ONC | HealthIT
ADVISORY COMMITTEE

Health Information Technology Advisory Committee (HITAC)
Annual Report for Fiscal Year 2022

Supplemental Background Research

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DEPARTMENT OF HEALTH & HUMAN SERVICES • USA

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Overview

LEGISLATIVE REQUIREMENTS

In December 2016, Congress passed the 21st Century Cures Act (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 about policies, standards, implementation specifications, and certification criteria relating to the implementation of a health information technology (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 the United States (U.S.) Department of Health and Human Services (HHS) and Congress each fiscal year, in consultation with the National Coordinator for Health Information Technology. 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.

A collaboration of the HITAC and the Office of the National Coordinator for Health IT (ONC), this research report supplements the HITAC Annual Report for Fiscal Year 2022 (FY22) with an in-depth discussion of various topic areas across the target areas.

HITAC TARGET AREAS

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

- **Design and Use of Technologies that Advance Health Equity** - The consideration of equity in health IT systems and policies to help reduce health disparities nationwide. Health equity is achieved when everyone has a fair and just opportunity to attain their highest level of health. The intentional design and implementation of health information technology infrastructures, policies, and practices are needed to identify and mitigate clinical and social inequities that contribute to unjust variations in health between populations.
- **Use of Technologies that Support Public Health** - Any technology component used, deployed, provisioned, or consumed as a service by a public health authority to address the public health mission.[1] Of particular importance is the facilitation of bidirectional information sharing between the clinical and public health communities.
- **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 the Health Insurance Portability and Accountability Act (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.”

Health IT Infrastructure Landscape Analysis

TARGET AREA: DESIGN AND USE OF TECHNOLOGIES THAT ADVANCE HEALTH EQUITY

Background

People may face health disparities based on race, ethnicity, physical or cognitive capabilities, and socioeconomic group. Disparities may be built into systems, tools, and data, making it difficult to identify and address health inequities. For example, at the federal level, race/ethnicity data is missing for almost 40 percent of people vaccinated against COVID-19.[2] Health IT can support unbiased equity-related data collection and exchange.

Current State

Health Equity by Design

Health equity by design is a systematic approach to health IT and health IT policy development in which equity considerations are identified and incorporated in the design, build, and implementation of health IT systems and policies, such that the resulting products and policies are foundationally equity-enforcing. The concept has been used to design health promotion interventions, such as reducing hypertension in African American patients through blood pressure control tracking via electronic health records (EHRs).[3] Health IT developers have begun to leverage the health equity by design approach in their health IT systems and programs.[4]

Health equity by design in health IT requires asking questions, such as, “How can existing standards benefit communities equitably?” and “What current regulations improve equity outcomes?”[5] Designing with health equity in mind means considering equity-related factors at the outset of policy and systems development, including assessing how an initiative can address the root causes of disparities. To achieve this, ONC is working to ensure that health IT systems can capture, exchange, and use health equity data. ONC is collaborating with other federal agencies to assure that this new functionality is used by providers operating EHRs, e.g., assuring that providers capture detailed race, ethnicity, and language data during patient encounters.[6] Intentional and meaningful use of health equity data in design can enhance the utility of health technology. For example, “smart watches” have not always been reliable in the capture of health data for individuals with darker skin tones due to the calibration of optical sensors on the watch, meaning those users could not accurately track their heart rates with this technology.[7] The examination of diverse data in the initial design of this technology could have potentially prevented this issue.[8]

Researchers released a framework for digital health equity that details “digital determinants of health.” Digital determinants of health are the conditions in the digital world that impact an individual’s life, such as access to and the ability to use technology.[9] The framework identifies four levels of influence in the digital environment: individual, interpersonal, community, and societal. The researchers suggest that conditions at each level of influence should be considered in the development of digital health tools.[10]

Inequities in Data Collection

Health disparities can be difficult to identify in data, often because relevant information is collected on an ad hoc basis or inconsistently, if at all. Data may be of low quality or insufficient quantity.[11,12] The integration of SDOH data into health IT provides a deeper context for patient care and sheds light on existing health disparities.[13] Often, equity and SDOH data are collected through disparate methods and systems.[14] Streamlining SDOH data collection can reduce duplication of efforts and can provide a more comprehensive understanding of health disparities.[15] The collection of sexual orientation and gender identity (SO/GI) data is particularly challenging because this data has historically been excluded from data collection tools.[16] As a result, those who identify as SO/GI minorities have faced disparate access to care. The Health Level 7 International (HL7®) Gender Harmony logical model proposes an approach to improving the accurate presentation of SO/GI-related demographics in clinical systems.[17,18]

Efforts are underway at the federal level to improve the collection of this data to ensure that individuals' information is interoperable for improved care transitions and thus improved health outcomes. United States Core Data for Interoperability (USCDI) Version 2 included sexual orientation and gender identity (SO/GI) and other SDOH standardized data points paving the way for enhanced utilization. USCDI Version 3 includes an expanded standardized set of health data classes (e.g., health insurance coverage and health status/assessments) and data elements (e.g., self-reported tribal affiliation) that support interoperable data exchange and can inform research on disparities. In June 2022, the Office of Management and Budget (OMB) announced plans to revise standards that aim to ensure that the government can compare race and ethnicity information across federal agencies. These standards will be derived from those used in the ONC Health IT Certification Program. Other federal organizations, like and Centers for Medicare & Medicaid Services (CMS), are increasing their capacity to collect demographic data through Fast Healthcare Interoperability Resources (FHIR®) standards for monitoring and evaluation to reduce disparities.[19]

Organizations are filling gaps in health equity and SDOH data collection through data enrichment, or the ability to add secondary sources of data into a dataset. Data enrichment can be completed in various ways, such as via machine learning inference or by natural language processing (NLP) that can be applied to unstructured notes to identify structured data.[20] For example, throughout the pandemic, Chesapeake Regional Information System for our Patients (CRISP) employed data enrichment processes to synthesize data from multiple sources to automate COVID-19 data requests.[21]

SDOH data can be used to inform the evaluation of communities and allocation of resources via vulnerability indices. A vulnerability index may use census data, natural and built environment data, and health data to identify geographic areas of greatest risk.[22] Within health care, social vulnerability indices use social-factor census data, such as poverty, housing, and access to a vehicle, to evaluate communities' risk. For example, the Centers for Disease Control and Prevention (CDC)/Agency for Toxic Substances and Disease Registry (ASTDR) Social Vulnerability Index derives information from 15 variables found in the U.S. Census in order to identify communities that may need support before, during, or after disasters.[23] The University of California, Los Angeles (UCLA) Center for Neighborhood Knowledge and UCLA BRITE Center for Science, Research, and Policy collaborated to develop a map highlighting areas of Los Angeles most at risk for COVID-19 transmission based on vulnerability indicators, including barriers to access and pre-existing health vulnerability.[24]

Electronic Exchange of Health Equity and Social Determinants of Health Data

Standardized data collection can support interoperability between systems, including smaller providers and community-based organizations. The HL7® Gravity Project is partnering with interested parties 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 balloting a FHIR® implementation guide in 2022.[25]

ONC has identified four areas of focus related to SDOH data: standards and data, policy, implementation, and infrastructure. ONC is producing an SDOH Information Exchange Toolkit that lays out interconnected foundational elements to support the exchange of this data, ranging from governance to community readiness and stewardship. The elements make clear that aligned processes and standards, as well as political and legal action, are necessary for productive SDOH data exchange.[26]

Bias Concerns – Algorithms, Clinical Decision Support (CDS) Tools, and Patient Interview/Questionnaire Data

Algorithms have the potential to improve health care but also to exacerbate existing care inequities because they may contain biases. For example, if an EHR limits sex designations to “male” or “female” and then feeds this data into a clinical decision-making algorithm, the algorithm’s output could be an inappropriate care recommendation, failing to represent optimal care for non-binary patients.

