ONC | HealthIT ADVISORY COMMITTEE

Health Information Technology Advisory Committee (HITAC) Annual Report for Fiscal Year 2023

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 for Health Information Technology (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 Department of Health and Human Services (HHS) and Congress each fiscal year, in consultation with the National Coordinator. 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 2023 (FY23) with an in-depth discussion of various topics across the target areas.

HITAC TARGET AREAS

Section 4003(e) of the Cures Act established target areas for the HITAC. The current priority target areas are:

- **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 IT 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

FEDERAL ACTIVITIES ACROSS THE TARGET AREAS

This section describes the health IT activities advanced by various agencies of the federal government during FY23. 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 FY23; 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.

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

In January 2024, ONC published its Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) final rule to implement provisions of the Cures Act and make updates to the ONC Health IT Certification Program with new and updated standards, implementation specifications, and certification criteria. Provisions in the HTI-1 final rule advance interoperability, improve transparency, and support the access, exchange, and use of electronic health information (EHI). The rule establishes first-of-its-kind transparency requirements for artificial intelligence (AI) and other predictive algorithms that are part of certified health IT. The final rule implements the Electronic Health Record (EHR) Reporting Program as the Insights Condition and Maintenance of Certification as part of the ONC Health IT Certification Program, enhances ONC's information blocking regulations, and adopts the United States Core Data for Interoperability (USCDI) v3 as the new baseline standard within the ONC Health Certification Program as of January 1, 2026.[2]

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." In February 2023, HHS held a Trusted Exchange Framework and Common Agreement (TEFCA) event recognizing six applicant organizations that have been approved for onboarding as Qualified Health Information Networks (QHINs): CommonWell Health Alliance, eHealth Exchange, Epic TEFCA Interoperability Services, Health Gorilla, Kno2, and KONZA. Each of the organizations agreed to go-live by the end of 2023.[3] In May 2023, a seventh QHIN application was accepted from MedAllies. In December 2023, HHS announced the designation of the first five QHINs: eHealth Exchange, Epic Nexus, Health Gorilla, Konza, and MedAllies, and data exchange began over the TEFCA network.[4] The Recognized Coordinating Entity (RCE), the Sequoia Project, has continued to release additional resources to operationalize the TEFCA, including standard operating procedures (SOPs), the TEFCA Facilitated FHIR® Implementation Guide, and the FHIR Roadmap for TEFCA Exchange Version 2.0. The SOPs include specific policies and procedures to further guide QHINs and identify, where applicable, necessary technical implementation requirements.[5] In August 2023, ONC awarded the Sequoia Project a new five-year contract to continue serving as the RCE.[6]

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. The USCDI is updated through a predictable, transparent, and collaborative process that allows interested parties the opportunity to comment on its expansion. In July 2023, ONC published the final USCDI v4 which added 20 new data elements and one new data class that focus on patient care and patient access while promoting equity, supporting communities, reducing disparities, and supporting public health data interoperability.[7] ONC also 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. In May 2023, ONC published the first draft of the USCDI+ data element list for quality measurement to serve as a baseline dataset to support electronically reported quality measures.[8] In December 2023, ONC unveiled a new platform for organizing the available USCDI+ datasets and released for comment the USCDI+ Public Health data sets for case reporting and laboratory data exchange.[9]

21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking Proposed Rule

In October 2023, HHS released the 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking proposed rule. The rule establishes a department-wide regulatory framework for managing disincentives for health care providers and proposes an initial set of appropriate disincentives in the following CMS programs: the Medicare Promoting Interoperability Program, the Merit-based Incentive Payment System (MIPS), and the Medicare Shared Saving Program. If finalized, the initial set of disincentives would apply to certain healthcare providers that have been found to have committed information blocking by the HHS Office of Inspector General (OIG) and are referred by OIG to CMS. Additional disincentives may be proposed in the future.[10]

Other Federal Activities

CMS's Advancing Interoperability and Improving Prior Authorization Processes Proposed Rule

The proposed rule, issued in December 2022, builds on the Centers for Medicare & Medicaid Services (CMS) 2020 Patient Access and Interoperability rule, adding new requirements on healthcare payers regulated by CMS to share data. The rule would require payers to use Health Level 7 International (HL7®) Fast Healthcare Interoperability Resources (FHIR®) based application programming interfaces (APIs) to (1) send information to healthcare providers about shared patients, (2) share information with other payers when patients change plans, (3) improve the electronic exchange of healthcare data, and (4) streamline processes related to prior authorization. CMS also proposes to create incentives for hospitals and clinicians to engage in electronic prior authorization using certified health IT through the Medicare Promoting Interoperability Program and MIPS.[11]

OIG Information Blocking Enforcement Final Rule

In July 2023, OIG published its final rule establishing the statutory penalties for health IT developers of certified health IT and health information exchanges/health information networks (HIEs/HINs) that are found to be engaged in information blocking. Enforcement of the information blocking penalties began on September 1, 2023. Information blocking complaints can be submitted via the ONC information blocking portal or the OIG hotline.[12] ONC operates a standardized process for the public to report possible claims

of information blocking.[13] As of November 2023, ONC had received 856 claims of possible information blocking. Most of these claims of alleged information blocking were made about healthcare providers.[14]

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

Background

Health equity continues to be a priority for many healthcare organizations and federal agencies as people face health disparities and experience social drivers of health (SDOH) that impact their health.[15] While challenges remain in health IT infrastructure to standardize and collect health equity and SDOH data, federal agencies, states, and private sector initiatives are moving the needle to provide more guidance for equitable data collection. As technology continues to advance, increasing the risk of disparities and furthering the digital divide, policies and regulations are needed to ensure equity.

