

Revised Draft Health Information Technology Advisory Committee (HITAC) Annual Report for Fiscal Year 2020

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Executive Summary

The 21st Century Cures Act (Cures Act) requires the Health Information Technology Advisory Committee (HITAC) to develop an annual report to be submitted to the Secretary of the U.S. Department of Health and Human Services (HHS) and to Congress each fiscal year. This report complies with that directive by reviewing fiscal year 2020 (FY20) HITAC activities, describing the landscape of health information technology (IT) infrastructure across target areas, analyzing infrastructure gaps, and offering recommendations for future HITAC activities.

HITAC Progress in FY20

The Cures Act directs the HITAC to make recommendations to the National Coordinator for Health IT regarding policies, standards, implementation specifications, and certification criteria related to the implementation of a health IT infrastructure, nationally and locally, that advances the electronic access, exchange, and use of health information.

The full committee, through the work of several subcommittees, developed recommendations to support the work of the Office of the National Coordinator for Health IT (ONC) required by the Cures Act. In FY20, the subcommittees included the:

- Annual Report Workgroup
- Interoperability Standards Priorities (ISP) Task Force
- Intersection of Clinical and Administrative Data (ICAD) Task Force
- U.S. Core Data for Interoperability (USCDI) Task Force

Health IT Infrastructure Landscape

The Cures Act specifies three priority target areas within which the HITAC should focus its activities: interoperability, privacy and security, and patient access to information. The Cures Act also defines certain additional target areas for the HITAC's consideration, including the use of technologies that support public health. These target areas are a key principle for classifying the HITAC's work and organizing this report.

Federal Activities across the Target Areas

In FY20, there were considerable health IT advancements throughout various agencies of the federal government. ONC released a final rule to implement provisions in Title IV of the Cures Act, called the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule (hereafter, referred to as the ONC Cures Act Final Rule). ONC also collaborated with 25 federal organizations to release the 2020-2025 Federal Health IT Strategic Plan (Strategic Plan). The Centers for Medicare & Medicaid Services (CMS) released a final rule to improve interoperability and expand patients' access to their health information. Several other federal activities addressed the HITAC's priority target areas including efforts to promote price transparency by hospitals and payers, the Food and Drug Administration's (FDA) Technological Modernization Action Plan, and the federal response to the COVID-19 pandemic.





Target Area: Use of Technologies that Support Public Health

The COVID-19 pandemic has highlighted the intersection of health IT, public health, and clinical care during a public health emergency. There has been widespread innovation to combat the pandemic, such as the roll-out of COVID-19 electronic case reporting, health information exchange notifications, CommonPass, and The Situational Awareness for Novel Epidemic Response (SANER) Project. However, the pandemic has also exposed deep, systemic gaps within the nation's public health and interoperability infrastructure presenting an opportunity to improve bidirectional information sharing between the clinical and public health communities and therefore enable increased coordination between federal, state, and local public health agencies.

Target Area: Interoperability

Although most clinicians now use electronic health records (EHRs), interoperability remains somewhat fragmented, variable across stakeholder groups, and several barriers need to be addressed. These barriers include areas where standards are lacking or there is limited adoption of existing standards. These barriers are hindering data exchange with the research community and across the care continuum, and adversely affecting the ability to track important information such as social determinants of health (SDOH) data. Additionally, tracking and sharing health information to support health equity initiatives, tracking adverse patient safety events, and attending to the needs of additional care settings are also essential to the success of the nation's health IT infrastructure.

Target Area: Privacy and Security

Privacy and security of health data are important considerations in advancing and maintaining trust in the healthcare delivery system and the electronic sharing of health information. Health data generated and/or stored outside the protection of federal privacy laws are growing, and patients are often unaware that some of their health data are not protected by laws such as the Health Insurance Portability and Accountability Act (HIPAA). There continues to be confusion among patients and clinicians about the rules for sharing data and when patient consent is required.

Target Area: Patient Access to Information

Patient access to health information can have a positive impact on health, healthcare, and health equity by supporting shared decision-making between patients, their caregivers, and clinicians. Continued education, improved accessibility, and increased use of application programming interfaces (APIs) and patient-generated health data (PGHD) are needed to increase patients' ability to safely and securely access, share, and use their data. Patients often have trouble correcting incorrect data in their health records and that data may be shared with other clinicians, perpetuating any errors across the health information ecosystem.





Health IT Infrastructure Gaps, Opportunities, and Recommendations

The Cures Act requires an analysis identifying existing gaps in policies and resources for achieving the ONC objectives and benchmarks and furthering interoperability throughout the health IT infrastructure, as well as recommendations for addressing the gaps identified. The HITAC has focused on key gaps and opportunities for the health IT industry and has recommended a set of related HITAC activities that act as a repository of ideas for future consideration.

The following table summarizes the HITAC’s assessment. Within each target area, topics are grouped by the timeliness of the opportunity to be addressed by the HITAC. An immediate opportunity correlates to planned topics for the HITAC within the next one to two years, i.e., calendar years 2021-22, while longer-term opportunities are anticipated to begin in three or more years, i.e., calendar year 2023 or later.

Topic	Key Gaps	Key Opportunities	Recommended HITAC Activities
Target Area: Use of Technologies that Support Public Health			
Immediate Opportunities			
Bidirectional exchange of clinical and administrative data for public health purposes	Public health authorities face interoperability challenges to be able to collect, access, and use information, as well as exchange it bidirectionally between clinicians and laboratories, particularly data needed for proper reporting.	<ol style="list-style-type: none"> 1. Improve bidirectional interoperability between public health information systems and EHRs. 2. Accelerate use of data standards to improve situational awareness for federal, state, and local government emergency response. 3. Explore an expanded role for Health Information Exchanges (HIEs) to support public health data access and exchange. 	<ol style="list-style-type: none"> 1. Encourage further support for the identification and exchange of minimum necessary datasets and consideration of technical requirements for exchange for public health, e.g., with laboratories, especially for test order entry, results, and case reporting. Additionally, encourage further support for the development of standards for population-level data exchange. 2. Identify interim solutions implemented to improve reporting capabilities and assess whether additional long-term solutions are needed. 3. Compile a set of useful health IT resources to raise awareness among public health organizations. 4. Facilitate acceleration of the practical use of data standards to improve situational awareness for local, state, and federal government public health emergency response. 5. Learn about the successes and remaining barriers to exchange by HIEs to support public health’s geographically oriented information needs, including how to optimize, standardize, and potentially expand their role and address regional differences in capacity to address any gaps. Identify approaches to combine data from national health information networks (HINs) to address regional public health data needs.
Privacy and security for public health purposes	Biosurveillance efforts, including case investigation, contact tracing, and proximity notification, as well as increased use of telehealth and remote monitoring face privacy and security issues.	<ol style="list-style-type: none"> 1. Discuss the tradeoffs between increasing interoperability, protecting privacy and security, and ensuring public safety during pandemics. 2. Increase the clarity about the privacy and security concerns associated with biosurveillance activities. 	<ol style="list-style-type: none"> 1. Help clarify what data can be collected and how it can be used. 2. Encourage clinical workforce and patient education/re-education on the use of technology for telehealth (including smartphones). 3. Identify educational approaches that offer improved transparency of privacy protections applicable to contact tracing applications and biosurveillance technologies such as contact tracing and exposure notification apps. 4. Encourage the development of guidance about and harmonization of privacy and security protections of mobile health data used for public health across varying state and local laws.





Topic	Key Gaps	Key Opportunities	Recommended HITAC Activities
Vaccine Tracking	Pre-COVID-19, questions arose about how various public health organizations might be able to monitor unimmunized populations, where patients are obtaining vaccines, and if others (e.g., payers) can access that data. The pandemic has greatly increased the need for health data collection and bidirectional exchange to support vaccine administration.	Investigate whether predictive analytics can be used to a) aggregate and analyze this data to anticipate needs for vaccines among vulnerable and/or high-risk populations, including for flu and COVID-19 prevention, and b) better target outreach, education, and response efforts and strategies.	<ol style="list-style-type: none"> 1. Identify opportunities and barriers for healthcare, home and community-based service (HCBS), and public health organizations to work together to target vulnerable populations for vaccination campaigns, highlight successful predictive analytics, and assess how health IT can better support a balance of vaccine data being pushed vs. pulled for public health purposes. 2. Encourage needed improvements to community registries for easier exchange and use, e.g., increased normalization and standardization of data.
Patient matching for public health purposes	Patient matching challenges exist due to gaps in information (particularly demographic) shared from commercial laboratories and contact tracing records, and lack of a unique patient identifier (UPI).	<ol style="list-style-type: none"> 1. Improve patient matching through expanded use of artificial intelligence (AI) while considering privacy and security concerns about AI algorithms, in order to accurately identify patients and locate at-risk individuals. 2. Increase alignment across federal, state, and local public health reporting requirements and guidance to support improved collection and consistency of demographic data. 	Develop tactical recommendations based on ONC's forthcoming Patient Matching Report to Congress, including consideration of expanded use of AI and related privacy and security concerns as well as increased alignment of government public health reporting requirements and guidance.
Longer-Term Opportunities			
International exchange of clinical data for public health purposes	Currently, countries are imposing significant restrictions on the movement of people and goods to ensure public safety, in part due to a lack of information about the health status of travelers.	Share and apply lessons learned across many countries about the use of health IT to support public health, e.g., for electronic case reporting.	Identify opportunities and barriers for the use of health IT in support of compliance with international health regulations and international data exchange. Experts to be consulted could include the Centers for Disease Control and Prevention (CDC), World Health Organization (WHO), Global Digital Health Partnership (GDHP), Department of Commerce, clinician representatives, and privacy and security experts.
Target Area: Interoperability			
Immediate Opportunities			
Exchange of health data more broadly across the care continuum	Interoperability needs to be increased across the broader care continuum.	Collection of more complete data about a patient will help clinicians identify risk factors for procedures, offer interventions, and provide targeted care. In particular, the Interoperability Standards Priorities Task Force	<ol style="list-style-type: none"> 1. Learn more about recent developments in standards and exchange in the areas of patient-reported outcomes (PROs), e.g., 2020 Agency for Healthcare Research and Quality (AHRQ) report, and SDOH data such as Health Level 7's (HL7®) Gravity project.





Topic	Key Gaps	Key Opportunities	Recommended HITAC Activities
		<p>identified a need for specialty-specific minimum standards to enable closed loop referrals and data exchange between clinicians.</p>	<ol style="list-style-type: none"> 2. Identify and help improve data streams where interoperability is a challenge to sharing broader datasets, especially when a pandemic affects healthcare settings like long-term post-acute care (LTPAC) and any transitions to and from those settings. For example, various care and community settings would benefit from increased consensus on datasets for exchange with that setting. 3. Leverage the current federally mandated assessment instruments as the basis for a shared, semantically interoperable dataset.
<p>Increased health equity across populations, locations, and situations</p>	<p>Data are not systematically collected nor used to identify disparities in care, outcomes, and risk. Non-traditional sources of health data exist that have not yet been mined nor shared to support more equitable distribution of health resources.</p>	<ol style="list-style-type: none"> 1. Advance requirements to collect and share data about groups experiencing health inequities. This data can be used to support the implementation of culturally and linguistically appropriate health IT solutions. 2. Identify non-traditional sources of health information that could be made interoperable, e.g., primary care doctors receive updates electronically from organizations offering exercise classes for seniors, school clinics, or third-party wellness services. 	<p>Convene stakeholders, e.g., healthcare organizations, health IT developers, and patient advocacy groups, to discuss:</p> <ol style="list-style-type: none"> a. How to improve the collection and sharing of data that can support identifying and addressing disparities in healthcare, e.g., race codes. b. The current state of and potential improvements for the accessibility of consumer-facing health IT by diverse populations. c. Non-traditional sources of health information that could be made interoperable to better serve at-risk populations.
<p>Exchange of SDOH data</p>	<p>Business models across healthcare sectors do not yet support the capture and use of SDOH data due to a lack of standards and data availability, patient matching challenges, and varying levels of technical maturity of community service providers' IT systems.</p>	<p>Develop and adopt standards for SDOH data collection, transfer, and integration for population health and individuals' needs.</p>	<ol style="list-style-type: none"> 1. Suggest updates on SDOH data to the ONC Patient Engagement Playbook. 2. Convene a group of stakeholders from healthcare entities, payers, SDOH technology companies, community-based organizations, and standards development projects to understand the state of SDOH data exchange in practice and identify gaps and barriers. 3. Suggest SDOH data elements for inclusion in the USCDI.
<p>Coordination of health IT standards to support interoperability: Priority Uses</p>	<p>The HITAC annual review and publication of priority uses of health IT and existing standards and implementation specifications related to the priority uses required by the Cures Act should be implemented.</p>	<p>Building on the prior work of the HITAC, establish an annual process for reviewing and publishing priority uses of health IT and related standards and implementation specifications.</p>	<p>Each year, review and publish priority uses of health IT and related standards and implementation specifications.</p>





Topic	Key Gaps	Key Opportunities	Recommended HITAC Activities
Coordination of health IT standards to support interoperability: USCDI	HITAC members often make suggestions for additions to the USCDI, but currently must submit them to ONC as an individual.	A new system exists for individuals to submit suggestions to ONC for consideration for the USCDI, called ONDEC, but some suggestions would benefit from public discussion by the HITAC first.	As needed, collect and discuss suggestions for consideration for inclusion in the USCDI.
Longer-Term Opportunities			
Association between EHRs and patient safety	The use of health IT can impact patient safety.	Define factors that increase and decrease the safety of health IT that affects patient outcomes.	<ol style="list-style-type: none"> 1. Review changes that could be made to the Health IT Certification Program to support improvements to EHRs to support patient safety. 2. Help further define patient safety and any gaps where technology does not support that definition. 3. Explore the use of health IT in automating the collection and sharing of data about adverse events for drugs and devices.
Sharing data with the research community	Researchers are challenged by data quality and consistency concerns, limited governance structures and policies allowing access to the data, inconsistent implementations across technical architectures, and varying needs of individuals and organizations that create and use data.	Increase alignment between the clinical and research health information ecosystems to enable prospective and ongoing research to happen more quickly and effectively.	<ol style="list-style-type: none"> 1. Learn more about gaps in new and existing standards needed by the research community, which is accountable to institutional review boards (IRBs). 2. Identify educational approaches that increase awareness and promote the implementation of the research priorities outlined in the National Health IT Priorities for Research: A Policy and Development Agenda.
Sharing data with the research community: Metadata	Many data management tasks are burdensome because they are manual and require human labor for reconciliation that could be automated.	Determine the type(s) of metadata and related standards necessary to facilitate machine-based, clinical data management, including management of exchanged data to reconcile data from multiple sources.	Identify needed metadata standards and potential additions to the USCDI.
Target Area: Privacy and Security			
Immediate Opportunities			
Beyond HIPAA: Rules for Sharing	Clear rules are lacking for data not subject to HIPAA protections.	Support increased transparency and patient education on business practices and other potential uses of patient health data when healthcare organizations share or license data to technology companies.	Define the roles, responsibilities, and operations of various technical actors in the app economy, building on work completed by a past FACA subcommittee. These technical actors include clinicians, developers, and patients.





Topic	Key Gaps	Key Opportunities	Recommended HITAC Activities
Beyond HIPAA: Patient Consent	A lack of clarity exists about the parameters for data sharing and disclosure, and their implications for consent.	In the near term, improve clarity around patient consent for research and exchange of their data, and further patient understanding of the accuracy and validity of clinical information offered by third-party applications (apps).	Suggest steps toward a consistent technical and operational approach to capturing and managing consent.
Longer-Term Opportunities			
Beyond HIPAA: Rules for Sharing	Clear rules are lacking for data not subject to HIPAA protections.	Support increased transparency and patient education on business practices and other potential uses of patient health data when healthcare organizations share or license data to technology companies.	<ol style="list-style-type: none"> 1. Learn more about HHS and Federal Trade Commission (FTC) activities, as well as security approaches of or any security lapses by third-party app developers. 2. Explore patient and clinician experiences with the sharing of health data with third-party technology companies to continue to identify best practices and gaps. 3. Review government and industry activities already underway protecting the privacy and security of health data shared with third-party technology companies.
Beyond HIPAA: Patient Consent	A lack of clarity exists about the parameters for data sharing and disclosure, and their implications for consent.	Over time, improve clarity around patient consent for research and exchange of their data, and further patient understanding of the accuracy and validity of clinical information offered by third-party apps.	<ol style="list-style-type: none"> 1. Identify educational approaches and potential regulatory solutions that offer improved transparency of privacy protections outside the purview of HIPAA. 2. Explore ways clinicians can educate patients about the benefits and potential risks of using third-party apps as contemplated by the ONC Cures Act Final Rule and about the need to review and comprehend the apps' privacy policies.
Beyond HIPAA: Internet of Things (IoT)	There is limited interoperability across IoT vendors. As IoT objects become more integrated with health IT systems, security risks increase. Additional concerns have been raised regarding the challenges of informed consent for users of IoT technologies.	Increase awareness of the privacy and security risks of using the IoT to collect health-related data.	<ol style="list-style-type: none"> 1. Identify best practices for increasing the privacy and security of health-related data collected from connected devices. 2. Identify educational approaches that increase awareness of the privacy and security issues for health-related data collected from devices connected to the IoT and ways to reduce them.
Privacy and security of synthetic data	HIPAA constraints limit the ability to conduct research and train machine learning models using large-scale datasets, in both research and healthcare settings.	Explore whether the use of synthetic health data raises privacy and security issues and, if so, to what extent.	Assess whether the use of synthetic data raises any unintended privacy risks, such as the ability to use AI to re-identify the actual patients on whom the synthetic health data are based.





