



Revised Draft Health Information Technology Advisory Committee (HITAC) Annual Report for Fiscal Year 2021

FEBRUARY 17, 2022



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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 United States (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 2021 (FY21) 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 FY21

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 FY21, the subcommittees included the:

- Annual Report Workgroup
- EHR Reporting Program Task Force 2021
- Interoperability Standards Priorities Task Force 2021
- Intersection of Clinical and Administrative Data Task Force
- Public Health Data Systems Task Force 2021
- U.S. Core Data for Interoperability (USCDI) Task Force 2021

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 used to organize this report.

Federal Activities across the Target Areas

In FY21, there were considerable health IT advancements throughout various agencies of the federal government. ONC's 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) went into effect. ONC also finalized changes to the ONC Health IT Certification Program, released USCDI Version 2, updated the timeline for the Trusted Exchange Framework and Common Agreement (TEFCA), collaborated to develop a unified specification for address in health care, and continued progress on the EHR Reporting Program for developers of certified health IT. Several other federal activities addressed the HITAC's target areas, including the HHS Office for Civil Rights' (OCR) proposed rule modifying the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and the federal response to the COVID-19 pandemic.





Target Area: Use of Technologies that Support Public Health

The COVID-19 pandemic has cast light on the importance of health IT and the need for robust public health data systems in disaster response and public health emergencies. New steps have been taken to combat the pandemic, such as efforts to develop and advance standards related to public health, enhance electronic case reporting and electronic lab reporting, increase funding to improve public health infrastructure, study Long COVID disease, and train more public health professionals in health informatics and data science. However, the pandemic has also exposed barriers to public health and population-level data sharing. These include a patchwork of discrete data systems, variable interoperability, and a lack of common data standards to respond to COVID-19 or prepare for future disasters.

Target Area: Interoperability

The healthcare ecosystem has made strides in data sharing. More health information exchanges (HIEs) have consolidated and collaborated to better support interoperability, and national networks have increased connectivity and the volume of data sharing. The use of prescription drug monitoring programs (PDMPs) and electronic prescribing to address the opioid epidemic is on the rise. Stakeholders have also been working on their compliance with the ONC Cures Act Final Rule, and several organizations, including ONC, have created educational resources to support those efforts. However, the extent of the prevalence of information blocking now that the ONC Cures Act Final Rule is in effect is unknown. Moreover, interoperability remains fragmented, pointing to the need for better patient matching, closed-loop referrals to coordinate care, the exchange of social determinants of health (SDOH) data, and the access and exchange of information for research purposes. The COVID-19 pandemic has also highlighted disparities in health care as well as racial/ethnic bias in algorithms used in healthcare artificial intelligence (AI), which can enforce existing inequities or create new ones.

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. As interoperability and access to patient information increase, the privacy and security of health data are primary concerns. Although the COVID-19 pandemic spurred more use of digital health IT solutions, many people held back, wary of whether technology companies would safeguard their information. People are still confused about the privacy and security of data not subject to HIPAA, and there's a lack of clarity on the impact of the use of health IT on consumers. In addition, this misalignment has caused uncertainty for developers and providers regarding their privacy and security compliance obligations when developing and using new technology.

Target Area: Patient Access to Information

Patient access to health information supports shared decision-making and increases patient engagement. Patients can use digital tools to manage their own care, obtain testing and other results, and receive treatment via telehealth. The use of remote patient monitoring (RPM) and the sharing of patient-generated health data (PGHD) have increased during the pandemic. As more patients use mobile health applications, concerns have arisen regarding their reliability, safety, and effectiveness. Efforts are underway to address these concerns. This increased patient access to information is also not uniform. Not all patients have access to digital tools or the literacy to use them, deepening the digital divide and increasing health disparities.





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 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 2022-23, while longer-term opportunities are anticipated to begin in three or more years, i.e., calendar year 2024 or later.

Topic	Key Gaps	Key Opportunities	Recommended HITAC Activities
Target Area: Use of Technologies that Support Public Health			
Immediate Opportunities			
Public Health Data Systems – Infrastructure	Public health infrastructure does not allow bidirectional clinical population reporting. Improvement of data quality, data standardization, and existing public health data systems is needed.	<ul style="list-style-type: none"> • Help relevant federal agencies (e.g., the Centers for Disease Control and Prevention (CDC), Centers for Medicare & Medicaid Services (CMS)) by exploring and sharing findings on approaches to achieving national public health reporting. • Improve bidirectional interoperability between public health reporting systems and electronic health records (EHRs). For example, public health data systems could deliver vaccine status for a list of patients. Immunization registries could be set up for data consumption, such as supporting vaccine monitoring for return to work, not only for reporting for agency use. • Improve bidirectional interoperability between public health reporting systems and HIEs. For example, public health data systems could leverage existing or potential data flows from EHRs to HIEs (e.g., testing, hospitalization data) for surveillance, to populate/enhance registries, and to share data, such as vaccination status, back to providers via the HIE. • Identify and publish best practices and guidance for applying standards for minimum necessary datasets to information sharing with public health authorities. 	<ol style="list-style-type: none"> 1. Explore collaborative approaches being considered for the national public health data infrastructure (e.g., leveraging EHRs, HIEs, and other technology providers) and share the findings with the CDC and CMS. 2. Provide guidance for policies and for operationalizing standards to address implementation variation of public health data access and exchange. 3. Convene a listening session to better understand barriers to sharing clinical datasets with public health authorities in a compliant manner, e.g., minimum necessary under HIPAA. 4. Assess public health activities and systems to understand what is needed to help public health data systems align with the use of the Health Level 7 (HL7®) Fast Healthcare Interoperability Resources (FHIR®) standard or another approach.
Public Health Data Systems – Incentives and Funding	There needs to be an incentive and funding structure that aligns incentives for public health data sharing. This is the result of having an EHR incentive program without a	<ul style="list-style-type: none"> • Align incentives and funding structures across clinical and public health data systems to create parity across infrastructures. 	<ol style="list-style-type: none"> 1. Continue to explore ways that the ONC Health IT Certification Program can support data exchange between public health organizations and stakeholders including clinicians, payers, patients, and laboratories.





Topic	Key Gaps	Key Opportunities	Recommended HITAC Activities
	corresponding public health incentive structure and funding model. Public health data is typically divided by program area due to funding which often makes it difficult to integrate with clinical data to show a broader picture across diseases and conditions. There is a need to encourage more bidirectional interoperability between public health and clinical data holders.	<ul style="list-style-type: none"> • More data collection is needed by public health organizations to support situational awareness and health equity. • Reduce siloes in data exchange by exploring the roles of HIEs, networks, frameworks, and other health data utilities in promoting the interoperability of public health and clinical data systems. 	<ol style="list-style-type: none"> 2. Explore how the ONC Health IT Certification Program can be aligned with other public health certification programs, e.g., electronic laboratory reporting certification and certified immunization registries receiving data from certified EHRs. 3. Partner with the National Committee on Vital and Health Statistics (NCVHS) to identify barriers to and potential opportunities for public health use of HIEs where available and affordable.
Electronic Case Reporting (eCR)	Improvements have made use of electronic case reporting more widespread yet could be optimized further.	<ul style="list-style-type: none"> • Expand the adoption and support for electronic case reporting and integration by public health authorities, healthcare providers, and health IT developers. • Encourage public health authorities to respond more fully to healthcare providers upon receipt of a report about a reportable disease and health IT developers to enhance such capabilities. 	<ol style="list-style-type: none"> 1. Learn about the experience of government agencies like the CDC and state health departments in developing tools and sharing data for electronic case reporting and assess what gaps remain. 2. Collaborate with convening groups across federal, state, tribal, local, and territorial governments to encourage both adoption and advancement of the technology and standards supporting bidirectional data exchange for public health purposes. For example, partner with NCVHS to identify gaps for standards needed to support electronic case reporting.
Electronic Laboratory Reporting (ELR)	The lack of use of standards creates a barrier to reporting and increases provider burden.	Improve the use of terminology standards in electronic laboratory reporting.	Encourage ONC to work with the CDC, public health entities, support organizations, and health IT vendors to standardize technical capabilities to facilitate laboratory results data collection and sharing by federal, state, tribal, local, and territorial public health authorities.
Syndromic Surveillance	Increased sharing of this information would improve clinical care and enhance decision-making.	Encourage public health authorities to provide timely population-level syndromic surveillance information back to healthcare providers and patients to support responding to public health threats.	Identify existing data sharing methods (e.g., the CDC's Health Alert Network) and best practices for federal, state, tribal, local, and territorial public health authorities to share real-time population-level syndromic surveillance data with healthcare providers and patients.
Information Exchange to Facilitate Care and Monitoring of Patients with Long COVID	Identification of patients with Long COVID is not straightforward. As a result, population-level analyses of this condition have been challenging.	Improve clinical documentation standards for patients with Long COVID and as a blueprint for other conditions.	Explore whether there are existing programs and data needs for documenting Long COVID cases among patients and populations, including standards, registries, and electronic patient-reported outcomes (ePROs).
Public Health Workforce Recruitment, Training, and Retention	Public health departments struggle to attract, train, and retain public health professionals with skills in public health informatics, data science, and health IT.	Improve public health information technology workforce resources and capacity.	Suggest ways to attract, train, and retain public health professionals with skills in public health informatics, data science, and health IT, in addition to the ONC Public Health Informatics and Technology (PHIT) Workforce Development Program.
Target Area: Interoperability			
Immediate Opportunities			
Patient Matching	Patient matching when sharing data needs to be improved.	Address alignment of incentives and certification programs across domains to encourage an ecosystem-based approach to improve patient matching as well as better match EHR and public health data in particular.	Define best practices at registration and other relevant collection points to improve the data quality of the core standard set of data elements defined in the USCDI and Project US@ to support patient matching across health care and public health data systems, including demographic information.
Information Blocking	Information blocking interferes with seamless and	Following the publication of the ONC Cures Act Final Rule, assess how the	Convene a listening session to assess the establishment of measures of the impact of the





Topic	Key Gaps	Key Opportunities	Recommended HITAC Activities
	secure access, exchange, and use of electronic health information.	information blocking requirements are being implemented in practice.	information blocking requirements of the ONC Cures Act Final Rule (including the transition from USCDI to the full scope of electronic health information) across the industry in conjunction with ONC's measurement efforts.
Exchange of Data for Transitions of Care	Poor exchange of information during transitions of care increases the likelihood of a poor outcome and increased cost.	The exchange of data for both transitions of care between care institutions and transfers of level of care between floors or units within a hospital needs stronger standards.	Investigate and document the requirements for improving the exchange of data during transitions and transfers of care, particularly around standards, to improve coordination of care.
Longer-Term Opportunities			
Increased Health Equity across Populations, Locations, and Situations – Data Collection	Ensure health equity topic includes health care, i.e., the tracking and sharing of health information to support both health and healthcare equity initiatives.	More industry standards supporting the collection of health equity data elements could be agreed upon.	Convene a listening session to identify barriers and opportunities related to standards for consistent collection of health equity data elements.
Increased Health Equity across Populations, Locations, and Situations – Algorithm Bias	Efforts are needed to better understand and reduce racial and ethnic bias in algorithms.	Screen healthcare and public health data systems for bias in algorithms to improve data used for decision-making.	Convene a listening session to identify sources of algorithmic bias in healthcare and public health data systems as well as potential solutions.
Interoperability Standards Priority Uses – Closed-Loop Referrals	There is a lack of cross-organization support for closed-loop referrals.	Explore the opportunities to advance standards that can improve systems for closed-loop referrals and prior authorizations.	Review the recent and planned activities of the CMS and payers regarding standards needed for closed-loop referrals and prior authorizations.
Target Area: Privacy and Security			
Longer-Term Opportunities			
Public Opinion about Impact of Use of Health IT on Privacy and Security of Data	Does public opinion data already exist that encapsulates user and consumer opinions about certain uses of health information technologies, e.g., contact tracing or ransomware/malware attacks?	Research these uses in the peer-reviewed literature.	Assess recent literature and suggest areas for more investigation of the consumer impact of certain uses of health IT.
Alignment of Innovation and Regulation of Privacy and Security of Data	Innovation sometimes gets ahead of the regulatory environment.	Align the health IT industry to accelerate innovation in areas where existing regulations are in place.	Learn about federal regulatory activities for areas of health IT innovation and assess the fit and remaining gaps.
Target Area: Patient Access to Information			
Immediate Opportunities			
Safety and Impact of Mobile Health Applications	As third-party apps continue to be introduced, there is concern about the clinical accuracy of these apps and the potential for patient harm.	<ul style="list-style-type: none"> Support initiatives that review and rank the validity and safety of mobile health applications. Support awareness and education for patients regarding digital therapeutics, leveraging alerts in patient portals. 	Define updates to past ONC patient access guides and educational materials needed since the start of the pandemic.
Increased Health Equity across Populations, Locations, and Situations – Accessibility of Health IT	The pandemic highlighted the ongoing digital divide regarding access to health IT by consumers for the purposes of testing, vaccine appointment booking, telehealth, etc.	Learn more about barriers for populations experiencing inequities to inform mitigation and intervention actions to ensure that such information is available to patients and consumers in the same ways that they access other relevant protected health information.	Explore barriers to the delivery of relevant public health-related information through application programming interfaces (APIs), patient portals, mobile device applications, and other digital distribution channels to stakeholders who have a right to the data and identify opportunities.