Understanding the biases of algorithms is an important step in preventing the exacerbation of disparities through machine learning. For instance, it is important that the data used for machine learning are representative of the population and the outputs are transparent. On June 16, 2022, the Federal Trade Commission (FTC) delivered a report to Congress that discussed the need for caution and thoughtfulness in using Artificial intelligence (AI) due to the potential for algorithm bias. The FTC recommended that (1) a human be involved in the data processing, (2) AI mechanisms are clear and understandable regarding personal data and usage rights, (3) companies using AI should regularly review the use and impacts of the algorithms, and (4) companies using AI should hire and retain diverse teams to reduce the potential for biased algorithms.[27] The Biden Administration has published a set of principles and associated practices for building and deploying automated systems and AI that includes algorithmic discrimination protections.[28]

Similarly, CDS tools can alleviate some burden placed on healthcare providers by facilitating decision-making based on current evidence without requiring excess research or recall. Patient demographic data can inform CDS algorithms to suggest the best course of treatment. However, if not built on data reflective of the diverse population, CDS tools are vulnerable to bias and improper recommendations.[29]

Patient data is often collected through patient interviews during clinical encounters or standardized survey instruments such as questionnaires. Biases of the interviewer or survey tool may be incorporated into the EHR. Such biases may be either implicit, such as failing to screen certain groups of people for conditions, or explicit, like using negative descriptors in EHRs. For example, in one study, patients identified as Black had more negative notes in their EHR than patients identified as White.[30]

TARGET AREA: USE OF TECHNOLOGIES THAT SUPPORT PUBLIC HEALTH

Background

The COVID-19 pandemic helped spur the rapid adoption of technology but also revealed areas of need within the U.S. public health system. Significant investments have been made to strengthen the U.S. public health infrastructure, data systems, and workforce. These investments are intended to prepare the U.S. public health system to respond to future public health emergencies like COVID-19 and to meet the evolving and complex needs of the communities and populations they serve.

The COVID-19 pandemic 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 FY22. This section examines the intersection of health IT and public health policies to support the usability, timeliness, and accessibility of data to meet today's challenges and beyond. Please refer to the HITAC's Public Health Data Systems Task Force 2022 Report for detailed recommendations.

Current State

Public Health Data Systems – Infrastructure

Public health data systems are critical sources of actionable intelligence used by state, tribal, local, and territorial (STLT) public health authorities to protect against infectious and non-infectious health threats. However, the nation's public health data systems are antiquated, siloed, and chronically underfunded, and rely on older surveillance methods, leading to delayed detection and response. The COVID-19 pandemic demonstrated a need to significantly improve the collection and use of critical health data at all levels of public health while reducing the burden placed on those who provide the data and underscored the need for a modernized public health data infrastructure.[31,32]

The CDC announced a funding opportunity on June 23, 2022, that will provide nearly $4 billion over five years to improve critical public health infrastructure in health departments across the country. Of the $4 billion, $900 million will be made available for public health infrastructure, foundational capabilities, and data modernization. The remaining $3.1 billion will be used for workforce and technical training.[33]

The CDC established the Data Modernization Initiative (DMI) in 2020 to establish an approach to sharing and using data that allows for faster action to protect health. In December 2021, the CDC shared a DMI progress update that highlighted the work done to move from siloed and brittle public health data systems to connected, resilient, adaptable, and sustainable "response-ready" systems that can help solve problems before they occur.[34] Significant progress has been made, but more work is needed to achieve the goals identified in the DMI to improve the collection and use of health data.

The DMI includes a priority to accelerate data into action for improved decision-making, using more interoperable data to share real-time, comprehensive information. To achieve this goal, ONC is working in collaboration with the CDC on initiatives such as USCDI+ and Helios. In October 2021, ONC launched USCDI+ for public health in collaboration with the CDC to identify a set of data elements that complement the USCDI but are specific to the needs of public health. This collaborative initiative aims to establish a nationwide public health data model based on USCDI standards.[35] Inclusion in the USCDI and USDCI+ makes mission-critical data more consistent, compatible, and usable for public health purposes.[36]

In November 2021, HL7®, in collaboration with the CDC and ONC, launched Helios to support the use of widely recognized data exchange standards to help advance public health and support the need to make public health data more interoperable. Helios is working to streamline data sharing across all levels of public health using the HL7® FHIR® standard for healthcare data exchange that defines data elements and classes. Increased adoption of FHIR®-based approaches will help public health authorities share information more broadly and seamlessly. This includes Bulk FHIR®, which allows data to flow in batches at a population level without manual processes and customization.[37]

Public Health Data Reporting

State laws and regulations mandate or authorize the reporting to public health authorities of certain diseases and related conditions. States determine who must report, what information must be reported, and the format and manner of reporting. The reporting of cases is a key tool that public health authorities use in controlling and preventing the spread of communicable diseases.[38]

In recent years the federal government has taken steps to incentivize providers to participate in electronic public health data reporting. To satisfy Medicare reporting requirements for public health measures, hospitals must use certified health IT to capture and share public health data (e.g., syndromic surveillance and case reporting).[39,40] ONC works closely with CMS on the Medicare Promoting Interoperability Program which has been an important mechanism for driving improvement in public health reporting through the program's Public Health and Clinical Data Exchange Objective. The 2023 Inpatient Prospective Payment System (IPPS) final rule expands the list of required public health measures under the Promoting Interoperability Program to include antimicrobial use and resistance (AUR) surveillance. Beginning in 2024, to earn full credit under the Public Health Objective, hospitals must report AUR data to the CDC's National Healthcare Safety Network (NHSN). These changes acknowledge advances in data modernization, technical capabilities in public health agencies to receive standardized data from providers, and the critical role that public health reporting plays in responding to public health emergencies.

Electronic Case Reporting

Electronic case reporting (eCR) is the automated, real-time exchange of case report information between EHRs and public health authorities. These timely data are more complete than manual reporting and include patient demographics (such as race and ethnicity), diagnoses, comorbidities, occupation, travel history, immunizations, medications, pregnancy status, and treatments.[41]

Healthcare organizations are connected with public health authorities using HL7® standard documents.[42] This hub-and-spoke model for eCR uses a single point of connection for healthcare organizations and health IT developers, easing the burden of having to connect to many jurisdictions, which often have different policies, systems, and standards that need to be implemented.[43] Reporting requirements can be complex so sorting out what is reportable to whom and when across jurisdictions can be cumbersome for providers. eCR helps alleviate the burden on providers as a decision support engine called AIMS has been established by the Association of Public Health Laboratories (APHL) that implements these rules based on variations in jurisdictional laws.[44]

The COVID-19 pandemic has helped accelerate the use of eCR. Facilities using eCR have significantly increased, growing from 187 facilities on January 20, 2020, to over 13,800 facilities as of June 30, 2022.[45,46] Beginning January 1, 2022, eCR was required by the Medicare Promoting Interoperability Program for eligible hospitals and the Merit-based Incentive Payment System (MIPS) Promoting Interoperability performance category for eligible clinicians. In August 2021, the CDC awarded $200 million from the CARES Act to eligible STLT public health authorities to build foundational data capabilities, accelerate eCR, and modernize vital statistics systems.[47]

Significant progress has been made and is expected to continue, as the CDC has developed a roll-out plan to expand eCR beyond COVID-19 to over 170 additional conditions. This progress will help the CDC achieve its DMI goal by fiscal year 2024 (FY24) of sending core public health data automatically and electronically to cloud-enabled public health systems.

Electronic Laboratory Reporting

Electronic laboratory reporting (ELR) for public health is the transmission of digital laboratory reports, often from laboratories to STLT public health authorities, healthcare systems, and the CDC.[48] ELR has enabled the CDC to receive comprehensive coronavirus data in near real-time to inform next steps and produce potentially life-saving recommendations.[49] By the end of 2021, more than 1.5 million results were delivered per day, alerting public health authorities to changing disease levels and the areas and populations most affected.[50] This progress is enabling the achievement of the DMI goal to automatically and electronically send core public health data ready for use in cloud-enabled public health systems by FY24.

While more results are being delivered using ELR, additional work is needed to ensure that the same standards are used between systems for ease of data sharing and data use. Variation across systems impacts data quality and interoperability.

Syndromic Surveillance

Syndromic surveillance provides public health authorities with a timely system for detecting, understanding, and monitoring health events. Syndromic data can serve as an early warning system for public health outbreaks.[51] Patient symptoms in EDs can be tracked before a diagnosis is confirmed, helping public health authorities to detect unusual levels of illness and determine whether a response is warranted.

