users have clear and shared expectations for data sharing
- Underserved communities and populations have access to infrastructure that supports health IT use
- Individuals' electronic health information is protected, private, and secure
- Communities are supported by modern and integrated U.S. public health data systems and infrastructure



Federal Health IT

GOAL 2 Enhance the Delivery and Experience of Care

Enhance the Delivery and Experience of Care

Goal 2 focuses on improving how patients and caregivers experience care, how health care providers and others across the health care continuum deliver care, and how health plans reimburse for care

Strategic Plan

OBJECTIVES

- A Providers deliver safe, equitable, high-quality, and improved care
- B Patients experience expanded access to quality care and reduced or eliminated health disparities
- Health care is improved through greater competition and transparency
- Providers experience reduced regulatory and administrative burden
- The health care workforce uses health IT with confidence





2024-2030

Federal Health IT Strategic Plan

Providers experience reduced regulatory and administrative burden



STRATEGIES			
The federal government plans to		So that	
Simplify and streamline electronic documentation requirements for provider payments	•••	Health care providers can reduce "note bloat" and crea coherent patient health records	ate more useful and
Leverage health IT to standardize data and processes related to electronic prior authorizations to allow for increased automation	• •	Health care providers experience reduced administrative timeliness of prior authorization decisions	ve burden and improved
Advance health IT and related policies to improve alignment and increase automation related to health care provider data collection and reporting	• • •	Health care providers experience reduced burden and chart abstraction) associated with federal clinical quali reporting requirements	
Provide education and outreach on applicable regulations and expected business practices related to EHI sharing	•••	Health care providers and health plans safeguard personal incorporate privacy and security into their practices, an security risk assessments of their practices	
Promote the safe and responsible use of Al tools	• •	Health care providers and patients experience streamli delivery supported by Decision Support Interventions (ined, more efficient care DSI)



Evaluating Burden of EHR Documentation and Work Processes Outside of Traditional Fee-For-Service (FFS)



Stage 1

 Conduct a comprehensive literature review of research that compares EHRs used in FFS environments to non-FFS.

Stage 2

- Conduct in-depth clinical and technical discussions with organizations who have developed/deployed non-FFS-driven EHRs.
- Conduct quantitative analyses that examine the association between the FFS environment, along with other factors, and time spent documenting.

Non-FFS environments being evaluated as a part of this study:

- Accountable Care Organizations
- Full-Risk Medicare Advantage
- **Integrated Payer-Provider Organizations**
- HEALTH:INTERNALI Concierge Medicine Practices



ONC: Health Equity and Health IT

Background:

- Performed an extensive landscape analysis, conducted a literature review, engaged federal partners and non-governmental entities through listening sessions, webinars, direct interviews, and held a health equity focused hearing through our Health IT Advisory Committee
- Completed a scrub of our activities and authorities to determine:
 - What are we currently doing from a health equity and health IT perspective?
 - What more can we be doing in our current activities and programs?
 - What new activities or programs could we initiate with existing authorities?

Current Status:

- Two key categories of health equity focused activities:
 - Collection and use of data to better identify health inequities
 - Mechanisms to mitigate health inequities
- Initial set of core activities developed some already implemented, others being scoped into discrete projects
- We developed and released a concept paper for public focused on Health Equity by Design

What Does "Health Equity by Design" Mean?

What is it?

 Equity considerations identified and incorporated as early as possible in design, build, implementation of health information technology policies, programs, projects, and workflows

 Health IT products and capabilities are designed to be foundationally equity enforcing, making the implicit explicit.