Topic	Key Gaps	Key Opportunities	Recommended HITAC Activities
			<ul style="list-style-type: none"> a. Locate or compile a catalog of efforts across federal agencies to learn from and collaborate with them. b. Discuss patient-facing third-party apps used to access provider EHRs via APIs and public health data systems. c. Discuss large-scale patient data capture via apps, e.g., the National Institutes of Health (NIH) All of Us program.





Illustrative Stories of What the Recommended HITAC Activities Will Enable

Target Area: Use of Technologies that Support Public Health

A local public health agency in an area with high rates of tourism hopes to collect more comprehensive demographic and clinical information about patients with positive cases of influenza so that it can better monitor and plan for outbreaks to keep both the residents and visitors safer. In the past, the agency has encountered clinicians who were hesitant to send their patients' medical records to an outside entity. **However, clinical datasets have become better defined and bidirectional exchange has improved.** A new federal educational initiative has helped clinicians understand that public health entities do not need a patient's entire medical record to perform their duties, only discrete information like vaccination data, ethnicity, and hospitalization status. The agency is now better able to work with its regional HIE to collect select patient information that enhances the agency's tracking of key indicators of potential surges and improves its response efforts.

Target Area: Interoperability

Clinicians can provide better care when they can easily access a comprehensive picture of the factors affecting the health of their patients. Most current EHR systems enable clinicians to capture certain types of data in standardized formats. Other data, such as a patient's preferred language, access to healthy food, or chosen pronoun use, can only be captured in free text which is difficult to find in the EHR and to share with other providers across the care continuum. Fortunately, standards organizations have been leveraging the Fast Healthcare Interoperability Resources (FHIR®) standard to create several national standards to collect SDOH and other data relating to health equity and the newest version of USCDI has been updated to include many of these data. These innovations have increased the collection of this patient information, improved interoperability among providers, enhanced patient care, and reduced health disparities.

Target Area: Privacy and Security

A hospital wants to adopt APIs for information sharing to improve its patients' experience and implement more value-based care in the facility. However, it is concerned that it would bear the legal burden of the use of any incorrect data. An analysis using the [Security Risk Assessment Tool](#) and other guidance has identified that both HIPAA and the Cures Act as well as existing applicable state law protect the hospital from privacy and security liability when using this technology. The hospital reviews the analysis' recommendations regarding how to safeguard the data and takes the appropriate steps to adopt APIs for data sharing while minimizing the risk that the data would be compromised or misused.

Target Area: Patient Access to Information

As a result of recent updates to federally sponsored patient education guides, individuals have easy online access to new information about the validity and safety of mobile health applications. For example, a consumer interested in downloading and using an app to help her monitor and control her diabetes can now review ratings of various diabetes apps for their accuracy, safety, and usability. She will also be able to compile records from multiple providers in one app. Upon hearing about this new tool, the consumer visits a recommended website to learn more about and compare the available apps. Armed with this information, she avoids the apps that are less helpful and potentially harmful. She opts to use one of the highest-rated ones that will better help her manage her condition and her care across multiple providers without adverse consequences from the app.





Foreword

We are pleased to present the annual report of the Health Information Technology Advisory Committee (HITAC) for FY21.

This report describes the work undertaken by the HITAC during its fourth 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 HITAC focused its evaluation on four target areas: technologies that support public health, interoperability, privacy and security, and patient access to information. In FY21, the HITAC made recommendations on priority uses of health IT, the USCDI, public health data systems, and the EHR Reporting Program. Several areas for future HITAC work were surfaced during the HITAC meetings in FY21, and robust discussion among the members yielded several areas for potential activity in FY22 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 beginning in 2021. We wish to also express our sincere thanks to the prior, inaugural HITAC co-chairs, Carolyn Petersen and Robert Wah. 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 the use of better information and technology to improve care delivery and the health and well-being of everyone in the United States.

Aaron Miri and Denise Webb
Co-Chairs, Health Information Technology Advisory Committee





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, 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. 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 FY21, 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 2022 (FY22) 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 target areas during FY21, outlined below. ONC has defined the benchmarks as progress toward measures of achieving milestones in activities related to Standards, Certification, and Exchange.

ONC Objectives in FY21

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

ONC Benchmarks in FY21-FY22

ONC Activity	FY21 Progress	FY22 Benchmarks
Standards	<p><i>USCDI</i></p> <ul style="list-style-type: none"> • Published USCDI Version 2, which includes three new data classes and 22 new data elements. <p><i>Standards Version Advancement Process (SVAP)</i></p> <ul style="list-style-type: none"> • Completed first cycle of SVAP process. <p><i>HL7® FHIR®</i></p> <ul style="list-style-type: none"> • Published HL7 FHIR US Core Implementation Guide STU 3.2.0 and 4.0.0. • Published FormatCode Implementation Guide. • Published Mobile Access to Health Documents Implementation Guide. • Published Patient Identifier Cross-reference for Mobile Implementation Guide. • Published Patient Demographics Query for Mobile Implementation Guide. <p><i>Public Health</i></p> <ul style="list-style-type: none"> • Balloted first version of the COVID-19 FHIR Profile Library. • Standardized over 1,800 lab test order names. • Developed 75 COVID-19 and public health-related LOINC special use codes. • Launched the Strengthening the Technical Advancement & Readiness of Public Health via Health Information Exchange Program (STAR HIE Program). 	<p><i>USCDI</i></p> <ul style="list-style-type: none"> • Publish USCDI Version 3. <p><i>SVAP</i></p> <ul style="list-style-type: none"> • Publish National Coordinator-approved updated versions of health IT standards and implementation specifications via SVAP process. <p><i>HL7® FHIR®</i></p> <ul style="list-style-type: none"> • Release HL7 FHIR R5. • Update HL7 US FHIR Core Implementation Guide to align with USCDI updates. • Collaborate with Standards Development Organizations (SDOs) to Accelerate FHIR API Standards' Ability to Support Use. Cases for Population-Level Query Services • Publish FHIR-related guidance on Integrating the Healthcare Enterprise® (IHE) profiles. <p><i>Public Health</i></p> <ul style="list-style-type: none"> • Develop FHIR resources to address disease, chronic conditions, and environmental factors. • Develop and update standards and Implementation Guides related to privacy, security, and consent. • Encourage the adoption of FHIR Bulk Data Access (Flat FHIR) Implementation Guide • Support HL7 US Realm. • Develop COVID-19 and public health-related LOINC special use codes that describe laboratory tests ordered and taken.





ONC Activity	FY21 Progress	FY22 Benchmarks
	<ul style="list-style-type: none"> Published Situation Awareness for Novel Epidemic Response (SANER) Implementation Guide. 	<ul style="list-style-type: none"> Standardize the lab test order names to reduce erroneous lab orders and results. Facilitate testing, final balloting, and real-world deployment of Situational Awareness for Novel Epidemic Response Implementation Guide for use by Federal partners.
Certification	<ul style="list-style-type: none"> Published Certification Fact Sheets. Compliance requirements went into effect for several Conditions of Certification, including for Information Blocking, Assurances, API, and Communications. 	<ul style="list-style-type: none"> Initial Real-World Testing Plans due. Initial Attestations to Conditions and Maintenance of Certification due.
Exchange	<p><i>Information Blocking</i></p> <ul style="list-style-type: none"> Information Blocking applicability for Health Care Provider, Health Information Network/Health Information Exchange, and Health IT Developer of Certified Health IT (for data elements in USCDI Version 1) Published 36 Information Blocking Frequently Asked Questions (FAQs) and 5 Fact Sheets. Held public webinars on Information Blocking and Healthcare Provider Information Sharing. <p><i>TEFCA</i></p> <ul style="list-style-type: none"> TEFCA public engagement webinars, HITAC engagement, and Common Agreement Work Group sessions 	<p><i>Information Blocking</i></p> <ul style="list-style-type: none"> From April 5, 2021, to October 6, 2022, the definition of information blocking is limited to the EHI that is also represented in the USCDI version 1. On and after October 6, 2022, the definition of EHI is no longer limited to the elements represented in the USCDI version 1. EHI means electronic protected health information (ePHI) to the extent that the ePHI would be included in a designated record set as these terms are defined for HIPAA. <ul style="list-style-type: none"> <i>Except for psychotherapy notes (45 CFR 164.501) and information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding.</i> <p><i>TEFCA</i></p> <ul style="list-style-type: none"> Final Trusted Exchange Framework, Final Common Agreement (CA) Version 1, and Final Qualified Health Information Network (QHIN) Technical Framework (QTF) QTF Version 1 published. QHINs begin signing Common Agreement. QHINs selection, onboarding, and sharing begin. <p><i>Health Information Exchange Services</i></p> <ul style="list-style-type: none"> Advance innovative health information exchange services that benefit public health agencies. Improve the health information exchange services available to support communities disproportionately impacted by the COVID-19 pandemic.





HITAC Progress in FY21

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 advances the electronic access, exchange, and use of health information.

Overall Accomplishments in FY21

The HITAC's focus in FY21 was on developing interoperability standards priorities and USCDI recommendations and evaluating the needs of public health data systems. The HITAC held 10 public meetings of the full committee, including a special meeting on public health data systems, and 72 public meetings of the subcommittees. The HITAC delivered 148 recommendations and its annual report 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 FY21

The Annual Report Workgroup held nine public meetings in FY21 to develop its recommendations. The HITAC approved the HITAC Annual Report for Fiscal Year 2020 for submission to the National Coordinator for Health IT in February 2021 and subsequent transmittal to the Secretary of Health and Human Services and Congress. The HITAC Annual Report reviewed HITAC activities in fiscal year 2020 (FY20), described the landscape of health IT infrastructure, identified gaps and opportunities, and offered 44 recommendations for future HITAC activities.





EHR Reporting Program Task Force 2021

The Electronic Health Record Reporting Program was required in Section 4002(c) of the Cures Act. Data collected and reported under the program will address information gaps in the health IT marketplace and provide insights on how certified health IT is being used. At the HITAC meeting on July 14, 2021, ONC charged the HITAC with providing recommendations to the National Coordinator for Health IT to address information gaps in the health IT marketplace among all stakeholders and provide insights on how certified health IT is being used. The HITAC then formed the EHR Reporting Program Task Force 2021 and charged it with the following:

- *Overarching Charge:* Make recommendations to prioritize and improve the draft set of developer-reported, interoperability-focused measures for the ONC EHR Reporting Program.
- *Specific Charge:*
Make recommendations on the following:
 - 1) Review the draft developer-reported measures and supporting materials developed by the Urban Institute, under contract with ONC, and provide recommendations to prioritize the measures and suggest ways to improve draft measures.
 - 2) Consider background research, reports, and other sources as relevant to inform analysis of draft measures.
 - 3) Consider both established and emerging measurement practices and capabilities, as well as technical, legal, and policy requirements.
 - 4) Consider the use, technical feasibility, and potential policy impacts of the draft measures.
 - 5) Prioritize the draft measures to elevate those with the most potential for addressing gaps and providing insights in the certified health IT marketplace.
 - 6) Consider ways to avoid placing undue disadvantage on small and startup health IT developers in reporting measures.
 - 7) Develop recommendations to inform revisions to improve an initial set of developer-reported, interoperability-focused measures.
 - 8) Suggest additional measures and measure categories to prioritize for subsequent iterations of the developer-reported measures.
 - 9) Approve recommendations for submission to the HITAC by September 9, 2021.