The National Syndromic Surveillance Program (NSSP) is a collaboration among the CDC, federal partners, local and state health departments, and academic and private sector partners that has formed a community of practice. The NSSP community of practice analyzes and shares electronic patient encounter data received from EDs, urgent and ambulatory care centers, inpatient healthcare settings, and laboratories. The electronic data received is integrated into the BioSense Platform, which is a shared platform. As of April 2022, 71 percent of the nation’s EDs contribute data to the BioSense Platform.[52]

An Important component of the CDC’s DMI is the work to modernize the National Electronic Disease Surveillance System Base System (NBS). The goals for NBS modernization include implementing a stable, secure, easily deployable integrated disease surveillance system that ingests all actionable information from ELR, eCR, and other formats such as vital records and immunization data.[53]

Public Health Informatics Workforce

Workforce development has fallen behind across public health, resulting in several challenges, including lagging skills among workers due to changes in technology, lack of systems and data to assess and monitor workforce needs, and hiring barriers that exist at all levels of government.[54] According to the 2021 Public Health Workforce Interests and Needs Survey, nearly one-third of state and local public health employees (32 percent) said they were considering leaving their organization in the next year and 44 percent said they were considering leaving within the next five years.[55] The federal government has made significant investments to train and expand the public health workforce; however, the time to train, retain, and recruit may not be able to keep up with the continuously evolving environment.

In May 2021, President Biden issued an Executive Order providing $7.4 billion in funding to create a unified public health workforce strategy that will hire and train public health workers. This funding facilitates investment in the people and expertise needed at the state and local levels to expand, train, and modernize the public health workforce for the future. Recruiting individuals from the communities they will serve and from backgrounds underrepresented in critical public health professions will be prioritized.

In September 2021, ONC launched the ONC Public Health Informatics & Technology (PHIT) Workforce Development Program to help address these issues. ONC selected 10 awardees from across the nation that represent a mix of Historically Black Colleges and Universities, Hispanic-Serving Institutions, Asian American and Native American Pacific Islander-Serving Institutions, and other institutions of higher education. Together, these awardees will collectively train more than 4,000 individuals in public health informatics and technology over a period of four years. Developing a diverse workforce with competencies in public health informatics and technology is critical and can contribute to more equitable public health activities, with the potential to yield better health outcomes.[56]

TARGET AREA: INTEROPERABILITY

Background

The health information ecosystem continues to strive for improved interoperability. The Cures Act certification criteria and information-blocking provisions have increased the interoperable exchange of health information. Increased interoperability can lead to positive results such as cost reduction, increased efficiency, and improved patient outcomes. The implementation of the ONC Health IT Certification Program Final Rule (ONC Cures Act Final Rule) aims to improve provider engagement in all four domains of interoperability: finding, sending, receiving, and integrating information.[57]

Current State

Streamlining of Health Information Exchange

The ability to easily exchange patient data is in high demand, and while there are still barriers to interoperability, adoption has been increasing. As of 2019, 65 percent of surveyed physicians participated in health information exchange by electronically sending, receiving, or querying patient health information.[58] Over 75 percent of those physicians reported improvements in quality of care, efficiency, and patient safety as a result of health information exchange. Important progress has been made toward supporting query-based exchange.[59]

Hospitals are also increasingly integrating external data into EHRs as a result of improved health information exchange. In 2019, around 70 percent of hospitals reported integrating data, an increase of 15 percent from 2018.[60] On average, hospitals used at least three different electronic methods for sending and receiving summary of care records in 2019.[61] To find or query patient health information, hospitals used at least two different electronic methods.[62] The use of multiple electronic exchange methods can be burdensome to hospitals, presenting an opportunity to advance interoperability and reduce the number of electronic methods that healthcare organizations need to use to send, receive, and find healthcare data.

HINs continue to consolidate and partner to share services across states to better support the evolving needs of providers, patients, and other interested parties while also improving integration into existing workflows and increasing adoption. HealthInfoNet, The Rhode Island Quality Institute, and VITL are collaborating to increase regional coverage and leverage each other's infrastructure to improve care.[63] 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. The interest in leveraging HIEs to support patient-centered outcomes research is also growing. For example, the Using Machine Learning Techniques to Enable Health Information Exchange to Support COVID-19-Focused PCOR Project is piloting the use of a machine-learning technique to leverage HIE information in research.[64]

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. For instance, Carequality modified its policy framework to enable federal agencies to participate.[65] National networks and other HINs are preparing for the launch of the Trusted Exchange Framework and Common Agreement (TEFCA) in 2023.[66]

Interoperability Standards Priority Uses – Closed-Loop Referrals

Successful 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. Closed-loop referrals allow clinicians to refer patients to specialists, community-based organizations, and others and receive a notification once that referral is acted upon. Closed-loop referrals include both clinical referrals and referrals to community-based organizations. Software providers, universities, vendors, and standards-developing organizations are releasing or developing closed-loop referral solutions.[67,68,69] For instance, the PACIO Project is an HL7® project that aims to advance interoperable health data exchange between post-acute care and other key interested parties across the continuum of care.[70,71]

Equitable Use of Telehealth

The usage of telehealth services increased significantly during the COVID-19 pandemic but continues to present unique interoperability and health equity considerations. Telehealth has the potential to reach communities that often face barriers to accessing care due to challenges such as stigma, location, or transportation. However, these populations may also face difficulty in accessing reliable telehealth services.

Telehealth usage can reinforce existing disparities, such as among young adults, uninsured, and rural populations, if it is not implemented equitably. While telehealth rates were similar for most demographic subgroups in 2019-21, the lowest telehealth usage was among young adults aged 18 to 24 (17 percent) and uninsured patients (nine percent).[72] Lower telehealth usage was also found among rural older adults with Medicare coverage, with only 17 percent utilizing telehealth visits from 2019 to 2021, compared to 26 percent of older adults living in non-rural areas. [73]

More significant disparities existed between audio versus video telehealth usage. The highest share of video visits occurred among young adults aged 18 to 24, people earning at least $100,000, patients with private insurance, and White individuals.[74] Video telehealth rates were lowest among Latino, Asian, and Black individuals, adults ages 65 and older, and those without a high school diploma.[75] Video visits often require more complex, video-enabled devices and broadband internet access, which may lead to barriers to access for older adults, lower-income households, and those with limited English proficiency.

Interoperability Standards Priority Uses – e-Prior Authorization*

Prior authorization is an administrative process used in health care for providers to request approval from payers to provide a medical service, prescription, or supply.[76] This process is a requirement enforced and developed by payers to ensure that care is medically necessary and financially covered.[77] Prior authorization aims to lower costs and enhance value-based care; however, it has also been identified as a source of administrative burden and negative patient impact.[78] According to an American Medical Association (AMA) survey, physicians receive an average of 31 prior authorization requests per week which consumes an average of 14.9 hours of practice time.[79]

ONC released a request for information (RFI) seeking input on electronic prior authorization data standards that could be adopted for the ONC Health IT Certification Program.[80,81] In November 2020, the HITAC made several recommendations addressing the streamlining of prior authorization processes. These recommendations include establishing a regular review of prior authorization rules, establishing standards for prior authorization workflows, creating extension and renewal mechanisms for authorizations, and ensuring that prior authorization systems are designed with the goal of improving patient engagement.[82]

Standards for Patient Matching*

Critical to interoperability, patient matching is the identification and linking of one patient's data across health systems in order to see a comprehensive view of that patient's healthcare record. Precise patient matching is essential to protecting patient privacy and ensuring patient safety.[83] Accurate patient matching rates vary widely across healthcare organizations and are difficult to compare because organizations may calculate rates differently.[84]

As noted above, ONC released Project US@ Technical Specification Final Version 1.0 which will help improve patient matching.[85] The CARIN Alliance is partnering with HHS to create a proof of concept that implements a voluntary, open framework for federating digital identities across healthcare entities using Identity Assurance Level 2 certified credentials.[86] Some parties believe that a unique patient identifier, a single medical identification number that can be used to connect individuals to their health information, would improve patient matching and thereby patient safety while saving time and money.