APRIL 2024



Health Equity by Design Concept Paper Available for Public Comment





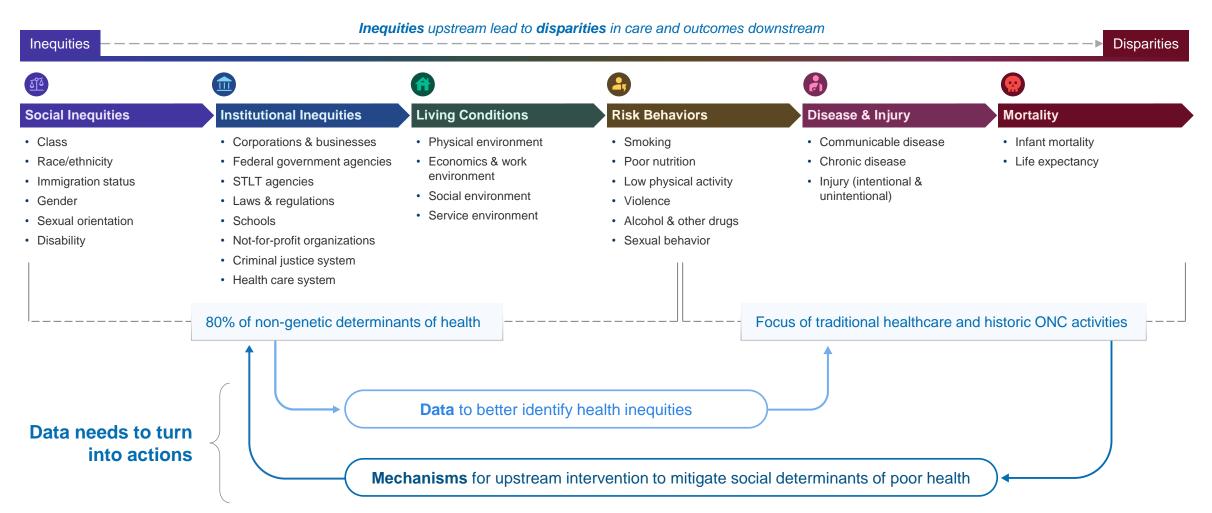
Advancing Health Equity by Design and Health Information Technology: Proposed Approach, Invitation for Public Input, and Call to Action

Prepared by:

The Office of the National Coordinator for Health Information Technology

APRIL 2024

Robert Wood Johnson Foundation: Achieving Health Equity Causal Chain of Health Disparities



Health Equity by Design Core Activities

Data to identify health inequities

1. US Core Data for Interoperability (USCDI):

2. Race, ethnicity, language (REL) data:

3. ONC Health IT Certification Program

v2: Added Social Determinants of Health and Sexual Orientation Gender Identity data elements

v3: Added additional HE data elements (disability status, mental function, and tribal affiliation

v4: Added Care experience & treatment intervention preferences

Identify levers for adoption of standards across USG and industry

Continue to update certification requirements to advance health equity

Mechanisms to mitigate health care inequities

4. Public Health IT Workforce Development program:

5. Referrals for social services:

6. Representation in policy development: HHS Federal Advisory / HITAC

Address Digital Divide (patient & provider)

8. AI / ML bias in health IT

10 awardees to train/place 4000+ students from MSI's and other institutions of higher education

Leading Edge Acceleration Project (LEAP)- innovative open-source technology tool development

2021 Award - UT Austin for SDOH referral systems to address food insecurity

2022 Award – OCHIN increasing HE by addressing housing insecurity needs in underserved communities

Health equity on 2024 Health IT Advisory Committee agenda

Support the development of FHIR-based API standards for data access to help close the digital divide

HTI-1 Final Rule - provides users of C-HIT with transparency to help determine if Ai tools exhibit bias

HTI-1 Final Rule

Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing

December 2023

HTI-1 Policies 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

Predictive DSI, supplied by Certified Health IT Developer

- Predictive Decision Support Intervention definition:
 - Technology that supports decision-making based on algorithms or models that derive relationships from training data and then produce an output that results in prediction, classification, recommendation, evaluation, or analysis
- Supplied by the health IT developer as part of its Health IT Module
 - Includes Predictive DSIs that are authored or developed by the certified health IT developer
 - Includes Predictive DSIs that are authored or developed by other parties if those Predictive DSIs are sold, marketed, or otherwise explicitly included as part of a Health IT Module
- Supplied by means that:
 - Certified health IT developer has taken on stewardship and accountability for that Predictive DSI for the purposes of the Health IT Module
 - Knowledge of its use is known by the certified Health IT developer

An inclusive framing of how to address challenges

FAVES is our quality framework describing the characteristics of "high-quality" algorithms and communicates how we may get the best out of predictive models in health care.

Fair (unbiased, equitable)

Model does not exhibit biased performance, prejudice or favoritism toward an individual or group based on their inherent or acquired characteristics. The impact of using the model is similar across same or different populations or groups.

Appropriate

Model is well matched to specific contexts and populations to which it is applied.

Valid

Model has been shown to estimate targeted values accurately and as expected in both internal and external data.

Effective

Model has demonstrated benefit and significant results in realworld conditions.

Safe

Model use has probable benefits that outweigh any probable risk.