Accomplishments in FY21

The EHR Reporting Program Task Force held eight public meetings in FY21. The HITAC approved and transmitted [20 recommendations](#) to the National Coordinator for Health IT in September 2021.

The EHR Reporting Program Task Force report summarizes general support for the majority of details, processes, and published priorities of the EHR Reporting Program established by ONC. The Task Force described specific recommendations for modification to the EHR Reporting Program developer measures.





Interoperability Standards Priorities Task Force 2021

The Cures Act requires the HITAC to set priorities for standards adoption. At the HITAC meeting on February 10, 2021, ONC charged the HITAC with providing recommendations to the National Coordinator for Health IT for the next round of standards priorities. The HITAC then formed the Interoperability Standards Priorities Task Force 2021 and charged the Task Force with the following:

- **Overarching Charge:** Identify opportunities to update the ONC Interoperability Standards Advisory (ISA) to address the HITAC priority uses of health IT, including related standards and implementation specifications.
- **Specific Charge:**
 - 1) Identify opportunities to update the “Interoperability Needs” within the ISA sections to address the HITAC priority uses of health IT (including new priority uses of health IT, if necessary).
 - 2) Recommend additional or modified “Interoperability Needs” for consideration in updates to the ISA, including related standards and implementation specifications.

Accomplishments in FY21

The Interoperability Standards Priorities Task Force 2021 held 14 public meetings in FY21. The HITAC approved and transmitted [six recommendations](#) in June 2021 and [one additional recommendation](#) in July 2021 to the National Coordinator for Health IT.

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) health equity, (2) EHR data use for the “Learning Health System” based on COVID-19 experience in pragmatic trials, real-world evidence, and comparative effectiveness, and (3) burden reduction and associated clinical/administrative data and standards harmonization. The Task Force additionally heard testimony on and provided recommendations for the use case of public health situational awareness. The recommendations included those that cross domains and those that focus on the three 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.
- 5) 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.
- 6) 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.
- 7) Make public a summary of its findings once task force activities are complete, no later than September 2020.

Accomplishments in FY21

The Intersection of Clinical and Administrative Data Task Force held five public meetings in FY21 in addition to the meetings held in FY20. The HITAC approved and transmitted [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.

Public Health Data Systems Task Force 2021

At the HITAC meeting on April 15, 2021, ONC charged the HITAC with providing recommendations on public health data systems. The HITAC then formed the Public Health Data Systems Task Force 2021 and charged it with the following:

- *Overarching Charge:* To inform HHS' response to the [Executive Order on Ensuring a Data-Driven Response to COVID-19 and Future High-Consequence Public Health Threats](#).
- *Specific Charge:*
 - 1) Identify and prioritize policy and technical gaps associated with the effectiveness, interoperability, and connectivity of information systems relevant to public health. This would include a focus on surveillance systems, infrastructure improvements, health equity, clinical engagement, research and innovation, education, and empowering individuals.





- 2) Identify characteristics of an optimal future state for information systems relevant to public health and their use.

Accomplishments in FY21

The Public Health Data Systems Task Force held 10 public meetings in FY21. The HITAC approved and transmitted [52 recommendations](#) to the National Coordinator for Health IT in July 2021. The Public Health Data Systems Task Force report summarizes the Task Force's findings on analyzing the interaction between clinical and public health data systems. The Task Force's recommendations center on the challenges, gaps, and ideal future state for data sharing between public health data systems and clinical data sources (i.e., EHRs, laboratory systems, immunization information systems, case reporting, and other relevant data sources).

U.S. Core Data for Interoperability Task Force 2021

At the HITAC meeting on January 12, 2021, ONC charged the HITAC with providing recommendations on the content in the Draft USCDI Version 2. The HITAC then formed the USCDI Data Task Force and charged it with the following:

- *Overarching Charge:* To review and provide feedback on the Draft USCDI Version 2 content and process.
- *Specific Charge:*
 - 1) Evaluate Draft USCDI Version 2 and provide the HITAC with recommendations for:
 - a. Data classes and elements from USCDI Version 1 including applicable standards version updates
 - b. New data classes and elements from Draft USCDI Version 2 including applicable standards
 - c. Level 2 data classes and elements not included in Draft USCDI Version 2
 - 2) Evaluate the USCDI expansion process and provide the HITAC with recommendations for:
 - a. ONDEC submission system improvements
 - b. Evaluation criteria and process used to assign levels to submitted data classes and elements
 - c. Prioritization process used by ONC to select new data classes and elements for Draft USCDI Version 2
 - 3) Recommend ONC priorities for USCDI Version 3 submission cycle.

Accomplishments in FY21

The USCDI Task Force held 26 public meetings in FY21. The HITAC approved and transmitted [22 recommendations](#) to the National Coordinator for Health IT in April 2021, [22 recommendations](#) in June 2021, and [10 recommendations](#) in September 2021. The USCDI Task Force reports summarize the Task Force's recommendations on the Draft USCDI Version 2, ways to improve the USCDI expansion process, and ONC priorities for the USCDI Version 3 submission cycle. Specific recommendations focus on methods to increase access for and engagement of members of the public who may not have deep technical expertise but would like to be able to contribute their suggestions and input to the USCDI expansion process.





Health IT Infrastructure Landscape Analysis

FEDERAL ACTIVITIES ACROSS THE TARGET AREAS

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. This section describes the health IT activities advanced by various agencies of the federal government during FY21. Certain key federal activities that the HITAC considered to intersect across the target areas have been included in this section. This section does not encompass all relevant federal activities conducted throughout FY21; some of them are addressed within the target area sections throughout this report.

Information Blocking

The Cures Act prohibits information blocking and authorizes the Secretary of HHS 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 (healthcare provider, health IT developer of certified health IT, HIE, or health information network (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. As of April 5, 2021, actors subject to the ONC Cures Act Final Rule must comply with the information blocking provisions. To assist actors with compliance, ONC has released educational materials including a series of frequently asked questions (FAQs) related to information blocking.

ONC Health IT Certification Program Updates

ONC finalized additions and changes to the ONC Health IT Certification Program in the ONC Cures Act Final Rule. One component of those changes was the addition of 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. During FY21, ONC continued work on implementing the new Conditions and Maintenance of Certification requirements. For example, ONC has released educational materials to assist the health IT developer community in understanding and complying with the new requirements. These resources include a consolidated view of key dates, a criterion-by-criterion resource for the 2015 Edition Cures Update, and a deep dive into certified API requirements. In addition, ONC has hosted webinars on a variety of topics.

United States Core Data for Interoperability

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. Over time, the USCDI will be updated through a predictable, transparent, and collaborative process that allows stakeholders the opportunity to comment on its expansion. In July 2021, ONC released USCDI Version 2 which adds standards to support the electronic exchange of sexual orientation, gender identity, and SDOH.





On October 8, 2021, ONC announced the new USCDI+ initiative which will support the identification and establishment of domain or program-specific datasets for federal partners that will operate as extensions to the existing USCDI. CMS and the CDC are initial partners with respective focuses on quality measurement and public health.¹

Trusted Exchange Framework and Common Agreement

The Cures Act requires ONC to “develop or support a trusted exchange framework, including a common agreement among health information networks nationally.” On July 13, 2021, ONC announced a new timeline for TEFCA that will have the new network based on the Common Agreement open for participation in the first quarter (Q1) of 2022. To reach this goal, ONC and the Recognized Coordinating Entity (RCE), The Sequoia Project, in Q1 of 2022 will finalize the Common Agreement, which sets the common terms and conditions for exchange, and the Qualified Health Information Network (QHIN) Technical Framework (QTF), which outlines functional and technical requirements for exchange. Once the final Version 1 of the Common Agreement and QTF are complete, HINs will be able to apply to become QHINs, which are networks that use the Common Agreement and QTF to exchange data with one another. The RCE released for public comment a new draft of the QTF in July 2021 and a summary of elements of the Common Agreement in September.^{2,3} In addition, ONC announced that it has awarded a new round of funding of \$942,000 to The Sequoia Project under the RCE cooperative agreement to support RCE activities from August 2021 to August 2022.⁴

Project US@ - Unified Specification for Address in Health Care

ONC, in collaboration with HL7®, the National Council for Prescription Drug Programs (NCPDP), X12, and members of the Health Standards Collaborative (HSC) has agreed to develop a unified specification for address in health care. The project’s goal is to issue a unified, healthcare industry-wide specification for representing addresses that can be applied across the standards developing organizations. Public comment periods were held by these organizations in July 2021 and the final specification is planned for release by the end of 2021.⁵

EHR Reporting Program

The Cures Act requires ONC to establish an EHR Reporting Program for developers of certified health IT to collect and report information that will address information gaps in the health IT marketplace and provide insights on how certified health IT is being used. ONC has engaged extensively with stakeholders to identify and develop measures that certified health IT developers will be required to report on as a Condition and Maintenance of Certification under the ONC Health IT Certification Program. The draft measures address the following domains: (1) patient access, (2) public health information exchange, (3) clinical care information exchange, and (4) standards adoption and conformance. ONC anticipates that the draft measures will inform future rulemaking.⁶

Response to the COVID-19 Pandemic

ONC funded five HIEs through the STAR HIE program. The HIEs will work with public health agencies for up to two years to improve information sharing. ONC provided supplemental funding to an additional 17 HIEs to support data exchange related to vaccinations.⁷ To further increase the information sharing between hospitals and public health agencies, CMS finalized modifications to its Medicare Promoting





Interoperability Program requiring hospitals to report on four public health and clinical data exchange measures.⁸

ONC awarded a cooperative agreement to HL7[®] to leverage FHIR[®] initiatives with a focus on COVID-19 gap areas. For example, this work would leverage the FHIR[®] Bulk Access API to improve the surveillance and management of COVID-19 patients.⁹

TARGET AREA: USE OF TECHNOLOGIES THAT SUPPORT PUBLIC HEALTH

Background

Public health focuses on protecting and improving health at a population level rather than at the individual level. All states and territories require clinicians to report specific diseases and conditions to public health agencies through various public health surveillance and information systems.¹⁰ Clinicians use EHR and HIE functionality for required reporting to public health agencies; however, some reporting remains paper-based. Public health agencies depend upon receiving data from clinicians through these systems. This reporting 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 the United States in early 2020 and continued through 2021 has cast light on the importance of health IT in disaster response and public health emergencies and exposed room for improvement. Therefore, the HITAC has decided to continue to include this topic in the HITAC Annual Report for FY21. This section examines the intersection of health IT and the public health and clinical response to the COVID-19 pandemic.

Current State

Public Health Data Systems Infrastructure

Several systems and processes have played important roles in responding to the COVID-19 pandemic: electronic lab reporting, electronic case reporting, syndromic surveillance, immunization information systems, hospital capacity/utilization reporting, and contact tracing. Data important to the public health response are generated from numerous, disparate sources. Useful data are collected at the federal, state, tribal, local, and territorial government levels. The public health data systems infrastructure is comprised of more than 100 distinct data systems through which data are collected by public health authorities but lack of integration slows the flow of information. Small and remote public health departments, in particular, do not have the resources or technical capability to handle the implementation of new information systems.¹¹ Moreover, the level of health IT activity varies significantly. For example, the most recent National Profile of Local Health Departments released by the National Association of County and City Health Officials found that while many local health departments use information technology systems for immunization registries and electronic disease reporting, they were less likely to use electronic lab reporting, and only a little more than half (59 percent) used EHRs.¹²

Furthermore, while a patchwork of public health data systems exists, these systems do not always operate using common data standards. A Government Accountability Office (GAO) report detailed that the federal





government does not have a process to systematically define and ensure the collection of standardized data across the relevant federal agencies and related stakeholders to respond to COVID-19, communicate the pandemic status with the public, or prepare for future pandemics.¹³ There are numerous standards development efforts underway to develop and advance standards related to public health. These include the Vaccine Credential Initiative SMART Health Card Framework Implementation Guide and the Situational Awareness for Novel Epidemic Response (SANER) Implementation Guide.^{14,15}

Public Health Data Systems Incentives and Funding

Public health data systems often have developed as a result of how public health authorities are funded. Historically, public health data systems have not received the same sustained financial investment to promote interoperability as clinical health IT systems. Public health often sees significant funding influxes following public health emergencies with funding dropping off afterward, creating challenges in updating and maintaining IT systems.¹⁶ Public health data systems were not included in the CMS Meaningful Use program, now known as the Medicare Promoting Interoperability Program. Even today program-specific funding often presents a disincentive to the development of common or program-agnostic IT infrastructure.¹⁷ However, the COVID-19 pandemic has become a catalyst for increased funding to improve the public health data infrastructure. The American Rescue Plan Act of 2021 provides an additional \$500 million to the CDC to advance surveillance and analytics infrastructure, as well as to establish a forecasting center for emerging biological threats.¹⁸