Current State

Artificial Intelligence — Algorithmic Bias and Transparency*

The use of artificial intelligence (AI), including generative AI, algorithms, and machine learning, is increasing in health care due to the potential to improve care decisions and analytics and reduce costs. Bias, however, is a consistent issue in the development and application of AI-powered systems and machine learning models. Federal agencies, states, and the private sector are increasingly undertaking efforts to reduce bias in AI and machine learning. These efforts are comprised of the implementation of principles and guidelines to build trust as well as initiatives to better monitor the use and impact of AI in healthcare.

In August 2022, HHS issued a proposed rule that included a provision to prohibit discrimination by covered entities through the use of algorithms in clinical decision-making. The final rule is anticipated to be released in 2023.[16] In October 2022, the White House Office of Science and Technology Policy (OSTP) published the "Blueprint for an AI Bill of Rights."[17] The Blueprint establishes five principles to protect civil rights, including specifically identifying AI in automated health diagnostic systems as an example of sector-specific guidance that will be necessary when creating regulations. The HTI-1 final rule includes provisions that support transparency for AI and other predictive models. HHS' leading-edge regulatory approach will promote responsible AI and make it possible for clinical users to access a consistent, baseline set of information about the algorithms they use to support their decision-making and to assess such algorithms for fairness, appropriateness, validity, effectiveness, and safety.[18] In October 2023, the Biden Administration published an Executive Order on Safe, Secure, and Trustworthy Artificial Intelligence that seeks to fulfill the promise of and manage the risks of AI.[19] The Executive Order directs HHS to establish a safety program to enable the reporting and remediation of unsafe healthcare practices or harms involving AI.[20]

Some states are launching initiatives to reduce bias in commercial AI products and to catalog and regulate the use of AI by state agencies.[21] Connecticut state agencies are now required to catalog their use of AI and conduct an impact assessment before implementing new AI tools.[22] In November 2022, California Attorney General Rob Bonta launched an inquiry into racial and ethnic biases in healthcare algorithms to evaluate how algorithmic discrimination impacts patients in California.[23] As the first step of the inquiry, the

Attorney General requested hospitals to share information about how they are identifying and addressing racial and ethnic disparities in their clinical decision-making tools. Combined with federal efforts, the information and best practices from these state initiatives will be useful for other states to address the impact of clinical algorithms on health disparities and inequities. These state initiatives are examples of monitoring to examine how AI is used in healthcare currently and to better understand the impact of biases on patient care.

Private sector organizations and coalitions are increasingly pursuing research and policies to ensure that AI is utilized in safe and non-biased ways. In April 2023, The Coalition for Health AI released a "Blueprint for Trustworthy AI Implementation Guidance and Assurance for Healthcare," which highlights recommendations to increase assurance standards on trustworthiness in AI.[24] The report notes that failure to provide information about AI system characteristics, efficacy, equity, and behavior can negatively impact the ethical and proper use of systems while simultaneously damaging patient and provider trust and acceptance. Researchers at Vanderbilt University Medical Center and IBM Watson Health published a research report outlining AI-related clinical competencies for healthcare professionals in an effort to address practical and ethical concerns raised by the adoption of AI tools in clinical settings.[25]

Reducing the Digital Divide – General

Initiatives to increase patient access to care and information, like telehealth and patient portals, rely on the availability of broadband connections as well as the possession and knowledge of smartphones or computers. The Federal Communications Commission estimates that 19 million people in the United States lack access to reliable broadband service (high-speed internet). In 2021, rates of high-speed internet use were lower in households where the main occupant was 65 years or older, had a disability, or was African American, American Indian, or Hispanic.[26]

Lack of broadband connection has far-reaching health impacts. Areas that have lower rates of broadband access tend to have higher rates of obesity, diabetes, and preventable hospitalization as well as lower access to physicians.[27] Counties with higher percentages of people lacking broadband access saw higher COVID-19 case and death rates throughout the pandemic and lower vaccination rates.[28] The Federal Trade Commission (FTC) and the Department of Commerce National Telecommunications and Information Administration are executing the Biden-Harris Administration's 2022 Internet for All Initiative so that all Americans can access affordable, reliable, and high-speed internet to close the digital divide.[29]

Digital literacy is defined as having the ability to use information and communication technologies to find, evaluate, create, and communicate information, requiring both cognitive and technical skills.[30] These skills can include knowing how to use a keyboard and mouse, typing proficiency, using video conferencing software, or understanding best practices for internet safety and security. Health literacy is defined as the ability of individuals to find, understand, and use services to inform health-related decisions and actions for themselves and others.[31] Approximately 88 percent of adults in the United States do not have the health literacy to navigate the healthcare system and are less likely to return medical forms or assessment tools, keep appointments with health providers, or attend follow-ups for medical procedures.[32] Lower health literacy levels are disproportionately found in older adults, adults with limited English proficiency, low-income adults, and those with less education.[33] As healthcare and public health initiatives and services are increasingly digitally based, it is imperative to evaluate if the target audiences of these programs have the digital and health literacy to properly participate and how to provide adequate education and resources.