Record linkage is the act of bringing together two or more sources of information that relate to the same individual, event, institution, or place.[87] Record linkage creates richer data about persons, families, places, and events.[88] Privacy-preserving record linkage (PPRL) shows promise as a method to combine patient data from various sources and improve interoperability across sectors while balancing patients' privacy. PPRL protects patients' identities while allowing researchers to access health data from EHRs and other sources for public health and clinical research.[89] PPRL leverages technology to produce unique sets of de-identified tokens that are used to match patients.[90] Since the tokens have no relationship with true identifiers, they cannot be used to reproduce those identifiers.

Provider Directory Standards and Management*

A provider directory supports the management of healthcare provider information, both individual and organizational, in a directory structure. Provider directories are used for a variety of purposes, such as informing consumers about the available providers in a health insurance network and supporting data exchange with other providers in a HIN. Having accurate provider electronic endpoint information is a foundational infrastructure element to support the electronic exchange of health information.

As mandated by the CMS Interoperability and Patient Access Rule, providers are required to add their electronic contact information to the National Plan & Provider Enumeration System (NPPES).[91], [92] Organizations like DirectTrust and Carequality have created their own aggregated directories to improve interoperable exchange for providers within their networks.[93] Similarly, a provider directory, populated by participating Qualified Health Information Networks (QHINs), will be a foundational element supporting exchange within the TEFCA.[94] In October, CMS released an RFI seeking public input about whether CMS should create a national directory of healthcare providers and services.[95]

Several efforts are underway to address making FHIR® endpoints more accessible. The Application Programming Interface (API) Conditions and Maintenance of Certification require certified health IT developers to publish FHIR® endpoints for all customers in a machine-readable format at no charge.[96] The FHIR® at Scale Taskforce (FAST) has proposed the technical framework and infrastructure for a scalable national directory of validated healthcare electronic endpoints.[97] Lantern, an ONC-developed tool, consumes public endpoint data and reports capabilities to a public-facing dashboard. This tool has informed health IT parties about an effective standardized format to publish FHIR® endpoint lists.[98]

TARGET AREA: PRIVACY AND SECURITY

Background

As interoperability and access to patient health information increase, the privacy and security of health data continue to be primary concerns. Robust privacy and security practices are important considerations in advancing and maintaining trust in interoperability. The use of granular data can enhance clinical care and the ability to protect the privacy of sensitive health data, although any additional burden on clinicians for granular data capture should also be considered. 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.

Current State

Appropriate Exchange and Use of Data

HIPAA's minimum necessary standard requires covered entities to use, disclose, or request only the PHI that is reasonably necessary to accomplish one's needs.[99] Currently, health IT systems cannot reliably segment discrete pieces of data, which limits their ability to meet the minimum necessary requirement. Difficulty in complying with the HIPAA minimum necessary standard at scale is one reason there has been limited adoption of exchange for payment and healthcare operations over national networks including eHealth Exchange, CommonWell Health Alliance, and Carequality. The capabilities exist in the FHIR® standard to segment data in units as small as an individual lab result. However, current regulations do not require health IT developers to implement this functionality, which impedes providers' ability to parse out and exchange smaller segments of a patient's record.[100]

The TEFCA aims to standardize health data exchange across participating networks by establishing a universal policy and technical floor of nationwide interoperability. The Common Agreement allows exchange for the following Exchange Purposes: "Treatment, Payment, Health Care Operations, Public Health, Government Benefits Determination, Individual Access Services, and any other purpose authorized as an Exchange Purpose by the Exchange Purposes Standard Operating Procedure (SOP)."[101] Version 1 of the TEFCA requires responses for treatment and individual access services. Other purposes will be required over time once additional implementation guidance is created to ensure, among other things, that the HIPAA minimum necessary requirement is adequately supported for exchange purposes where it applies.

Privacy of Sensitive Health Data

The regulatory landscape of patient consent and rules for sharing sensitive health data continues to vary across the country.[102] For instance, many states have laws and regulations protecting the privacy of health information that are stricter than the HIPAA Privacy Rule. Since these laws and regulations vary from state to state, it not only increases risk to patients and providers but also causes confusion among interstate exchange partners and makes it more difficult and expensive to manage technology to ensure privacy compliance.[103] Notable examples include data indicating a patient's HIV status or SUD (the former is sometimes more strictly protected in some states while the latter is governed by the federal 42 CFR Part 2 regulations).

Sensitive health data increasingly exist in digital environments not governed by HIPAA, as the proliferation of digital health apps continues. On June 29, 2022, HHS issued guidance on how federal law protects sensitive health information and how patients can protect their information on personal devices and apps following the U.S. Supreme Court decision *Dobbs vs. Jackson Women's Health Organization.*[104]

Current health IT system capabilities and the regulatory environment present challenges for protecting sensitive data across platforms while also making it accessible. Standards exist to support data tagging and data segmentation of sensitive health data such as FHIR®, yet these standards have yet to be proven at scale in health care.[105] There are no federal regulations that mandate granular data segmentation, so while the technical capability exists, its availability remains dependent upon the specific system implementation.[106]

Cybersecurity Events across the Healthcare Infrastructure*

The number of cyber-attacks in the healthcare industry from March 2021 to March 2022 rose almost 10 percent over the same period from 2020 to 2021 at an average cost of $10 million. Of all industry sectors, health care experiences more cyber events than any other industry, making it the costliest industry for cybersecurity.[107] Moreover, as healthcare IT systems become more complex and interconnected, the growing number of cybersecurity attacks (e.g., ransomware, phishing, denial of service) cause broader damage.[108] There are several federal efforts underway to improve cybersecurity in health care:

- In March 2022, President Biden signed the Cyber Incident Reporting for Critical Infrastructure Act of 2022, requiring private entities to report cyber-attacks and any ransom payments to the U.S. Cybersecurity and Infrastructure Security Agency.[109]
- On April 6, 2022, OCR solicited public comment on two requirements of the HITECH Act to determine how well "recognized security practices" are implemented in health care.[110]
- In an effort to educate and improve routine cybersecurity protections in the healthcare sector, on May 10, 2022, the National Committee on Vital and Health Statistics (NCVHS) sent recommendations to HHS on ways to strengthen cybersecurity in health care.[111]
- On July 22, 2022, the National Institute of Standards and Technology updated cybersecurity and HIPAA Security Rule guidance to assist healthcare entities in keeping PHI safe.[112]
- HHS also runs the 405(d) program, which is a collaboration between government and industry on implementing best cybersecurity practices throughout the healthcare industry.[113]

Alignment of Innovation and Regulation

When innovations and advances in technology become more advanced than existing regulations, gaps in privacy and security protections for health data can be exposed. The ability to reidentify de-identified data is an example of current technologies possibly outpacing existing regulations.[114] The lack of alignment between regulations and technology makes it difficult for patients to understand how and when their data is protected, raises liability concerns for providers when data is shared outside of the HIPAA framework, and leaves developers unclear about their regulatory obligations. Moreover, regulators face a challenge in ensuring that regulations both support innovation and protect the privacy and security of patient data.[115,116]

Since the ONC Cures Act Final Rule enabled patients to use APIs to access their medical records and share their PHI with third-party apps, the availability and use of APIs have increased significantly. Many in the healthcare industry have expressed concern about whether patients understand the boundaries of current health information privacy and security rules as they apply to third-party apps.[117] For instance, when sharing information with a third-party app developer, the information is often no longer subject to HIPAA protections but may be subject to the app developer's privacy policy. App developer privacy policies, which often are less stringent than HIPAA, can allow developers and advertisers to collect and monetize patients' personal information.[118]

As a result, providers and some of their business associates have expressed concerns about the increased risk of liability if they share data with an entity not subject to HIPAA that then misuses the data. Providers have noted that they support patient access to PHI and believe patients should not have to sacrifice privacy for greater access but are concerned about unauthorized data exposure and the resulting liability it represents.[119,120] Some providers may opt to share less data to mitigate any liability. In response to these concerns, OCR issued a series of FAQs clarifying in what circumstances a covered entity or business associate could be subject to HIPAA liability.[121]

Alignment of Innovation and Regulation for Consent Directives

To comply with HIPAA, a healthcare provider must obtain a patient's authorization in certain circumstances in order to share the patient's PHI.[122] Often, this authorization is captured in paper form which impedes the ability to share it. Even when it is collected in electronic form, it often is not in a computable form that allows interoperability or nuance. For example, the authorization could be in the form of a PDF attachment that is not interoperable; if it is in a computable form, it might only allow a binary decision (share or do not share) without providing the ability to discriminate which data to share. In addition, current health IT systems are not set up to allow for granular data segmentation.