State and local public health departments are funded through federal grants and cooperative agreements that are specific to particular diseases, public health functions, or emergency preparedness. This structure results in information systems that serve a specific purpose without requirements for interoperability with other systems or the ability to support a common infrastructure that meets multiple use cases.¹⁹ For example, public health departments may host IT systems to track data related to tobacco use, communicable diseases, or public health outbreaks; however, each disease or program may be tracked in separate IT systems and may have different reporting streams and data requirements. Additionally, public health departments vary in governance and centralization across the country. For example, some local health departments are governed by their state health departments while other local health departments are decentralized with no oversight by the state government. The latter governance structure can create additional silos between state and local health department data systems.²⁰

Electronic Case Reporting

In August 2020, the eHealth Exchange launched a new approach to eCR in connection with the Association of Public Health Laboratories (APHL) and OCHIN, Inc. to increase interoperability between healthcare providers and public health agencies. With this eCR approach, EHRs automatically capture and report required information to a centralized platform which then determines if the data meet jurisdictional reporting requirements. This initiative uses eCR Now, a FHIR®-based application that non-eCR-enabled EHRs can rapidly implement to automate eCR for COVID-19. As of October 15, 2021, there are more than 9,400 facilities in the United States actively sending electronic case reports to public health agencies.²¹ Moreover, in both 2018 and 2019, half of all hospitals reported the capacity to electronically exchange information with public health agencies.²²





Electronic Lab Reporting

In order to help laboratories comply with the CDC's daily laboratory reporting guidelines, the National Electronic Laboratory Reporting (ELR) Flat File and HL7® Generator Tool were created by a private-public partnership among APHL, the Council of State and Territorial Epidemiologists, and the CDC. Additionally, APHL supports the APHL Informatics Messaging System (AIMS) which provides technical infrastructure to quickly exchange COVID-19 test results and support critical public health tools.²³ The AIMS portal can support public health functions for conditions in addition to COVID-19.

Syndromic Surveillance

Syndromic surveillance provides a timely system for detecting, understanding, and monitoring public health events. For instance, syndromic surveillance data related to patients' symptoms in emergency departments can be reported to public health authorities and tracked to detect unexpected levels of illness. It can serve as an early warning system for public health events, e.g., flu outbreaks and emerging infections.²⁴ Starting in 2022, syndromic surveillance reporting will be a required activity for hospitals participating in the Medicare Promoting Interoperability Program.²⁵

Information Exchange to Facilitate Care and Monitoring of Patients with Long COVID

Some people who have had COVID-19 continue to suffer from a diverse spectrum of symptoms for a prolonged period after their initial diagnosis, a phenomenon referred to as Long COVID. Some health systems have set up specific clinics to treat these patients. As the symptomatology of this condition varies significantly across the population, predicting who will develop Long COVID is difficult.²⁶ Many clinicians have begun using third-party applications (apps) to collect real-time symptom tracking and patient-reported outcomes for Long COVID patients. One such app, COVID Symptom Study, has collected data on almost four million users across the United States and the United Kingdom to provide data to researchers at Harvard University and Massachusetts General Hospital.²⁷ The NIH has released a series of funding opportunities to support researchers who are grappling with these issues to conduct large-scale EHR studies of Long COVID patients.²⁸

Public Health Informatics Workforce

Public health departments at the state, tribal, local, and territorial government levels struggle to attract, train, and retain public health professionals with skills in informatics, data science, and health information technology. A 2017 survey found that nearly half of the public health workforce is considering leaving their organization in the next five years.²⁹ These staffing shortages stifle innovation and present workflow challenges when new IT systems are implemented to exchange data.³⁰ The CDC has made \$2 billion available to eligible public health jurisdictions to establish, expand, and sustain a public health workforce.³¹ ONC is also making \$73 million available to implement or expand training, certification, and degree programs in public health informatics and data science at minority-serving institutions and other colleges and universities. The goals of this funding program, known as the PHIT Workforce Development Program, are to train at least 4,000 individuals over four years through an interdisciplinary approach in public health informatics and technology and to ensure that these training, certification, and degree programs are sustainable to create a continuous pipeline of diverse public health informatics and technology professionals. ONC announced in September 2021 that it will award cooperative agreements to 10 awardees, comprising of Historically Black Colleges and Universities, Hispanic Serving Institutions, Asian American and Native American Pacific Islander-Serving Institutions, and other institutions of higher education.³²





TARGET AREA: INTEROPERABILITY

Background

Interoperability remains a challenge for clinicians across care settings because information that has been captured and stored in health IT systems is still not easily shared. Although barriers still exist, the ability to easily exchange patient data has been increasing, especially in hospitals.³³ For example, about 70 percent of hospitals reported integrating data into their EHR – a nearly 15 percent increase from 2018. Between 2018 and 2019, there was about a 40 percent increase in the proportion of hospitals that leveraged a national network to find patient data.³⁴

Current State

Health Information Exchange

The health information ecosystem continues to advance 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.

HIEs continue to consolidate and partner to share services across states to better support the evolving needs of stakeholders while also improving integration into existing workflows and increasing adoption. For example, CORHIO and Health Current merged their organizations to better serve healthcare needs across Colorado and Arizona.³⁵ In the Midwest, HIEs continue to scale with the merger of the Nebraska Health Information Initiative and the Iowa Health Information Network.³⁶

A number of HIEs are exploring models that rely on shared technical infrastructure but still maintain local governance. In a recent survey of HIEs, 24 percent of the respondents noted they are selling or providing infrastructure to other HIEs, while 13 percent buy or use infrastructure from another HIE.³⁷ For instance, CRISP offers shared services that are used in Connecticut, the District of Columbia, Maryland, and West Virginia. Additionally, six HIEs – CRISP, CORHIO, CyncHealth, Health Current, IHIE, and Manifest MedEx – have created the Consortium for State and Regional Interoperability (CSRI) to develop solutions and promote patient data exchange across the country.³⁸

National networks like the eHealth Exchange, CommonWell Health Alliance, and Carequality continue to grow in terms of connectivity and volume and are expanding their supported use cases.^{39,40,41} For example, in response to the COVID-19 pandemic, Carequality released new implementation guides and policies that temporarily removed barriers for public health organizations to participate.⁴² Carequality and eHealth Exchange enabled COVID-19 eCR reporting which allows automated generation of case reports for public health agencies during the pandemic.^{43,44}

Patient Matching

Patient matching connects disparate patient records across different medical providers or facilities. 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. 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.⁴⁵





As noted earlier, in 2021 ONC released the Project US@ initiative that aims to standardize the patient address format across health IT. Standardizing the address format will increase consistency across the care continuum and aid in COVID-19 contact tracing efforts, and can help reduce errors that lead to patient safety and security risks.^{46,47} Patient ID Now, a coalition of healthcare organizations, released a framework that aims to create a national strategy for patient identification. The coalition recommended that a national strategy include guidance on calculating error rates, defining minimum levels of acceptable accuracy, and developing a minimum standardized dataset.⁴⁸ Some stakeholders believe a unique patient identifier (UPI), a single medical identification number that can be used to connect individuals to their health information, would increase patient matching and therefore patient safety while saving time and money.⁴⁹ Opponents argue that its use could put patient privacy at risk and expose patients to increased risk of identity theft and fraud.⁵⁰

Information Blocking

Stakeholders have been working to educate themselves about information blocking and how to comply with regulations. ONC and a variety of other organizations have developed educational resources to help these stakeholders. For instance, before the information blocking mandates went into effect on April 5, 2021, The Sequoia Project held an Information Blocking Compliance Boot Camp which provided educational resources on the information blocking requirements. The program was intended to teach stakeholders how to develop effective implementation plans and ensure compliance with the Cures Act Final Rule.⁵¹ Additionally, the American Medical Association, College of Healthcare Information Management Executives, and six other organizations collaborated to launch a resource center to help healthcare professionals comply with the requirements.⁵²

ONC has continuously offered resources to help actors better understand the Cures Act Final Rule, including the information blocking provisions. Resources include ongoing public meetings, videos, FAQs, and fact sheets.⁵³ ONC will continue to release educational materials, such as updated FAQs, plain language blogs, social media posts, and outreach from ONC technical, policy, and clinical teams to support compliance.⁵⁴ Continued education of providers and patients will facilitate understanding of the breadth and reach of the new regulations. Patients need to understand the application of the new regulations, their rights under the provisions, and relevant privacy and security considerations.⁵⁵ To date, there are limited data on the impact of the regulations since taking effect.

Exchange of Data for Transitions of Care

Transitions of care, the movement of a patient from one setting of care to another, are essential to the overall care of an individual. Poor transitions of care increase the risk of adverse events, especially for individuals with multiple conditions and care teams. Adverse events can lead to poor patient outcomes and increased costs. The most complex transitions of care tend to be between multiple care sites including emergency departments, acute care hospitals, long-term post-acute care (LTPAC) sites, and in-home support services.⁵⁶ The data needs of different care sites vary and often are not considered by the sending organization.⁵⁷

There are various efforts underway to improve the sharing of information during transitions of care. ONC's 360X Project aims to define implementation guidance that supports patient transitions of care. The guidance and specifications allow certified EHR systems to push C-CDA documents using standardized vocabularies required by CMS incentive programs.⁵⁸ Due to the COVID-19 pandemic, the project focused on the





development, adoption, and expansion of two new use cases which support transfers from skilled nursing facilities to acute emergency departments and close the referral loop with social care entities.⁵⁹ In 2018 eHealth Exchange started a content testing program for exchange over its networks that includes testing infrastructure, dedicated testing staff, and overtime policy changes to require compliance.⁶⁰ This testing provides an estimate of the types of technical standards that its participants are meeting when sending care summary documents that support transition of care documentation. Its findings showed that 89 percent of participants meet the content standards, which means that their documents conform to industry standards for the clinical care summary document types.⁶¹

Increased Health Equity Across Populations, Locations, and Situations

Health equity is achieved when all people can attain their full health potential without facing disadvantages based on socially determined circumstances.⁶² People may face health disparities because of their race, ethnicity, physical or cognitive capabilities, or socioeconomic group. Initiatives aimed at addressing health disparities have increased over the last few years.

Definition of Health Equity

The Biden Administration established the COVID-19 Health Equity Task Force to mitigate inequities caused or exacerbated by the COVID-19 pandemic and prevent them in the future. The Task Force will submit a report to the President “addressing ongoing health inequities faced by COVID-19 survivors that may merit a public health response, describing the factors that contributed to disparities in COVID-19 outcomes, and recommending ways to combat such disparities in future pandemic responses.”⁶³ The CDC’s current director has declared racism a severe public health threat, calling for the organization to begin initiatives to understand the impacts of racial disparities in the United States and improve community-level care.⁶⁴ In addition to race and ethnicity minorities, those who identify as sexual and gender minorities have faced disparate access to care. A lack of data on such individuals is exacerbated by the lack of standard collection of sexual orientation and gender identity (SO/GI) data.