Topic	Key Gaps	Key Opportunities	Recommended HITAC Activities
Target Area: Patient Access to Information			
Immediate Opportunities			
<p>Safety and impact of mobile health applications</p>	<p>Existing concern about the clinical accuracy of mobile apps and the potential for patient harm is increasing.</p>	<p>Provide reliable information about the quality of apps to enable clinicians to advise patients about app use and to empower patients when using apps to make decisions about their care.</p>	<ol style="list-style-type: none"> 1. Support the existing efforts of consortia that are working to vet apps based on their safety and accessibility and educate patients about the findings of the consortia. In particular, investigate if frameworks or scorecards for assessing apps exist or are being developed; if so, raise awareness of these efforts. 2. Explore ways the safety of mobile health applications could be enhanced. 3. Evaluate the impact of the use of apps (as opposed to the current portal systems) on patient challenges in collecting, accessing, using, and sharing their health data. Areas to consider include the efficacy, patient experience, and remaining challenges of the use of apps.
<p>Correction of incorrect clinical data and the ramifications of exchange of this data</p>	<p>Today, there is a limited ability to correct data that has already been exchanged. As a result, these incorrect data might persist and be further disseminated. Transparency about the accuracy of patient data and consent to share it are lacking for patients, which in turn affects patient safety.</p>	<p>Increase clarity on the applicable statutes and liability that apply to the exchange of incorrect data, and on methods for correction.</p>	<ol style="list-style-type: none"> 1. Identify approaches that clinicians and HIEs are taking to correct incorrect data, including incentives for widespread correction. 2. Discuss liability considerations related to exchanging and correcting incorrect data. 3. Learn about organizational policies and mechanisms for patients to document change requests, and how data provenance of patient corrections is being tracked.





Illustrative Stories of What the Recommended HITAC Activities Will Enable

Target Area: Use of Technologies that Support Public Health

A patient who lives in a rural county underwent a nasal swab test for COVID-19 at a county-run public testing site and received a positive result while still at the site, which was also reported to the state public health agency. However, key demographic data were not collected for the patient so timely contact tracing and notification of proper quarantine conduct could not be undertaken. As a result of improved patient matching techniques, the state public health agency has begun investigating artificial intelligence-based solutions to improve its ability to conduct patient matching and to use other data sources to fill in missing demographic information to increase the precision of case reporting and subsequent vaccination programs.

Target Area: Interoperability

An academic medical center wants to use its clinical data for population health purposes and community outreach. It finds that it needs to capture more patient demographic data to be able to identify health disparities and implement community benefit programs. The academic medical center institutes a new process based on recommended best practices to collect standardized, patient-reported demographic data such as race, ethnicity, gender identity, and preferred language. Applying appropriate privacy protections, it then shares this data with social service organizations to improve care and outreach in its service area as well as with public health organizations and state agencies to support public health efforts.

Target Area: Privacy and Security

Several of an internist's patients have asked her to accept some of the electronic data collected on their fitness trackers so that she can monitor their weight and activity levels as they start new exercise programs. She is hesitant at first because she is not familiar with the privacy and security risks of devices connected to the IoT and how these risks might compromise her EHR system. Luckily, best practices for developers have been identified to increase the privacy and security of health-related data collected from connected devices. Additionally, tools to increase awareness of the risks of connected devices have been made available to healthcare providers. As a result of outreach efforts, the internist accesses relevant guidelines and takes steps to reduce the privacy and security risks of receiving information from the IoT while more effectively partnering with her patients.

Target Area: Patient Access to Information

As a result of public deliberation about improving the governance process, data correction requests from patients are addressed more quickly and seamlessly. For example, a patient notices in her patient portal that a medication dosage is listed incorrectly. Fortunately, she can easily report this error to her primary care provider using the portal. Once the provider verifies and corrects the error, the patient's entire care team is automatically notified of the change electronically, including specialists outside her network who use different EHRs. In this case, the correction was made widely within a week of the patient reporting the error rather than over several weeks, if at all. The medication dosage was listed correctly in her medical record the next time she had an appointment with one of her specialists, thereby avoiding the adverse event of a drug-drug interaction.





Foreword

We are pleased to present the annual report of the Health Information Technology Advisory Committee (HITAC) for FY20.

This report describes the work undertaken by the HITAC during its third year. The HITAC was formed by the Cures Act and is governed by the Federal Advisory Committee Act. The HITAC is a federal advisory committee composed of members representing hospitals and health systems, healthcare providers, health information exchanges, insurers, health IT developers, universities, and federal agencies, as well as patients and consumers. Working together, HITAC members make recommendations about policies, standards, implementation specifications, and certification criteria to the National Coordinator for Health Information Technology within HHS.

In this report, the HITAC evaluates the health IT infrastructure landscape of the United States for gaps, opportunities, and recommendations. The committee focused its evaluation in four target areas: technologies that support public health, interoperability, privacy and security, and patient access to Information. In FY20, the HITAC published reports on priority uses of health IT and on the intersection of clinical and administrative data. The HITAC also transmitted recommendations on the USCDI Data Element Promotion Model. Several areas for future HITAC work were surfaced during the HITAC meetings in FY20, and robust discussion among the members yielded several areas for potential activity in FY21 and beyond.

We wish to acknowledge and appreciate all the hard work done by committee members and additional members of the public serving on the HITAC subcommittees, as well as by committee members participating in the deliberations of the committee as a whole. In addition, we thank the staff of ONC and the other federal agencies that support the HITAC.

It has been our privilege to serve as co-chairs for the HITAC from 2018 through 2020. The commitment and diverse expertise of the HITAC members have brought both energy and insight to this evaluation of the U.S. health IT infrastructure. We look forward to another busy year as we continue to identify and promote use of better information and technology to improve care delivery and the health and well-being of everyone in the United States.

Carolyn Petersen and Robert Wah
Co-Chairs, Health Information Technology Advisory Committee during FY20*

* Two new HITAC co-chairs began their terms on January 1, 2021: Aaron Miri and Denise Webb. However, this foreword was authored by the prior co-chairs, Carolyn Petersen and Robert Wah, who led the HITAC during its FY20 activities.





Overview

LEGISLATIVE REQUIREMENTS

In December 2016, Congress passed the Cures Act, P.L. 114-255, with a bipartisan majority. The Cures Act created the HITAC, which is governed by the provisions of the Federal Advisory Committee Act (FACA), P.L. 92 - 463, as amended, 5 U.S.C. App. 2. The HITAC makes recommendations to the National Coordinator for Health IT about policies, standards, implementation specifications, and certification criteria relating to the implementation of a health IT infrastructure, nationally and locally, that advances the electronic access, exchange, and use of health information.

The Cures Act requires the HITAC to develop an Annual Report to be submitted to the Secretary of Health and Human Services and Congress each fiscal year (FY). The annual report must provide:

- Analysis of HITAC progress related to the target areas;
- Assessment of health IT infrastructure and advancements in the target areas;
- Analysis of existing gaps in policies and resources for the target areas; and
- Ideas for potential HITAC activities to address the identified gaps.

HITAC TARGET AREAS

Section 4003(e) of the Cures Act established the following priority target areas for the HITAC:

- **Interoperability** - “Achieving a health information technology infrastructure, nationally and locally, that allows for the electronic access, exchange, and use of health information, including through technology that provides accurate patient information for the correct patient, including exchanging such information, and avoids the duplication of patient records.”
- **Privacy and Security** - “The promotion and protection of privacy and security of health information in health information technology, including technologies that allow for an accounting of disclosures and protections against disclosures of individually identifiable health information made by a covered entity for purposes of treatment, payment, and healthcare operations (as such terms are defined for purposes of the regulation promulgated under section 264(c) of HIPAA), including for the segmentation and protection from disclosure of specific and sensitive individually identifiable health information with the goal of minimizing the reluctance of patients to seek care.”
- **Patient Access to Information** - “The facilitation of secure access by an individual to such individual’s protected health information and access to such information by a family member, caregiver, or guardian acting on behalf of a patient, including due to age-related and other disability, cognitive impairment, or dementia.”
- **Any other priority target area** that the HITAC identifies as an appropriate target area to be considered. In FY20, the HITAC did not identify a need for additional priority target areas as defined in the Cures Act. The HITAC will revisit this consideration in the FY 2021 (FY21) annual report.

Section 4003(e) of the Cures Act established additional target areas for the HITAC, including the use of technologies that support public health.





ONC OBJECTIVES AND BENCHMARKS

As required by the Cures Act, ONC established a set of objectives and benchmarks against which to measure the advancement of the priority target areas during FY19-FY20, outlined below.

ONC Objectives in FY19-20

1. Advance the development and use of health IT capabilities
2. Establish expectations for data sharing

ONC Benchmarks in FY19-20

ONC Activity	ONC Benchmark*	Progress in Meeting in FY19-20
Publish final rule covering secure, standards-based APIs for patients to access their medical records and information blocking exceptions.	<ul style="list-style-type: none"> • Final rule published 	<ul style="list-style-type: none"> • The ONC Cures Act Final Rule was published on May 2, 2020. • The ONC Cures Act Interim Final Rule with Comment Period was published on November 4, 2020.
Publish TEFCA to support exchange.	<ul style="list-style-type: none"> • RCE cooperative agreement awarded. • Final Trusted Exchange Framework published. • Draft Common Agreement made available for public comment. 	<ul style="list-style-type: none"> • ONC awarded the cooperative agreement for the RCE on September 3, 2019. • ONC published the first draft of Trusted Exchange Framework on January 5, 2018, and the second draft on April 19, 2019. The final version is expected to be published in FY21-22. • The draft Common Agreement is expected to be made available for public comment in FY21-22.
Coordinate health IT standards and certification to support interoperability.	<ul style="list-style-type: none"> • The HITAC final report on priority uses of health IT and associated standards and implementation specifications transmitted to the National Coordinator for Health IT. • The HITAC recommendations on the USCDI Data Element Promotion Model transmitted to the National Coordinator for Health IT. • HL7® published Fast Healthcare Interoperability Resources (FHIR®) Release 4 (R4), updated US Core Profiles for R4, and published a Bulk Data Access Implementation Guide. 	<ul style="list-style-type: none"> • The HITAC Interoperability Standards Priorities Task Force addressed three Priority Use Cases (Orders & Results, Closed Loop Referrals & Care Coordination, and Medication & Pharmacy Data) with detailed recommendations included in the final report transmitted to the National Coordinator on December 9, 2019 • The HITAC transmitted recommendations on the USCDI Data Element Promotion Model to the National Coordinator on December 9, 2019. • HL7® published FHIR® R4, updated US Core Profiles for R4, and published a Bulk Data Access Implementation Guide in 2019.

* To date, ONC has defined the HITAC benchmarks as standalone measures rather than comparisons to an established industry standard of excellence. Infrastructure advancements compared to a baseline may be assessed in future annual reports.





HITAC Progress in FY20

Summary of HITAC Subcommittee Meetings and Recommendations

The Cures Act directs the HITAC to make recommendations to the National Coordinator for Health IT regarding policies, standards, implementation specifications, and certification criteria relating to the implementation of a health IT infrastructure, nationally and locally, that advance the electronic access, exchange, and use of health information.

Overall Accomplishments in FY20

The HITAC's focus in FY20 was on developing interoperability standards priorities recommendations and evaluating the intersection of clinical and administrative data. The HITAC held nine public meetings of the full committee, including a special meeting on the COVID-19 pandemic response, and 45 public meetings of the task forces and workgroups. The HITAC delivered 52 recommendations to the National Coordinator for Health IT.

The charges and accomplishments of the subcommittees are as follows:

Annual Report Workgroup

The Cures Act requires the HITAC to develop an annual report to be submitted to the Secretary of Health and Human Services and Congress each fiscal year. At the HITAC meeting on June 20, 2018, the HITAC formed the Annual Report Workgroup and charged it with the following:

- *Overarching Charge:* The workgroup will inform, contribute to, and review draft and final versions of the HITAC Annual Report to be submitted to the Secretary of Health and Human Services and to Congress each fiscal year. As part of that report, the workgroup will help track ongoing HITAC progress.
- *Specific Charge:*
 - 1) Analysis of HITAC progress related to the target areas
 - 2) Assessment of health IT infrastructure and advancements in the target areas
 - 3) Analysis of existing gaps in policies and resources for the target areas
 - 4) Ideas for potential HITAC activities to address the gaps

Accomplishments in FY20

The Annual Report Workgroup held 11 public meetings in FY20 to develop its recommendations. The HITAC approved the HITAC Annual Report for Fiscal Year 2019 for submission to the National Coordinator for Health IT in February 2020 and subsequent transmittal to the Secretary of Health and Human Services and Congress. The HITAC Annual Report reviewed HITAC activities in FY19, described the landscape of health IT infrastructure, identified gaps and opportunities, and offered recommendations for future HITAC activities.





Interoperability Standards Priorities Task Force

The Cures Act requires the HITAC to set priorities for standards adoption. At the HITAC meeting on June 20, 2018, ONC charged the HITAC with providing recommendations to the National Coordinator on standards priorities. The HITAC then formed the Interoperability Standards Priorities Task Force and charged the Task Force with the following:

- *Overarching Charge:* To make recommendations on priority uses of health information technology and the associated standards and implementation specifications that support such uses.
- *Specific Charge:*
 - 1) Make recommendations on the following:
 - a. Priority uses of health IT (consistent with the Cures Act's identified priorities)
 - b. The standards and implementation specifications that best support or may need to be developed for each identified priority
 - c. Subsequent steps for industry and government action
 - 2) Publish a report summarizing its findings

Accomplishments in FY20

The Interoperability Standards Priorities Task Force held three public meetings in FY20. The HITAC approved and transmitted [42 recommendations](#) to the National Coordinator for Health IT in October 2019.

The Interoperability Standards Priorities Task Force report summarizes the activities of the Interoperability Standards Priorities Task Force, describing priorities, recommendations, and suggested policy actions for ONC consideration. It covers three priority use cases: (1) Orders and Results, (2) Closed Loop Referrals and Care Coordination, and (3) Medication and Pharmacy Data. Recommendations include those that cross domains and those that focus on the three priority use cases.

For each of the priority use cases, the report includes a patient story that illustrates how the recommendations, if adopted, could improve health and healthcare. Tier 1 issues, along with observations, recommendations, and potential policy levers, are the top priority issues the HITAC recommends addressing. Tier 2 issues, along with observations, recommendations, and potential policy levers, are also important issues in the view of the HITAC, but with less urgency compared to the Tier 1 issues. The policy levers expounded on the report apply to ONC as well as other federal agencies, such as CMS and the FDA.

The Interoperability Standards Priorities Task Force identified additional use cases of interest that it did not explore in detail in the report: (1) evidence-based care for common chronic conditions, (2) SDOH, and (3) cost and price transparency beyond medications. Its role is unique in the evolution of interoperability standards by applying a review of current-state standards to pressing clinical issues and processes. The Task Force identified gaps in standards and implementation of standards needed to support advances in the Task Force's priority use cases.

Intersection of Clinical and Administrative Data Task Force

At the HITAC meeting on January 15, 2020, ONC charged the HITAC with providing recommendations on the convergence of clinical and administrative data. The HITAC then formed the Intersection of Clinical and Administrative Data Task Force and charged it with the following:





- *Overarching Charge:*
 - Produce information and considerations related to the merging of clinical and administrative data, its transport structures, rules, and protections, for electronic prior authorizations to support work underway, or yet to be initiated, to achieve the vision.
 - Leverage existing information from HITAC and National Committee on Vital and Health Statistics (NCVHS) prior authorization hearings, and other sources, to inform the Task Force’s information acquisition and analysis efforts.
- *Specific Charge:*
 - 1) Design and conduct research on emerging industry innovations to:
 - a. Validate and extend landscape analysis and opportunities
 - b. Invite industry to present both established and emerging end-to-end solutions for accomplishing medical and pharmacy priority authorizations (PAs) that support effective care delivery, reduce burden, and promote efficiencies
 - 2) Identify patient and process-focused solutions that remove roadblocks to efficient medical and pharmacy electronic prior authorization and promote clinical and administrative data and standards convergence
 - 3) Produce Task Force recommendations and related convergence roadmap considerations for submission to the HITAC for its consideration and action. The Task Force will share deliverables with NCVHS to inform its convergence and PA activities
 - 4) Make public a summary of its findings once task force activities are complete, no later than September 2020

Accomplishments in FY20

The Intersection of Clinical and Administrative Data Task Force held 30 public meetings in FY20. It brought draft recommendations to the HITAC in September 2020 and final recommendations in November 2020. The HITAC approved and transmitted the [15 recommendations](#) to the National Coordinator for Health IT in November 2020.

The Intersection of Clinical and Administrative Data Task Force report provides an analysis of the current prior authorization landscape, identifying standards alignment, capability, and adoption status, and provides commentary on the major applicable standards —X12, NCPDP, HL7®, and SMART® on FHIR®. The Task Force developed an ideal state vision of prior authorization based on an integrated workflow for prior authorization. The Task Force then developed guiding principles to ensure its recommendations address the current gaps and advance the ecosystem towards the envisioned ideal state as well as fostering the intersection of administrative and clinical frameworks.

The Intersection of Clinical and Administrative Data Task Force then developed its 15 recommendations for achieving data integration. The recommendations identify the specific areas in which resources and energies must be focused to bring about the desired ideal state. The recommendations describe the needed actions without prescribing how they should be undertaken. Federal leadership and broad participation and coordination will be needed to clarify and carry out the details needed to accomplish each one.





U.S. Core Data for Interoperability Task Force

At the HITAC meeting on February 20, 2019, ONC charged the HITAC with developing recommendations to inform the development of the ONC Cures Act Final Rule. The HITAC then formed the U.S. Core Data for Interoperability Task Force and charged it with the following:

- *Overarching Charge for Phase 1:* Review the newly specified data elements proposed in USCDI v1.
- *Specific Charge:* Provide recommendations on the following:
 - 1) Inclusion of Provenance Data Elements
 - 2) Inclusion of Clinical Notes Data Elements
 - 3) Inclusion of Pediatric Vital Signs Data Elements
 - 4) Inclusion of Address and Phone Number Data Elements
 - 5) Missing Data Elements within the Data Classes
- *Overarching Charge for Phase 2:* Provide recommendations for the USCDI Data Element Promotion Model.
- *Specific Charge:* Provide recommendations on the following:
 - 1) Promotion Model Lifecycle for Submitted Data Elements
 - 2) Data Element Submission Information
 - 3) Data Element Promotion Criteria

Accomplishments in FY20

The U.S. Core Data for Interoperability Task Force focused on the overarching charge for Phase 2 in FY20. It held one meeting in FY20 to review final edits to its Phase 2 recommendations. The HITAC approved and transmitted [10 recommendations](#) to the National Coordinator for Health IT in October 2019.