Nine Predictive DSI Source Attribute Categories

1

Details and output of the intervention

2

Purpose of the intervention

3

Cautioned Out-of-Scope Use of the intervention

4

Intervention development details and input features

5

Process used to ensure fairness in development of the intervention

6

External validation process

7

Quantitative measures of performance

8

Ongoing maintenance of intervention implementation and use

9

Update and continued validation or fairness assessment schedule

1. Details and output of the intervention, including:

- · Name and contact information for the intervention developer;
- Funding source of the technical implementation for the intervention(s) development;
- Description of value that the intervention produces as an output; and
- Whether the intervention output is a prediction, classification, recommendation, evaluation, analysis, or other type of output.

4. Intervention development details and input features, including at a minimum:

- Exclusion and inclusion criteria that influenced the training data set:
- Use of variables in paragraph (b)(11)(iv)(A)(5)-(13) as input features;
- Description of demographic representativeness according to variables in paragraph (b)(11)(iv)(A)(5)-(13) including, at a minimum, those used as input features in the intervention;
- Description of relevance of training data to intended deployed setting.

7. Quantitative measures of performance, including:

- Validity of intervention in test data derived from the same source as the initial training data;
- Fairness of intervention in test data derived from the same source as the initial training data;
- Validity of intervention in data external to or from a different source than the initial training data;
- Fairness of intervention in data external to or from a different source than the initial training data;
- References to evaluation of use of the intervention on outcomes, including, bibliographic citations or hyperlinks to evaluations of how well the intervention reduced morbidity, mortality, length of stay, or other outcomes.

2. Purpose of the intervention, including:

- Intended use of the intervention;
- Intended patient population(s) for the intervention's use;
- Intended user(s); and
- Intended decision-making role for which the intervention was designed to be used/for (e.g., informs, augments, replaces clinical management).

3. Cautioned out-of-scope use of the intervention, including:

- Description of tasks, situations, or populations where a user is cautioned against applying the intervention; and
- Known risks, inappropriate settings, inappropriate uses, or known limitations.

5. Process used to ensure fairness in development of the intervention, including:

- Description of the approach the intervention developer has taken to ensure that the intervention's output is fair; and
- Description of approaches to manage, reduce, or eliminate bias.

8. Ongoing maintenance of intervention implementation and use, including:

- Description of process and frequency by which the intervention's validity is monitored over time;
- Validity of intervention in local data;
- Description of the process and frequency by which the intervention's fairness is monitored over time:
- Fairness of intervention in local data.

6. External validation process, including:

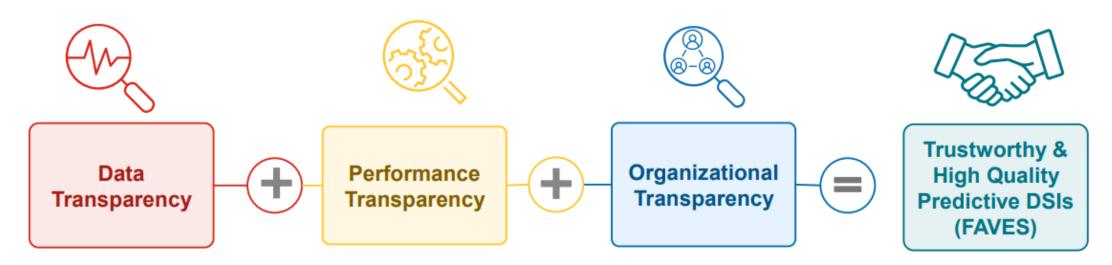
- Description of the data source, clinical setting, or environment where an intervention's validity and fairness has been assessed, other than the source of training and testing data;
- Party that conducted the external testing;
- Description of demographic representativeness of external data according to variables in paragraph (b)(11)(iv)(A)(5)-(13) including, at a minimum, those used as input features in the intervention; and
- Description of external validation process.

9. Update and continued validation or fairness assessment schedule, including:

- Description of process and frequency by which the intervention is updated; and
- Description of frequency by which the intervention's performance is corrected when risks related to validity and fairness are identified.

[ADVENTISTHEALTH:INTERNAL]

Transparency Is a Prerequisite for Trustworthy Al



Data Transparency

Requirements enable users to know when a DSI uses specific data elements relevant to health equity

Performance Transparency

Enable users to have consistent and routine electronic access to technical, and performance information on Predictive DSIs

Organizational Transparency

Requirement for Certified Health IT developers to apply intervention risk management for each Predictive DSI they supply as part of their Health IT Module

Resources Available on HealthIT.gov!

Visit https://healthIT.gov/HTI-1 for additional information.