The digital divide also affects patients' access to health information. The ability to use a patient portal is predicated upon a patient having access to the internet to sign up and log into the portal. This impacts a patient's ability to schedule appointments or communicate with care providers through messaging features. An ONC study found that racial and ethnic disparities in patient portal access persist, as Black and Hispanic individuals are offered and access patient portals at significantly lower rates than White individuals.[34] This disparity suggests that policy efforts to enable easier patient access to their EHI should embrace health equity by design.[35]

Reducing the Digital Divide – Increasing Access to and Accessibility of Telehealth Services

Telehealth has provided opportunities to improve health equity by enabling care for vulnerable populations that may not have access to care otherwise. The COVID-19 pandemic and the temporary waiving of many policies that limited telehealth significantly increased the usage of both video and audio telehealth as a way to provide access to care without requiring in-person visits. After the expiration of the COVID-19 public health emergency in May 2023, federal agencies announced support for continuing telehealth flexibilities while considering long-term solutions. CMS has stated that a majority of the current Medicare telehealth flexibilities will remain in place through December 2024.[36] The Drug Enforcement Administration (DEA) and the HHS Substance Abuse and Mental Health Services Administration (SAMHSA) issued a temporary six-month extension of COVID-19 telehealth flexibility of controlled medication through November 11, 2023.[37] However, long-term policies and regulations on telehealth flexibilities are still in process, leading to uncertainty about pre-COVID telehealth restrictions being reimposed.

While telehealth improves access to care, barriers still exist. For example, language barriers can create significant issues in successful telehealth usage, which indicates a need for more language translation services to support better access to care for limited English proficiency patients. During the COVID-19 pandemic, patients with limited English proficiency were less likely to use video telehealth, which may be due to limited access to broadband connection and technology or privacy concerns related to immigration status.[38] The languages offered for interpretation also impacted whether populations used telehealth.[39]

Patients with visual and hearing impairments often cannot take advantage of telehealth due to a lack of accessibility tools. A report from the American Foundation for the Blind found that while 71 percent of patients with visual impairments attempted to use telehealth during the pandemic, of these patients, 57 percent reported accessibility challenges with telehealth platforms.[40] In addition, patients who are deaf or hard of hearing experienced significant issues utilizing telehealth during and after the COVID-19 pandemic. In one study, half of the participants reported the need to use a video relay service that employs interpreters, but the interpreters only had general certifications instead of specialized healthcare interpreting certifications.[41] In July 2022, the Department of Justice and HHS issued guidance on nondiscrimination in telehealth to ensure accessibility to people with disabilities.[42] The guidance provided direction, explanations, and examples for providers to understand how to prevent unlawful discrimination against people with disabilities, including deafness and intellectual disabilities, and limited English-proficient persons.

Health IT Infrastructure for Health Equity and SDOH Data

Health disparities can be challenging to identify due to the inconsistent and non-standardized collection of data. In order to integrate social care into the delivery of health care, community-based organizations (CBOs) need to have access to bidirectional, secure systems to effectively and safely share patient health

information across the entire care continuum. Efforts to improve health equity data collection and exchange are underway. While a majority of people are comfortable with their healthcare providers sharing information about their social needs with other providers for treatment purposes, 40 percent expressed some level of unease with this type of information sharing.[43]

In February 2023, ONC released a toolkit to support communities advancing health equity through the use of interoperable, standardized data, and SDOH data exchange.[44] The toolkit provides information on the current SDOH data exchange landscape and guidance for common challenges and opportunities in exchanging SDOH information. The toolkit provides a conceptual framework to help community resource referral programs, HIEs, provider networks, CBOs, and others plan, design, implement, and evaluate processes of SDOH information exchange initiatives.

The Centers for Disease Control and Prevention (CDC) found that in a dataset of more than 50 million COVID-19 cases, race and ethnicity data were missing for more than 17 million people, or 34 percent of cases. In comparison, only one percent of cases were missing data on age and sex.[45] In January 2023, the White House Office of Management and Budget (OMB) released initial proposals to update the minimum standards for collecting and presenting data on race and ethnicity for federal reporting, which were last updated in 1997.[46] The Center for Medicare and Medicaid Innovation (CMMI) has announced its intention to support the collection and submission of SDOH and demographic data in its models.[47] CMMI has noted that the submission of demographic data will be required annually for certain models in 2023 such as the ACO REACH Program and will likely be required in submissions for future model years.[48]

Public health plays a significant role in addressing SDOH. In addition to supporting data standardization, public health authorities can assist in assessing and monitoring population health status, community needs and assets, and factors that influence health.[49] For example, PLACES, which is a collaboration between the CDC, the Robert Wood Johnson Foundation, and the CDC Foundation, provides a model-based, population analysis and community estimates of health measures to all counties, places, census tracts, and zip code tabulation areas nationally.[50] The improved availability of data allows for the development of model-based, small-area estimates to support efforts to improve population health interventions. PLACES data can be used to create, set, and measure key SDOH issues and guide the development of interventions.[51]