The recommendations focus on: (1) promotion model lifecycle for submitted data elements (Promotion Model), (2) data element submission information, and (3) data element promotion criteria. The U.S. Core Data for Interoperability Task Force was given the supplemental charge to discuss additional defining criteria as needed. As a result, it identified the need to provide details to ONC's Draft USCDI Data Element Promotion Model from the user's perspective. The recommendations describe the three focus areas, along with the HITAC's role in the USCDI promotion process.

The U.S. Core Data for Interoperability Task Force recommends shortening the timeline for the Promotion Model because feedback was in favor of a more rapid process. Additionally, the Task Force recommends an annual review of the overall USCDI process and the creation of a users' guide for data element submission and advancement. The remaining recommendations focus on the details of the Promotion Model and provide concrete actions to operationalize the process.





Health IT Infrastructure Landscape Analysis

FEDERAL ACTIVITIES ACROSS THE TARGET AREAS

Office of the National Coordinator for Health IT

ONC's key responsibilities include formulating the federal government's health IT strategy and promoting coordination of federal health IT policies, technology standards, and programmatic investments. ONC helps coordinate health IT initiatives across HHS's programs and other relevant executive branch agencies to avoid duplication of effort and to ensure that each agency undertakes activities primarily within the areas of its greatest expertise and technical capability. This section describes the health IT activities advanced by various agencies of the federal government during FY20. Certain key federal activities that the HITAC considered to be cross-cutting across the target areas have been included in this section. It does not encompass all relevant federal activities conducted throughout FY20; some of them are addressed within the target area sections throughout this report.

ONC's Regulation for the 21st Century Cures Act

On May 1, 2020, the ONC Cures Act Final Rule was published in the Federal Register. The ONC Cures Act Final Rule implements provisions in Title IV of the Cures Act. The ONC Cures Act Final Rule promotes patient access to their electronic health information (EHI), supports clinicians' needs, advances innovation, and addresses industry-wide information blocking practices. ONC received more than 2,000 comment submissions on the proposed rule, including those from the HITAC. These comments informed the ONC Cures Act Final Rule. Considering the additional burdens on clinicians, health systems, and health IT developers from the COVID-19 pandemic, ONC announced that it will exercise its discretion in enforcing certain new requirements under the ONC Cures Act Final Rule that have compliance dates and timeframes until three months after each initial compliance date or timeline.¹ On November 4, 2020, the Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID-19 Public Health Emergency Interim Final Rule was published in the Federal Register. In the rule, ONC extended the applicability and compliance dates of some provisions in the ONC Cures Act Final Rule to give the health information ecosystem additional flexibility and time to effectively respond to the COVID-19 pandemic.²

The following sections summarize key provisions of the ONC Cures Act Final Rule for which the HITAC provided recommendations to ONC.

Information Blocking

The Cures Act prohibits information blocking and authorizes the Secretary of Health and Human Services to identify reasonable and necessary activities that do not constitute information blocking. In the ONC Cures Act Final Rule, ONC identified eight exceptions for reasonable and necessary activities that do not constitute information blocking, provided certain conditions are met. If the actions of a regulated actor (health care provider, health IT developer of certified health IT, HIE, or HIN) satisfy one or more exceptions, the actions would not be treated as information blocking and the actor would not be subject to civil monetary penalties or other disincentives under the law.





In response to public comments, the ONC Cures Act Final Rule encourages regulated actors to provide accurate, objective, unbiased, fair, and non-discriminatory information to patients related to the privacy practices of third-party apps to help patients select trusted apps. However, regulated actors may not prevent patients from sharing their data with a particular app.

Revised and New Certification Criteria, and Conditions and Maintenance of Certification

ONC finalized additions and changes to the ONC Health IT Certification Program to implement provisions of the Cures Act. ONC added Conditions and Maintenance of Certification requirements for health IT developers and voluntary certification of health IT for use by pediatricians. ONC finalized a small number of new certification criteria, revised several existing certification criteria, and removed a few certification criteria. These changes constitute the “2015 Edition Cures Update.”

More specifically, ONC finalized Conditions and Maintenance of Certification requirements that outline initial and ongoing requirements for health IT developers and their certified Health IT Modules related to: (1) information blocking; (2) assurances; (3) communications; (4) APIs; (5) real-world testing; and (6) attestations. ONC finalized an oversight and enforcement approach to encourage consistent compliance with the requirements, including a corrective action process for ONC to apply when there are potential or known instances where a health IT developer is not meeting a Condition or Maintenance of Certification. The Conditions and Maintenance of Certification can cover both the actions of the developer that offers a certified product and the actual certified product. For example, this means that if a health IT developer with multiple products has at least one product certified to at least one criterion, the developer must not take any action that constitutes information blocking, and must provide assurances satisfactory to the Secretary that the developer will not take any action that constitutes information blocking with respect to any of its products.

Application Programming Interfaces

The Cures Act calls on health IT developers to publish APIs and allow health information to be accessed, exchanged, and used without special effort through the use of APIs or successor technology or standards, as provided for under applicable law. ONC finalized provisions implementing this requirement to support patients’ ability to securely and seamlessly access, exchange, and use their EHI via internet-enabled devices (such as smartphone apps).

Furthermore, ONC finalized certification requirements that will improve interoperability by focusing on standardized, transparent, and pro-competitive API practices that allow for real-time access to EHI. For instance, ONC adopted HL7® FHIR® Release 4.0.1 and a set of implementation specifications that provide known technical requirements against which third-party apps can be developed. The certified API technology must support read access for both a single patient and a population of patients. ONC also set parameters for what fees are allowable and to whom those fees can be charged with respect to certified API technology. These requirements will further support the access, exchange, and use of EHI by patients and clinicians.

United States Core Data for Interoperability

To advance interoperability and support the move towards value-based care, ONC replaced the Common Clinical Data Set (CCDS) referred to in the 2015 Edition Health IT Certification Criteria (2015 Edition) with the broader dataset of the USCDI. The USCDI establishes a set of data classes and constituent data elements required to be exchanged in support of interoperability nationwide. These





classes and elements will be required to be available in certain certified Health IT Modules. The USCDI includes all the information required in the CCDS in addition to new required data classes and data elements. This change will increase the minimum baseline of data that must be commonly available for interoperable exchange. Over time, the USCDI will be updated through a predictable, transparent, and collaborative process that allows stakeholders the opportunity to comment on its expansion.

Trusted Exchange Framework and Common Agreement

The Cures Act requires ONC to develop or support a trusted exchange framework (TEF), including a common agreement among HINs nationally. The Common Agreement is intended to provide a single “on-ramp” to nationwide connectivity while advancing a landscape where health information securely follows the patient when and where it is needed. As of December 2020, the Recognized Coordinating Entity (RCE), The Sequoia Project, held more than 30 public stakeholder engagement calls to provide status updates and to gather feedback to inform the development of the draft Common Agreement and the Qualified Health Information Network (QHIN) Technical Framework, which outlines the technical requirements that QHINs must use to exchange data with one another. ONC and the RCE are working together to develop the draft Common Agreement and QHIN Technical Framework that will be released for public comment. ONC is committed to continuing to work with the RCE and has awarded an additional approximately \$1.1 million for the second year of its activities.³

2020-2025 Federal Health IT Strategic Plan

ONC, in collaboration with more than 25 federal agencies, released the Strategic Plan for public comment in January 2020. The Strategic Plan outlines how the federal government intends to use health IT to: (1) promote health and wellness; (2) enhance the delivery and experience of care; (3) build a secure, data-driven culture to accelerate research and innovation; and (4) connect healthcare and health data through an interoperable health IT infrastructure.⁴ ONC received more than 90 comments on the Strategic Plan.⁵ ONC released the final Strategic Plan on October 30, 2020.⁶

Clinician Burden Reduction

ONC, in partnership with CMS, released a final comprehensive strategy to reduce the regulatory and administrative burden that clinicians experience relative to the use of health IT and EHRs, as required by the Cures Act.⁷ ONC and CMS revised the strategy based on 208 public comments. The strategy includes recommendations to reduce clinicians’ time and effort needed to document information in EHRs and meet EHR-related regulatory reporting requirements, increase the standardization of public health reporting, and improve the usability of health IT.⁸

ONC Research Agenda

ONC released the National Health IT Priorities for Research: A Policy and Development Agenda (Research Agenda), summarizing its plans to advance the use of health IT in research from 2020 to 2025. The Research Agenda outlines two overarching goals: (1) leveraging high-quality electronic health data for research; and (2) advancing a health IT infrastructure to support research. It also includes strategies to advance nine priorities within the two goals.⁹





ONC Precision Medicine Standards and Pilot Initiatives

ONC is leading multiple-precision medicine-related pilot efforts to test out data standards related to genomics and SDOH. The genomic pilot sites are part of the Sync for Genes project, which is designed to pilot test and demonstrate how genomic data can be used at the point of care and for research. The genomic pilot sites tested exchanging data for newborn screening, cancer treatment, pharmacogenomics, and bone marrow matching between genomic labs, healthcare entities, researchers, and patients.¹⁰ The SDOH pilot sites are focused on leveraging digital tools and questionnaires to advance the standardized collection of SDOH data.¹¹

Other Federal Activities

CMS's Interoperability Rule

CMS's Interoperability and Patient Access Final Rule (hereafter, referred to as the CMS Interoperability Rule) was published in the Federal Register on May 1, 2020, introducing new policies that will expand patients' access to health information and improve the seamless exchange of data in healthcare. The CMS Interoperability Rule requires certain Medicare, Medicaid, Children's Health Insurance Program (CHIP), and Qualified Health Plans on the Federally Facilitated Insurance Exchanges to:

- Give patients easy access to their health information via FHIR®-based APIs. The API must provide access to claims, encounter information, and a sub-set of clinical information and allow the patient to send the data to any third-party app of his or her choosing.
- Exchange patient clinical data with another payer at the patients' request, allowing patients to take their information with them as they move from payer to payer over time to help create a longitudinal health record with patients' current payer.

The final rule also requires hospitals to send electronic notifications of a patient's admission, discharge, or transfer to another healthcare facility or community clinician.

Price Transparency

Incorporating information on healthcare costs in discussions with patients can inform and facilitate shared decision-making processes to establish treatment plans.¹² In November 2019, CMS finalized price transparency requirements effective January 1, 2021, that mandate hospitals to establish, update, and make public a yearly list of the hospital's standard charges (including gross charges, discounted cash prices, payer-specific negotiated charges, and de-identified minimum and maximum negotiated charges) for items and services provided by the hospital.¹³ Building on this requirement, in May 2020, CMS issued a proposal to collect hospitals' median payer-specific negotiated inpatient services charges for Medicare Advantage organizations and third-party payers. CMS also requested information regarding the potential use of these data to set relative Medicare payment rates for hospital procedures.¹⁴ In November 2020, CMS, the Department of Labor, and the Department of the Treasury finalized a rule that requires most health plans to give patients access to real-time prices so that patients can know what their healthcare will cost before going in for treatment.¹⁵





Department of Veterans Affairs and Department of Defense Data Exchange

In April 2020, the Department of Veterans Affairs (VA) and the Department of Defense (DoD) launched a joint HIE capability through the eHealth Exchange, a nationwide HIE network that provides a single point for bidirectional exchange between community clinicians and the departments. The joint HIE capability allows for patients to opt out and will serve as the basis for future interoperability initiatives of the departments, including connecting to the CommonWell Health Alliance.¹⁶

HHS Office for Civil Rights Patient Right of Access Enforcement

In 2019, the Office for Civil Rights (OCR) launched an initiative to vigorously enforce the HIPAA Privacy Rule provision for the right of patients to access their medical records promptly, without being overcharged, and in the readily producible format of their choice. As of October 9, 2020, OCR has resolved nine cases with healthcare entities by entering into settlement agreements that require the entities to pay a monetary settlement, implement a corrective action plan, and face monitoring by OCR for at least a year.¹⁷

Health IT Certification Violations Enforcement by the Department of Justice and HHS Office of Inspector General

In recent years, the federal government has increased its focus on health IT certification and financial relationships in enforcement actions. The Department of Justice (DOJ) and HHS Office of Inspector General (OIG) have reached settlement agreements with several health IT developers based on falsely obtained ONC Health IT Certification Program certifications. The health IT developers concealed from their ONC-Authorized Certification Body (ONC-ACB) that the health IT module did not comply with all the applicable requirements to be certified.¹⁸ In addition, one health IT developer engaged in a kickback scheme with an opioid company by implementing a clinical decision support (CDS) tool in a manner that influenced opioid prescriptions.¹⁹

National Institutes of Health All of Us Research Program

The National Institutes of Health's All of Us Research Program consists of a longitudinal national research cohort of one million or more U.S. volunteers from which clinical, environmental, genetic, and behavioral data will be collected to enable precision medicine. The All of Us Research Program is focused on collecting data from multiple sources, including EHRs and mobile health technology.²⁰ Through October 2020, more than 359,000 people have completed the consent process and more than 271,000 participants have completed the initial steps of the program.²¹

National Institutes of Health and Agency for Healthcare Research and Quality Standards Support

NIH and the AHRQ are promoting the use of FHIR® in their funded research projects.^{22,23} NIH-supported researchers are encouraged to adopt and use the USCDI to improve the interoperable exchange of clinical and research data.²⁴

U.S. Food and Drug Administration

In September 2019, the FDA released its Technology Modernization Action Plan (TMAP). The TMAP describes important near-term actions that the FDA is taking to modernize the use of technology—computer hardware, software, data, and analytics—to advance its public health mission. The TMAP outlines three strategies to achieve this goal: (1) modernization of the FDA's technical infrastructure; (2) enhancing the





FDA's capabilities to develop technology products to support its regulatory mission; and (3) communication and collaboration with stakeholders to drive technological progress that is interoperable across the system and delivers value to patients. The TMAP is aimed at preparing the FDA to harness the ever-increasing amount of data, from both real-world evidence and clinical trials, to assist it in responding to novel technology reviews and a rapidly increasing workload.²⁵ In addition, the FDA launched the Digital Health Center of Excellence (DHCoE) in September 2020. The DHCoE is focused on aligning and coordinating digital health work across the FDA and will serve as a centralized resource for digital health technologies and policy.²⁶

Federal Response to the COVID-19 Pandemic

The federal government mounted a widespread response to the COVID-19 pandemic. For example, to highlight and share best practices across the health IT industry to advance interoperability for the COVID-19 pandemic response, ONC is using the Interoperability Proving Ground to collect information on relevant industry projects. There have been many projects submitted from academic institutions and industry stakeholders across the country.²⁷

ONC conceptualized the Patient Unified Lookup System for Emergencies (PULSE) to enable health information exchange during declared disasters or public health emergencies. PULSE-COVID, a new iteration of this concept, was developed through a public-private partnership. This allows verified users, e.g., public health authorities and clinicians, to find and view electronic patient health and medication histories from across nationwide HIE networks. With a simple search on PULSE-COVID, users can access and view clinical care documents including medications, allergies, diagnoses, lab results, and other relevant information to augment clinical care, identify patient comorbidities, and fill in gaps related to patient health or demographic characteristics. Users can also utilize PULSE-COVID to access clinical histories for patients in non-routine care settings such as quarantine centers and other alternate care sites. PULSE-COVID has been successfully deployed in five states.

Furthermore, OCR has issued multiple bulletins, notifications of enforcement discretion, guidance, and resources to explain how patient health information may be used and disclosed during the COVID-19 pandemic response. Notable guidance specific to health IT includes: (1) enforcement discretion for telehealth remote communications during the public health emergency; (2) enforcement discretion to allow uses and disclosures of protected health information (PHI) by business associates for public health and health oversight activities during the public health emergency; and (3) guidance on how covered entities may disclose PHI about an individual who has been infected with or exposed to COVID-19 to law enforcement, paramedics, other first responders, and public health authorities.^{28,29}

As mentioned above, additional discussions of federal activities are detailed within the target area and topics below.





TARGET AREA: USE OF TECHNOLOGIES THAT SUPPORT PUBLIC HEALTH

Background

Public health focuses on protecting and improving health at a population level rather than one person at a time. All states and territories require clinicians to report specific diseases and conditions to public health agencies through various public health surveillance and information systems.³⁰ Clinicians use EHR and health information exchange functions for required reporting to public health agencies. Public health agencies depend upon receiving data from clinicians through these systems. This helps public health agencies measure the prevalence and incidence of diseases, maintain high immunization coverage rates, manage outbreak investigations, and plan for and respond to public health emergencies.

The COVID-19 pandemic that emerged in early 2020 has cast light on the importance of health IT in disaster response and public health emergencies, and exposed room for improvement. Moreover, the pandemic has increased the urgency of addressing gaps within the public health infrastructure. The HITAC convened a listening session to better understand the limitations of health IT with regard to public health and, as such, this topic is included in the HITAC Annual Report for FY20. This section will examine the intersection of health IT and the public health and clinical response to the COVID-19 pandemic.

Current State

Bidirectional Exchange of Clinical and Administrative Data for Public Health Purposes

The bidirectional exchange of clinical and administrative data between clinicians providing patient care and public health entities is essential to better understand and combat a public health emergency, such as the COVID-19 pandemic.

Diagnostic Code Value Sets

As COVID-19 cases began to increase in the United States, a need arose to have standardized diagnostic coding for patients with the virus. The use of diagnostic code sets such as the 10th Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10) makes syndromic surveillance possible across a state or region of the country. In January 2020, the WHO met to establish a new diagnostic code for COVID-19, U07.1. Initially, the CDC directed clinicians in the United States to code using a grouping of diagnostic codes that describe a patient's symptoms; however, the CDC acted quickly to adopt the WHO diagnostic code into the ICD-10 value sets for standardized use. This rapid, off-cycle addition of a new diagnostic code is unprecedented.³¹ Although the CDC implemented this code rapidly, there has been slow adoption in using this diagnostic code for clinical documentation.³² As COVID-19 vaccines become readily available, distinct ICD-10 and Current Procedural Terminology (CPT®) codes have been established for the COVID-19 vaccines authorized for emergency use by the FDA to allow for tracking and reporting. The level of specificity for these codes, which describe both the manufacturer and the specific dose, has not been previously established for other vaccine codes.^{33,34} However, widespread implementation of the new vaccine administration codes may take some time.