Organizations spearheading efforts to support more seamless exchange of patient consent include the Stewards of Change Institute and the National Interoperability Collaborative. They are collaborating on Project Unify to create a consent service utility which would be an open-source, open-API, standards-based solution to manage, provide, and cancel patient consent.[123] San Diego Health Connect's Leading Edge Acceleration Projects in Health IT (LEAP) project developed a proof of concept for sharing computable consent directives using HL7® FHIR®-based APIs. This proof of concept used a variety of complex use cases for consent and showed they can be automated and scalable.[124]

TARGET AREA: PATIENT ACCESS TO INFORMATION

Background

Enhanced patient access to health records can benefit both patients and providers. Sharing health information with patients in a timely manner supports patients' autonomy over their health care while improving patient-provider communication.[125] The number of individuals accessing a patient portal has been steadily increasing since 2014.[126] The ONC Cures Act Final Rule mandated patients' access to their electronic health information (EHI), including clinical notes. According to a 2022 study, there is no evidence of increased burden on providers due to EHI sharing with patients.[127] However, even if records are completed correctly, concerns regarding the safety of the data remain, including protection and recovery from the increased number of data breaches of health apps.[128]

Current State

Patient Consolidation of Health Information from Multiple Sources

Twenty percent of patients access their information using more than one method, such as a smartphone app and a computer, including almost half of those who accessed their health information six or more times.[129] However, patients may utilize portals from multiple providers. For example, a patient with a chronic condition that requires multiple specialist visits may have an app or portal for their health record from each specialist.[130]

The ONC Cures Act Final Rule requires standards-based APIs to be used to provide data to apps to help patients access and consolidate their health information from across different portals. The preliminary results of an ongoing UCSF survey of digital health companies show that 84 percent of the respondents use FHIR® in their EHR integration.[131] Half of the surveyed digital health companies rely on proprietary APIs, at least partially, while the other half rely on standards-based APIs. However, some barriers exist to using APIs for EHR integration, such as high fees, lack of realistic clinical testing data, lack of standards-based APIs, and lack of valuable data elements.[132] In addition, patients face burden due to the difficulty in accessing multiple API endpoints to aggregate their health information.[133] For example, the TEFCA proposes to reduce the burden of access on patients by providing them with one access point to request data from all organizations participating in the TEFCA.[134]

Safety and Impact of Mobile Health Apps*

Mobile health apps include everything from simple apps to track symptoms or fitness to digital therapeutic (or "digiceutical") apps prescribed by providers to manage health outcomes.[135] Mobile health apps can increase patient engagement and improve patient outcomes. In 2020, about 70 percent of individuals with a mobile health app used it to track progress on a health-related goal. More than half of individuals used their mobile health app to facilitate discussions with their healthcare provider.[136]

There are more than 350,000 mobile health apps available today.[137] From 2019 to 2020, there was a more than 20 percent increase in the number of apps that connect users with their health information.[138] In 2021, 70 percent of hospitals gave patients the ability to access their health information using a mobile app or other software. Of those hospitals providing patient access, over half did so using FHIR®-based APIs.[139]

The ONC Cures Act Final Rule established standards and technical requirements for third-party apps to connect to certified health IT modules using HL7® FHIR®-based APIs. The API provision is set to go into effect on December 31, 2022. It will likely continue increasing reliable access to health information for patients because FHIR®-based APIs make it easier for third-party apps to access data from certified health IT developers.

As mobile health apps become more complex and are used in more medical treatments, concerns have been raised about the clinical efficacy of apps with many apps lacking any data demonstrating their clinical effectiveness and about the security of data held by apps.[140,141] For patients, it can be challenging to discern which apps provide accurate clinical guidance, the best privacy and security, or the most usability. There are a few private sector efforts underway to vet apps. For instance, there is a collaboration between the American College of Physicians, the American Telemedicine Association, and the Organization for the Review of Care and Health Applications (ORCHA) called the Digital Health Assessment Framework. This framework assesses apps based on data and privacy, clinical assurance and safety, usability and accessibility, and technical security and stability.[142,143,144] The CARIN Alliance offers a code of conduct with best practices that encourage better and safer apps to which app developers can attest.[145] In the public sector, the FDA issued updated guidance in September 2022 to provide clarity and predictability for mobile health app developers about when apps need to be approved by the FDA.[146]

Electronic Patient-Reported Health Record Update Processes*

Clinicians can use information stored in the EHR to make well-informed clinical decisions. However, up to 70 percent of patient records contain incorrect information.[147] Of patient-reported medical record errors, 42 percent were described by the patient as serious or very serious, such as those related to diagnoses, medications, allergies, test procedures or results, and notes on the wrong patient.[148] Patients often have difficulty getting incorrect EHR data corrected. The HIPAA Privacy Rule provides individuals with the right to ask for a correction, but healthcare entities are not obligated to make changes and may reject a patient's request. The covered entity must act in a timely manner, usually within 60 days, to correct the record as requested by the individual or to notify the individual that the request was denied. When a correction is made, the covered entity must make reasonable efforts to see that the corrected information is provided to its business associates and others who are known to have the PHI that was amended.[149] Although some requests for health record corrections are resolved quickly, others are denied without feedback provided to the patient.[150] Lessons learned from the OpenNotes project can help inform greater patient engagement and how to best incorporate patient corrections, amendments, addenda, and deletions that may impact the legal health record.

Patient-Generated Health Data (PGHD)*

The use of PGHD has grown significantly as consumer adoption of health technologies continues to increase. Gathering information outside the clinical setting such as biometric data, clinical information, activity level, medication effects, and patient preferences that were previously only collected by a clinician in the office can improve providers' workflow. It also contributes to positive outcomes for patients by offering a holistic view of a patient, giving a provider visibility into a patient's adherence to protocols or providing data for timely interventions when needed.[151] However, the expanding pool of PGHD presents certain challenges that can include interoperability (providers may have difficulty integrating PGHD into their EHRs), patient adoption (due to lack of either technological literacy or internet access), and lack of standards governing PGHD including privacy and security standards. There is also a concern about the integrity of the data and legal impacts on a provider.[152]

Price/Cost Transparency*

In recent years, CMS has finalized multiple rules promoting price and cost transparency by healthcare providers and health plans. The CMS Hospital Price Transparency Final Rule took effect on January 1, 2021, and requires health systems to publicly share the costs of services. On July 1, 2022, CMS released the Transparency in Coverage Final Rule. This rule requires health plans to share pricing for covered services and items, including negotiated rates with providers and allowed billed amounts.[153] The Transparency in Coverage Final Rule contains two elements intended to increase information accessibility: requirements for personalized information, including underlying negotiated rates; and requirements for machine-readable files detailing pricing information.[154] This rule could empower employers who provide insurance to employees to save money by securing lower prices from providers.[155] App developers and other groups are making innovative tools to support patient understanding of coverage and hospital cost data, which can be dense and confusing to the average consumer. For example, the Health Care Cost Institute has created a web-based tool that allows users to browse prices of health treatments nationally, by state, or locally to compare price and quality and make more informed decisions in their health care.[156]

FEDERAL ACTIVITIES ACROSS THE TARGET AREAS

This section describes the health IT activities advanced by various agencies of the federal government during FY22. Certain key federal activities that the HITAC considered to be cross-cutting across the target areas have been included in this section. It does not encompass all relevant federal activities conducted throughout FY22; some of them are addressed within the target area sections throughout this report.