Algorithm Bias

The implementation of AI and machine learning in health care has the potential to improve health care but also to exacerbate existing inequities. For example, if an algorithm is trained with biased data, it can reinforce existing inequities or create new ones.⁶⁵ While these advances have the potential to transform medical decision-making, such tools need to be tested thoroughly to ensure that they do not perpetuate existing biases in health care or create unintended consequences for patients. Clinical decision support (CDS) tools can exacerbate or fail to address inequities in care. For example, researchers have questioned whether forthcoming CDS tools for melanoma will appropriately support diagnoses for patients of varying skin complexions.⁶⁶ As a result, many groups are evaluating existing algorithms and metrics to determine whether they are biased. For instance, the Organ Procurement and Transplantation Network (OPTN) formed a workgroup to study the impact of a race-based adjustment to a common measure of kidney function.⁶⁷ The Minimum Information for Medical AI Reporting (MINIMAR) standards set an example for evaluating training data and model architecture to ensure transparency and equity when developing AI solutions.⁶⁸ Additionally, the IEEE 7000™-2021 standard aims to integrate ethical and functional requirements that ensure responsible innovation of AI systems.⁶⁹ The American Medical Informatics Association has developed a position paper that identifies policies and necessary steps for the development and maintenance of adaptive (self-training) CDS.⁷⁰





Federal agencies are also undertaking efforts to better understand and reduce racial/ethnic bias in algorithms. The Federal Trade Commission (FTC) will build on its experience with automated decision-making to provide oversight of algorithms to ensure that they do not worsen health disparities.⁷¹ The Agency for Healthcare Research and Quality (AHRQ) published a request for information seeking input on how clinical algorithms may introduce bias into clinical decision-making and influence care provided to racial and ethnic minorities.⁷²

Closed-Loop Referrals

Closed-loop referrals allow clinicians to refer patients to specialists, community-based organizations, and others and receive a notification once that referral is acted on. With closed-loop referrals, when a referral is not fulfilled, the clinician is made aware of a gap in care.⁷³ However, clinicians often fail to close the loop and to leverage interoperability tools, causing inefficiencies in the referral process. Moreover, as patients move across the care continuum, there are multiple opportunities for data to be lost or miscommunicated.⁷⁴

Efforts are underway to improve transitions of care by using closed-loop referrals. 360X is a series of Integrating the Health Care Enterprise (IHE) International profiles that address patient transitions of care.⁷⁵ The profile notifies providers when a patient is referred from one provider to another, and when the expectation is that the patient will eventually return to the referring provider for continued care. The profiles include two transitions of care use cases: ambulatory referrals and acute/ambulatory transfers to skilled nursing facilities. 360X introduced two new use cases for balloting and deployment in 2021: transfers from skilled nursing facilities to acute emergency departments and SDOH needs-based referrals.⁷⁶ The PACIO Project is an HL7[®] project that aims to advance interoperable health data exchange between post-acute care and other key stakeholders across health care by developing FHIR[®] technical and implementation guides. The deliverables from this project will support a new standard for electronic exchange between care settings.⁷⁷

Exchange of Social Determinants of Health Data

SDOH data are defined as data referring to the conditions in which people live, learn, work, and play. Such data affects a wide range of health risks and outcomes.⁷⁸ ONC continues to lead projects which seek to improve the exchange of SDOH data. In January 2021, ONC began the Advancing SDOH Health IT Enabled Tools and Data Interoperability: Electronic CDS and Data Tagging Project. This project aims to advance the interoperability of SDOH data by supporting efforts to conduct data tagging and by assessing the feasibility of developing electronic CDS tools that incorporate SDOH data.⁷⁹ In February 2021, ONC released a Leading Edge Acceleration Projects (LEAP) in Health IT notice of funding opportunity focused on supporting referral management applications that address the intersection between SDOH and clinical care. ONC announced in July 2021 that the USCDI Version 2 added new data elements that support SDOH initiatives.⁸⁰ In August 2021, the University of Texas at Austin was awarded a LEAP cooperative agreement to use FHIR[®] to integrate a closed-loop social services referral system for Federally Qualified Health Centers.⁸¹

The integration of SDOH data into patient health records is limited, but many clinicians and organizations are exploring ways to integrate SDOH data into the clinical workflow.⁸² The HL7[®] Gravity Project is partnering with stakeholders to continue developing standards that address SDOH and increase interoperability. In 2021, the Gravity Project focused on addressing SDOH domains, such as financial strain, material hardship, stress, and social isolation. Based on this work, the Gravity Project is working to ballot a





FHIR® implementation guide in 2021.⁸³ Real-world applications of SDOH are being researched by HIEs like CyncHealth, San Diego Health Connect, and Bronx RHIO. These projects aim to explore how SDOH data can be leveraged to promote health equity and improve patient outcomes when successfully integrated into EHRs.⁸⁴

Association between EHRs and Patient Safety

Health IT can improve patient safety by better supporting clinical workflows and decision-making. For example, CDS alerts in EHRs allow clinicians to have access to real-time patient data which can notify clinicians of potential patient warnings or adverse events.⁸⁵ The positive effects are seen in patients across many diseases, including cardiovascular disease, high blood pressure, and diabetes. Additionally, EHR-integrated CDS alerts have been shown to reduce up to 81 percent of medication errors.^{86, 87} However, CDS alerts can also introduce new patient safety risks, especially those associated with nurse burnout, medication errors, and alert fatigue.⁸⁸ The World Health Organization submitted the final draft of its Global Patient Safety Action Plan 2021-2030 which listed one of its strategic objectives as further researching ways to reduce patient harm. One key strategy is to promote and support the application of digital technologies and research for improving the safety of patients.⁸⁹

Information Exchange for Research

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. The COVID-19 pandemic highlighted the need for available data that researchers can access for developing health solutions, including vaccines and therapeutics.⁹⁰ The Cures Act Final Rule seeks to accelerate the use of standardized APIs to use, share, and aggregate data. Standardization and adoption of the FHIR® Bulk Data Access API could enable researchers to access large amounts of population data.⁹¹ Additionally, ONC announced the winners of the Synthetic Health Data Challenge which invited providers, researchers, and technology developers to develop innovative tools and resources that support validation and novel uses of synthetic data for patient-centered outcome research.⁹² Winners of the challenge created and tested solutions that enhanced the open-source synthetic health data generator. Use cases included medication diversification, co-morbidity modeling, and social determinant-based transition logic.⁹³ The NIH leads the All of Us Research Program, 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 Hub allows researchers to access participant data to address various aspects of health from general wellness to disease prevention.⁹⁴

Metadata helps contextualize data and keep track of where it is captured, transformed, transferred, stored, and processed. Integrating clinical data for research relies on collecting standardized data and ensuring that it can be merged from multiple sources over time. One of ONC's goals of the National Health IT Priorities for Research is to "identify and develop metadata standards that capture more information about a given data point at the time of capture."⁹⁵ Additionally, metadata can be key for clinical research because it enriches data and can add value to research.⁹⁶

Management of Data from Outside Sources

The ability to incorporate, deduplicate, reconcile, and use data from external sources can be a challenge for many clinicians. EHR implementations between organizations can be highly customized depending on clinicians' needs and workflows, which can make data integration more difficult.⁹⁷ Some clinicians note that





helpful information about patients can be hidden in free-text or notes sections that are not easy to access.⁹⁸ Additionally, electronic health data can be generated outside of EHRs through third-party apps. For example, Apple created Apple Health Records so patients could request their data from participating providers. Moreover, iOS 15, Apple's latest iOS operating system released to the public on September 20, 2021, enables patients to use their smartphone to share health data directly with their providers by using FHIR®.⁹⁹

Health IT Support for Opioid Response

Health IT is an important tool in addressing the opioid epidemic, which has persisted during the COVID-19 pandemic. PDMPs, state-run electronic databases that capture pharmacy data on controlled substances, have aided clinicians in reducing the risk of addiction and overdose.¹⁰⁰ PDMPs also allow states to evaluate the data and inform targeted interventions, such as education campaigns. However, PDMP information is most effective if it can be accessed easily and integrated with EHR systems.¹⁰¹

Electronic prescribing also improves patient safety by allowing clinicians to view patient medication histories while reducing clinician burden.¹⁰² In 2020, e-prescribing became critical as more physicians began delivering care virtually: there was a 52 percent increase in the electronic prescription of controlled substances.¹⁰³ CMS issued a final rule requiring that Medicare providers use electronic prescribing for controlled substances effective January 1, 2021, pursuant to the requirements of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act). States are also taking actions to advance electronic prescribing of controlled substances: twenty-four states have state-specific electronic prescribing mandates in place, seven have upcoming mandates planned, and four have proposed their implementation.¹⁰⁴

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 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 and Patient Access Final Rule will reduce the ability of healthcare entities and others to use the privacy and security regulations as a barrier to evade sharing health data.^{105,106} In December 2020, HHS OCR issued a proposed rule modifying the HIPAA Privacy Rule.¹⁰⁷ The rule proposes several changes to HIPAA to strengthen individuals' right to access their health information and improve information sharing to support care coordination and case management. In addition, OCR has increased its enforcement of patient right of access complaints. As of September 30, 2021, OCR has resolved 20 cases with healthcare entities since 2019 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.¹⁰⁸





Current State

Beyond HIPAA: Rules for Sharing and Patient Consent

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.^{109,110} This fact is often not transparent to patients.

The COVID-19 pandemic brought to the forefront various data collection mechanisms that were not subject to HIPAA provisions. For example, encounter notification apps that used geolocation and self-reported test results to notify individuals if they were exposed to COVID-19 collected sensitive health information outside of the HIPAA framework. Additionally, third-party websites, like [Dr. B](#), collected information on millions of people to connect individuals to unused COVID-19 vaccines without clear guidelines on how this data will be used in the future.¹¹¹

Public Opinion about the Impact of Use of Health IT on Privacy and Security of Data

The use of digital health IT solutions has increased generally over the past few years and significantly during the COVID-19 pandemic. For example, remote patient monitoring tripled compared with pre-pandemic numbers. In early 2020, only seven percent of people had a virtual consultation with a provider compared with nearly 32 percent in 2021.¹¹² Although these statistics demonstrate the growth of consumer use of health IT, the public is still wary; many people did not adopt the use of digital health IT due to a lack of trust in technology companies to safeguard their information. For example, contact tracing apps, originally touted to help control the pandemic, were not well-received in the United States because of consumer distrust that their data would be kept private.¹¹³ Generally, consumers were more likely to trust their clinicians to recommend digital health tools than health insurance companies, technology companies, pharmaceutical companies, or the government.¹¹⁴

Alignment of Innovation and Regulation of Privacy and Security of Data

As the ONC Cures Act Final Rule enables patients to use APIs to access their medical records and share their protected health information (PHI) with third-party apps, the availability and use of APIs will increase significantly. Many industry stakeholders have expressed concern about whether patients understand the boundaries of current health information privacy and security rules as they apply to third-party apps. For example, when sharing information with a third-party app developer, the information is often not subject to HIPAA but is subject to the app developer's privacy policy.¹¹⁵ APIs can be used by developers and advertisers to collect and monetize consumers' personal information but most privacy choices are opt-out, requiring individuals to deliberately change their privacy settings.¹¹⁶ As the field advances, a gap has developed between the boundaries of regulation and the capabilities of technology. Current laws protect certain data in particular market sectors but do not provide specific protection for some of the newer technologies and their use of data.¹¹⁷ For instance, when technology is more advanced than existing regulation, developers do not know what privacy and security obligations apply, leaving them unclear about their regulatory obligations. Moreover, regulators face a challenge in ensuring that regulations both support innovation and protect users.





Cybersecurity Events across the Healthcare Infrastructure

Health data continues to be vulnerable to cybersecurity threats. Ransomware attacks against health organizations increased by 55 percent in 2020, affecting the PHI of an estimated 26 million people in the United States.¹¹⁸ Malicious cyber activity also increased as actors attacked 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.^{119, 120} The Food and Drug Administration (FDA) and DHS issued several warnings in 2020 about potential cybersecurity vulnerabilities in certain medical devices.^{121, 122} 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 risks of using certain video conferencing platforms.¹²³ In January 2021, an amendment to the Health Information Technology for Economic and Clinical Health Act (HITECH Act) became law, requiring that “recognized cybersecurity practices” be considered by OCR in determining any HIPAA fines, audit results, or mitigation remedies for covered entities or business associates after a cybersecurity breach.¹²⁴

TARGET AREA: PATIENT ACCESS TO INFORMATION

Background

Patients’ access to their health records allows them to track and manage their health outside of the clinical setting. The ability to integrate patient health information in health apps on a smartphone can support disease management, allowing users to engage in their health and track their health over time.¹²⁵ The ONC Cures Act Final Rule and CMS Interoperability and Patient Access Final Rule seeks to improve patients’ access to their health information. The ONC Cures Act Final Rule supports this access 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.¹²⁶ The CMS Interoperability and Patient Access Final Rule supports patient access by requiring payers to provide patients access to a claims and clinical dataset via a FHIR® API.¹²⁷

Current State

Safety and Impact of Mobile Health Applications

Standardized use of APIs could enable prompt and increased access to medical records and improve patients’ ability to obtain them. There are over 350,000 health-related mobile apps available to patients to download via app stores. There are more than 250 digital therapeutics, software that is used to treat, prevent, or manage specific diseases or conditions, available to patients.¹²⁸ The private sector is supporting opportunities for patients to access, manage, and share their health data with trusted parties. For example, the Xcertia initiative is developing mobile health app guidelines.¹²⁹ The American Telemedicine Association is launching a resource for measuring mobile health apps against more than 300 standards developed by the Organization for the Review of Care and Health Applications (ORCHA), a health app evaluation and advisor organization. ORCHA provides an assessment of an app’s compliance with current standards, regulations, and good practices to measure an app’s reliability, safety, and effectiveness.¹³⁰ At the end of 2020, OCR released its new “Health Apps” website which shares existing guidance for mobile health apps





regarding HIPAA regulations. The website's interactive tools and guides focus on educating mobile health app providers.¹³¹ The FDA has a similar web tool that helps app developers identify federal laws and regulations that may apply to them.¹³²