Hospitals are increasingly collecting social needs data. In 2022, 83 percent of hospitals reported collecting social needs data, although only 54 percent reported collecting this data routinely. The most popular way to collect social needs data in clinical settings is the use of structured electronic screening tools, followed by free text notes.[52] Of the 60 percent of hospitals that reported receiving social needs data from sources outside their hospital or system, HIEs were the largest source of data (46 percent), while social service or community-based referral platforms and community or social service providers were sources of social needs data 22 percent and 18 percent of the time, respectively. This information was used to inform clinical decision-making and discharge planning for patients, conduct population health analytics, and support community needs assessment and equity initiatives. The adoption of SDOH Z codes, which are medical codes that enable providers to document SDOH, has been slow due to a lack of standards, a lack of provider awareness, and administrative burden.[53] According to a CMS report, Z code adoption increased from 1.31 percent in 2016 to 1.59 percent in 2019.[54] Potential barriers to increasing the use of Z codes include the fact that Z code claims are not generally used for payment purposes and are therefore not financially

incentivized, there are a limited number of Z codes that may not capture all patient needs, and physicians may not feel responsible for helping patients with social needs.[55]

The Health IT End-Users Alliance released a consensus statement regarding the collection of SDOH data to support health equity, calling for additional efforts to standardize and increase the uniform collection and reporting of SDOH. A key missing component the Alliance identifies is the need for more training on collecting this data and better use of appropriate tools and processes to manage and share SDOH data for providers.[56] Beginning July 1, 2023, the Joint Commission set health equity as a National Patient Safety Goal for accredited organizations and unveiled a new Health Care Equity certification program to recognize and certify hospitals that wish to demonstrate efforts in achieving health equity.

TARGET AREA: USE OF TECHNOLOGIES THAT SUPPORT PUBLIC HEALTH

Background

Public health data systems are essential for monitoring and addressing public health issues, as well as collecting, managing, analyzing, and disseminating data on diseases, injuries, and health outcomes to guide public health policy and decision-making. Unfortunately, the nation's public health data systems are outdated, fragmented, and chronically underfunded, resulting in delayed detection and response. These systems need to be modernized to enhance their effectiveness, efficiency, and user-friendliness.

Current State

Supporting Data Sharing for Public Health Purposes

States mandate or authorize public health data reporting to help control and prevent the spread of communicable diseases. States determine who must report, what information must be reported, and the format and manner of reporting. The COVID-19 pandemic has shown the need for improved public health data systems. The federal government is taking steps to improve these systems through efforts such as the CDC's Data Modernization Initiative (DMI) and North Star Architecture. The DMI is working to promote data standardization and advance standards for public health data exchange. ONC's TEFCA initiative will also help further advance interoperability for healthcare providers and public health authorities.[57]

AI is increasingly being used in public health to improve health outcomes, enhance disease surveillance, prevent diseases, and respond to health emergencies.[58] For example, AI can be used to develop predictive models of public health outcomes, such as the likelihood of a child being hospitalized with pneumonia. AI can also be used to analyze large datasets, such as EHR and social media data, to identify trends and patterns that would be difficult to detect using traditional methods. This information can be used to target interventions and develop tailored messages to those most at risk, prevent outbreaks, and improve the allocation of healthcare resources. As AI technology continues to develop, it will likely have an even greater impact on public health.[59]

Electronic Case Reporting

eCR is the automated, real-time exchange of case report information between EHRs and public health authorities. eCR provides timely and more complete data, including patient demographics, diagnoses, comorbidities, occupation, travel history, immunizations, medications, pregnancy status, and treatments.

Healthcare organizations are connected with public health authorities using HL7® standard documents, following a hub-and-spoke model that eases the burden of connecting to multiple jurisdictions with various policies, systems, and standards. The Association of Public Health Laboratories established a decision support engine to help providers navigate complex reporting requirements based on jurisdictional laws.[60]

As of October 2023, more than 29,200 facilities in all 50 states are actively sending electronic initial case reports to public health using eCR.[61] To further advance eCR, ONC's HTI-1 final rule revised the "Transmission to Public Health Agencies – Electronic Case Reporting" criterion to adopt consensus-based, industry-developed electronic standards and implementation guides. The rule now allows Health IT Modules to support either the Clinical Document Architecture (CDA) suite of implementation guides or the FHIR®-based implementation guide.[62]

Electronic Laboratory Reporting

Electronic laboratory reporting (ELR) for public health transmits digital laboratory reports from laboratories to state, tribal, local, and territorial (STLT) public health authorities, healthcare systems, and the CDC. ELR enabled the CDC to receive comprehensive coronavirus data in real-time, helping inform the next steps and produce recommendations. At the end of 2022, the CDC exceeded its goal of sending core public health data automatically and electronically for use in cloud-enabled public health systems by FY 2024 (FY24). The CDC is now sending over two million results per day.[63] In addition, ONC added six new data elements to the Laboratory data class in USCDI v4 to support ongoing public health reporting needs and provide patients and providers with more details for interpreting laboratory data.[64]

Syndromic Surveillance

Syndromic surveillance is a valuable public health tool that tracks real-time patient symptoms. It can help detect, understand, and monitor health events, providing early warning of potential outbreaks or unusual levels of illness. This information can enable public health authorities to respond promptly to public health emergencies and implement effective interventions. The National Syndromic Surveillance Program (NSSP) promotes and advances the development of a system to collect and share syndromic surveillance data. The data are integrated into the BioSense Platform, a shared platform for syndromic surveillance. As of September 2023, 78 percent of the nation's emergency departments contribute data to the BioSense Platform, and more than eight million electronic health messages are received by NSSP every day, indicating widespread adoption of syndromic surveillance across the United States.[65] As part of the CDC's DMI, the National Electronic Disease Surveillance System Base System (NBS) is being modernized to enhance syndromic surveillance capabilities. This modernization effort aims to strengthen syndromic surveillance beyond COVID-19 to include other conditions and to improve population health outcomes.[66]

TARGET AREA: INTEROPERABILITY

Background

Data exchange among providers, payers, and other healthcare entities has historically been challenging. The CURES Act's requirements have substantially increased data sharing. While significant efforts have taken place to promote interoperability, there are opportunities to improve the sharing of EHI.