Public Health Reporting

For federal and state public health officials to be able to accurately categorize the breadth of COVID-19 infection, robust reporting is essential. Federal reporting requirements on COVID-19 testing, patient impacts, and hospital capacity are based on manual push reporting.³⁵ Additionally, CMS published an interim final rule requiring hospitals, critical access hospitals, and CMS-certified long-term care facilities to report COVID-19 metrics at least once every seven days.^{36,37} However, there is a paucity of data standards to allow for standardized electronic reporting from EHRs directly to public health or government officials. Hospitals have experienced a significant burden in reporting this data in a timely and accurate manner.³⁸

Realizing the gravity of this problem, a group of diverse industry stakeholders organized a coalition called The SANER Project to develop a FHIR® resource to report such metrics. This effort is focused on improving state and federal response operations through real-time situational awareness of the healthcare delivery system. Healthcare facilities and government response authorities can leverage the standards developed through the SANER Project to collect data that is critical for controlling the spread of COVID-19 and managing limited healthcare resources across the country. These data include the number and status of specific hospital bed types, number of ventilators, and availability of staffing and other critical supplies.³⁹

Information Exchange

The COVID-19 pandemic has demonstrated the need for robust data exchange and interoperability within the healthcare field. There is a wide spectrum of reporting capabilities across the country, from the rollout of electronic case reporting to persistent manual data exchange. HIEs have deployed innovative technologies to inform state and local authorities on trends in biosurveillance and hospital usage.⁴⁰ By nature, HIEs are well-connected to gather near-real-time data such as positive lab tests, hospital admission information, co-morbidities, and length of stay information. These capabilities have been integral in gathering data that is not available through the existing public health reporting infrastructure.⁴¹ For example, Indiana Health Information Exchange, Delaware Health Information Network, and Nebraska Health Information Initiative have been sending enriched data and daily alerts of positive and negative COVID-19 tests to public health agencies and hospitals.⁴²

Privacy and Security for Public Health Purposes

Although a federal or state public health emergency declaration allows for more flexibility in information exchange, ensuring privacy and security for patients' health information is also of importance.

Minimum Necessary Datasets for Public Health Allowable Use

When sharing information, the HIPAA Privacy Rule requires covered entities and their business associates to limit the disclosure of PHI to the minimum amount necessary to accomplish the intended purpose. During the COVID-19 public health emergency, public health authorities began to experience roadblocks when trying to access clinical data for case investigations and contact tracing because information disclosed from covered entities was not standardized and did not meet their robust data needs.⁴³ Policy and legal guidance have been issued by state and local governments to define what the HIPAA "minimum necessary" dataset is for public health authorities using PHI. However, no additional guidance on the topic has been issued by OCR. Many states or cities have designated that a Continuity of Care Document or its equivalent may qualify as the minimum data necessary.⁴⁴ In





December 2020, OCR issued guidance clarifying when a covered entity can rely on the representation from a public health agency that its request for data is the minimum necessary.⁴⁵

Novel Biosurveillance Technologies

There is an urgent need to be able to conduct nationwide surveillance and contact tracing of COVID-19 cases. To supplement traditional contact tracing strategies, various IT companies have proposed solutions using cell phone location data and mobile apps to enable exposure notifications. In April 2020, Google and Apple launched a collaborative tool for individuals and state public health agencies to support exposure location using Bluetooth technology. Apple and Google have also developed a tool that allows state jurisdictions to rapidly build an app from a standardized template. Exposure notification apps notify users when they have been in the same geographical location in the past 14 days as another user who has reported a positive COVID-19 test; however, the app's success depends upon adoption rates and voluntary reporting of results.⁴⁶ Additionally, various employers have adopted mobile app tools that harness employee data, such as COVID-19 test results, to facilitate a return to office work.⁴⁷

These technologies have raised privacy and security concerns. These apps, which may be required by employers, are typically not subject to HIPAA protections. Employees, state public health authorities, and other stakeholders have voiced concerns over how these companies will handle and store the data long-term and will restrict data usage for unrelated activities.^{48, 49} Although multiple states have incorporated similar digital technologies into their public health response strategies, adoption has not been widespread.^{50,51}

Telehealth

The COVID-19 pandemic led to widespread temporary closures of outpatient clinical offices and heightened risk for non-COVID-19-related care in hospitals. In response, the federal government provided flexibility to encourage the use of telehealth. CMS relaxed several requirements pertaining to telehealth and expanded reimbursement for telehealth, with commercial insurers following suit, to rapidly adapt to the conditions imposed on the healthcare system.⁵² Because many clinicians were not well-equipped for a remote modality of patient care, the Federal Communications Commission (FCC) provided funding for telehealth infrastructure. The Health Resources & Services Administration (HRSA), with support from ONC, has continued to offer technical assistance for telehealth.⁵³ The relaxed CMS regulations on telehealth, along with the need to limit in-person contact, created strong demand for telehealth visits during the spring of 2020. Estimates showed that the number of telehealth visits rose rapidly through mid-April but then leveled, and even slightly declined as states began to relax stay-at-home orders in May 2020.⁵⁴ CMS estimated that from mid-March 2020 to July 2020, more than 9 million beneficiaries used telehealth in traditional Medicare, an increase of more than 5,000 percent from the prior three months. Of those 9 million beneficiaries, 5.8 million used telehealth for a common office visit.⁵⁵ Furthermore, there were more than 34.5 million services provided via telehealth to Medicaid beneficiaries between March and June 2020.⁵⁶

This change in practice has shown early success in the provision of care for patients who would otherwise have had to delay care in the pandemic. As a result, there have been calls from many stakeholder groups to make these reforms long-term changes.⁵⁷ In the 2021 Physician Fee Schedule, CMS extended many of the telehealth policies previously introduced under Medicare as part of the response to the pandemic. In the 2021 Physician Fee Schedule, CMS extended many of the telehealth policies previously introduced under Medicare as part of the response to the pandemic.⁵⁸





CMS also issued a proposed rule on June 30, 2020, and a final rule on November 4, 2020, to permanently expand telehealth flexibility for home healthcare services.⁵⁹ Furthermore, with the regulatory support for telehealth, EHR vendors are launching new tools and services that allow clinicians to conduct video visits while updating clinical documentation and reviewing patient histories in the EHR workflow.⁶⁰ Although the regulatory support and financial incentives have helped spur the adoption of telehealth, clinicians and patients still needed to learn how to use this technology to successfully adapt to a new paradigm of care. Many professional medical associations began to share educational resources for clinicians to ensure that they were successful in using telehealth. Furthermore, health systems that have implemented telehealth services have had to consider diverse technological capabilities and access among their patients.⁶¹

Vaccine Tracking

Vaccine tracking is a common practice during a communicable disease outbreak. The administration of multi-dose vaccines requires mechanisms to track and match individual patients across doses as well as the supply and administration of COVID-19 vaccines throughout the country.⁶² The CDC has developed the Vaccine Administration Management System (VAMS) to support data collection for the COVID-19 vaccine.⁶³ In addition, the Immunization Gateway sponsored by the CDC is working to simplify the sharing of vaccine information across states for providers already connected to existing immunization information systems and to the CDC.

States are using diverse, existing immunization information systems to track this information. However, the magnitude of the COVID-19 pandemic is greater than other recent outbreaks and is straining these systems.⁶⁴ Each state manages the rollout of its own vaccine administration, resulting in widespread use of disparate IT systems to handle each step in the process, such as registration, scheduling, inventory management, and clinical records. The standardization of data elements collected by each IT system in a state may not be uniform across other systems in the state or nationwide.⁶⁵ In addition, while the majority of state immunization information systems (IIS) can share data bidirectionally, some lack the capacity for returning data to clinical information systems for tracking the delivery of immunizations to targeted groups of patients as part of population health strategies.

Patient Matching for Public Health Purposes

The ability to complete patient matching efficiently, accurately, and at scale has long been identified as key to the success of the nation's health IT infrastructure.⁶⁶ Precise patient matching is essential to protecting patient privacy and ensuring patient safety. Accurate patient matching rates vary widely across healthcare organizations and are difficult to compare because organizations may calculate rates differently. Patient matching has become a prominent issue during the COVID-19 pandemic. Early in the COVID-19 pandemic, incomplete or missing demographic information from lab reports was widespread. This missing data complicated aggregate analysis and contact tracing efforts.⁶⁷ State public health agencies often needed to take additional measures to use patient matching technologies to confirm patient identities, leading to delayed contact tracing outreach.⁶⁸ In June 2020, HHS released guidance that outlined required data elements for all lab tests conducted. These data elements include demographic information such as the patient's address, phone number, sex, race, and ethnicity. These data elements support the application of advanced technologies for patient matching.





Complementary to the patient matching work during the COVID-19 pandemic, the 2020 appropriations bill explanatory statement requires ONC to provide a report to Congress that outlines the current technological and operations methods that improve the identification of patients.⁶⁹ To support this work, ONC conducted two working sessions in the summer of 2020. The first, held on June 1, 2020, discussed the current challenges with patient matching, the promise and potential implementation of a UPI, and privacy and security concerns.⁷⁰ The second session held on August 31, 2020, focused on privacy and security, research and evaluation, standards, and innovation.⁷¹

International Exchange of Clinical Data for Public Health Purposes

With the onset of the COVID-19 pandemic, countries began imposing significant restrictions on travel to ensure public safety and control the spread of COVID-19.⁷² Many implemented screening protocols and information collection at their airports; however, there has been inconsistent implementation across the globe. As countries plan their strategies to be able to safely reopen their borders to visitors, the ability to understand the potential for COVID-19 exposure will be paramount. At present, there is minimal health data exchange internationally and each country has a unique standard for documentation.⁷³ The Commons Project Foundation, a non-profit that creates public data trusts, created a joint project with The World Economic Forum to address this issue. The project, called CommonPass, aims to provide travelers with a secure and verifiable way to document their health status as they travel and cross borders.⁷⁴ As the world prepares to tackle other public health challenges of the future, these information-sharing channels and tools will be crucial. The exchange of clinical data between countries can also provide insights for surveillance, operational response, treatment, and therapeutic development.⁷⁵

TARGET AREA: INTEROPERABILITY

Background

During the past decade, hospitals and clinician offices have made tremendous gains in shifting from paper record-keeping to computerized systems. Although barriers to achieving interoperability still exist, there has been significant progress. For example, 56 percent of hospitals had electronic patient information from outside sources available at the point of care in 2018, an increase of 10 percent from 2015. Three-quarters of hospitals use both electronic and non-electronic methods for exchanging summary of care records.⁷⁶ Small, rural, and critical access hospitals trail larger, suburban, and urban hospitals in participation with information-sharing networks.⁷⁷ Office-based clinicians' rates of electronically finding or querying data from outside sources increased by 50 percent from 2015 to 2017.⁷⁸





Current State

Health Information Exchange

The health information ecosystem continues to strive towards interoperability for its cost-saving potential and benefits to clinical care. Connectivity and interoperability remain a challenge for clinicians across care settings because information that has been captured and stored in health IT systems is still not easily shared. Progress has been made but interoperability remains fragmented.

Increased use of nationwide health information networks—such as eHealth Exchange, Carequality, and CommonWell Health Alliance—is anticipated to significantly improve interoperability. Many of the national health information networks publish data on the number of participating organizations and data exchange volume. Beyond these data points, however, there is little information available describing the benefits of increased connectivity and data flow, or on the gaps that remain to be addressed.

Specific use cases that require significant amounts of specialized clinical data are also not well supported today. Organ procurement and transplants are examples of a vital part of healthcare that has complex data needs that often have to be addressed through significant manual inputs and with non-standard data. Health systems and organ procurement organizations (OPOs) are developing automated processes to streamline the identification, evaluation, and placement of transplantable organs. For instance, health systems and OPOs are working to replace manual processes with electronic interfaces in hospital EHRs, allowing hospital staff to generate a report to an OPO and donor registry communication hub with the press of a button.⁷⁹ These organizations are also working on APIs to assist with seamless data exchange. Transplant centers are increasingly adopting these APIs, with 50 out of 250 transplant centers using at least one API solution.⁸⁰ CDS systems are being implemented to facilitate the early referral of potential organ donors to an OPO, which may positively impact donation outcomes.

Exchange of Health Data More Broadly across the Care Continuum

Interoperability challenges are even greater in care settings such as behavioral health, LTPAC, and home health, which were not eligible to participate in the CMS Medicare and Medicaid EHR Incentive Programs (now known as the Promoting Interoperability Programs). Many of these healthcare entities continue to rely on fax and phone communication to accept referrals and exchange clinical information.⁸¹ As of 2017, just 29 percent of substance abuse treatment centers use only electronic methods to store and maintain health records.⁸² About 25 percent of substance use disorder (SUD) treatment facilities use only paper methods to send and receive health information, whereas less than 10 percent use only electronic methods.⁸³

Under the broad LTPAC umbrella, there are varying rates of adoption of health IT and abilities to send and receive data electronically. To help advance interoperability in LTPAC settings and to align data reporting requirements, CMS created the Data Element Library (DEL), which is a collection of interoperable data elements and their associated health IT standards.⁸⁴ CMS is working to align the DEL with health IT content standards, such as Logical Observation Identifiers Names and Codes (LOINC), Consolidated-Clinical Document Architecture (C-CDA), and FHIR®, which will allow data generated by LTPAC providers for payment and reporting to CMS to be repurposed for broader interoperable data exchange.⁸⁵ In addition to clinical data exchange, administrative data interoperability is critical for efficiency across the care continuum. Administrative data, such as prior authorizations, may be recorded in one care setting; however, this information is not always exchanged for reuse in other care settings.⁸⁶





New rules and ongoing projects may further interoperability between LTPAC and inpatient and ambulatory clinicians. The CMS Interoperability Rule requires hospitals to send LTPAC providers and other clinicians event notifications about shared patients.⁸⁷ AHRQ is funding projects that advance the standardization and integration of PRO data.⁸⁸ The 360 Exchange Closed Loop Referral Project aims to streamline the referral process by standardizing data exchange and transport.⁸⁹ To address the exchange of functional and cognitive status data specifically, CMS supports the PACIO Project. This project aims to advance data exchange between LTPAC providers and other providers using FHIR® standards.⁹⁰

LTPAC sites use a variety of standardized measurement tools to assess patient outcomes and compare them across the post-acute care continuum as well as improve care transitions. These include the Minimum Data Set (MDS) for skilled nursing facilities, Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI), Outcome and Assessment Information Set (OASIS), and Long-Term Care Hospital CARE Data Set (LCDS). Data elements are easily available with national standards to support LTPAC health IT and care communication.⁹¹

Increased Health Equity across Populations, Locations, and Situations

Health equity means that everyone has an opportunity to achieve their full health potential without disadvantage from achieving this potential because of social position or other socially determined circumstances. Outcomes that reflect health inequities include differences in length of life, quality of life, rates of disease, disability and death, severity of disease, and access to treatment.⁹² To achieve health equity, it is important to identify health disparities, understand why they exist, and reduce them with evidence-based interventions that take into account unique regional and cultural needs. One of the key components of identifying health disparities and promoting health equity is data that allows for the analysis of health processes and outcomes by race, ethnicity, language, sexual orientation, gender identity, and disability status.⁹³

Race, ethnicity, and language data are noted for collection in several rules and standards. Historically the CMS Promoting Interoperability programs required clinicians and hospitals to collect race and ethnicity data using standards developed by the U.S. Office of Management and Budget (OMB).⁹⁴ The CDC publishes a race and ethnicity code set that has more granular categories for race and ethnicity and allows multiple races and ethnicities to be chosen for the same patient, and rolls up the OMB standards.⁹⁵ The USCDI specifies race, ethnicity, and language as part of demographics using the OMB or CDC standards. HHS promulgated a rule requiring labs to include race and ethnicity on COVID-19 test results submitted to the CDC.⁹⁶

Sexual Orientation and Gender Identity (SO/GI) data are captured less frequently and are therefore often not included in analyses of quality of care or health disparities.⁹⁷ Clinicians and hospitals are required to have certified Health IT Modules that allow users to record, modify, and access structured SO/GI data. However, clinicians and hospitals are not required under the Promoting Interoperability programs to collect or use SO/GI data.⁹⁸ Studies suggest that rates of SO/GI data collection are low, with 22 percent of patients asked for this information in an Emergency Department setting.⁹⁹ California, Michigan, New Mexico, Pennsylvania, and Washington are advancing policies for SO/GI data collection related to COVID-19 cases.¹⁰⁰

The Patient Protection and Affordable Care Act (the ACA) includes provisions for documenting disability status with six questions developed by the US Census Bureau. They include questions to ascertain if a





patient has difficulty hearing, seeing, concentrating, making decisions, or performing activities of daily living. There are no standards for storing and sharing disability information, making it difficult to accurately identify people with disabilities and detect health disparities.¹⁰¹

Exchange of Social Determinants of Health Data

SDOH data are defined as “the conditions in which people are born, grow, work, live, age, and the wider set of forces and systems shaping the conditions of daily life.” This information can be used to identify patient-specific needs, enhance patient engagement, and share information across healthcare and social service organizations.