Fact Sheets

- General Overview
- Final Rule At-a-Glance
- Decision Support Interventions and Predictive Models
- Insights Condition
- HTI-1 Information Blocking
- HTI-1 Key Dates

Measurement Spec Sheets

For each of the Insights Condition measures







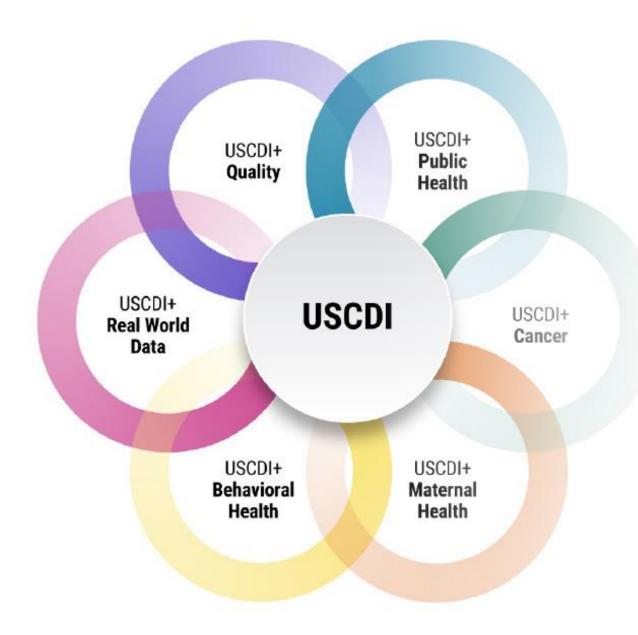
How HHS is Aligning Health IT Policies

HIMSS24

Wednesday, March 13, 2024

11:45am - 12:05pm





USCDI+: Extending Beyond the USCDI

USCDI+: Extending Beyond the USCDI

- Unique program and use case-specific data needs are sometimes not fully met by USCDI.
- Helps government and industry partners build on USCDI to support specific program needs.
- Applies USCDI processes for submission and harmonization while focusing on programmatic priorities.
- Seeks to leverage programs and authorities across HHS to drive adoption.
- USCDI+ for Quality Measurement and Public Health kicked off with CDC, CMS & HRSA.

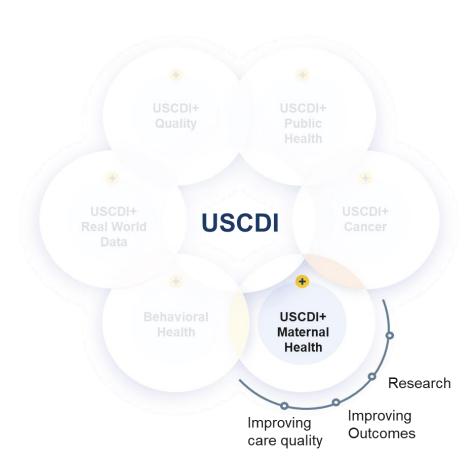
ONC is advancing USCDI+ efforts with support and input from federal and industry partners including and not limited to:

- The Assistant Secretary for Preparedness and Response (ASPR)
- The Centers for Medicare & Medicaid Services
- The Centers for Disease Control and Prevention
- The Health Resources and Services Administration
- The National Institutes of Health
- The National Cancer Institute
- The U.S. Food and Drug Administration
- The Substance Abuse and Mental Health Services Administration

USCDI+ Maternal Health

- Goals of Proposed Maternal Health Dataset
 - Establish a core set of data necessary for high quality care, equitable outcomes, and maternal health research
 - Advance care delivery and research during the prenatal, birth, and postpartum periods
 - Facilitate standard implementation and support of core data for maternal health care within:
 - One or more implementation guides
 - Healthcare technology systems
- Dataset Inclusion or Exclusion Considerations
 - Importance for promoting high quality care and addressing care gap
 - Likelihood of data availability through routine documentation
 - Potential implementation burden (e.g., electronic capture in discrete, structured fields)
 - Exploration of emerging use cases (e.g., SDOH, SOGI, Respectful Care/Care Experience)

Currently Open for comment until July 31



USCDI+ Maternal Health Draft Dataset

32 Data Classes, 222 Data Elements

The number of data elements per data class is represented in the parenthesis

Advance Directives (4)
Adverse Event (4)
Allergies and Intolerances (6)
Behavioral Health (4)
Care Team Member(s) (6)
Clinical Notes (11)
Clinical Tests (2)
Diagnostic Imaging (2)
Encounter Information (7)
Facility Information (4)
Family Health History (1)

Newborn's Delivery Information (11)
Patient Demographics (24)
Patient Summary and Plan (1)
Postpartum (8)
Pregnancy Information (15)
Problems (6)
Procedures (8)
Provenance (2)
/ital Signs (15)
Work Information (5)

New HHS Policy on Alignment of Health IT Activities

Interoperability

E Pluribus Unum

Micky Tripathi and Steven Posnack | AUGUST 5, 2022











As our nation transitions to a digital healthcare system, our stakeholders are discovering new opportunities for using health information technology to advance health care delivery, public health, and research to improve people's lives. The federal government is no exception in this regard; agencies across the Department of Health and Human Services (HHS) are beginning to leverage the data and capabilities available through electronic health records for a broad range of federal activities and programs, including product safety and surveillance, real world data and real world evidence for regulatory approvals, research, pandemic response, and social service integration, to name just a few.