Current State

Supporting Interoperability Standards – Laboratories and Pharmacies

Laboratory results influence a majority of medical decisions. Increasing the interoperability of laboratory data can improve the timely delivery and use of test results by healthcare providers and public health authorities.[67] Medical centers, test manufacturers, and other organizations involved in laboratory testing vary in the methods used to organize, categorize, and store laboratory information systems, which can impact data quality and interoperability. Improving data quality is important to establishing trust in the data delivered through interoperability. USCDI is promoting the increased standardization of laboratory data. For instance, USCDI v3 added specimen type and results status and USCDI v4 added six new data elements to the Laboratory data class.[68] The HITAC has developed recommendations on how to improve laboratory interoperability generally and specifically ELR to public health authorities.[69]

The role of pharmacists in clinical care has increased in recent years. New care models continue to develop that incorporate pharmacists with a focus on pharmacy-based clinical services and care coordination. Pharmacists have also played a role in responding to public health emergencies, such as administering vaccines, testing, and therapeutics during the COVID-19 pandemic. [70] Interoperability in pharmacies, to date, has largely focused on use cases related to electronic prescribing with less participation in the broader exchange ecosystem established to support the bidirectional exchange of data to support treatment and care coordination.[71]

Information Blocking

In the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule (ONC Cures Act Final Rule) ONC finalized eight exceptions to the prohibition on information blocking. When an actor's practice meets the condition(s) of an exception, it will not be considered information blocking. Three categories of actors are regulated by information blocking: healthcare providers, HINs/HIEs, and health IT developers of certified health IT. The HTI-1 final rule revised certain information blocking definitions and exceptions to support information sharing and added a new exception to encourage secure, efficient, standards-based exchange of electronic health information under TEFCA.[72]

Standards to Support Data Linking and Patient Matching*

Patient matching, particularly of records from more than one provider, continues to be a costly and burdensome issue, leading to duplication of tests and administrative time spent resolving patient identity issues. Patient matching mistakes can also lead to clinical and outcome issues. For instance, incomplete patient and medication data accounts for nearly half of all medication errors.[73] Healthcare organizations spend an average of 109.6 hours per week resolving patient identity issues.[74] Over half spend 21-80 hours per week and have an average of 10 full-time employees dedicated to patient identity resolution – despite nearly all participating organizations reporting that they had a unique patient identifier in place.[75]

Guidance is also needed to assess the minimum standardized dataset needed for patient identification and matching and encourage a standard format for addresses and other data elements in collaboration with federal efforts to improve standardization. ONC has taken steps to standardize patient matching data elements through the USCDI and Project US@, which seeks to create a unified industry-wide specification for addresses.[76] Last name and address standardization has been found to improve patient matching

accuracy by up to eight percent.[77] More work is needed at both the research and policy levels to expand evidence for real-world matching system performance and develop consistent approaches to data standardization and collection.

Data linkage, sometimes referred to as record linkage, is the act of bringing together two or more sources of information that relate to the same individual, event, institution, or place. Record linkage creates richer data about persons, families, events, and places.[78] 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. PPRL leverages technology to produce unique sets of de-identified tokens that are used to match patients. Since the tokens have no relationship with true identifiers, they cannot be used to reproduce those identifiers.[79]

Efforts are underway to address data linkage and patient matching at a national level. In March 2023, the White House OSTP published the National Strategy to Advance Privacy-Preserving Data Sharing and Analytics which sets out strategic priorities for public and private organizations to incorporate privacy-preserving data sharing and analytics technologies, which includes data and record linkage. [80] The report noted that privacy-preserving data sharing and analytics (PPDSA) technologies can advance American innovation by facilitating data sharing and analytics while protecting sensitive information and privacy. To create a future data ecosystem that includes PPDSA technologies, the report outlined five strategic priorities: (1) advance governance and responsible adoption, (2) elevate and promote foundational research to advance PPDSA, (3) accelerate findings into practice through pilot implementations and technical standards, (4) build expertise and promote training, and (5) foster international collaboration to support common values while protecting national and economic security.[81] The strategy is the first step in advancing PPDSA technologies that will benefit healthcare and public health initiatives.

STLT public health authorities are increasingly leveraging PPRL to report data to the CDC and other federal agencies while protecting personally identifying information. For example, the reporting of STLT vaccination records enables the CDC and HHS to track vaccinated populations by status and associated outcomes for populations with HIV and viral hepatitis. This information allows the CDC to better understand vaccination coverage, identify communities at risk of vaccine-preventable disease outbreaks, and target STLT resources to improve the health of communities.