Despite strong evidence linking patients' social circumstances to their health status, the healthcare system is struggling to capture SDOH information from patients to inform clinical decision making. There are several initiatives underway to standardize the capture and use of SDOH data in health IT. The HL7® Gravity Project is developing consensus-based documentation standards to capture SDOH data as part of the patient health record.¹⁰² Started in May 2019, the Gravity Project has developed a master list of data elements for: (1) housing instability and homelessness; (2) food insecurity; and (3) transportation access.¹⁰³ It submitted ICD-10, LOINC, and Systematized Nomenclature of Medicine (SNOMED) codes for food insecurity to the respective standards development organizations and is working to do the same for housing instability, homelessness, and transportation access.¹⁰⁴ ONC and HHS are working to advance SDOH standards initiatives and are promoting the interoperable capture, use, and exchange of SDOH data through the Health IT Certification Program. The HHS Office of the Chief Technology Officer launched a department-wide SDOH strategy in 2019.¹⁰⁵ A number of HIEs are actively working to support the sharing of SDOH data.¹⁰⁶

Association between EHRs and Patient Safety

Well-designed, properly implemented, and responsibly used health IT can improve patient safety by better supporting clinical workflows and decision making. At the same time, health IT can introduce new patient safety risks, especially those associated with poor usability, such as incorrect drug dose administration, delays in care, and other adverse events. For example, hospitals with the same EHR developer have different rates of detecting adverse drug events using CDS, suggesting that technology as well as organizational safety, culture, and processes are important contributors.¹⁰⁷ ONC and CMS's joint Clinician Burden Reduction Strategy describes how improved EHR usability and user experience can positively impact patient safety. For example, some design features, such as screen emphasis, typography, and color choices, can make it easier for a clinician to locate the correct medication or laboratory order.¹⁰⁸

The ONC Health IT Certification Program includes patient safety components that increase safety-enhanced design requirements.¹⁰⁹ Some experts have suggested additional steps that could be taken in the ONC Health IT Certification Program, such as a safety reporting system for EHRs, to improve patient safety.¹¹⁰ The Cures Act called for the creation of the EHR Reporting Program to collect information from technology developers and clinicians to assess EHR performance. Stakeholders identified safety as a measure to be included in the EHR Reporting Program assessment.¹¹¹ The voluntary reporting criteria for the EHR Reporting Program include a focus on usability and its impact on patient safety.¹¹² ONC's SAFER Guides recommend practices to optimize the safe use of EHRs and guide technology teams in conducting self-assessments and implementing high priority safety practices.¹¹³





Sharing Data with the Research Community

Due to the large volume of electronic health data created by EHRs and consumer electronics, researchers are increasingly conducting clinical studies based on this data.¹¹⁴ EHRs may act as an evidence base for research that can help guide health-related decisions made by clinicians and patients.¹¹⁵ Some EHRs have self-service search tools that allow clinicians to understand patient populations and informally investigate data in the pre-research phase.¹¹⁶ However, challenges with data quality, consistency, and health IT infrastructure have made it difficult to use clinical data for research purposes.¹¹⁷

Historically, clinical data and research data have been siloed, i.e., clinical data are not available to researchers and research data are not available in EHRs. Clinicians and researchers share a set of data use functions including data capture, access and transport, storage, aggregation, and knowledge sharing. However, the structure and storage of data vary between the two domains. In response, the first goal of ONC's National Health IT Priorities for Research is "leveraging high-quality electronic health data for research" and priorities that focus on improving data quality at the point of capture, increasing data harmonization to enable research uses, and improving access to interoperable health data.¹¹⁸

Projects and initiatives are underway to harmonize health IT infrastructure and make it easier for researchers and clinicians to share clinical data. One such initiative is Making EHR Data More Available for Research and Public Health. Funded by HHS' Assistant Secretary for Planning and Evaluation (ASPE) and executed by the CDC, the project aims to use FHIR® standards to extract data from multiple clinical platforms and create a reliable, scalable, and interoperable method to obtain EHR data for multiple public health and research scenarios using a scalable and extensible application.¹¹⁹ Additional initiatives focus on other needs of the health IT infrastructure, such as efficiently honoring data use agreements between the two parties, supporting easier identification, consent, and consent management of research participants, and implementing research findings at the point of care.¹²⁰ In addition, technical advances are creating new opportunities to leverage data for research and other uses in a manner that allows the data to be accessed for a specific purpose, such as training algorithms, without sharing or centralizing the data.¹²¹

HHS' Federal Policy for Protection of Human Research Subjects (known as the "Common Rule") sets forth requirements that protect human subjects involved in research conducted or supported by HHS. Efforts are underway to support the alignment of the FDA research regulation requirements with the Common Rule human research requirements as required by the Cures Act. Currently, researchers must follow the regulation that offers the greater protection to human subjects when the investigation is both supported by HHS and involves an FDA-regulated product.

Metadata

An important component of integrating clinical data for research is facilitating data management to collect data and ensure it is standardized, can be merged from multiple sources over time, and can be related to outcomes.¹²² Clinical research standards, which are governed by the Clinical Data Interchange Standards Consortium, leverage metadata nomenclature to facilitate machine-based, clinical data management.¹²³ Metadata is data about data, or information about information, or the information required to contextualize and understand a given data element. It is widely used in clinical trials to efficiently manage and use data and keep track of where it is captured, transformed, transferred, stored, and processed.¹²⁴ In the delivery of care outside of clinical trials, metadata is often limited and includes when data was created as well as who accessed the data and when it was updated.¹²⁵ The United States Information Knowledge Base is a repository of healthcare metadata, specifications, and standards funded and directed by AHRQ.





Management of Data from Outside Sources

The ability to incorporate, de-duplicate, reconcile, and use data from external sources is important to support clinicians' management of data from outside sources. As of 2017, one in 10 office-based physicians send, receive, find, and integrate patient health information from outside sources.¹²⁶ The most common reasons for not using health information received electronically from outside sources include: (1) information is not available when needed; (2) information is available but not integrated into the EHR; (3) information is not presented in a useful format, e.g., too much information, redundant information, or unnecessary information.

Many solutions that enable clinical access to data from outside sources require deviations from the typical workflow in one of two ways. One requires clinicians to leave the EHR for another website and the other requires clinicians to move to a separate section of the EHR that houses the outside data. Users are less likely to access data from external sources if it requires added steps, such as navigation to parts of the EHR outside of the standard workflow. One health system found that a change in user interface whereby local and outside data are comingled, or presented alongside local data in an integrated and logically organized way, results in increased views of outside data in inpatient, outpatient, and emergency encounters by all clinician types.¹²⁷

HL7® FHIR® Standard

FHIR® facilitates interoperability between legacy health IT systems, eases the provision of healthcare information to clinicians and individuals on a variety of devices such as computers, tablets, and cell phones, and enables third-party app developers to provide medical apps that can be easily integrated into existing systems. ONC's adoption of FHIR® release 4.0.1 in the ONC Cures Act Final Rule is anticipated to significantly advance the use of FHIR® across the industry. Several industry groups are actively working to use, improve, and refine the FHIR® standard. Their efforts serve purposes such as exchanging SDOH data, advocating for consumer-directed exchange, identifying common oncology data elements, connecting clinical research and healthcare, and promoting interoperability across value-based care stakeholders.¹²⁸

Unique Device Identifiers

A unique device identifier (UDI) is an alphanumeric code that identifies a specific medical device that may be added to relevant records such as hospital purchase orders, patients' health records, or insurance claim forms. The UDI enables device tracking throughout the health information ecosystem and the ability to quickly identify faulty products and issue recalls, thereby improving patient safety. As a result of the COVID-19 pandemic, the FDA announced it will delay enforcement of compliance with its requirement for medical devices to have a UDI from September 24, 2020, to September 24, 2022.¹²⁹ CMS is still determining whether it will include UDI information on the next version of the Medicare claims form.

Health IT Support for Opioid Response

Health IT is an important tool in addressing the opioid epidemic. The use of health IT has been demonstrated to improve adherence to opioid prescribing guidelines, increase the safety of prescribing for controlled substances, enhance clinician access to Prescription Drug Monitoring Programs (PDMPs), and expand access to substance use disorder treatment and recovery support.

Currently, all states except Missouri have an operational statewide PDMP.¹³⁰ PDMPs can provide health authorities with timely information about prescribing and patient behaviors that may contribute to the opioid





epidemic, which can facilitate a nimble and targeted response.¹³¹ Rates of PDMP and EHR integration vary widely by state, with high rates of interoperability in some states and nearly none in others. One report shows that 29 percent of hospitals have EHR capabilities to allow prescribers to check the state PDMP via the EHR while 14 percent of hospital EHRs automatically integrate data from the state PDMP.¹³² Many state PDMPs need technical enhancements and significant EHR integrations to maximize utilization. One study found that viewing PDMP data when it is integrated into the EHR takes up to 15 seconds, while viewing the data when it is not integrated into the EHR may take up to five minutes.¹³³

The use of CDS for safe opioid prescribing practices is gaining traction. CDS Hooks is a standard for notifying an external service when a specific activity occurs within an EHR user session. The external service can then return information including text, actionable suggestions, or links to launch to an app from within the EHR workflow.¹³⁴ When implemented well, CDS can prompt clinicians to write more appropriate pain medication prescriptions.¹³⁵ To advance this work, AHRQ is supporting projects aimed at developing CDS tools for patients and clinicians.¹³⁶

TARGET AREA: PRIVACY AND SECURITY

Background

As interoperability and access to patient health information increase, the privacy and security of health data are primary concerns for stakeholders. Robust privacy and security practices are important considerations in advancing and maintaining trust in interoperability, while poor privacy and security practices heighten the vulnerability of patient information stored in health information systems and elsewhere. In addition, inadequate privacy and security practices have the potential to create data management problems for healthcare entities via unauthorized and/or unintended disclosure, ransomware, and other avenues.

Privacy and security regulations are sometimes cited as a barrier to sharing health information. It is anticipated that the ONC Cures Act Final Rule and CMS Interoperability Final Rule will reduce the ability of healthcare entities and others to use the existing privacy and security regulations to evade sharing health data.^{137,138}

Current State

Beyond HIPAA: Protections for Data Generated Outside of the HIPAA Framework

Health data are increasingly collected, shared, and used by entities that are not subject to HIPAA. HIPAA does not apply to data created by an entity that is not a covered entity or business associate, or to data disclosed to an entity not subject to HIPAA, such as a digital app.^{139,140} This fact is often not transparent to patients.

Several federal privacy laws and regulations provide additional protections to health data. These include the Substance Abuse Confidentiality Regulations (42 CFR Part 2), and the Family Educational Rights and Privacy Act (FERPA) (20 U.S.C. § 1232g; 34 CFR Part 99). 42 CFR Part 2 protects the confidentiality of patient records related to SUDs by restricting disclosure of the records to a greater extent than as required by HIPAA. FERPA protects the privacy of student education records, including students' health records maintained by a school nurse of a covered institution. The HIPAA Privacy Rule specifically excludes from





PHI student education records that are protected by FERPA. As a result, health IT used to support clinicians in institutions covered by FERPA must address the unique privacy requirements of FERPA, which differ from HIPAA requirements.

The Coronavirus Aid, Relief, and Economic Security Act (CARES Act), which became law on March 27, 2020, amended 42 CFR Part 2 by relaxing some of the specific patient consent requirements to facilitate information sharing and better align 42 CFR Part 2 with HIPAA.¹⁴¹ These changes were made to improve access and coordination of care for patients with SUD. Now, once a patient provides initial consent to the disclosure of SUD data, the data can be used or disclosed by a covered entity, business associate, or 42 CFR Part 2 program for treatment, payment, or healthcare operations without obtaining additional consent. The CARES Act balances this softening of the consent requirements by strengthening the prohibition against using unconsented SUD records against the patient and prohibiting discrimination based on the information contained in the records or received because of their disclosure.¹⁴² In July 2020, the Substance Abuse and Mental Health Services Administration (SAMHSA) published a final rule which modernizes 42 CFR Part 2 to improve care coordination and update patient consent requirements without altering the basic framework for confidentiality protections for SUD patient records.¹⁴³

In December 2019, OCR and the Department of Education released updated joint guidance clarifying the application of FERPA and the HIPAA Privacy Rule on records maintained on students.¹⁴⁴ The guidance, originally published in November 2008, details when each law applies and when records can be disclosed.¹⁴⁵

Rules for Sharing

There have been some recent attempts to increase transparency and improve privacy protections of data not subject to HIPAA. The Consumer Technology Association issued industry-developed guidelines for companies that handle electronic consumer health and wellness data. The voluntary guidelines aim to address privacy risks, discover consumer preferences, and earn consumer trust.¹⁴⁶ The eHealth Initiative and the Center for Democracy and Technology have partnered to create a framework to protect health data not protected by current privacy laws.¹⁴⁷ In May 2020, the American Medical Association (AMA) published a list of privacy principles to respond to Americans' growing reluctance to share health data.¹⁴⁸ The AMA plans to use the principles to create changes to improve the privacy and security of health data in the hands of parties not subject to HIPAA. The National Institute of Standards and Technology (NIST) published recommended activities that IoT manufacturers can take to make it easier for users to keep devices secure.¹⁴⁹ The FDA has issued formal guidance on how medical device manufacturers should handle reports about cyber vulnerabilities.¹⁵⁰ The FTC has enforcement authority over the privacy practices of many entities that fall outside of HIPAA. The FTC's enforcement authority applies to acts and practices that are unfair and deceptive and does not prescribe privacy requirements that must be adopted or followed.¹⁵¹

Patient Consent

Healthcare entities are partnering with outside parties, particularly technology companies, to improve the clinicians' technology, develop data analytics, conduct research, and other purposes. Although such arrangements are not new, questions have recently arisen regarding the propriety or legality of some of these arrangements involving PHI, perhaps because they are becoming more prevalent and involve larger amounts of data.





For example, St. Louis-based Ascension Health announced in November 2019 that it had engaged Google to help it improve its technology operations and move its infrastructure to a cloud-based platform.¹⁵² Although the parties signed a business associate agreement and Google has stated that it has taken steps to ensure the privacy of the patient data,¹⁵³ the endeavor, called “Project Nightingale,” has sparked federal scrutiny amid concerns that the data are not being adequately protected, that patients had not received advance notice about the deal, and whether patients can opt out of such data sharing.¹⁵⁴

Similarly, Mayo Clinic has licensed its patient data to 16 technology companies to train AI systems without notifying patients of the deals or asking them for consent to use their data. After patients raised concerns, the Mayo Clinic now says it is reexamining its consent process.¹⁵⁵ This will become a bigger problem as more entities acquire PGHD technologies, such as Google’s anticipated acquisition of Fitbit, which has raised questions regarding how Google would handle and safeguard the data of Fitbit’s 28 million users.¹⁵⁶ As a result, some people do not trust that their health data would be protected, stymieing the adoption of health technology although health IT can improve patient outcomes.¹⁵⁷

Internet of Things

The IoT refers to the technology and connectivity of various objects including appliances, devices, wearables, and sensors to the Internet or other networks.¹⁵⁸ Connecting these objects enables organizations to collect and analyze data to gather new insights into how to optimize processes, improve decisions, and automate responses to health events. The IoT has many potential applications in healthcare, such as remote monitoring, medical device integration, smart pills, and smart facilities, i.e., inventory management.¹⁵⁹ Patient-generated health data (PGHD) can be collected and shared using the IoT.

There are privacy and security concerns with the IoT.¹⁶⁰ Devices such as fitness trackers link data to online user accounts, which can be used for advertising or to determine insurance rates. Connected devices can also be used to eavesdrop on users.¹⁶¹ As IoT objects become more integrated with health IT systems, security risks increase. These include the potential for unauthorized access, misuse of personal information, and the ability of IoT objects to be used to facilitate attacks on other systems.¹⁶² Most users are unaware that devices in the IoT, including medical devices, are typically not subject to HIPAA.¹⁶³ Additional concerns have been raised regarding the limited interoperability across IoT vendors and the challenges of informed consent for users of IoT technologies.¹⁶⁴

Privacy and Security of Synthetic Data

Researchers who want to conduct large-scale, population-level research on de-identified data are often not able to because privacy concerns about health data make it difficult to perform analyses used for predictive analytics, improved outcomes, and other topics.¹⁶⁵ For example, de-identified data may be easily re-identified using AI, reducing the ability of researchers to access data of real patients due to the privacy risk.¹⁶⁶ Synthetic data statistically mirrors the real population in terms of demographics, disease burden, vaccinations, medical visits, and social factors. Because it is not related to actual clinical data, the use of synthetic data can alleviate many privacy and security concerns for experimenting with large-scale data. For example, Synthetic Mass is a synthetic database based on the population of Massachusetts, with patients generated by Synthea, an open-source synthetic patient population simulation.¹⁶⁷ ONC is supporting an effort to enhance Synthea to produce high-quality synthetic data for opioid, pediatric, and complex care use cases focusing on Patient-Centered Outcomes Research (PCOR).¹⁶⁸ Examples of





additional organizations conducting synthetic data projects include the VA and Boston Children's Hospital.¹⁶⁹

However, synthetic data are not a panacea from a privacy and security standpoint. Questions have been raised whether AI could be used to re-identify the real patient populations on whom the synthetic health data were based. Also, typically real data needs to be used to verify the results of synthetic data, so the records of actual patients are still vulnerable.¹⁷⁰

International Data Exchange and Privacy Considerations

The European Union's (EU) General Data Protection Regulation (GDPR) established new rules on how companies manage and share personal data. The GDPR is more expansive than HIPAA and requires entities to implement new privacy and security measures as well as to obtain explicit consent to the acquisition and processing of individuals' data.¹⁷¹ There is still much to be determined about how the GDPR will affect U.S. companies, including health IT developers. Recent guidance has clarified some of the GDPR's provisions and additional clarification is expected.¹⁷² It is anticipated that enforcement will increase in 2020 and several large fines will be imposed.¹⁷³ For instance, in June 2020, a French court fined Google €50 million for GDPR violations.¹⁷⁴

Other international changes in data privacy protections law may also affect U.S. entities. For example, in June 2020, Japan promulgated an amendment to its Personal Information Protection Act that extends the applicability of the law to certain foreign businesses that handle the information of individuals in Japan and establishes more stringent requirements for cross-border transfers of information.¹⁷⁵

The COVID-19 pandemic may affect the implementation and enforcement of these privacy changes, as work locations are moved and governments around the world have loosened their privacy restrictions to support public health.¹⁷⁶

State Privacy Considerations

Many states have laws and regulations to protect the privacy of health information. They often have stricter privacy protections on use and disclosure than the HIPAA Privacy Rule, which increases the complexity of compliance.^{177,178} These laws and regulations also vary from state to state, causing confusion among inter-state exchange partners and making it more difficult and expensive to manage technology to ensure privacy compliance.