Office of the National Coordinator for Health IT

ONC's key responsibilities include formulating the federal government's health IT strategy and promoting coordination of federal health IT policies, technology standards, and programmatic investments. ONC helps coordinate health IT initiatives across HHS's programs and other relevant executive branch agencies. HHS Secretary Becerra has put into place a department-wide policy directing ONC to engage with HHS agencies to align and coordinate health IT-related activities in support of HHS health IT and interoperability goals.[157]

Information Blocking

The Cures Act prohibits information blocking. Starting October 6, 2022, regulated actors are subject to a claim of information blocking for the full scope of EHI rather than just EHI represented by the data elements identified by USCDI Version 1.[158] To assist actors with compliance, ONC has released educational materials including a series of frequently asked questions (FAQs) related to information blocking. ONC operates a standardized process for the public to report possible claims of information blocking.[159] As of November 4, 2022, ONC had received 539 information-blocking submissions. Most of these claims of alleged information blocking were made about healthcare providers. Several claims were also made about CHPL-listed health IT developers.[160]

ONC Health IT Certification Program Updates

ONC continued work on implementing the new Conditions and Maintenance of Certification requirements related to (1) information blocking; (2) assurances; (3) communications; (4) APIs; (5) real-world testing; and (6) attestations. ONC has achieved two major milestones in implementing the new requirements:

- The ONC Health IT Certification Program's real-world testing processes require certified health IT developers to demonstrate the interoperability and functionality of their products in real-world settings, moving beyond testing only in a controlled environment. ONC received the first real-world test plans for all covered certified health IT developers by the December 15, 2021, deadline. Every December, certified health IT developers need to submit updated plans for testing over the coming calendar year, with results made available to the public by March 15 of the following year.[161]
- During the first attestation period in April 2022, all certified health IT developers attested to their compliance with each of the specified Conditions and Maintenance of Certification requirements.[162]

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 starting December 31, 2022. The USCDI is updated through a predictable, transparent, and collaborative process that allows interested parties the opportunity to comment on its expansion. In July 2022, ONC released USCDI Version 3 which adds two new data classes (health insurance information and health status/assessments) and 24 new data elements.[163] As part of the 2022 Standards Version Advancement Process (SVAP), ONC also announced that USCDI Version 2 can be voluntarily adopted by health IT developers under the ONC Health IT Certification Program.[164]

ONC continued advancing the USCDI+ initiative that supports the identification and establishment of domain- or program-specific datasets for federal partners that will operate as extensions to the existing USCDI. CMS, the CDC, and the Health Resources and Services Administration (HRSA) are initial partners with focuses on quality measurement and public health.[165,166]

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 January 18, 2022, ONC and the Recognized Coordinating Entity (RCE, The Sequoia Project, announced the launch of the TEFCA with the publication of the Common Agreement, QHIN Technical Framework, and the TEFCA FHIR® Roadmap.[167] Since this announcement, the RCE has also released a number of resources to operationalize the TEFCA, including SOPs. The SOPs include specific policies and procedures to further guide QHINs and identify, where applicable, necessary technical implementation requirements. The RCE opened the QHIN application process in October 2022. QHIN onboarding to the network will occur in 2023.[168]

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) developed a unified specification for address in health care. Removing variability in addresses exchanged between health IT systems will improve patient matching by allowing the receiving system to be able to better match the received address with one already on file for a patient. On January 7, 2022, ONC announced the release of Project US@ Technical Specification Final Version 1.0 which will advance the healthcare industry's proficiency in recording and managing accurate and consistently formatted patient addresses and support more efficient patient matching and record linkage.[169]

Other Federal Activities

CARES Act Changes to 42 CFR Part 2

The Coronavirus Aid, Relief, and Economic Security Act (CARES Act) requires certain changes to the existing 42 CFR Part 2 regulations governing the confidentiality of substance use disorder (SUD) records. In November 2022, the HHS Office for Civil Rights (OCR) and the Substance Abuse and Mental Health Services Administration (SAMHSA) issued a proposed rule to implement these changes. Until the rule is finalized, SAMHSA has noted that the existing 42 CFR Part 2 requirements still apply.[170]

Health IT Infrastructure Gap Analysis

TARGET AREA: DESIGN AND USE OF TECHNOLOGIES THAT ADVANCE HEALTH EQUITY

Systems Designed Without Health Equity as an Integral Component

Ongoing efforts promote equity as a core design feature of health IT initiatives. However, many health IT systems and initiatives were not designed with health equity in mind.

As highlighted by the COVID-19 pandemic, existing health IT initiatives can leave gaps and disparities in data collection and reporting for vulnerable populations. Often health IT organizations will adopt and promote standards or processes that do not take health equity into account, instead of incorporating health equity from the beginning as health equity by design promotes. This results in the need to mitigate any disparities the standard or process created.[171]

Variability in Data Collection

Inequities in data availability and use often stem from inequities in data collection. When it is collected, health equity-related data is often collected inconsistently among and within sources.

Organizations are implementing ways of integrating health equity data into their systems. However, the collection of health equity data elements related to race, ethnicity, disability status and resulting impacts, preferred language, SO/GI, and data for SDOH is inconsistent.[172] While future versions of the USCDI aim to add more of these data elements to the standard set of data that is collected and exchanged, it will take time before widespread industry adoption occurs. There is also a need for standardized screening tools and data collection to support the interoperability of health disparity-related data.

Interoperability Gaps for Exchanging Health Equity and SDOH Data

The electronic exchange of health equity and SDOH data, even when it is available electronically, remains uneven.

SDOH data are often used for quality reporting, yet this reporting is not accessible to use for decision-making.[173] Existing policies and procedures for information sharing can be applied more broadly to the exchange of SDOH data to enhance interoperability, as well as technical approaches and data standards.[174] Incentives are needed to build infrastructure for SDOH data sharing and investing in communities. Imbalances of power between those governing communities, standards-developing organizations, and community members have hindered the exchange of this information in meaningful ways.[175]

Biased Algorithms, CDS, and Patient Interview/Questionnaire Data

The design of AI algorithms raises concerns about implicit biases in machine learning, e.g., regarding gender, race, and ethnicity. CDS tools may also contain implicit biases that impact care decisions or can *be applied inappropriately. Biases of standardized survey instruments and individuals conducting patient interviews may impact data entered in patient records.*

Researchers have attempted to mitigate algorithmic bias in AI and CDS 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, models trained on these datasets can continue to perpetuate racial and other health disparities. Standardized representative data collection can be used to inform algorithms for AI, CDS, and machine learning to ensure more equitable outputs as well as support the identification of disparities through data in efforts to design more equitable interventions. This includes the creation of responsive tools able to capture diverse data on SDOH.[176] Clinician biases that influence patient interviews and the use of biased survey instruments such as questionnaires may result in biased data being used to drive algorithms and clinician decision-making. Therefore, it is important clinicians be trained in unbiased interview techniques and provided with unbiased interview documentation tools.

TARGET AREA: USE OF TECHNOLOGIES THAT SUPPORT PUBLIC HEALTH

Gaps in Infrastructure to Support Data Sharing

Coordination and standardization are needed to reduce gaps that impede the sharing of data important to public health.

Infrastructure gaps in public health reporting capabilities have prevented public health authorities from receiving timely information on reportable conditions. Public health data collection is decentralized in the United States, with localities setting the standards for data collection and reporting. This is problematic when there are nationwide reporting needs. For instance, there are 64 immunization information systems, with variations in the implementation of the common reporting standard they use. STLT-funded systems are evolving without a centralized approach, causing gaps in coordination.[177] Alignment of health IT standards is needed to ensure interoperability with all authorized public and private users.

Lack of Consistent Use of Standards to Support eCR

The rapid expansion and adoption of eCR have enhanced communication between clinicians and public health authorities; however, improvements are still needed.

Enhancements have been made the use of eCR more widespread, but more are needed for optimization. For instance, while an increasing number of facilities have adopted eCR, a lack of standardization remains. HL7® Version 2.5.1 is the primary standard for communicating health data, however, it allows organizations to use different aspects and versions of the standard.

Need for Increased ELR Standardization

ELR adoption has increased, but standardization is needed to ensure consistency across systems.