Some stakeholders and patients still have concerns about the validity of third-party apps and the safety of their data. HHS continues its ongoing effort to determine the best way to regulate mobile health technology. In 2019, the FDA updated its Policy for Device Software Functions and Mobile Medical Applications Guidance to align with the Cures Act. This update reflects that the FDA is using a risk-based approach which focuses on “the software that presents a greater risk to patients if it doesn't work as intended and on software that causes smartphones, computers, or other mobile platforms to impact the functionality or performance of traditional medical devices.”¹³³ The FTC adopted a policy that requires that “health apps and connected devices that collect or use consumers' health information comply with the Health Breach Notification Rule and notify consumers and others when their health data is breached.”¹³⁴ The international *Digital Health Trends 2021* report highlighted at least 25 digital therapeutics that have been granted market authorization through a regulatory process while another 23 are commercially available.¹³⁵

Accessibility of Health IT

During the COVID-19 pandemic, providers and patients relied on technology and digital solutions to deliver and receive care while social distancing and following public health safety measures.¹³⁶ According to one study, four in 10 survey respondents said the coronavirus pandemic made them more likely to support efforts that enable people to download their personal data from EHRs to apps on smartphones and other devices. Patients relied on digital tools to effectively receive testing results, book vaccine appointments, and meet with providers via telehealth.¹³⁷ Telehealth in particular saw a rapid uptake from patients and providers, and the Health Resources and Services Administration is now leading multiple projects to strengthen telehealth services in rural and underserved communities.¹³⁸ Tools such as Apple Health Records and CommonHealth let patients aggregate all their digital patient information into one digitized personal health record through the use of APIs and then easily share that information.¹³⁹ Telehealth and mobile health tools will continue to grow beyond the pandemic; however, more focus is needed on reducing the digital divide by ensuring that everyone has access to these tools.¹⁴⁰

Sharing and Correcting Incorrect Clinical Data

Clinicians may use EHR data to make clinical decisions, but such clinical data can contain incorrect information. Barriers still exist when patients try to correct information. The information blocking provisions of the Cures Act Final Rule will help patients increase access to their personal health information, including clinical notes, test results, and medications. As this information becomes more accessible, it may be easier for patients to identify incorrect clinical data. Additionally, access to visit notes and patient information could improve patient-doctor communication and thus make it easier for patients to identify incorrect data.¹⁴¹ With the progressing integration of APIs, services could arise that help patients to integrate their data across different systems, giving them a chance to not only decide where their clinical data goes but also a chance to verify its accuracy.

Overall, the ability to identify and correct incorrect clinical data improves patient safety. One survey reported that patients who notice incorrect data may not report it because they do not know the proper process for correcting the information or out of fear of being perceived as disruptive. Although APIs will improve





interoperability of patient data, creating a supportive environment and providing patient education are needed to empower patients to make corrections when needed.¹⁴²

Use and Sharing of Patient-Generated Health Data

Remote patient monitoring, or RPM, is the use of connected electronic tools to record personal health and medical data in one location to be reviewed by a provider in another location, usually at a different time. It can be used to collect PGHD to support those with chronic diseases. ONC defines PGHD as “health-related data created, recorded, or gathered by or from patients (or family members or other caregivers) to help address a health concern,” and it can be collected from various sources including patient-entered health history, biometrics captured by wearable technology, or even data from medical devices, such as blood-glucose monitors.¹⁴³ Clinicians find PGHD valuable because it offers insight into a patient’s health when the patient is not in the office. However, both patients and providers find it burdensome when PGHD is not easily integrated into the patient portal. The use of APIs could help streamline this process. For example, an API could make it easier for a patient to submit data from a smartphone nutrition app to the patient’s doctor.¹⁴⁴

RPM and the sharing of PGHD have skyrocketed during the pandemic. Clinicians with patients managing a chronic illness explored ways to collect PGHD so they could support patients without having them come into the office. For instance, in Massachusetts, South Shore Health added RPM functionality to its Mobile Integrated Health program during 2020. The Mobile Integrated Health program focuses on in-person and virtual care at home for patients who might otherwise be housed in skilled nursing facilities. South Shore Health partnered with Current Health, an RPM solution, to allow patients to integrate data from wearable, wireless health devices, including respiration rate, oxygen levels, mobility, and body temperature.¹⁴⁵ CMS has codified RPM reimbursement in the 2021 Physician Fee Schedule, making it more feasible for providers to include these tools in patient care management.¹⁴⁶ With the CMS release of the 2021 Physician Fee Schedule, there have been increased discussions about RPM devices and how providers can be paid for using RPM platforms.¹⁴⁷

EMERGING ISSUES

Robotics

Surgical robots have been in use for almost 30 years and robotics continues to spread into new arenas in health care, such as data collection, pharmacy, and rehabilitation medicine. Robotics can be used to augment staff capabilities and perform diagnostics and treatment.¹⁴⁸ Robots are particularly useful in automating rule-based, repetitive tasks that require attention to detail.¹⁴⁹ The Department of Veterans Affairs is exploring robotic process automation as a way to streamline the process of digitizing external documents received by email, fax, referral management systems, and electronic exchange, and integrating these documents into the EHR.¹⁵⁰ In the pharmacy setting, this could include packaging, storing, and dispensing filled prescriptions. Automation of pharmacy inventory and medication distribution could increase patient safety and staff productivity.¹⁵¹ In rehabilitation medicine, robots assist patients with their range of motion and in completing exercises.

A federal regulatory framework for the use of robotics in health care is needed. Use cases such as medication delivery and support for sterile environments/isolation units in hospitals lack federal oversight.





The FDA has cleared robotically assisted surgical devices for some common procedures, such as gallbladder removal, hysterectomy, and prostatectomy. However, the use of surgical robots for other procedures has not been authorized yet.¹⁵² The use of drones for medication delivery falls under the regulations of the FAA. A coordinated effort to regulate these activities across agencies could lead to more innovative applications of robotics to solve health needs and management of related health IT requirements.





Health IT Infrastructure Gap Analysis

TARGET AREA: USE OF TECHNOLOGIES THAT SUPPORT PUBLIC HEALTH

Need for Improved Infrastructure to Support Public Health Data Sharing

Public health authorities face interoperability challenges around collecting and exchanging information from and with clinicians and laboratories.

There are long-standing infrastructure gaps in public health reporting capabilities that have prevented public health authorities from receiving and sharing timely information on COVID-19 infections and other reportable conditions. Public health data collection is decentralized in the United States, with each locality setting standards for data collection and reporting. Because COVID-19 has affected the entire nation, this decentralization has been problematic.¹⁵³ Public health authorities have been unable to receive complete data on patients' demographics, medical history, and their course of the disease due to lack of connectivity across public health IT systems, varying state requirements about what data must be reported, and inadequate access to clinical data from EHRs.

Additionally, bidirectional information exchange between clinicians and public health authorities, while valuable to patient care and public health interventions, is not supported consistently across the country. Public health authorities have faced technical and policy challenges using national networks. For instance, the data exchanged over national networks are clinically focused, often only required for treatment, and do not provide public health authorities with compliant minimum necessary datasets.¹⁵⁴ Although existing technologies such as FHIR® APIs could provide a channel for public health agencies to pull and push targeted information from and to EHRs, many public health departments do not have the technical infrastructure to support such exchange, especially on a large scale.¹⁵⁵ These obstacles have led to delays in contact tracing and case investigations, which can have direct effects on the spread of COVID-19. Moreover, providers have expressed value in being able to retrieve data from public health information systems. For example, during the COVID-19 pandemic, providers reported that it would have been beneficial to be able to access electronic information from public health departments' case investigations to better understand a patient's disease course.¹⁵⁶

Moreover, there is a paucity of data standards to allow for standardized reporting of situational awareness data from EHRs directly to public health or government officials.¹⁵⁷ 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 actionable only if the data are 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 and is currently being tested by a STAR HIE awardee to validate the standards in a practical setting.¹⁵⁸ There has been success in standardizing EHR reporting for immunizations; this use case can serve as an example for COVID-19-related data.





Need for Improved Incentives and Funding to Support Public Health Data Sharing

More bidirectional interoperability is needed between the currently siloed public health and clinical data systems.

The historical underfunding of public health infrastructure, short-term funding cycles, and funding siloes around specific diseases or programs have resulted in data systems that are not robust or well-connected to other systems. For example, only 21 percent of local health departments use HIEs to share information with clinicians and others; this is particularly true for small health departments, where only 18 percent do so.¹⁵⁹ Moreover, public health information systems often serve a specific purpose without certification requirements for interoperability with other systems or the ability to share data to support clinical treatment. Likewise, certified EHRs are not required to support data collection and sharing for public health purposes and national networks had to create a workaround in response to COVID-19 to enable widespread automated support for queries by public health authorities.¹⁶⁰ Accurate and automated bidirectional exchange reduces the risk of error and frees up staff for other work.¹⁶¹ Increasing the financial support for more bidirectional flow of both public health and clinical datasets would be mutually beneficial to public health organizations and clinicians.

Need for Further Improvements to Optimize Electronic Case Reporting

The rapid expansion and adoption of electronic case reporting during the pandemic have enhanced communication between clinicians and public health; however, improvements are still needed to ensure timely and accurate reporting to public health agencies from all facilities.

Electronic case reporting is not implemented in all organizations' EHRs and other relevant IT systems.¹⁶² During the pandemic, many non-traditional testing sites, such as schools and stadiums, could not easily establish an electronic connection to report to public health authorities. Moreover, as testing options for COVID-19 expanded, an increasing number of facilities were able to conduct point-of-care testing, the results of which may not have been included in established electronic reporting feeds.¹⁶³ As a result, positive COVID-19 cases were not reported in a timely manner to public health authorities, hampering their understanding of key indicators of the pandemic and the impact of response efforts. Additionally, the information transmitted through electronic case reporting and electronic lab reporting messages needs to be optimized to ensure that public health departments receive complete and accurate information that can support their work.¹⁶⁴

Need to Improve Standardization of Electronic Laboratory Reporting

The lack of use of standards creates a barrier to reporting and increases provider burden.

While a significant improvement over paper-based reporting, electronic laboratory reporting still faces challenges. Laboratories and hospitals often use varying local codes for results that have to be mapped to terminology standards (i.e., LOINC, SNOMED CT). This lack of use of standardized terminology leads to mapping errors and can require that manual mapping be conducted.¹⁶⁵ 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.¹⁶⁶





Need to Improve Sharing of Syndromic Surveillance Data

Increased sharing of this information would improve clinical care and enhance decision-making.

As of 2020, 69 percent of emergency departments, and smaller percentages of other providers, report syndromic surveillance data to the CDC.¹⁶⁷ Emergency department reporting is anticipated to rise in response to the new Medicare Promoting Interoperability Program reporting requirement. Syndromic surveillance can identify health threats at a community level and has been useful for public health authorities with early identification and response to threats. While data sharing to providers does occur (e.g., the CDC's Health Alert Network), there is inconsistent real-time sharing of syndromic surveillance data back to healthcare providers to assist them with a timely response to emerging public health threats.^{168, 169} In addition, patients could benefit from increased access to public health data to improve their decision-making.

Challenges in Understanding Long COVID

The ability to conduct analyses on patients with Long COVID is limited.

There is a gap in easily using EHRs to identify patients with Long COVID or those that may develop the condition, although this situation is slowly improving. For example, early in the pandemic, there was no ICD-10 code for clinicians to use to identify cases of Long COVID but an ICD-10 code for Long COVID was added in October of 2021.¹⁷⁰ The initial absence of such a code made it difficult to systematically identify and quantify how many patients were suffering from this condition.

Difficulty in Public Health Workforce Recruitment, Training, and Retention Regarding Health IT Skills

Challenges exist in recruiting, training, and retaining a public health workforce highly skilled in health IT.