Additionally, states have begun to enact new privacy laws that likely encompass data collected by and/or maintained by healthcare entities and other entities that fall outside the scope of HIPAA.¹⁷⁹ For instance, the California Consumer Privacy Act of 2018 (CCPA), which expands the privacy rights of California consumers, went into effect on January 1, 2020; enforcement began on July 1, 2020.¹⁸⁰ Other states contemplating their own versions of CCPA include Florida, Hawaii, Illinois, Nebraska, New Hampshire, New Jersey, and Wisconsin.¹⁸¹ Another new state law that increases healthcare entities' privacy and security obligations is New York's Stop Hacks and Improve Electronic Data Security (SHIELD) Act, which went into effect on March 21, 2020. This law creates new data security requirements for HIPAA covered entities, which now need to protect data elements that are not PHI.¹⁸²





Privacy and Security Issues with Artificial Intelligence

Data analytics and AI are increasingly being developed and used in healthcare. According to the National Academy of Medicine, AI offers opportunities to improve patient and clinical team outcomes, reduce costs, and impact population health.¹⁸³ For example, ONC is collaborating with the National Institutes of Health on a project to train data for AI to enhance the PCOR data infrastructure.¹⁸⁴ This trend is raising new privacy and security concerns. For example, AI automation raised the risk that the patient data and the AI systems themselves may become the subject of manipulation and data breaches.¹⁸⁵ In recognition of this growing issue, the FTC issued general guidance in April 2020 about using AI, including a warning to AI users that the algorithms be protected from unauthorized use.¹⁸⁶ The FDA is considering a new framework for regulating AI software as a medical device.¹⁸⁷

Collecting, using, and sharing data for AI also raises the risk of violating patient privacy. This is especially problematic when the data are shared with third parties for developing and training AI systems because it is harder to keep patients' identities confidential. Under HIPAA's Privacy Rule, a covered entity may disclose PHI to third parties without patient consent if it is de-identified. It has been shown that AI technology can easily and quickly pair information and re-identify individuals.¹⁸⁸ The recent partnerships between healthcare entities and technology companies that already hold large amounts of consumer data may mean that no data can remain de-identified because AI can combine healthcare data with consumer data.^{189,190}

Cybersecurity

Health data continues to be vulnerable to cybersecurity threats. Ransomware attacks against health data ramped up in 2019 and are expected to continue in the future.¹⁹¹ Malicious cyber activity has also increased by actors trying to take advantage of U.S.-based healthcare entities during the COVID-19 pandemic. Both the Federal Bureau of Investigation (FBI) and the Department of Homeland Security (DHS) have issued warnings about such targeting.^{192,193} The FDA and DHS have issued several warnings in 2020 about potential cybersecurity vulnerabilities in certain medical devices.^{194,195} The dramatic rise in telehealth and telework due to the COVID-19 pandemic has also increased the risk that electronic health data will be stolen, compromised, or otherwise adversely affected. For instance, the FBI issued a warning about the privacy and security risk of using certain video conferencing platforms.¹⁹⁶ Remote healthcare workers are also being targeted by new voicemail phishing attacks, known as "vishing" attacks.¹⁹⁷

Cybersecurity and privacy are seen as the largest barrier to the adoption of digital strategies in the healthcare industry.¹⁹⁸ Even though CMS has urged for the end of the use of fax machines by 2020 due to interoperability issues and privacy risks at fax endpoints, 90 percent of clinicians are still using fax machines and eschewing health IT for data sharing due to cybersecurity concerns.¹⁹⁹ The rise of e-faxing, also known as cloud faxing, may alleviate some of these concerns and increase interoperability.²⁰⁰ In December 2019, the EU released new guidance on the cybersecurity for medical devices which may inform other guidance helpful to the United States.²⁰¹

Privacy Issues with Genomic Data Sharing

The use of genomic data collection is expanding, fueled by the potential of precision medicine and personalized therapies, as well as the wider availability of testing. Much of this data collection is dependent on the donation of such data to academic and research institutions. However, the data are increasingly





being used in areas other than biomedical research and by commercial entities, which has raised concerns about the protection of the data. A recent study has found that as patients learned more about the potential privacy risks of genomic data and the acquisition of genomic data for commercial use, they were more concerned about the privacy and security of their data and less likely to share it.²⁰² Less than 12 percent of respondents were willing to donate their genetic data, more than 50 percent expected to be paid for it, and almost 38 percent refused to share it, even if they would have been paid for it.²⁰³

TARGET AREA: PATIENT ACCESS TO INFORMATION

Background

Patients' electronic access and use of their health information are critical to enabling individuals to better monitor their health as well as manage and coordinate their care.²⁰⁴ The ONC Cures Act Final Rule and CMS Interoperability Final Rule will help improve patient access to their health information. The ONC Cures Act Final Rule will support this by enabling patients to receive on-demand access to certain information in their medical records, specifically the data included in the USCDI-defined data elements, and allowing patients to choose which apps they want to use to access their medical records. Additionally, the ONC Cures Act Final Rule requires the capability for patients to electronically access their health information at no cost and addresses information blocking practices.²⁰⁵

Current State

Safety and Impact of Mobile Health Applications

Standardized use of APIs could enable prompt increased access to medical records and improve patients' ability to obtain them.²⁰⁶ The ONC Cures Act Final Rule includes provisions that improve patients' ability to access and use their data from clinicians by establishing secure, standards-based API requirements and gives patients electronic access to their health information at no cost. These provisions enable patients to choose which apps they authorize to access their data. The CMS Interoperability Final Rule builds on these provisions by requiring certain payers to give patients access to their data through standards-based APIs.²⁰⁷

The private sector is also providing innovative opportunities for patients to access, manage, and share their health data with trusted parties. The CARIN Alliance is facilitating increased consumer-mediated exchange through third-party apps. In 2020, it released the My Health Application where consumers can select a healthcare app of their choice to help collect health information across clinicians, hospitals, and payers. My Health Application acts as a centralized vendor and platform agnostic location with 11 consumer-facing apps available on release.²⁰⁸ Each app featured on the website has attested to the CARIN Code of Conduct. Users can see each app's affiliations with other trusted organizations (such as CMS, VA, Carequality, CommonWell Health Alliance, 1up Health, and Apple Health), and can easily access the app's privacy policies.²⁰⁹ Additionally, Xcertia has created guidelines to support the safe and effective development of mobile health apps.²¹⁰ Organizations including Ranked Health and PsyberGuide are reviewing and ranking healthcare apps to help patients and clinicians adopt clinically proven and high-quality digital health solutions.^{211,212,213}

However, some stakeholders have expressed safety concerns with healthcare-related, consumer-facing third-party apps, including fears that these apps may be developed without expert involvement, an evidence





base, or strong validation.²¹⁴ For instance, a study that evaluated asthma management apps found that only one out of the eight reviewed apps was consistent with clinical guidance. Another study found that just 10 percent of apps for depression include evidence-based principles. Moreover, there are concerns related to the information presented to the consumer, such as incorrect or incomplete information, content variation, and incorrect or inappropriate response to consumer needs. For example, an app for bipolar disorder incorrectly differentiated between condition types and suggested that it was contagious.²¹⁵ Some prescription benefit managers have introduced programs to review digital health apps on a variety of factors including clinical accuracy. One large prescription benefit manager introduced a digital health formulary that includes a curated set of apps.²¹⁶

Correction of Incorrect Clinical Data and the Ramifications of Exchange of this Data

Clinicians can use information stored in the EHR to make well-informed clinical decisions. However, up to 70 percent of patient records contain incorrect information.²¹⁷ Of patient-reported medical record errors, 42 percent were described by the patient as serious or very serious, such as those related to diagnoses, medications, allergies, test procedures or results, and notes on the wrong patient.²¹⁸ Patients often have difficulty getting incorrect EHR data corrected. HIPAA provides patients with the right to ask for a correction, but healthcare entities are not obligated to make changes and may reject a patient's request for correction. Although some requests for health record corrections are resolved quickly, others may not be corrected with little feedback from the clinician or healthcare entity.²¹⁹

One of the ramifications of incorrect data is the subsequent electronic sharing of the data with other healthcare entities and incorporation of that data into various medical records. For example, in regions with a strong HIE presence, the HIE may transmit incorrect data it receives to other participants. Even if the source of the incorrect data subsequently updates it in the HIE, facilities that received the incorrect data and incorporated it into their system may never know about the change.

Use and Sharing of Patient-Generated Health Data

PGHD are data created, recorded, or gathered by or from patients (or family members or other caregivers) to support their health. This data may include health history, biometric data, symptoms, and lifestyle information. PGHD captured and shared in a non-clinical setting can offer insights into a patient's health and potentially enable care teams to make timely and well-informed decisions.²²⁰

As a result of the COVID-19 pandemic, there has been an increased need for tracking personal metrics such as temperature, heart rate, and oxygen levels, which are common symptoms of the disease. The collection of such PGHD could help monitor and mitigate the spread of the virus.²²¹

Consumer interest in the use of PGHD has increased with the growing prevalence of wearable fitness trackers and mobile health apps. The increasing number of devices and apps on the market along with differing data preferences have some clinicians concerned about the interoperability and scalability of PGHD efforts.²²² For example, since VA's launch of Apple Health Records in late 2019, VA has established the VETERANS (Veteran Engagement Through Electronic Resources and Notifications Study) pilot program which monitors 25 veterans with atrial fibrillation using the electrocardiogram (EKG) functionality in Apple watches.²²³ As part of the pilot program, veterans are taught how to share their EKGs through secure messaging on My HealtheVet. VA is also developing the ability to gather data from wellness devices and glucometers using a mobile app.²²⁴





Health IT Infrastructure Gap Analysis

TARGET AREA: USE OF TECHNOLOGIES THAT SUPPORT PUBLIC HEALTH

Limited Bidirectional Exchange of Clinical and Administrative Data for Public Health Purposes

Public health authorities face interoperability challenges to be able to collect, access, and use information, as well as exchange it bidirectionally between clinicians and laboratories, particularly data needed for proper reporting.

There are long-standing infrastructure gaps in public health reporting capabilities that have prevented public health authorities from receiving timely information on COVID-19 infections. Public health data collection is decentralized in the United States, meaning that each locality sets the standards for data collection and reporting. Because COVID-19 has a nationwide reach, this has had problematic effects.²²⁵ Public health authorities have been unable to receive complete information on patient demographic information, medical history, and course of the disease because of incomplete data and inadequate access to clinical data from EHRs. Additionally, bidirectional information exchange between clinicians and public health agencies, while valuable to patient care and public health interventions, is not supported consistently across the country. Existing technologies such as FHIR[®] APIs could provide a channel for public health agencies to pull information from EHRs; however, some public health agencies may not choose to implement these technologies, in part because they do not have the technical infrastructure to support such exchange.²²⁶ These obstacles have led to delays in contact tracing and case investigations, which can have direct effects on the spread of COVID-19.

In addition, there is a paucity of data standards to allow for standardized reporting from EHRs directly to public health or government officials, and some data are not stored in the EHR. These stakeholders are only able to collect data in manual, error-prone manners. Data on measures such as bed availability, staffing, and equipment inventory are only actionable if the data are real-time or near-real-time. A delay in understanding these important measures can result in grave harm. The SANER Project developed an HL7[®] FHIR[®] Implementation Guide to enable standardized reporting of bed availability, staffing availability, and equipment inventory. This Implementation Guide has set the technical standards for such capability; however, the standards need to be validated in a practical setting. There has been success in standardizing EHR reporting for immunizations, therefore this use case can serve as an example for COVID-19-related data.

Privacy and Security Concerns Related to Public Health

Biosurveillance efforts, including case investigation, contact tracing, and exposure notification, as well as increased use of telehealth and remote monitoring, face privacy and security issues.

There is an urgent need to be able to conduct nationwide surveillance and contact tracing of COVID-19 cases. Various IT companies have proposed solutions to accomplish this using cell phone location data. However, there are privacy concerns regarding these systems. Due to the novel nature of these





technologies, ambiguity exists about the privacy protections afforded to the users of such technology, hindering widespread use because the data can fall outside the scope of federal or state privacy laws. In addition, much of the data generated from these mobile apps and technologies are siloed from health delivery and public health systems, so public health authorities are often not able to access insights from these apps. A systematic review of the data from exposure notification systems is needed, including the accuracy and completeness of tracking of exposures, rates of adoption, and their impact on pandemic control.

Lack of Nationwide Infrastructure to Track Vaccine Supply and Administration

Even pre-pandemic, questions arose about whether various public health organizations might be tracking unimmunized populations, where patients are obtaining vaccines, and if others can access that data.

As the country's public health entities prepare for the availability of COVID-19 vaccines, existing gaps in the infrastructure to track the supply and administration of these vaccines have come to light. Because vaccine databases, also known as immunization information systems, are administered on a state level, there is no nationwide database to track the administration of the future COVID-19 vaccines and other vaccines.²²⁷ A nationwide database would allow federal agencies to track vaccine supply and distribution on a macro level, making it easier to predict resource allocation and understand patterns across the country.²²⁸ The HITAC has noted in the past, while deliberating on pediatric voluntary criteria in the ONC Health IT Certification Program Proposed Rule, that the lack of ability to track vaccines is problematic.

Need for Improved Patient Matching when Sharing Data for Public Health Purposes

Patient matching challenges exist due to gaps in information (particularly demographic) shared from commercial laboratories and from contact tracing records, and lack of a UPI.

Public health authorities have been unable to receive complete information on patient demographics, creating significant challenges in accurately matching patients to reported data. Missing or incorrect data that limits or prevents accurate patient matching can delay a public health authority's response.²²⁹ Patient matching errors can originate from multiple aspects of the healthcare experience, such as during patient registration or data sharing among organizations. Matching errors can result in inaccurate creation, inadvertent merging, and duplication of patient records. These errors can negatively impact public health due to delays in contact tracing and present patient safety risks.²³⁰

Many stakeholders believe that a lack of standardization of demographic data elements collected at the point of care and a lack of a national unique patient identifier limit their ability to effectively match patient records.²³¹ Proponents of a unique patient identifier suggest that it will save time and money currently spent on patient matching.²³² They also suggest that it is key to improving interoperability and will increase patient safety and quality of care.²³³ Some who oppose the use of identifiers raise privacy and security concerns and note that a unique patient identifier does not solve all patient matching problems. Proponents of a unique patient identifier respond by pointing to the success of Europe's unique patient identifier and suggest that privacy can be further enhanced by encrypting other elements of PHI.²³⁴ Others suggest requiring additional data elements, such as an e-mail address, for use in patient matching.²³⁵ ONC is partnering with several industry organizations for an initiative called "Project US@" to issue a unified, health care industry-wide specification for representing a patient's address for the purposes of patient matching and linking records.²³⁶





Challenges with International Exchange of Clinical Data for Public Health Purposes

Currently, countries are imposing significant restrictions on the movement of people and goods to ensure public safety, in part due to a lack of information about the health status of travelers.

Although there is potential value of exchanging clinical data between countries to support public health, the ability to do so is not yet present. Within the United States, the prevailing interoperability challenges would preclude data sharing with other countries. Such data may be critical in understanding transmission risks and the impact of policies in the early phases of a pandemic. Additionally, each country utilizes its own information systems and data standards to collect data. Operational obstacles exist, but there is also an absence of trust frameworks among countries to share health data. Countries may be hesitant to share sensitive patient data of their citizens with other countries without outlined principles of how the data will be used.

TARGET AREA: INTEROPERABILITY

Interoperability Needs to be Increased More Broadly across the Care Continuum

LTPAC, behavioral health, and home and community-based service settings are limited in their ability to exchange data with other clinicians, including SDOH data, in part due to EHR design.

When transferring patients from an LTPAC setting to another care setting, the accompanying documentation frequently does not include the reason for transferring the patient. Similarly, many acute care clinicians do not share data when transitioning patients to LTPAC facilities. Sixteen percent of acute care clinicians reported sharing all patient data with skilled nursing facilities and 35 percent sharing some data, leaving almost half reporting no data sharing.²³⁷ When data are shared between care settings, data elements include medications, demographics, and diagnoses, while other data such as measurements, observations, and advance care planning remains unshared. Acute care and LTPAC providers often communicate by fax or paper hand-offs, leading to data entry errors during transcription.²³⁸

Privacy concerns around sensitive behavioral health data contribute to limited information sharing.²³⁹ As integrated behavioral and physical health services gained traction in recent years, it has become apparent that EHRs are not equipped to designate specific components of the record as confidential. Redisclosure rules make it difficult for offices that provide physical health, mental health, and SUD services to share data with patients and other members of the care team inside and outside the organization.²⁴⁰

Limited Exchange of Social Determinants of Health Data

Business models across healthcare sectors do not yet support the capture and use of SDOH data due to a lack of standards and data availability, imperfect patient matching, and varying levels of technical maturity of community-based organizations' IT systems.

For example, if SDOH data are collected, they are usually documented in free-text portions of the EHR, limiting the ability for data exchange between clinicians. Healthcare entities have been reluctant to share PHI with social service agencies or community-based providers, who may not be covered by HIPAA, due to concerns that such sharing will result in HIPAA violations by the healthcare entities.²⁴¹





Need for Annual Review of Priority Uses of Health IT

The HITAC annual review and publication of priority uses of health IT and existing standards and implementation specifications related to the priority uses required by the Cures Act needs to be implemented.

Need for Increased Coordination of USCDI Submissions

HITAC members often make suggestions for additions to the USCDI, but currently must submit them to ONC as an individual.

Impact of Health IT on Patient Safety

Stakeholders continue to express concern about the impact health IT can have on patient safety, for example, resulting from EHR configuration.

EHR configuration checklists can help ensure that EHRs are configured with patient safety in mind at the time of implementation.²⁴² However, the large number of items in the checklist illustrates the complexity of EHR software and the lack of vendor focus on usability.²⁴³

Lack of Data to Support Health Equity and Equitable Distribution of Resources

Data are not systematically collected nor used to identify disparities in outcomes, quality of care, or risk.

Although EHRs can capture race and ethnicity data, they may not be recorded in the EHR or may be of poor quality. At one health system serving a racially and ethnically diverse population, race or ethnicity was unknown 57 percent of the time. When patients directly reported this information, it was different from what was already recorded 66 percent of the time.²⁴⁴ Non-traditional sources of health data, such as the Neighborhood Atlas, exist but have not yet been mined or shared to support more equitable distribution of health resources.²⁴⁵

The COVID-19 pandemic is a recent example of how data are needed to support the equitable distribution of resources. Failing to collect race and ethnicity for COVID-19 tests created a gap in understanding of and response to the pandemic. Early in the COVID-19 pandemic, data showed that a disproportionate number of people hospitalized with COVID-19 were African American. At the same time, states struggled to report COVID-19 case numbers by race and ethnicity because those data were not collected systematically by laboratories and others conducting testing. Published best practices encourage state and local leaders to disaggregate data related to COVID-19 cases, and measures of access to testing and treatment among others, by age, race, ethnicity, gender, disability, neighborhood, and other sociodemographic characteristics. Analyzing data this way illustrates the interplay between place and social factors, allowing for informed decision making to ensure equitable access to resources and determine the burden of infection across populations.²⁴⁶

Inability to Use and Share Health Data for Research Purposes





Regarding data captured in EHRs, researchers are challenged by data quality and consistency concerns, limited governance structures and policies allowing access to the data, inconsistent implementations across technical architectures, and varying needs of individuals and organizations that create and use data.