Coordination between STLTs' public health authorities and federal partners is needed to increase the adoption and use of standardized ELR reports and to ensure that a standardized set of demographic information is both collected and sent from clinical and laboratory systems to STLT public health authorities in a timely manner. While ELR standards are required for EHR certification, these standards are currently optional and variable across public health systems. More standardization is needed to ensure data consistency (e.g., that “Hispanic” is routinely categorized as an ethnicity) so that data flows seamlessly among providers, labs, and public health authorities.

Lack of Syndromic Surveillance Outside Acute Care

Syndromic surveillance today is often limited to acute care settings.

Syndromic surveillance reporting needs to be optimized to increase participation beyond acute care. Data collection should be expanded to capture and integrate data from all methods of patient care, including telehealth visits, home health care, travel health, and blood banks. Data should also be expanded to include data from global sources.[178] Federal agencies have the opportunity to work together to ensure that there is more alignment and standardization of data collection and reporting, which will also improve data sharing and interoperability.

Difficulty in Public Health Workforce Recruitment and Training

Challenges remain to establishing and maintaining a well-equipped public health workforce.

Historically, the public health workforce has been under-resourced and unable to recruit and retain top talent to execute the public health mission.[179] STLT public health authorities struggle to attract, train, and retain public health professionals with skills in informatics, data science, and health IT. This issue stifles innovation and presents workflow challenges when new IT systems are implemented to exchange data.[180] For example, some public health authorities may only have a few employees to complete the vast functions required. As the public health infrastructure becomes more ingrained with informatics and data science, fewer employees will have the training necessary to fill these technological advances.

TARGET AREA: INTEROPERABILITY

Varied Approaches to Exchange Between Health IT Systems

While electronic data exchange adoption continues to grow, interoperability between different health IT systems remains a challenge.

Various federal programs and requirements from ONC and CMS are continuing to address technical and business challenges to the electronic exchange of health information. For instance, the TEFCA, the Medicare Promoting Interoperability Program, and MIPS are promoting data exchange by providers and health IT developers. However, many health organizations rely on multiple methods of electronic data exchange which utilize multiple systems, vendors, and HINs to enable exchange. Even with these multiple approaches, gaps in interoperability remain. Eighty-five percent of physicians participating in health information exchange reported challenges electronically exchanging information with providers using a different EHR developer. About 70 percent of physicians who engaged in health information exchange reported challenges exchanging information with providers in referral networks.[181]

Insufficient Interoperability for Closed-Loop Referrals

There is a lack of cross-organization support for closed-loop referrals, including for social services.

Poor exchange of information during transitions of care increases the likelihood of a poor outcome and increased cost. For instance, individuals with intellectual and developmental disabilities and those with chronic conditions require well-coordinated care across both the health and social sectors. A lack of interoperability between clinical settings (including behavioral health, dental, alternative therapies, complementary medicine, and clinics at employers, schools, camps, and correctional facilities) as well with the social sector inhibits closed-loop referrals which can lead to loss of information, increased administrative burden, and poor health outcomes.

Inequitable Use of Telehealth

Unique interoperability considerations exist for the equitable use of telehealth to help reduce the digital divide. While an increasing number of telehealth providers access patient health data by leveraging the existing interoperability framework, many do not. Few telehealth providers make their documentation readily available for query by other members of patients' care teams.

Increased adoption of telehealth spurred by the COVID-19 pandemic highlighted infrastructure and technological barriers that impede access to care for many underserved populations. Examples of these barriers include access to broadband internet, a smartphone or other video-connected device, or reliable cell signals. These barriers can hinder the full effect of telehealth services and further exacerbate health disparities, particularly among older adults, lower-income households, and those with limited English proficiency. To reduce the digital divide and health disparities related to telehealth usage, there is a need to explore best practices to support equitable telehealth implementation.[182]

Expanding interoperable data sharing for telehealth services is also a key opportunity for improvement. Bidirectional data exchange between telehealth providers and a patient's care teams should be encouraged to improve knowledge-sharing, care coordination, and healthcare outcomes. Health IT developers working on telehealth initiatives should be aware of potential barriers to care, such as unreliable internet access, language barriers, and difficulty of use for callers with disabilities.[183]

Variability in e-Prior Authorization Processes Across Payers

There is a lack of common standards to support electronic prior authorization across payers.

The e-prior authorization process aims to improve quality and promote evidence-based care; however, the lack of standardization and integration of clinical and administrative data remain barriers to achieving those aims.[184, 185] Today each payer typically has its own system and process for receiving and reviewing prior authorization requests which can hinder timely exchange.[186] The 2021 AMA prior authorization physician survey found that inefficient prior authorizations can result in care delays, abandoned treatment, and provider burden.[187]

Lack of Standards for Patient Matching

Patient matching when sharing data needs to be improved, especially for vulnerable populations.

There is a lack of standards for consistently and accurately linking patients to their medical records. This results in record mismatches and duplications which can negatively impact clinical decision-making, treatment, patient outcomes, and patient privacy; it also results in duplicative testing.[188] Misidentification can cost healthcare facilities over $17 million a year in denied claims and lost revenue. The merging of separate records can lead to duplications and even incorrect matches, causing the disclosure of the PHI of one individual to another.[189] While a unique patient identifier could create more opportunities for fraud, it could also alleviate existing privacy concerns.[190,191] One possible solution to improve patient matching is record linkage which can create an enriched picture of a person through data from many sources; however, additional work is needed to further data reuse taking into account privacy and security considerations.[192]

Underserved populations can face unique patient-matching challenges that need to be considered in creating equitable solutions. For example, homeless patients face challenges when trying to link healthcare records with social care system records, such as those contained in communities' homeless management information systems, which store data on the characteristics and needs of homeless individuals. In California, some healthcare databases require a full social security number to match patients to their records. However, in the homeless management information system, users were only entering the last four digits of clients' social security numbers. As a result, both clinicians and social care groups were not able to see patient record overlap because the records could not be matched.[193]

Incomplete Provider Directories

Industry partners struggle to find the digital contact information for healthcare providers for health information exchange.

Electronic endpoints remain difficult to find and discover for various entities because there is not one central reliable directory that acts as a "source of truth". Many HINs have provider directories, but they only cover their participants and are generally not publicly available. While CMS is working to improve NPPES endpoint data, many providers have yet to upload their digital contact information.[194]

TARGET AREA: PRIVACY AND SECURITY

Difficulty in Tracking and Complying with Privacy Rules for Data Exchange

Complying with the HIPAA minimum necessary standard is difficult without improved electronic data segmentation capabilities.

There are currently no nationally adopted implementation guides for exchanging data for the purposes of payment and healthcare operations.[195] Additionally, the data segmentation capabilities of health IT systems are limited. Both of these issues make it difficult for providers to comply with HIPAA's minimum necessary standard. If a healthcare provider receives a health data query for payment or operations purposes, a manual process must be engaged, such as sending the request to the provider's medical records department to handle the request and determine what constitutes the minimum necessary data. Without additional guidance or technical capabilities, healthcare organizations have no standardized way to implement an approach for complying with the minimum necessary requirement when responding to requests for health information.

Lack of Technical Capabilities to Segment and Protect Sensitive Health Data

There is a lack of standards supporting the segmentation of sensitive health data, including for women, pediatrics, and gender-diverse populations.

Providers and patients continue to experience constraints on their ability to choose whether to electronically exchange sensitive data, even those that are subject to redisclosure or other restrictions by state and federal privacy laws. Sensitive health data is protected to differing degrees across states and there is no nationwide rule that protects most sensitive health data.[196] Healthcare providers' IT systems cannot currently support data segmentation at scale even though standards, such as FHIR®, and others have data segmentation capabilities. This means there is still limited capability for patients or providers to choose which data to share and which to not share.[197]

Cybersecurity Events Across the Healthcare Infrastructure

Cybersecurity events continue to increase.

Cyber-attackers' skills and resources are outpacing the ability of cybersecurity professionals in health care to prevent cyber-attacks. The United States tops the list of countries for costliest cybersecurity breaches and within the United States, health care tops the list of industries as the costliest for cyber-attacks.[198] The healthcare industry is considered critical infrastructure but is increasingly less protected from cyber-attacks as its losses mount.