Supporting Interoperability Standards – Long-Term and Post-Acute Care Providers

While significant progress has been made to advance interoperability within the acute care space, the long-term and post-acute care (LTPAC) sector has been slower to adopt health IT and engage in electronic health data exchange. Historically, LTPAC providers were ineligible for incentive payments from past federal efforts to advance the adoption of interoperable health IT. Infrastructure and staffing challenges have further stagnated progress.[82]

The need for care coordination and better care transitions from hospitals to LTPAC providers has illustrated the importance of interoperable health IT. LTPAC providers include assisted living, skilled nursing facilities, rehabilitation facilities, long-term care hospitals, and home health agencies.[83] One challenge in measuring the adoption of interoperable health IT by LTPAC providers is the lack of ongoing tracking of their implementation and use. For example, in 2017, 78 percent of home health agencies and 66 percent of SNFs had adopted EHRs.[84] To exchange health information, 32 percent of home health agencies and 27

percent of SNFs used their EHR, and more than half of home health agencies and SNFs had information available at the point of care from other providers. Of the SNFs surveyed, a third did not use an EHR or health information organization for the electronic exchange of patient health information.[85] There has been little up-to-date information since then.

As LTPAC providers increasingly coordinate with acute care providers for transitions of care, the most commonly identified barrier in sharing clinical information was an EHR that lacked interoperability to receive and integrate information from outside sources.[86] A 2022 survey found that 79 percent of SNFs planned to invest in more advanced interoperability capabilities in the future as more revenue is attributed to value-based care arrangements and referring entities are more likely to send referrals to SNFs capable of receiving orders electronically.[87] The need for improved interoperability resources for increased referrals and data exchange is supported by the finding that 99 percent of hospitals and physicians are more likely to refer patients to LTPAC providers that have interoperable health IT.[88]

A report by the National Academies of Sciences, Engineering, and Medicine provided multiple recommendations to improve and better track health IT adoption and interoperability by LTPAC providers. While some of them are implementing the necessary infrastructure, the report suggests that federal regulations and financial incentives are necessary to ensure the adoption of health IT across LTPAC providers nationally.[89] For health IT tools to realize their potential to improve care quality and increase LTPAC staff productivity it is also essential to train LTPAC staff on how to use the systems.[90]

Streamlining of Health Information Exchange*

The adoption of health IT systems by providers and the electronic exchange of health information has increased significantly in the last decade. In 2011, only 28 percent of non-federal acute care hospitals and 34 percent of office-based physicians had adopted a certified EHR.[91] In 2019, 96 percent of all non-federal acute care hospitals and 78 percent of office-based physicians had adopted a certified EHR.[92]

Since 2017, hospital engagement in HIE increased across the three domains of interoperability (receive, find, integrate) with 88 percent of hospitals engaging in electronically sending or obtaining patient health information in 2021.[93] Hospitals integrating patient health information into EHRs grew by 40 percent from 2017 to 2021 and 74 percent have bulk data export capabilities. Rural and small hospitals are now able to have more information available at the point of care and usage of electronically querying outside sources increased to 40 percent in 2021, up from 20 percent in 2017.[94] Despite the significant progress, rural and small hospitals still face significant challenges and lag behind larger and urban hospitals in interoperability.

ONC's HTI-1 final rule outlines the "Insights Condition and Maintenance Certification" that implements the EHR Reporting Program required by the Cures Act. The new Condition of Certification calls for increased transparent reporting by certain certified health IT developers to address information gaps in the health IT marketplace and provide insights on the use of specific certified health IT functionalities.[95]

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. National networks, other HINs, and healthcare providers are preparing for the launch of the TEFCA in late 2023. An ONC analysis found that over 50 percent of hospitals are aware of the TEFCA and plan to participate, while only one percent were aware of the TEFCA and not planning to participate. Independent hospitals and critical access hospitals are less likely to be planning to participate in the TEFCA.[96]

Hospital participation in state, regional, or local networks increased from 53 to 64 percent between 2018 and 2021.[97] In 2021, over 60 percent of hospitals used an HIE to query or find patient health information from external sources. HIEs and Health Information Service Providers (Direct Secure Messaging) were the most frequent methods for sending and receiving patient health information, with four in 10 hospitals participating in multiple networks.[98] The launch of the TEFCA will enable hospitals to participate in cross-network exchange and potentially reduce the number of different networks necessary for data exchange.

TARGET AREA: PRIVACY AND SECURITY

Background

Protecting the privacy and security of health data, particularly sensitive health data, is important to maintaining provider and patient trust in health IT and the electronic exchange of health data. Sensitive health data increasingly exist in digital environments not governed by HIPAA in some cases yet are governed by a patchwork of privacy laws that are inconsistent and create confusion for providers and patients.[99,100] For instance, many states have laws and regulations protecting the privacy of sensitive health information that are stricter than the HIPAA Privacy Rule. Since these laws and regulations vary from state to state, it causes confusion among interstate exchange partners and makes it more difficult and expensive to manage technology to ensure privacy compliance.[101] States are also enacting comprehensive privacy laws, some of which affect patients' health information.

Comprehensive, preventative privacy and security measures continue to be a critical priority for the healthcare industry. For example, in July 2023, the FTC and HHS' Office for Civil Rights (OCR) sent a joint letter to over 130 hospitals and other healthcare providers alerting them to the fact that online tracking apps such as Google Analytics and Meta/Facebook Pixel share sensitive health data without users knowing and recommended caution when using such apps.[102] It was reported that, as of mid-August 2023, as many as 664 healthcare systems were still sending sensitive data to Meta.[103]

In addition, the ability to share discrete elements from a health record has not been widely implemented, and healthcare data remains a high-value target for bad actors.