Data quality and consistency challenges limit the availability of health data captured in EHRs for research purposes. They include linking data across systems, ensuring privacy for study participants, and engaging patients in the consent process when necessary.²⁴⁷ In terms of linking data across systems, healthcare entities and researchers can work together to harmonize data standards, establish common nomenclatures, and manage metadata.²⁴⁸ The process of gathering EHR data for research being conducted outside the health institution is expensive and labor-intensive with differing goals among researchers, the healthcare system, and research participants.²⁴⁹ Researchers often transcribe clinical data, demonstrating the need to streamline data transfer methodologies.²⁵⁰

The clinicians and researchers maintain their own systems for capturing and storing electronic data. Common data standards and technology to easily integrate, aggregate, or compare data among research studies do not currently exist. For example, there are no interoperability standards between HL7® and the Clinical Data Interchange Standards Consortium, the standards body for clinical research data.²⁵¹ Although half of research organizations plan to create a strategy for using EHRs, only 20 percent currently use them. Electronic consent, which would further researchers' ability to use EHR data, is not yet widely adopted. There is no unified approach to obtaining and maintaining electronic consent, resulting in inefficiencies for researchers working with multiple institutions in the form of additional workflows and interfaces.²⁵²

Lack of Metadata Standards Hinders Reuse of Data for Research

Many data management tasks are burdensome because they are manual and require human labor for reconciliation that could be automated.

The lack of a common metadata nomenclature and description of data elements translates to burdensome data management tasks that often require manual processes for reconciliation. For example, clinical registries, developed by professional societies and other organizations, support health outcomes research. However, they are often standardized at the database level, requiring manual chart abstraction and data entry for submission to the registry. For many registries, manual chart abstraction results in significant financial burden for data collection and data analysis.²⁵³

TARGET AREA: PRIVACY AND SECURITY

Beyond HIPAA: Protections for Data Generated Outside of the HIPAA Framework

Lack of Clear Rules for Data Not Subject to HIPAA Protections

Health data not subject to HIPAA lacks clear legal privacy protections. Health data sent to a third-party app that is not the business associate of, owned, or affiliated with a covered entity would likely put that data outside of the protections of HIPAA.

Consumers are often unaware that the data they generated and collected are not protected by HIPAA, and any privacy protections are voluntary, not mandatory.²⁵⁴ The exchange of health data with entities not subject to HIPAA is expected to increase due to the implementation of the ONC Cures Act Final Rule and





developments such as Google's acquisition of Fitbit and Facebook's launch of a new preventive health tool.²⁵⁵ HIPAA's limitations may erode public trust in sharing digital health data outside of the HIPAA framework.²⁵⁶ In addition, initiatives between big technology companies and health systems like "Project Nightingale" have raised privacy and transparency concerns from providers, patient advocates, and government agencies.²⁵⁷

Lack of Clarity about the Parameters for Disclosures and Their Implications for Patient Consent

There is confusion about patient consent for research and other uses or sharing of their data. Additionally, rules for consent have not been established for receivers of pushed (received) data when they receive it.

Patients continue to experience constraints on their ability to choose whether to electronically exchange sensitive data. They are often unaware that their data, including genomic data, may be used or disclosed without their knowledge or consent or disclosure about how it will be shared.²⁵⁸ More than four-fifths of Americans say that they feel very little or no control of the data collected about them.²⁵⁹ Consumers also often do not read the terms of service contracts for third-party apps and other recipients of data so they do not understand the extent to which they have permitted the use and sharing of their information.²⁶⁰

Lack of Understanding of the Vulnerabilities of Devices Connected to the Internet of Things

There is limited interoperability across IoT vendors. As IoT devices become more integrated with health IT systems, security risks increase. Additional concerns have been raised regarding the challenges of informed consent for users of IoT technologies.

Medical and other devices connected to the IoT are vulnerable to hacking and other privacy and security risks. However, privacy and security are not necessarily considered when these devices are designed, and most of them are not subject to HIPAA.²⁶¹ Users typically are unaware of the risks of using connected devices. As the use of these devices increases, so does the risk of exploitation.²⁶²

Potential Privacy and Security Risks Associated with the Use of Synthetic Data

HIPAA constraints limit the ability to conduct research and train machine learning models using large-scale datasets, in both research and healthcare settings.

Although synthetic data reduces some privacy and security risks because it uses fabricated patient records, it may not be a cure-all mechanism to protect the confidentiality of healthcare data. There is the potential that AI could be used to re-identify the actual patients on whom the synthetic data are based.

TARGET AREA: PATIENT ACCESS TO INFORMATION

Concerns about the Safety and Impact of Mobile Health Applications

As the quantity and use of third-party apps grow, there is increasing concern about the clinical accuracy of these apps and the potential for patient harm. The use of apps that are built without using sound clinical knowledge can produce incorrect conclusions or readings.

Most apps are not regulated, resulting in tools that are not validated for quality and safety.²⁶³ Research has identified 80 unique patient safety concerns associated with health apps, the most serious of which cause





potential or actual harm or other hazardous events.²⁶⁴ The use of apps that are built without using sound clinical knowledge can produce incorrect conclusions or readings, such as over-diagnosis of benign skin lesions, incorrect insulin dose calculations, and improper brain function assessments, adversely affecting patient safety.^{265,266}

Barriers to Correcting Incorrect Clinical Information and Mitigating Its Exchange

There is a limited ability to correct data that has already been exchanged. As a result, these incorrect data might persist and be further disseminated. Transparency about the accuracy of patient data is lacking for patients, which in turn affects patient safety.

It is not clear who is responsible for correcting incorrect data exchanged electronically via an HIE.²⁶⁷ Some state laws and organizations' internal policies dictate the HIE's role and responsibility for correcting incorrect clinical data in its possession. For example, Arizona law provides patients with the right to request that the HIE amend incorrect health information.²⁶⁸ Other HIEs place the responsibility of managing incorrect data on participants, noting that all HIE data originates from data sources, not from the HIE itself.²⁶⁹ Exploring the use of data provenance to help identify potentially incorrect information could improve patient safety and data accuracy by supporting error identification and corrections up and downstream.²⁷⁰





Recommendations for Addressing Health IT Infrastructure Gaps

The Cures Act requires this annual report to include recommendations for addressing the identified gaps in policies and resources across the target areas and for furthering interoperability throughout the health IT infrastructure. The HITAC offers the following suggestions for HITAC activities that could result in future recommendations that would be transmitted to the National Coordinator for Health IT. Within each target area, topics are grouped by the timeliness of the opportunity to be addressed by the HITAC. An immediate opportunity correlates to planned topics for the HITAC within the next one to two years, while longer-term opportunities are anticipated to begin in three or more years.

TARGET AREA: USE OF TECHNOLOGIES THAT SUPPORT PUBLIC HEALTH

Illustrative Story of What the Recommended HITAC Activities Will Enable

A patient who lives in a rural county underwent a nasal swab test for COVID-19 at a county-run public testing site and received a positive result while still at the site, which was also reported to the state public health agency. However, key demographic data were not collected for the patient so timely contact tracing and notification of proper quarantine conduct could not be undertaken. As a result of improved patient matching techniques, the state public health agency has begun investigating artificial intelligence-based solutions to improve its ability to conduct patient matching and to use other data sources to fill in missing demographic information to increase the precision of case reporting and subsequent vaccination programs.

Immediate Opportunities

Exchange of Bidirectional Clinical and Administrative Data for Public Health Purposes

Opportunity: Improve bidirectional interoperability between public health information systems and EHRs.

Local, state, and federal public health authorities will continue to need data to measure the impact of COVID-19 infections throughout this pandemic and equivalent measures for future public health emergencies. It is necessary to understand the continued gaps and potential solutions that can advance interoperability between public health reporting systems and EHRs.

Recommended HITAC Activity: Encourage further support for the identification and exchange of minimum necessary datasets and consideration of technical requirements for exchange for public





health, e.g., with laboratories, especially for test order entry, results, and case reporting. Additionally, encourage further support for the development of standards for population-level data exchange.

Recommended HITAC Activity: Identify interim solutions implemented to improve reporting capabilities and assess whether additional long-term solutions are needed.

Recommended HITAC Activity: Compile a set of useful health IT resources to raise awareness among public health organizations.

Opportunity: Accelerate the use of data standards to improve situational awareness for federal, state, and local government emergency response.

The efficacy of standards and implementation guides need to be validated in real-world settings.

Recommended HITAC Activity: Facilitate acceleration of the practical use of data standards to improve situational awareness for local, state, and federal government public health emergency response.

Opportunity: Explore an expanded role for HIEs to support public health data access and exchange.

Public health authorities need to be able to collect and exchange information from clinicians and laboratories for proper reporting in their jurisdictions.

Recommended HITAC Activity: Learn about the successes and remaining barriers to exchange by HIEs to support public health's geographically oriented information needs, including how to optimize, standardize, and potentially expand their role and address regional differences in capacity to address any gaps. Identify approaches to combine data from national HINs to address regional public health data needs.

Privacy and Security for Public Health Purposes

Opportunity: Discuss the tradeoffs between increasing interoperability, protecting privacy and security, and ensuring public safety during pandemics.

The COVID-19 pandemic has shed light on existing interoperability barriers; however, concerns exist about how to ensure public safety, privacy, and security when exchanging information between clinical and public health stakeholders.

Recommended HITAC Activity: Help clarify what data can be collected in a public health emergency and how it can be used.

Recommended HITAC Activity: Encourage clinical workforce and patient education/re-education on the use of technology for telehealth (including smartphones).

Opportunity: Increase clarity on the privacy and security concerns associated with biosurveillance activities.

Technologies that facilitate biosurveillance and contact tracing have raised privacy concerns. Additional clarity is needed about how existing privacy laws affect these technologies.





Recommended HITAC Activity: Identify educational approaches that offer improved transparency of privacy protections applicable to contact tracing apps and biosurveillance technologies such as contact tracing and exposure notification apps.

Recommended HITAC Activity: Encourage the development of guidance about and harmonization of privacy and security protections of mobile health data used for public health information across varying state and local laws.

Vaccine Tracking

Opportunity: Investigate whether predictive analytics can be used to a) aggregate and analyze data to anticipate needs for vaccines among vulnerable and/or high-risk populations, including for flu and COVID-19 prevention, and b) better target outreach, education, and response efforts and strategies.

Existing health IT solutions may help facilitate vaccine tracking to anticipate needs for vaccines among vulnerable and high-risk populations.

Recommended HITAC Activity: Identify opportunities and barriers for healthcare, home and community-based service, and public health organizations to work together to target vulnerable populations for vaccination campaigns, highlight successful predictive analytics, and assess how health IT can better support a balance of vaccine data being pushed vs. pulled for public health purposes.

Recommended HITAC Activity: Encourage needed improvements to community registries for easier exchange and use, e.g., increased normalization and standardization of data.

Patient Matching for Public Health Purposes

Opportunity: Improve patient matching through expanded use of AI while considering privacy and security concerns about AI algorithms, in order to accurately identify patients and locate at-risk individuals.

Opportunity: Increase alignment across federal, state, and local public health reporting requirements and guidance to support improved collection and consistency of demographic data.

ONC is developing a report for Congress to outline a path forward on patient matching. The HITAC could assist and accelerate this work to improve patient matching.

Recommended HITAC Activity: Develop tactical recommendations based on ONC's forthcoming Patient Matching Report to Congress, including considerations of expanding the use of AI and related privacy and security concerns as well as increased alignment of government public health reporting requirements and guidance.

Longer-Term Opportunities

International Exchange of Clinical Data for Public Health Purposes

Opportunity: Share and apply lessons learned across countries about the use of health IT to support public health, e.g., for electronic case reporting.

The ability to share health data with organizations in other countries may have value during the pandemic; however, the legal and operational parameters that support or inhibit this exchange are unclear.





Recommended HITAC Activity: Identify opportunities and barriers for the use of health IT in support of compliance with international health regulations and international data exchange. Experts to be consulted could include the CDC, WHO, GDHP, Department of Commerce, clinician representatives, and privacy and security experts.

TARGET AREA: INTEROPERABILITY

Illustrative Story of What the Recommended HITAC Activities Will Enable

An academic medical center wants to use its clinical data for population health purposes and community outreach. It finds that it needs to capture more patient demographic data to be able to identify health disparities and implement community benefit programs. The academic medical center institutes a new process based on recommended best practices to collect standardized, patient-reported demographic data such as race, ethnicity, gender identity, and preferred language. Applying appropriate privacy protections, it then shares this data with social service organizations to improve care and outreach in its service area as well as with public health organizations and state agencies to support public health efforts.

Immediate Opportunities

Exchange of Health Data More Broadly across the Care Continuum

Opportunity: Collect more complete data about patients, which will help clinicians identify risk factors for procedures, offer interventions, and provide targeted care.

Behavioral health and long-term care providers have lower rates of adoption of EHRs and use of HIEs compared to hospitals and ambulatory clinicians. Addressing this gap is important for enabling behavioral health and long-term care providers to successfully participate in the care continuum. Regarding standards, the HITAC's Interoperability Standards Priorities Task Force identified a need for specialty-specific minimum standards to enable closed loop referrals and data exchange between clinicians.

Recommended HITAC Activity: Learn more about recent developments in standards and exchange in the areas of PROs, e.g., 2020 AHRQ report, and SDOH, such as HL7's® Gravity Project.

Recommended HITAC Activity: Identify and help improve data streams where interoperability is a challenge to sharing broader datasets, especially when a pandemic affects healthcare settings like LTPAC and any transitions to and from those settings. For example, various care settings would benefit from increased consensus on datasets for exchange with that setting.

Recommended HITAC Activity: Leverage the current federally mandated assessment instruments as the basis for a shared, semantically interoperable dataset.

Increased Health Equity across Populations, Locations, and Situations

Opportunity: Advance requirements to collect and share data about groups experiencing health inequities. This data can be used to support the implementation of culturally and linguistically appropriate health IT solutions.

Opportunity: Identify non-traditional sources of health information that could be made interoperable, e.g., primary care doctors receive updates electronically from organizations offering exercise classes for seniors, school clinics, or third-party wellness services.





Standards and requirements regarding data collection to identify individuals who may experience health inequities. Taking a holistic approach to updating data exchange requirements and standards can help promote health equity.

Recommended HITAC Activity: Convene stakeholders, e.g., healthcare organizations, health IT developers, and patient advocacy groups, to discuss:

- a. How to improve collecting and sharing of data that can support identifying and addressing disparities in healthcare, e.g., race codes.
- b. The current state of and potential improvements for the accessibility of consumer-facing health IT by diverse populations.
- c. Non-traditional sources of health information that could be made interoperable to better serve at-risk populations.

Exchange of Social Determinants of Health Data

Opportunity: Develop and adopt standards for SDOH data collection, transfer, and integration for population health and individuals' needs.

The collection, transfer, and integration of SDOH data is fragmented and varies significantly. Expanding the use of standards for non-health data presents an opportunity to integrate health and social support systems in healthcare delivery.

Recommended HITAC Activity: Suggest updates on SDOH data for the ONC Patient Engagement Playbook.

Recommended HITAC Activity: Convene a group of stakeholders from healthcare entities, payers, SDOH technology companies, community-based organizations, and standards development projects to understand the state of SDOH data exchange in practice and identify gaps and barriers.

Recommended HITAC Activity: Suggest SDOH data elements for inclusion in the USCDI.

Coordination of Health IT Standards to Support Interoperability: Priority Uses

Opportunity: Building on the prior work of the HITAC, establish an annual process for reviewing and publishing priority uses of health IT and related standards and implementation specifications.

Recommended HITAC Activity: Each year, review and publish priority uses of health IT and related standards and implementation specifications.

Coordination of Health IT Standards to Support Interoperability: USCDI

Opportunity: A new system exists for individuals to submit suggestions to ONC for consideration for the USCDI, called ONDEC, but some suggestions would benefit from public discussion by the HITAC first.

Recommended HITAC Activity: As needed, collect and discuss suggestions for consideration for inclusion in the USCDI.





Longer-Term Opportunities

Association between EHRs and Patient Safety

Opportunity: Define factors that increase and decrease the safety of health IT that affects patient outcomes.

Health IT can pose patient safety risks, in part due to usability challenges, but factors that increase or decrease these risks are emerging. Highlighting these factors and making information about them publicly available can help organizations consider patient safety as they purchase, implement, and/or upgrade health IT systems.

Recommended HITAC Activity: Review changes that could be made to the Health IT Certification Program to support improvements to EHRs to support patient safety.

Recommended HITAC Activity: Help further define patient safety and any gaps where technology does not support that definition.

Recommended HITAC Activity: Explore the use of health IT in automating the collection and sharing of data about adverse events for drugs and devices.

Sharing Data with the Research Community

Opportunity: Increase alignment between the clinical and research health information ecosystems to enable prospective and ongoing research to occur more quickly and effectively.

Current standards used to capture clinical data are not used by the research community, slowing the ability to use data captured for clinical purposes to conduct research and advance medicine's body of knowledge. To realize this potential, clinicians and researchers need standards and systems that support interoperability and the use of clinical data by research stakeholders.

Recommended HITAC Activity: Learn more about gaps in standards needed by the research community, which is accountable to institutional review boards.

Recommended HITAC Activity: Identify educational approaches that increase awareness and promote the implementation of the research priorities outlined in the National Health IT Priorities for Research: A Policy and Development Agenda.

Opportunity: Determine the type(s) of metadata and related standards necessary to facilitate machine-based, clinical data management, including management of exchanged data to reconcile data from multiple sources.

Current metadata standards do not meet the needs of the research and clinical communities, lacking a common nomenclature and use.

Recommended HITAC Activity: Identify needed metadata standards and potential additions to the USCDI.