Need for Alignment of Regulation of Health App Market to Prevent Unauthorized Access

Providers and hospital systems are adopting APIs but are concerned about unauthorized data exposure and added liability.

As hospitals and other healthcare providers rely more heavily on APIs to enable patient access and consent, there is growing concern about how health apps use the data and about unauthorized data exposure.[199] The proliferation of health apps accessing data through APIs has also raised concern among consumers about the privacy and security of their data and if it is sufficiently safeguarded.[200] The largely unregulated health app market creates doubt in consumers that their data will be protected and raises liability concerns for providers.[201] There is a growing gap between the advancing technology for patient access and consent and the standards and regulations needed to safeguard data in the healthcare industry.

Need for Improved Electronic Consent Directives

The pace of industry innovation is sometimes faster than that of the regulatory environment for consent directives.

The ability to exchange computable consent directives across health IT systems is limited today. Without this capability, it is difficult for providers and health IT developers to support the seamless electronic exchange of data where affirmative consent is required.

TARGET AREA: PATIENT ACCESS TO INFORMATION

Health Information Distributed Among Multiple Sources

Challenges persist in patients' ability to access and share their health information across multiple sources (e.g., portals, labs, payers, and other health IT systems), and consolidate their data into a single system providing integrated data view and utilization.

There is no simple method for patients to consolidate their health information from different providers to receive, share, or request adjustments. The distribution of patient data among multiple portals and systems can lead to serious challenges for patients, including ease of access and use of their health information. For example, patients with a chronic condition may rely on multiple portals to receive test results or clinician instructions if they are required to see more than one specialist. The burden then falls on the patient to consolidate this information and subsequently follow appropriate instructions.[202]

Limited Guidance for Safety and Security of Mobile Health Applications

There is a lack of meaningful analyses of mobile health app efficacy as well as guidance on data security.

Implementation and enforcement of ONC's information-blocking provisions will increase patient access to clinical notes, which can be effective in improving patient engagement. However, some clinicians are concerned that this increased access will increase the chances of clinician burnout, present new legal risks, and negatively impact the privacy of patient data.

App developers face barriers to accessing and sharing protected information. Security risk assessments can be lengthy and delay information sharing. More guidance is needed for developers of information-sharing apps on providing privacy statements, privacy and security requirements, and data use agreements.[203]

Underserved patients face unique challenges in using apps. For instance, most health apps are available only in English, presenting access and use challenges to individuals who do not speak English. Fourteen percent of individuals living in rural areas own a cellphone but not a smartphone and 40 percent of Medicare patients lack a smartphone with a wireless data plan, making it difficult to access digital health tools.[204] Other barriers underserved populations often face with mobile health apps include low health literacy or fluency in utilizing the application.[205]

Lacking Electronic Patient-Reported Health Record Update Processes

Transparency about the accuracy of patient data and consent to share it are lacking for patients, which in turn affects patient safety.

As patients have become increasingly engaged in their care, patient requests for changes have increased. Clear policies and procedures are needed to identify how requests from patients are processed and disseminated. Patients need an easy way to request changes and be sure that the requests will be reviewed, information will be updated as needed, and results of the review will be shared with the patient.[206]

Liability Concerns about Use of Patient-Generated Health Data

The use of PGHD may present liability concerns ***both*** *if inaccurate PGHD are used in clinical decisions or if the clinician chooses not to act based on the PGHD received.*

With the proliferation of PGHD, there are continuing concerns about the accuracy and reliability of data collected by a patient. Certain data collected by wellness devices not subject to FDA approval were shown to be inaccurate.[207] If a patient collects inaccurate data and a provider makes a clinical decision based on that data, this could present a liability risk for the provider. The same is true if the provider accepts accurate data collected by the patient but chooses not to act on it, thereby becoming liable for not using this data. Data used by the research community requires a high degree of accuracy and must be valid and reliable, which can present challenges to using PGHD received directly from patients.[208]

Limited Price/Cost Data Transparency

Low compliance among hospitals with price/cost transparency rules, as well as non-user-friendly methods of sharing complex data, hinder patient access and use of price-related information.

The CMS Hospital Price Transparency Final Rule requires hospitals to publicly share the costs of services. However, over a year after implementation, compliance from hospitals has been low. As of January 2022, less than 20 percent of hospitals were in compliance with the new rule.[209] This is true for even some of the largest health systems in the country. On June 7, 2022, CMS issued the first fines for transparency rule non-compliance.[210] Hospitals have expressed opposition to this rule, claiming that this information could confuse consumers even more.[211]

As insurers begin to comply with the Transparency in Coverage Final Rule, the files they share can be difficult for the average patient to decipher. The data, shared on public websites, can also be difficult to access due to their size and inconsistent reporting approaches. The data needs to be transformed in an accurate and consumer-friendly way so that patients can take advantage of the information and make informed health decisions. Until more of this data is transformed and shared, it is unclear what story the data will tell.[212]

Conclusion

Significant progress was made in advancing the use of technologies that support health equity, public health, interoperability, privacy and security, and patient access to information in FY22. However, work remains in these target areas to achieve the full potential of using health IT tools to help transform the healthcare sector. In fiscal year 2023 (FY23), ONC and the HITAC will continue to focus on advancing the implementation of the health IT provisions of the Cures Act including the TEFCA, as well as address evolving issues including health equity and public health-related technology concerns, contributions to the USCDI, and priority uses of health IT and related standards and specifications.

*Topics that tend to recur across HITAC annual reports

Appendices

GLOSSARY

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.

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.

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 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 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.

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.

Public Health Authority – A federal, state, territorial, local, and tribal agency that is responsible for public health matters as part of its official mandate.

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

Recognized Coordinating Entity (RCE) – A governance body that will operationalize the 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.

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.

X12 – ANSI-accredited, consensus-based, non-profit organization focusing on the development, implementation, and ongoing use of interoperable electronic data interchange standards.

ABBREVIATIONS

AI – artificial intelligence

API – application programming interface

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

CDC – Centers for Disease Control and Prevention

CDS – clinical decision support

CHPL – Certified Health IT Product List

CMS – Centers for Medicare & Medicaid Services

COVID-19 – Coronavirus Disease 2019

CRISP – Chesapeake Regional Information System for Our Patients

DMI – Data Modernization Initiative

eCR – electronic case reporting

EHI – electronic health information

EHR – electronic health record

ELR – electronic laboratory reporting

FAST – FHIR® at Scale Taskforce

FDA – Food and Drug Administration

FHIR® – Fast Healthcare Interoperability Resources

FTC – Federal Trade Commission

FY – fiscal year

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

HRSA – Health Resources and Services Administration

HSC – Health Standards Collaborative

ISA – Interoperability Standards Advisory

LEAP – Leading Edge Acceleration Projects in Health IT

MIPS – Merit-based Incentive Payment System

NBS – National Electronic Disease Surveillance System Base System

NCPDP – National Council for Prescription Drug Programs

N3C – National COVID Cohort Collaborative

NIH – National Institutes of Health

NLP – natural language processing

NPPES – National Plan & Provider Enumeration System

NPRM – Notice of Proposed Rulemaking

NSSP – National Syndromic Surveillance Program

OCR – Office for Civil Rights

OIG – Office of Inspector General of HHS

OMB – Office of Management and Budget

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

PGHD – patient-generated health data

PHI – protected health information

PHIT – Public Health Informatics & Technology Workforce Development Program

PPRL – privacy-preserving record linkage

QHIN – Qualified Health Information Network

OSTP – White House Office of Science and Technology Policy

RCE – Recognized Coordinating Entity

RFI – request for information

SAMHSA – Substance Abuse and Mental Health Services Administration

SDOH – social determinants of health

SO/GI – sexual orientation/gender identity

SOP – Standard Operating Procedure

STLT – state, tribal, local, and territorial

SUD – substance use disorder

SVAP – Standards Version Advancement Process

TEFCA – Trusted Exchange Framework and Common Agreement

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

2020-2025 Federal Health IT Strategic Plan

Health IT Data Briefs

Health IT Playbook

Trusted Exchange Framework and Common Agreement

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