Historically, the public health workforce has been under-resourced and unable to recruit top talent to execute the public health mission.¹⁷¹ For example, many jurisdictions may have only a few employees to complete the multitude of job functions required of a public health department. As the public health infrastructure integrates more informatics and data science, these workforce gaps stifle innovation and present workflow challenges when new IT systems are implemented to exchange data.

TARGET AREA: INTEROPERABILITY

Patient Matching

Patient matching when sharing data needs to be improved.

Matching errors can result in inaccurate record creation, inadvertently merged records, and duplication of records, all of which can negatively affect healthcare costs and patient safety. Patient matching challenges can arise due to gaps in information (particularly demographic) or incorrect information. Further data elements could be defined to support patient matching across both public health and healthcare systems.¹⁷²





Information Blocking

Information blocking interferes with seamless and secure access, exchange, and use of electronic health information.

There is limited data available about the prevalence of information blocking and no common framework for measuring compliance. The start of information blocking enforcement may provide additional insights into compliance rates and key gaps. A survey of HIE organizations revealed that 55 percent of HIEs reported that EHR vendors sometimes engage in information blocking. The data from this survey could serve as a baseline once enforcement aimed at reducing information blocking begins.¹⁷³

Exchange of Data for Transitions of Care

Poor exchange of information during transitions of care increases the likelihood of a poor outcome and increased cost.

An absence of shared semantically interoperable data and inconsistently applied standards contribute to incomplete information exchange at care transitions. Misunderstandings between care teams can lead senders to provide information that is not necessarily important to the receiver. For example, acute and ambulatory care sites are largely unaware of what information LTPAC care teams require at transitions of care. A recent study of information exchange between 471 skilled nursing facilities and their two largest referral volume acute care hospitals showed that key information at the transition of care was often missing, delayed, and difficult to use, compounding the risk of an adverse event.¹⁷⁴

One major barrier is that not all care systems use and share the same data elements. For example, many LTPAC sites require the inclusion of certain data elements from the CMS Data Element Library (DEL) to meet requirements for payment and quality measurements. Although this standardized vocabulary is used throughout the LTPAC community, it has not been adopted outside of CMS and is not used in acute or ambulatory care environments.¹⁷⁵ Acute and ambulatory care environments use C-CDA, the ONC recommended mechanism for transitions of care, to describe similar clinical concepts or use non-standardized vocabulary that is not semantically interoperable. Additionally, while the DEL contains many of the required data elements, many transitions require more detailed problem-specific and medication-specific data to ensure safe and effective care.¹⁷⁶ Addressing gaps in interoperable information exchange at the time of transition will require identifying essential content across standards and harmonizing it so that it can be expressed using a shared, unambiguous vocabulary.

Expanding the Health Equity Definition and Improving Algorithms to Reduce Bias

Ensure meaning of health equity includes health care.

To effectively address health disparities in the United States, the healthcare lexicon must address equity to address historically under-resourced needs. The tracking and sharing of health equity data elements should support both health and healthcare equity initiatives. With the explicit inclusion of health care in the definition of health equity, standards that promote health equity can be implemented across public health authorities, healthcare providers, individuals, and governing bodies at the federal, state, tribal, local, and territorial government levels.¹⁷⁷





Efforts are needed to better understand and reduce racial and ethnic bias in algorithms.

Researchers have attempted to mitigate algorithmic bias; however, gaps persist because health data is complicated, and its inclusion in algorithms does not always acknowledge underlying characteristics, such as demographics and SDOH. Existing datasets also may have disparities built into them. As a result, machine learning models trained on these datasets can continue to perpetuate racial health disparities. In one study, researchers looked at the outcomes of algorithms that detect post-partum depression in white and black women. According to the models, white women were more likely to be diagnosed with postpartum depression and more likely to seek out mental health services; however, the models do not consider that lower odds among black women could be the result of underlying disparities.¹⁷⁸

Interoperability Standards Priority Uses – Closed-Loop Referrals

There is a lack of cross-organization support for closed-loop referrals. This lack of standardized systems can make closed-loop referrals and prior authorizations an administrative burden to providers.

There is growing research showing a lack of coordination between social and clinical services can harm patients and increase burden on healthcare providers. This lack of coordination means that the responsibility of navigating these complicated systems falls on the patient. This can lead to stress, confusion, and an increase in the cost of care, hospital readmissions, and emergency department visits.¹⁷⁹ The lack of interoperability between EHRs and between EHRs and community-based organizations makes it difficult for clinicians to “close the loop” on referrals. Many community-based organizations and social services organizations have their own e-referral processes that are difficult to integrate with EHRs for clinical access. It is also difficult for smaller organizations to implement EHR-compatible workflows; they typically have to spend money and resources hiring technical experts to do it for them.¹⁸⁰ Transitions across varied healthcare settings highlight the gaps in referrals and communication between healthcare domains. Effective closed-loop referral systems could help reduce hospital readmissions and improve patient outcomes.¹⁸¹

TARGET AREA: PRIVACY AND SECURITY

Lack of Clarity on the Impact of Use of Health IT on Privacy and Security of Data

Not much is known about the public’s opinion and perception of how health IT affects data privacy and security.

While there are some sources available regarding consumer use and perception of health IT, peer-reviewed literature regarding this topic is inadequate. As the availability of health IT tools increases, more research is needed to further understand how people use these tools as well as the perceived benefits and aversions to their use, particularly due to privacy and security concerns. In order to develop programs to encourage the use of these tools, information is needed to shed light on why consumers choose certain tools but do not feel comfortable using others.¹⁸²





Lack of Alignment between Innovation and the Privacy and Security Regulatory Environment

Health systems are concerned that using APIs may expose them to liability.

As health systems plan to adopt APIs, these health systems have concerns about whether they will be held liable for any information sharing misbehavior by third-party app developers. At present, the FDA has noted that many mobile apps are not medical devices and are therefore not regulated under its purview.¹⁸³ This regulatory framework has begun to show that the development of APIs may be more advanced than the existing regulations to help set boundaries for privacy and security practices these app developers must follow.¹⁸⁴

TARGET AREA: PATIENT ACCESS TO INFORMATION

Safety and Impact of Mobile Health Applications

As the third-party app market grows, there is concern about the clinical accuracy of these apps and the potential for patient harm.

The market for digital health tools is growing, and some clinicians are concerned that these tools cannot deliver what they promise. The stakes are high for patients; for example, if a digital mental health tool fails to function appropriately, a delay in care could result.¹⁸⁵ One ONC report found that key characteristics of effective health APIs and apps include interoperability, detailed information, accurate information, and timely data collection. The use of apps that are built without using sound clinical knowledge can produce inaccurate readings or incorrect conclusions. So long as there is a gap in established infrastructure, adoption, and regulatory guidance for app developers, patients may be reluctant to invest time and trust in apps with which they lack an established relationship.¹⁸⁶ ONC's Consumer Perspectives report suggests that apps use clear language to clarify the purpose, use, and security of user data. Models like the CARIN Code of Conduct can help provide guidance to app developers on best practices for encouraging better and safer mobile health app use.¹⁸⁷

Health Equity and the Accessibility of Health IT

The pandemic highlighted the ongoing digital divide regarding access to health IT by consumers for testing, vaccine appointment booking, and telehealth.

Digital tools have been effective at making access to care more convenient; however, several barriers to the use of this technology still exist in many underserved communities. The digital divide regarding access to technologies and the literacy needed to use them can contribute to greater health inequity and potential patient safety risks.¹⁸⁸ The primary barriers that keep individuals from using digital health tools include lack of internet connection, lack of access to a connected device, and lack of digital literacy.¹⁸⁹ At least 30 percent of rural residents lack broadband services, and 24 percent of individuals living in rural areas own a cellphone but not a smartphone. As a result, they cannot take advantage of certain mobile health apps, patient portals, or healthcare services offered online and via smartphones. Although there have been significant increases in the possession of computers and smartphones, disparities remain in certain race/ethnicity, income, education, and age groups.¹⁹⁰ Similar to other social determinants, minorities are disproportionately affected. Communities of color are less likely to have broadband service at home.¹⁹¹





Many patients may want to receive care through telehealth but cannot access it because their providers do not offer it or for other reasons, such as language barriers. Efforts to promote digital health tools to underserved communities could increase access, uptake, and experience with these resources. Digital health innovations will continue to grow and affect population health; therefore, such tools must be designed to be accessible so disparities in access to digital health are not exacerbated.¹⁹²





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 local public health agency in an area with high rates of tourism hopes to collect more comprehensive demographic and clinical information about patients with positive cases of influenza so that it can better monitor and plan for outbreaks to keep both the residents and visitors safer. In the past, the agency has encountered clinicians who were hesitant to send their patients' medical records to an outside entity. **However, clinical datasets have become better defined and bidirectional exchange has improved.** A new federal educational initiative has helped clinicians understand that public health entities do not need a patient's entire medical record to perform their duties, only discrete information like vaccination data, ethnicity, and hospitalization status. The agency is now better able to work with its regional HIE to collect select patient information that enhances the agency's tracking of key indicators of potential surges and improves its response efforts.

Immediate Opportunities

Infrastructure to Support Public Health Data Sharing

Opportunity: Help relevant federal agencies (e.g., the CDC, CMS) by exploring and sharing findings on approaches to achieving national public health reporting.

Federal agencies have the opportunity to further promote streamlined electronic public health reporting.

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

For example, public health data systems could deliver vaccine status for a list of patients. Also, immunization registries could be set up for data consumption, such as supporting vaccine monitoring for return to work as well as for reporting for agency use.

Opportunity: Improve bidirectional interoperability between public health reporting systems and HIEs.





For example, public health data systems could leverage existing or potential data flows from EHRs to HIEs (e.g., testing, hospitalization data) for surveillance, to populate/enhance registries, and to share data, such as vaccination status, back to providers via the HIE.

Opportunity: Publish best practices and guidance for minimum necessary datasets standard to information sharing with public health authorities.

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, EHRs, and other clinical IT systems.

Recommended HITAC Activity: Explore collaborative approaches being considered for the national public health data infrastructure (e.g., leveraging EHRs, HIEs, and other technology providers) and share the findings with the CDC and CMS.

Recommended HITAC Activity: Provide guidance for policies and for operationalizing standards to address implementation variation of public health data access and exchange.

Recommended HITAC Activity: Convene a listening session to better understand barriers to sharing clinical datasets with public health authorities in a compliant manner, e.g., minimum necessary under HIPAA.

Recommended HITAC Activity: Assess public health activities and systems to understand what is needed to help public health data systems align with the use of the HL7[®] FHIR[®] standard or another approach.

Incentives and Funding to Support Public Health Data Sharing

Opportunity: Align incentives and funding structures across clinical and public health data systems to create parity across infrastructures.

Recommended HITAC Activity: Explore how the ONC Health IT Certification Program can be aligned with other public health certification programs, e.g., electronic laboratory reporting certification and certified immunization registries receiving data from certified EHRs.

Opportunity: More data collection is needed by public health organizations to support situational awareness and health equity.

Public health data systems historically have been funded at lower rates than clinical data systems, creating a disparity in the functional capabilities of the two types of systems.

Recommended HITAC Activity: Continue to explore ways that the ONC Health IT Certification Program can support data exchange between public health organizations and stakeholders including clinicians, payers, patients, and laboratories.





Opportunity: Reduce siloes in data exchange by exploring the roles of HIEs, networks, frameworks, and other health data utilities in promoting the interoperability of public health and clinical data systems.

Public health funding is often siloed around specific diseases or programs that have differing requirements, e.g., immunization data for children. These siloed funding streams create challenges for state, tribal, local, and territorial public health authorities to build a common infrastructure that supports multiple use cases. The data are often stored in disparate datasets that are not integrated with other databases, even within a particular public health department. However, some HIEs have extensive connectivity with clinicians across a region that allows comprehensive and timely data capture and exchange.

Recommended HITAC Activity: Partner with NCVHS to identify barriers to and potential opportunities for public health use of HIEs/health data utilities where available and affordable.

Electronic Case Reporting

Opportunity: Expand the adoption and support for electronic case reporting by public health authorities, healthcare providers, and health IT developers.

Opportunity: Encourage public health authorities to respond more fully to healthcare providers upon receipt of a report about a reportable disease and health IT developers to enhance such capabilities.

Electronic case reporting can be optimized to improve interoperability between clinical systems and public health authorities.

Recommended HITAC Activity: Learn about the experience of government agencies like the CDC and state health departments in developing tools and sharing data for electronic case reporting and assess what gaps remain.