While this is an exciting development for HHS overall, it does call for more proactive alignment and coordination of health IT activities across the department to ensure that we are operating as efficiently and cohesively as possible. To that end, Secretary Becerra has put into place a department-wide management policy directing ONC to engage with HHS agencies to align and coordinate health IT-related activities in support of HHS health IT and interoperability goals. Specifically, the secretary has directed ONC to establish and oversee a consistent HHS-wide approach for: 1) incorporating standard health IT requirements language in all applicable HHS funding programs, contracts, and policies; and 2) providing direct ONC assistance to HHS agencies to maximize the use of HHS-approved standards and authorities (such as Section 3004 of the Public Health Service Act) in their agency

While it won't happen overnight, what we expect to see over time is greater consistency in health IT-based activities across HHS, which should result in lower cost and higher effectiveness agency programs, more sharing of data and health IT infrastructure across programs and agencies, and lower burden on health care providers, technology developers, and other stakeholders who engage with multiple HHS agencies. Maximizing federal use of open-industry, non-proprietary, scalable standards and approaches - such as the US Core Data for Interoperability (USCDI) and FHIR APIs as called for by the 21st Century Cures Act - will multiply the impact of the department's regulations and purchasing power to reinforce HHS health IT and interoperability goals. It will also directly support key Biden-Harris Administration priorities in health equity, federal customer experience and service delivery, and promoting competition. ONC already works collaboratively with our federal agency partners, and we are excited to be able to better support our sister HHS agencies and ensure that HHS is more than the sum of its parts.

- HHS Health IT Alignment Policy established in July 2022
- Secretary directs ONC to establish and oversee a consistent HHS-wide approach for:
 - 1. incorporating standard health IT requirements language in all applicable HHS funding programs, contracts, and policies; and
 - 2. providing direct ONC assistance to HHS agencies to maximize the use of HHS-approved standards and authorities





OCAIO's Primary Function:

- Drive implementation of the HHS AI strategy
- Stand up the HHS AI governance structure
- Coordinate the HHS response to Al-related federal mandates
- Foster collaboration across HHS agencies and offices

Interoperability Standards Advisory (ISA)

Annual comment period is open until August 12, 2024 for the 11th Annual ISA Reference Edition in January 2025

The ISA is organized and structures into four sections:

- Vocabulary/Code Sets/Terminology Standards and Implementation Specifications (i.e., "semantics").
- Content/Structure Standards and Implementation Specifications (i.e., "syntax").
- Standards and Implementation Specifications for Services and Exchange (i.e., the infrastructure components deployed and used to address specific interoperability needs)
- Administrative Standards and Implementation Specifications (i.e., payment, operations and other "non-clinical" interoperability needs)

Leading Edge Acceleration Projects (LEAP)

FY 2024 Special Emphasis Notice of Funding Opportunity:

Area of Interest 1: Develop innovative ways to evaluate and improve the quality of healthcare data used by artificial intelligence (AI) tools in healthcare

Area of Interest 2: Accelerate adoption of health information technology in behavioral health

The application period closes July 12, 2024, at 12:00PM ET.

Notice of Funding Opportunity – Assessing Use of Health IT by US Physicians Providing Outpatient Care



The application period closes on July 22, 2024 at 12:00PM ET.

- Assess extent to which physicians use interoperable health IT and their experience using that technology to support effective care of their patients
- Provide insights into whether Federal policy is having the intended effect of leading better health enabled by data and to highlight remaining challenges, inadequacies, and pain points
- Inform ongoing policy and coordination work by ONC to address remaining barriers to the widespread use of interoperable health IT



Thank you!!

Contact ONC

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Health IT Feedback Form:
https://www.healthit.gov/form/
healthit-feedback-form

Twitter: @onc_healthIT

in LinkedIn: Office of the National Coordinator for Health Information Technology

Youtube:
https://www.youtube.com/user/HHSONC



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