TARGET AREA: PRIVACY AND SECURITY

Illustrative Story of What the Recommended HITAC Activities Will Enable

Several of an internist's patients have asked her to accept some of the electronic data collected on their fitness trackers so that she can monitor their weight and activity levels as they start new exercise programs. She is hesitant at first because she is not familiar with the privacy and security risks of devices connected to the IoT and how these risks might compromise her EHR system. Luckily, best practices for developers have been identified to increase the privacy and security of health-related data collected from connected devices. Additionally, tools to increase awareness of the risks of connected devices have been made available to healthcare providers. As a result of outreach efforts, the internist accesses relevant guidelines and takes steps to reduce the privacy and security risks of receiving information from the IoT while more effectively partnering with her patients.

Immediate Opportunities

Beyond HIPAA: Rules for Sharing

Opportunity: Support increased transparency and patient education on business practices and other potential uses of patient health data when healthcare organizations share or license data to technology companies.

Healthcare organizations are increasingly sharing or licensing patient information to technology companies to help improve their health IT systems, develop data analytics, and for other purposes, often without patient knowledge or consent.

Recommended HITAC Activity: Define the roles, responsibilities, and operations of various technical actors in the app economy, building on work completed by a past FACA subcommittee.²⁷¹ These technical actors include clinicians, developers, and patients.

Beyond HIPAA: Patient Consent

Opportunity: In the near term, improve clarity around patient consent for research and exchange of their data, and further patient understanding of the accuracy and validity of clinical information offered by third-party apps.

Large amounts of health data are generated and collected by entities not subject to HIPAA. Educating patients about the limits of HIPAA protections enables them to make more informed decisions about sharing their health data for research and other purposes.

Recommended HITAC Activity: Suggest steps toward a consistent technical and operational approach to capturing and managing consent.

Longer-Term Opportunities

Beyond HIPAA: Rules for Sharing

Opportunity: Support increased transparency and patient education on business practices and other potential uses of patient health data when healthcare organizations share or license data to technology companies.





Healthcare organizations are increasingly sharing or licensing patient information to technology companies to help improve their health IT systems, develop data analytics, and for other purposes, often without patient knowledge or consent.

Recommended HITAC Activity: Learn more about HHS and FTC activities, as well as security approaches of or any security lapses by third-party app developers.

Recommended HITAC Activity: Explore patient and clinician experiences with the sharing of health data with third-party technology companies to continue to identify best practices and gaps.

Recommended HITAC Activity: Review government and industry activities already underway protecting the privacy and security of health data shared with third-party technology companies.

Beyond HIPAA: Patient Consent

Opportunity: Over time, improve clarity around patient consent for research and exchange of their data, and further patient understanding of the accuracy and validity of clinical information offered by third-party apps.

Large amounts of health data are generated and collected by entities not subject to HIPAA. Educating patients about the limits of HIPAA protections enables them to make more informed decisions about sharing their health data for research and other purposes.

Recommended HITAC Activity: Identify educational approaches and potential regulatory solutions that offer improved transparency of privacy protections outside the purview of HIPAA.

Recommended HITAC Activity: Explore ways clinicians can educate patients about the benefits and potential risks of using third-party apps as contemplated by the ONC Cures Act Final Rule and about the need to review and comprehend the apps' privacy policies.

Beyond HIPAA: Internet of Things

Opportunity: Increase awareness of the privacy and security risks of using the IoT to collect health-related data.

Device developers, healthcare entities, and consumers lack knowledge of the vulnerabilities of medical and other devices connected to the IoT.

Recommended HITAC Activity: Identify best practices for increasing the privacy and security of health-related data collected from connected devices.

Recommended HITAC Activity: Identify educational approaches that increase awareness of the privacy and security issues for health-related data collected from devices connected to the IoT and ways to reduce them.

Synthetic Data

Opportunity: Explore whether the use of synthetic health data raises privacy and security issues and, if so, to what extent.

AI could be used to re-identify the actual patient populations on whom synthetic health records are based.





Recommended HITAC Activity: Assess whether the use of synthetic data raises any unintended privacy risks, such as the ability to use AI to re-identify the actual patients on which the synthetic health data are based.

TARGET AREA: PATIENT ACCESS TO INFORMATION

Illustrative Story of What the Recommended HITAC Activities Will Enable

As a result of public deliberation about improving the governance process, data correction requests from patients are addressed more quickly and seamlessly. For example, a patient notices in her patient portal that a medication dosage is listed incorrectly. Fortunately, she can easily report this error to her primary care provider using the portal. Once the provider verifies and corrects the error, the patient's entire care team is automatically notified of the change electronically, including specialists outside her network who use different EHRs. In this case, the correction was made widely within a week of the patient reporting the error rather than over several weeks, if at all. The medication dosage was listed correctly in her medical record the next time she had an appointment with one of her specialists, thereby avoiding the adverse event of a drug-drug interaction.

Immediate Opportunities

Safety and Impact of Mobile Health Applications

Opportunity: Provide reliable information about the quality of apps to enable clinicians to advise patients about app use and to empower patients when using apps to make decisions about their care.

As the use of third-party apps grows, regulation and validation of the clinical accuracy will be important to protect patient safety. Expert guidance on clinical information will help ensure that information delivered to patients is accurate and appropriately communicated.

Recommended HITAC Activity: Support the existing efforts of consortia that are working to vet apps based on their safety and accessibility and educate patients about the findings of the consortia. In particular, investigate if frameworks or scorecards for assessing apps exist or are being developed; if so, raise awareness of these efforts.

Recommended HITAC Activity: Explore ways the safety of mobile health apps could be enhanced.

Recommended HITAC Activity: Evaluate the impact of the use of apps (as opposed to the current portal systems) on patient challenges in collecting, accessing, using, and sharing their health data. Areas to consider include the efficacy, patient experience, and remaining challenges of the use of apps.

Correction of Incorrect Clinical Data and the Ramifications of Exchange of this Data

Opportunity: Increase clarity on the applicable statutes and liability that apply to the exchange of incorrect data, and on methods for correction.

Errors in patient information need to be corrected. However, once the data has been shared, it becomes significantly more difficult to determine how to correct it. There are also issues regarding honoring patient requests to correct data and tracking patient corrections.





Recommended HITAC Activity: Hold a listening session to:

- a. Identify approaches that clinicians and HIEs are taking to correct incorrect data, including incentives for widespread correction.
- b. Discuss liability considerations related to exchanging and correcting incorrect data.
- c. Learn about organizational policies and mechanisms for patients to document change requests, and how data provenance of patient corrections is being tracked.

Suggestions for Additional HITAC Initiatives

The HITAC did not identify additional target areas or related HITAC initiatives as defined in the Cures Act in FY20. The HITAC will revisit this opportunity in the FY21 annual report.

Conclusion

The HITAC made significant progress in advancing interoperability, privacy and security, and patient access to information in FY20; however, work remains in these target areas to achieve the full potential using health IT tools to help transform the healthcare sector. In FY21, ONC and the HITAC will continue to focus on advancing the implementation of the health IT provisions of the Cures Act including the EHR Reporting Program and the Trusted Exchange Framework and Common Agreement, as well as address emerging issues including public health-related technology concerns, contributions to the USCDI, and priority uses of health IT and related standards and specifications.





Appendices

GLOSSARY

2015 Edition Health Information Technology Certification Criteria - The standards and implementation specifications that certified health IT modules would need to include to, at a minimum, support the achievement of meaningful use by eligible clinicians, eligible hospitals, and critical access hospitals under the CMS Promoting Interoperability Programs when such edition is required for use under these programs.

Application Programming Interface (API) - A set of tools, definitions, and protocols for building and integrating application software. It lets a product or service communicate with other products and services without needing to know how they are implemented.

Artificial Intelligence - The theory and development of computer systems able to perform tasks that normally require human intelligence, such as visual perception, speech recognition, decision making, and translation between languages.

CDS Hooks - A technical functionality supporting clinical decision support that enables the creation of standardized places within an EHR workflow where the EHR can issue a notification that an event is occurring. This notification can be received by an external application, which in turn can return pertinent information to the EHR for display to the EHR user.

Certified Electronic Health Record Technology (CEHRT) - Electronic health record technology that meets the 2015 Edition Health IT Certification Criteria and is required for use to qualify for the CMS Promoting Interoperability Programs and to receive a score in the Merit-based Incentive Payment System Promoting Interoperability performance category.

Common Agreement - A set of terms and conditions for health information exchange between health information networks set by the Recognized Coordination Entity (RCE) as required by the Cures Act.

Consolidated-Clinical Document Architecture (C-CDA) - A document standard for the transmission of structured summary data between clinicians, and between clinicians and patients. Transmitted data supports care transitions, referrals, and care coordination.

Contact Tracing - The identification, monitoring, and support of a confirmed or probable communicable disease case's close contacts who have been exposed to, and possibly infected with, the disease.

Covered Entity - An individual, organization, or agency that must comply with HIPAA requirements to protect the privacy and security of health information and must provide individuals with certain rights to their health information. Examples include a health plan, a health clearinghouse, or a healthcare provider who transmits any information in an electronic form for a transaction for which HHS has adopted a standard.

Electronic Case Reporting - The automated, real-time exchange of case report information between electronic health records and public agencies using a shared standards-based, interoperable infrastructure.

Exchange Purposes - A proposed subset of payment, healthcare operations, treatment, public health, and benefits determination purposes for which exchange of electronic health information would be governed under the Trusted Exchange Framework and Common Agreement.

Family Educational Rights and Privacy Act (FERPA) - A federal law that protects the privacy of student education records. The law applies to all schools that receive funds under an applicable program of the U.S. Department of Education.

Fast Healthcare Interoperability Resources (FHIR®) Standard - An interface specification that specifies the content of the data exchanged between healthcare applications, and how the exchange is implemented





and managed. The data exchanged includes clinical data as well as healthcare-related administrative, public health, and research data.

Fee-For-Service (FFS) - A method in which clinicians and other healthcare organizations are reimbursed for each service performed.

Health Equity - Achieving fair and just opportunities for all to be as healthy as possible requires removing obstacles to health such as poverty, discrimination, and their consequences, including powerlessness and lack of access to good jobs with fair pay, quality education and housing, safe environments, and healthcare.²⁷²

Health Information Exchange (HIE) - Both the act of moving health data electronically between organizations and an organization that facilitates information exchange. HIEs may be statewide, regional, metropolitan, or organization-specific and may be privately owned or publicly funded.

Health Information Network (HIN) - An individual or entity that (a) determines, oversees, or administers policies or agreements that define business, operational, technical, or other conditions or requirements for enabling or facilitating access, exchange, or use of electronic health information between or among two or more unaffiliated individuals or entities; (b) provides, manages, or controls any technology or service that enables or facilitates the exchange of electronic health information between or among two or more unaffiliated individuals or entities; or (c) exercises substantial influence or control with respect to the access, exchange, or use of electronic health information between or among two or more unaffiliated individuals or entities.

Health Level Seven International (HL7®) - A not-for-profit, standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery, and evaluation of health services.

Information Blocking - A practice that (a) is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information; and (b) if conducted by a health information technology developer, exchange, or network such developer, exchange, or network knows, or should know, that such practice is likely to interfere with, prevent, or materially discourage the access, exchange, or use of electronic health information; or (c) if conducted by a healthcare provider, such provider knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.

Internet of Things (IoT) - The networking capability that allows information to be sent to and received from objects and devices (such as medical devices and kitchen appliances) using the Internet.

Interoperability - Health information technology that (a) enables the secure exchange of information with, and use of electronic health information from, other health information technology without special effort on the part of the user; (b) allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable state or federal law; and (c) does not constitute information blocking as defined in section 3022(a) of the Cures Act.

Location Tracking - The use of apps and phone signals, often Bluetooth, to detect potential encounters with a COVID-19 case.

Logical Observation Identifiers Names and Codes (LOINC) - A common language (set of identifiers, names, and codes) for identifying health measurements, observations, and documents.

Medical Device - An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease.





Metadata - Data about data, or information about information, or the information required to contextualize and understand a given data element.

Patient-Generated Health Data (PGHD) - Health-related data created, recorded, or gathered by or from patients (or family members or other caregivers) to help address a health concern.

Patient Matching - The process of comparing several demographic data elements from different health IT systems to determine if they refer to the same patient.

Prescription Drug Monitoring Program (PDMP) - A statewide electronic database that tracks all controlled substance prescriptions. Authorized users can access prescription data such as medications dispensed and doses.

Qualified Health Information Network (QHIN) - A network of organizations working together to share data to implement the Trusted Exchange Framework, having agreed to the Common Agreement.

Recognized Coordinating Entity (RCE) - A governance body that will operationalize the Trusted Exchange Framework by incorporating it into a single, all-encompassing Common Agreement to which Qualified HINs will agree to abide.

Social Determinants of Health (SDOH) - The conditions in which people are born, grow, work, live, age, and the wider set of forces and systems shaping the conditions of daily life.

Systematized Nomenclature of Medicine (SNOMED) - A systematically organized computer processable collection of medical terms providing codes, terms, synonyms, and definitions used in clinical documentation and reporting.

Title 42 of the Code of Federal Regulations, Part 2: Confidentiality of Substance Use Disorder Patient Records (42 CFR Part 2) - A federal rule first promulgated in 1975 to address confidentiality concerns about the use of substance use disorder information in non-treatment-based settings, such as administrative or criminal hearings related to the patient. This law protects the confidentiality of the identity, diagnosis, prognosis, or treatment of any patient records maintained in connection with the performance of any federally assisted program or activity relating to substance abuse education, prevention, training, treatment, rehabilitation, or research.

Trusted Exchange Framework (TEF) - A set of principles and minimum required terms and conditions for trusted exchange, as required by the Cures Act.

Unique Device Identifier (UDI) - An alphanumeric code that identifies a specific medical device that may be added to relevant records such as patients' health records and insurance claim forms.

Usability - The extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use.

U.S. Core Data for Interoperability (USCDI) - A common set of data classes and data elements that are required for interoperable exchange. The USCDI will be expanded over time.





ABBREVIATIONS

42 CFR Part 2 - Title 42 of the Code of Regulations, Part 2: Confidentiality of Substance Use Disorder Patient Records

ACA - Affordable Care Act

AHRQ - Agency for Health Research and Quality

AI - Artificial Intelligence

AMA - American Medical Association

API - Application Programming Interface

APM - Alternative Payment Model

ASPE - Assistant Secretary for Planning and Evaluation

C-CDA - Consolidated-Clinical Document Architecture

CARES Act - The Coronavirus Aid, Relief, and Economic Security Act

CCDS - Common Clinical Data Set

CCPA - California Consumer Privacy Act of 2018

CDC - Centers for Disease Control and Prevention

CDS - Clinical Decision Support

CEHRT - Certified Electronic Health Record Technology

CMS - Centers for Medicare & Medicaid Services

CMS Interoperability Rule - Centers for Medicare & Medicaid Services Interoperability and Patient Access Final Rule

COVID-19 - Coronavirus

DEL - Data Element Library

DHCoE - Digital Health Center of Excellence

DHS - The United States Department of Homeland Security

DoD - The United States Department of Defense

DOJ - The United States Department of Justice

EHI - Electronic Health Information

EHR - Electronic Health Record

EKG - Electrocardiogram

EU - European Union

FBI - Federal Bureau of Investigation

FCC - Federal Communications Commission

FDA - United States Food and Drug Administration

FERPA - Family Educational Rights and Privacy Act

FFS - Fee-For-Service

FHIR® - Fast Healthcare Interoperability Resources





FTC - Federal Trade Commission
FY20 - Fiscal Year 2020
GAO - Government Accountability Office
GDHP - Global Digital Health Partnership
GDPR - General Data Protection Regulation
HHS - United States Department of Health and Human Services
HIE - Health Information Exchange
HIN - Health Information Network
HINTS - Health Information National Trends Survey
HIPAA - Health Insurance Portability and Accountability Act
HITAC - Health Information Technology Advisory Committee
HL7® - Health Level Seven International
HRSA - Health Resources & Services Administration
ICD-10 - 10th Revision of the International Statistical Classification of Diseases and Related Health Problems
IoT - Internet of Things
LTPAC - Long-term Post-Acute Care
LOINC - Logical Observation Identifiers Names and Codes
NCVHS - National Committee on Vital and Health Statistics
NIH - National Institutes of Health
NIST - National Institute of Standards and Technology
OCR - Office for Civil Rights
OIG - Office of Inspector General
OMB - Office of Management and Budget
ONC - Office of the National Coordinator for Health Information Technology
ONC-ACB - ONC-Authorized Certification Body
ONC Cures Act Final Rule - 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule
OPO - Organ Procurement Organization
PCOR - Patient-Centered Outcomes Research
PDMP - Prescription Drug Monitoring Program
PGHD - Patient-Generated Health Data
PHI - Protected Health Information
PRO - Patient-Reported Outcome
PULSE - Patient Unified Lookup System for Emergencies
QHIN - Qualified Health Information Network
QTF - QHIN Technical Framework





- RCE** - Recognized Coordinating Entity
- SAMHSA** - Substance Abuse and Mental Health Services Administration
- SANER** - Situational Awareness for Novel Epidemic Response
- SDOH** - Social Determinants of Health
- SHIELD Act** - Stop Hacks and Improve Electronic Data Security Act
- SNOMED** - Systematized Nomenclature of Medicine
- SO/GI** - Sexual Orientation/Gender Identity
- SUD** - Substance Use Disorder
- TEF** - Trusted Exchange Framework
- TEFCA** - Trusted Exchange Framework and Common Agreement
- TMAP** - Technology Modernization Action Plan
- UDI** - Unique Device Identifier
- UPI** - Unique Patient Identifier
- USCDI** - United States Core Data for Interoperability
- VA** - Department of Veterans Affairs
- VAMS** - Vaccine Administration Management System
- WHO** - World Health Organization





RESOURCE LIST

ONC Publications

[21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule](#)

[Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID-19 Public Health Emergency](#)

[2020-2025 Federal Health IT Strategic Plan](#)

[National Health IT Priorities for Research: A Policy and Development Agenda](#)

Patient Matching Report [Placeholder]

Patient Safety Report [Placeholder]

[Health IT Data Briefs](#)

[Health IT Playbook](#)

[COVID-19 Response](#)





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