Recommended HITAC Activity: Collaborate with convening groups across federal, state, tribal, local, and territorial governments to encourage both adoption and advancement of the technology and standards supporting bidirectional data exchange for public health purposes. For example, partner with NCVHS to identify gaps for standards needed to support electronic case reporting.

Electronic Laboratory Reporting

Opportunity: Improve the use of terminology standards in electronic laboratory reporting.

The lack of use of standardized terminology impedes the prompt and accurate exchange of this information.

Recommended HITAC Activity: Encourage ONC to work with the CDC, public health entities, support organizations, and health IT vendors to standardize technical capabilities to facilitate laboratory results data collection and sharing by federal, state, tribal, local, and territorial public health authorities.

Bidirectional Exchange of Syndromic Surveillance Data

Opportunity: Encourage public health authorities to provide timely population-level syndromic surveillance information back to healthcare providers and patients to support responding to public health threats.

Increased data sharing by public health authorities with healthcare providers and patients can improve care.





Recommended HITAC Activity: Identify existing data sharing methods (e.g., the CDC’s Health Alert Network) and best practices for federal, state, tribal, local, and territorial public health authorities to share real-time population-level syndromic surveillance data with healthcare providers and patients.

Information Exchange to Facilitate Care and Monitoring of Patients with Long COVID

Opportunity: Improve clinical documentation standards for patients with Long COVID and as a blueprint for other conditions.

Challenges with identifying affected patients and conducting population-level analyses of Long COVID create barriers to the care of these patients and research to improve understanding of the disease.

Recommended HITAC Activity: Explore whether there are existing programs and data needs for documenting Long COVID cases among patients and populations, including standards, registries, and electronic patient-reported outcomes (ePROs).

Public Health Workforce Recruitment, Training, and Retention

Opportunity: Improve public health information technology workforce resources and capacity.

Public health workforce gaps stifle innovation and present workflow challenges when new IT systems are implemented to exchange data.

Recommended HITAC Activity: Suggest ways to attract, train, and retain public health professionals with skills in informatics, data science, and health IT, in addition to the ONC PHIT Workforce Development Program.

TARGET AREA: INTEROPERABILITY

Illustrative Story of What the Recommended HITAC Activities Will Enable

Clinicians can provide better care when they can easily access a comprehensive picture of the factors affecting the health of their patients. Most current EHR systems enable clinicians to capture certain types of data in standardized formats. Other data, such as a patient’s preferred language, access to healthy food, or chosen pronoun use, can only be captured in free text which is difficult to find in the EHR and to share with providers across the care continuum. Fortunately, standards organizations have been leveraging the FHIR® standard to create several national standards to collect SDOH and other data relating to health equity and the newest version of USCDI has been updated to include many of these data. These innovations have increased the collection of this patient information, improved interoperability among providers, enhanced patient care, and reduced health disparities.

Immediate Opportunities

Patient Matching

Opportunity: Address alignment of incentives and certification programs across domains to encourage an ecosystem-based approach to improve patient matching, as well as better match EHR and public health data in particular.





Patient matching errors can result in inaccurate record creation, inadvertently merged records, and duplication of records, all of which can adversely affect healthcare costs and patient safety.

Recommended HITAC Activity: Define **best practices at registration and other relevant collection points to improve the data quality of the** core standard set of data elements **defined in the USCDI and Project US@** to support patient matching across healthcare and public health data systems, including demographic information.

Information Blocking

Opportunity: Following the publication of the **ONC Cures Act Final Rule**, assess how the information blocking requirements are being implemented in practice.

No common framework for measuring compliance with new information blocking requirements has been proposed or implemented yet. The industry and consumers want to know that information blocking is being addressed and reduced.

Recommended HITAC Activity: Convene a listening session to assess the establishment of measures of the impact of the information blocking requirements of the **ONC Cures Act Final Rule (including the transition from USCDI to the full scope of electronic health information)** across the industry in conjunction with **ONC's** measurement efforts.

Exchange of Data for Transitions of Care

Opportunity: The exchange of data for both transitions of care between care institutions and transfers of level of care between floors or units within a hospital needs stronger standards.

A uniform process is needed for the standardized exchange of essential information at the point of transfer from one site or care team to another.

Recommended HITAC Activity: Investigate and document the requirements for improving the exchange of data during transitions and transfers of care, particularly around standards, to improve coordination of care.

Longer-Term Opportunities

Collection of Health Equity Data

Opportunity: More industry standards supporting the collection of health equity data elements could be agreed upon.

The collection of health equity data elements related to race, ethnicity, disability condition and resulting impacts, preferred language, SO/GI, and data for SDOH is inconsistent.

Recommended HITAC Activity: Convene a listening session to identify barriers and opportunities related to standards for the consistent collection of health equity data elements.

Health Equity and Bias in Algorithms





Opportunity: Screen healthcare and public health data systems for bias in algorithms to improve data used for decision-making.

Decision-making should be more equitable, particularly in support of public health needs.

Recommended HITAC Activity: Convene a listening session to identify sources of algorithmic bias in healthcare and public health data systems as well as potential solutions.

Interoperability Standards Priority Uses – Closed-Loop Referrals

Opportunity: Explore the opportunities to advance standards that can improve systems for closed-loop referrals and prior authorizations.

Lack of standardized systems can make closed-loop referrals and prior authorizations an administrative burden to providers.

Recommended HITAC Activity: Review the recent and planned activities of CMS and payers regarding standards needed for closed-loop referrals and prior authorizations.

TARGET AREA: PRIVACY AND SECURITY

Illustrative Story of What the Recommended HITAC Activities Will Enable

A hospital wants to adopt APIs for information sharing to improve its patients' experience and implement more value-based care in the facility. However, it is concerned that it would bear the legal burden of the use of any incorrect data. An analysis has identified that both HIPAA and the Cures Act as well as existing applicable state law protect the hospital from privacy and security liability when using this technology. The hospital reviews the analysis' recommendations regarding how to safeguard the data and takes the appropriate steps to adopt APIs for data sharing while minimizing the risk that the data would be compromised or misused.

Longer-Term Opportunities

Lack of Clarity on the Impact of Use of Health IT on Privacy and Security of Data

Opportunity: Research consumer impact of certain uses of health information technology in peer-reviewed literature.

Not much is known yet about public opinion of certain uses of health information technologies, e.g., contact tracing and ransomware/malware attacks, and their effect on data privacy and security.

Recommended HITAC Activity: Assess recent literature and suggest areas for more investigation of the consumer impact of certain uses of health IT.





Alignment between Innovation and the Privacy and Security Regulatory Environment

Opportunity: Align the health IT industry to accelerate innovation where existing regulations are in place.

Hospital systems are adopting APIs but have concerns about unauthorized data exposure and added liability.

Recommended HITAC Activity: Learn about federal regulatory activities for areas of health IT innovation and assess the fit and remaining gaps.

TARGET AREA: PATIENT ACCESS TO INFORMATION

Illustrative Story of What the Recommended HITAC Activities Will Enable

As a result of recent updates to federally sponsored patient education guides, individuals have easy online access to new information about the validity and safety of mobile health applications. For example, a consumer interested in downloading and using an app to help her monitor and control her diabetes can now review ratings of various diabetes apps for their accuracy, safety, and usability. She will also be able to compile records from multiple providers in one app. Upon hearing about this new tool, the consumer visits a recommended website to learn about and compare the available apps. Armed with this information, she avoids the apps that are less helpful and potentially harmful. She opts to use one of the highest-rated ones that will better help her manage her condition and her care across multiple providers without adverse consequences from the app.

Immediate Opportunities

Safety and Impact of Mobile Health Applications

Opportunity: Support initiatives that review and rank the validity and safety of mobile health applications.

Opportunity: Support awareness and education for patients regarding digital therapeutics, leveraging alerts in patient portals.

The use of apps that are built without using sound clinical knowledge can produce incorrect conclusions or readings.

Recommended HITAC Activity: Define updates to past ONC patient access guides and educational materials needed since the start of the pandemic.

Health Equity and the Accessibility of Health IT

Opportunity: Ensure that such information is available to patients and consumers in the same ways that they access other relevant protected health information and facilitate the largest impact and reach.





Barriers impede the delivery of relevant public health-related information through APIs, patient portals, mobile device applications, and other digital distribution channels.

Recommended HITAC Activity: Explore barriers to the delivery of relevant public health-related information through APIs, patient portals, mobile device applications, and other digital distribution channels to stakeholders who have a right to the data and identify opportunities.

1. Locate or compile a catalog of efforts across federal agencies to learn from and collaborate with them.
2. Discuss patient-facing third-party apps used to access provider EHRs via APIs and public health data systems.
3. Discuss large-scale patient data capture via apps, e.g., the NIH All of Us program.

Suggestions for Additional HITAC Initiatives

The HITAC did not identify additional target areas or related HITAC initiatives as defined in the Cures Act in FY21. The HITAC will revisit this opportunity in the FY22 annual report.

Conclusion

Significant progress was made in advancing the use of technologies that support public health, interoperability, privacy and security, and patient access to information in FY21. However, work remains in these target areas to achieve the full potential using health IT tools to help transform the healthcare sector. In FY22, ONC and the HITAC will continue to focus on advancing the implementation of the health IT provisions of the Cures Act including TEFCA, 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 Medicare Promoting Interoperability Program 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.

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 Medicare Promoting Interoperability Program 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 support care transitions, referrals, and care coordination.

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.

Electronic Laboratory Reporting - The transmission of digital laboratory reports, often from laboratories to state and local public health departments, healthcare systems, and the CDC.

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.

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.





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 health care.

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.

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.

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 TEFCA by incorporating it into a single, all-encompassing Common Agreement to which QHINs 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.

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

AHRQ - Agency for Health Research and Quality

AI - Artificial Intelligence

APHL - Association of Public Health Laboratories (APHL)

API - Application Programming Interface

C-CDA - Consolidated-Clinical Document Architecture

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

CDC - Centers for Disease Control and Prevention

CDS - Clinical Decision Support

CMS - Centers for Medicare & Medicaid Services

COVID-19 - Coronavirus

DHS - The United States Department of Homeland Security

eCR – Electronic Case Reporting

EHI – Electronic Health Information

EHR - Electronic Health Record

ELR – Electronic Laboratory Reporting

FAA - Federal Aviation Administration

FBI - Federal Bureau of Investigation

FDA - United States Food and Drug Administration

FHIR® - Fast Healthcare Interoperability Resources

FTC - Federal Trade Commission

FY20 – Fiscal Year 2020

FY21 - Fiscal Year 2021

GAO - Government Accountability Office

HHS - United States Department of Health and Human Services

HIE - Health Information Exchange

HIN - Health Information Network

HIPAA - Health Insurance Portability and Accountability Act

HITAC - Health Information Technology Advisory Committee

HL7® - Health Level Seven International

ICD-10 - 10th Revision of the International Statistical Classification of Diseases and Related Health Problems

LTPAC – Long-Term Post-Acute Care

NCVHS - National Committee on Vital and Health Statistics

NIH - National Institutes of Health

OCR - Office for Civil Rights





OIG - Office of Inspector General

ONC - Office of the National Coordinator for Health Information Technology

ONC Cures Act Final Rule - 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule

ORCHA - Organization for the Review of Care and Health Applications

PDMP - Prescription Drug Monitoring Program

PGHD - Patient-Generated Health Data

PHI - Protected Health Information

PHIT - Public Health Informatics & Technology Workforce Development Program

QHIN - Qualified Health Information Network

QTF - QHIN Technical Framework

RCE - Recognized Coordinating Entity

RPM - Remote Patient Monitoring

SAMHSA - Substance Abuse and Mental Health Services Administration

SANER - Situational Awareness for Novel Epidemic Response

SDOH - Social Determinants of Health

SO/GI - Sexual Orientation/Gender Identity

TEFCA - Trusted Exchange Framework and Common Agreement

UPI - Unique Patient Identifier

USCDI - United States Core Data for Interoperability





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](#)

[Information Blocking FAQs](#)

[ONC CURES Act Final Rule Fact Sheets](#)

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

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

[Health IT Data Briefs](#)

[Health IT Playbook](#)

[COVID-19 Response](#)





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ACKNOWLEDGEMENTS

- Michelle Murray, ONC
- Seth Pazinski, ONC
- Michael Berry, ONC

- Marla Durben Hirsch, Audacious Inquiry
- Katie Iser, Audacious Inquiry
- Maxine LeSaux, Audacious Inquiry
- Kory Mertz, Audacious Inquiry





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