Current State

Privacy of Sensitive Health Data - Gender and Reproductive Health

The *Dobbs vs. Jackson Women's Health Organization (Dobbs)* Supreme Court decision in 2022 returned to the states the power to regulate reproductive health services. Along with the growing number of states' legislative bans on gender-affirming care, this case has highlighted the lack of comprehensive privacy laws designed to protect sensitive health data.[104,105]

In the aftermath of *Dobbs,* sensitive health data, including a person's location, can potentially be used to identify patients who have received reproductive health services.[106] With the explosion of digital health apps used for tracking everything from menstrual cycles to fertility, this sensitive health data becomes discoverable for law enforcement purposes. For example, if a patient received reproductive services in a state where the services are legal and then required follow-up services in the patient's home state where it is not legal, the reproductive health data shared across state lines could be used in a lawsuit or enforcement action against the provider, the patient, or others.[107] HIPAA requires covered entities to maintain

confidentiality, but it also includes exceptions that could allow another state to demand sensitive health data from a provider across state borders.[108]

Recognizing the risk to patients' privacy, OCR issued guidance post-*Dobbs* outlining federal protections for protected health information (PHI) including sexual health data. This guidance additionally stated that providers are not required to furnish such data to third parties.[109,110] OCR also issued a Notice of Proposed Rulemaking (NPRM) in April 2023 to enhance the HIPAA Privacy Rule protections.[111] This NPRM would prohibit the use or disclosure of PHI to identify, investigate, prosecute, or sue patients, providers, and others involved in the provision of legal reproductive health care, including abortion.[112] ONC's HTI-1 final rule includes a provision to support an internet-based method for a patient to request a restriction on the use of certain data but does not adopt standards for granular data segmentation.[113] There are currently also legislative efforts in some states to prohibit state agencies and courts from cooperating with out-of-state investigations related to reproductive health services.[114]

In addition to protecting reproductive healthcare, there is a growing concern from both providers and patients that the current definition of sensitive health data is too narrow and could also include information such as sexual health and gender-affirming care.[115] Several states have passed new privacy laws aimed at broadening the definition of sensitive health data to include genetic or biometric, sexual health, sexual orientation, and/or geolocation data.[116] In July 2023, HHS issued an NPRM that would prohibit discrimination based on sexual orientation or gender identity for any health services obtained through HHS programs.[117]

Privacy of Sensitive Health Data – Consent

Now that more sensitive health data exist in the digital realm, studies show that patients would like more control over who sees this data and how it is shared.[118] Efforts are underway to mature granular data segmentation and put the patients at the center of their own data-sharing decisions, advancing interoperability and informed consent more consistently across states. However, EHRs cannot finely segment parts of a digital health record at scale.[119,120] Other challenges in modernizing the digital consent process are the changing landscape of privacy laws at the state level, the lack of infrastructure and uniform standards for sharing consent between different systems, ensuring consent is meaningful, and the difficulty in discovering which systems have a patient's data so the patient can manage it.[121,122] Current efforts to develop digital consent software are mostly siloed and proprietary and would benefit from services that make it easily available and user-friendly.[123]

Multiple efforts have been launched to improve the consent process. For example, Shift is a collaboration of health IT experts from different healthcare arenas working with ONC to advance granular segmentation of data, in part, by defining high-value clinical use cases that reflect the post-*Dobbs* world.[124] The Sequoia Project has also convened a Privacy and Consent Workgroup charged with identifying key impediments and determining whether and how standards-based automated solutions can support proper information exchange while appropriately protecting patient privacy.[125] The HL7® FHIR® standard supports data tagging and segmentation of sensitive health data which allows a provider to choose more discrete pieces of a health record to share.

Accounting of Disclosures

The Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 amended HIPAA to provide patients with the right to request an accounting of all disclosures their provider has made

of their PHI. In 2011, OCR proposed changes to implement this new provision. However, the proposal was not implemented for reasons of cost, lack of technical tools, and the perceived burden on providers.[126] With technological advancements and the increased electronic exchange of health information through national networks (and the TEFCA in the future), there is renewed interest in implementing the HITECH accounting of disclosure provisions to provide patients with a comprehensive accounting of their health data.[127]

While not PHI, there is a continuing conversation across the health IT industry around de-identified data and the risk of re-identification, including whether de-identified data should also be a part of future accounting of disclosure requirements. These concerns arise from the growth in de-identified data, including from the increased use of wearable devices. De-identified biometric data from such wearables can be re-identified if it is linked to a unique digital identifier. While there are great benefits to research from sharing de-identified data, there is also a risk to patient privacy if such data are re-identified.[128,129]

Cybersecurity Events across the Healthcare Infrastructure*

Healthcare data networks are increasingly interconnected as interoperability advances. The healthcare sector, considered a critical national infrastructure, experiences the highest data breach costs of any sector and from 2022 to 2023 was the third most attacked industry.[130] The average cost of a data breach reached over $10 million in 2023.[131]

The federal government has recently taken several steps in response to the severity of cyber-attacks in the healthcare industry. For example:

- In March 2023, the White House released a new National Cybersecurity Strategy which states that cybercrime is a national security threat and urges focus on defending critical infrastructure such as health care.[132]
- In August 2023, the Advanced Research Projects Agency for Health, a research support agency within HHS, announced the Digital Health Security Project, or Digiheals, aimed at gathering the most innovative cybersecurity solutions to protect the healthcare sector.[133]
- In September 2023, OCR and ONC issued an update to the Security Risk Assessment tool designed to help small- and medium-sized businesses secure PHI within their networks.[134]
- In September 2023, NIST announced plans to provide more resources for small covered entities including use cases, tools, and further guidance on how to prevent cybersecurity events.[135]
- In October 2023, the Cybersecurity and Infrastructure Security Agency (CISA) teamed up with HHS to release a cybersecurity tool kit to assist healthcare organizations in developing stronger cybersecurity defenses.[136]

TARGET AREA: PATIENT ACCESS TO INFORMATION

Background

Patient interest in accessing health records is increasing.[137] In 2022, 73 percent of patients were provided access to their medical records, a 24 percent increase from 2020. Of patients offered online access to their medical records, 57 percent accessed those records, a 50 percent increase over 2020. The most common reason why patients accessed medical records was to view test results or clinical notes.[138] This increase

has the potential to improve patient satisfaction. In an effort to improve patient access, in August 2023, the patient advocate group Open Notes launched an online resource to assist patients in accessing their health records.[139] There has also been increased enforcement against providers that hinder patient access. As of October 2023, OCR settled 45 HIPAA violations under its Right of Access Initiative.[140] Moreover, patients are increasingly collecting and using data in mobile health apps, but concerns persist regarding the apps' clinical validity, safety, and impact. There are also risks with patient-generated health data (PGHD), which is increasingly incorporated into patient health records.

Current State

Safety and Impact of Mobile Health Apps*

Despite more than 350,000 mobile health apps on the market today, their potential has not yet been realized due to issues including the absence of a nationwide framework to vet apps for their clinical validity and safety, and the variable quality of apps.[141],[142]

There is no overarching regulation of the mobile health app field, which means that some apps are relatively unregulated and developed without sufficient expert involvement, creating a wide range of app quality.[143] This also creates confusion about which apps are subject to which laws. For example, in 2016, the Cures Act removed certain mobile health apps from the FDA's regulatory purview.[144] The health app market is typically not bound by HIPAA's Privacy and Security Rules because most apps are not subject to HIPAA. The FTC looks at certain aspects of privacy and in 2023, it expanded its enforcement efforts on health apps.[145] In May 2023, the FTC released a proposed rule to clarify that the Health Breach Notification Rule (HBNR) applies to health apps and similar technologies not covered by HIPAA.[146]

While health apps can benefit consumers, the lack of adequate regulation or supervision has the potential to act as a barrier to improved quality of health apps.[147] For instance, many health apps are not based on clinical evidence or do not comply with public health guidelines, making them potentially unsafe for consumers.[148] There is currently no universal rating system for mobile health apps to inform patients and providers of their clinical validity, privacy and security measures, and usability characteristics. Consumers also do not understand how their health app data are protected or shared with third parties.[149] In July 2023, the Peterson Center on Healthcare created the Peterson Health Technology Institute to analyze and assess digital health technologies with a focus on clinical benefits and economic impact as well as privacy, security, and health equity.[150]

Patient-Generated Health Data Interoperability Standards and Data Access*

The use of PGHD can support patient-centered care by creating better outcomes with more detailed patient information. Sources used to collect PGHD continue to proliferate with the internet of things (IoT) including wearable devices, digiceuticals, and mobile health apps. APIs are increasingly used to facilitate PGHD collection. A 2022 survey showed that 45 percent of hospitals use standards-based APIs to support the submission of PGHD.[151] However, the variety of sources of data creates challenges in integrating the data with patient records in EHRs and with various provider workflows.[152] Also, data collected from digital health technologies are sometimes incomplete due to user error or device limitations, creating inaccurate data. To achieve better data access for providers and patients, more medical devices would need to employ open API- and standards-based technology. In some cases, patients lack adequate access to internet service which is a barrier for under-resourced populations.[153] As with all digital data, there is a risk that PGHD data can be hacked, and because some of the collection sources are not subject to HIPAA, the legal and

regulatory framework for protecting this data is inconsistent.[154] Standards that support the seamless integration with EHRs and patient consent mechanisms that allow for informed consent and further trust in the patient population are also needed.[155]

Patient-Reported Electronic Health Records Update Processes*

While the EHR is a primary source of information for clinicians, EHRs continue to contain a high rate of errors, with some putting the number at 70 percent of all patient records.[156] In one study of ambulatory EHR visit notes, one in five patients who read a note reported an error and of these over 40 percent perceived the error as serious.[157] These errors can not only result in incorrect billing but can also lead to patient harm. A recent survey found that 43 percent of patients accessing their records do so to check for accuracy in the record, indicating the importance of record accuracy.[158] The HIPAA Privacy Rule states that patients have the right to request changes to their medical records, but in practice, there is still no simple technology to achieve these changes. A provider has no later than 60 days, with some exceptions, to implement a record change request or deny it. Often, requests for medical record changes are not fulfilled. In addition, some states have laws that include provisions on patient access and the right to amendment.

User-Friendly Price/Cost Data Transparency*

CMS has made strides toward greater price transparency through its rules requiring payers and hospitals to provide publicly accessible pricing information.[159,160] Compliance rose from 65 percent in the fourth quarter of 2022 to 84 percent in the first quarter of 2023.[161] During this period, CMS also increased the potential penalty levied on hospitals from over $100,000 to $2 million annually.[162] However, challenges remain. As of October 2023, CMS issued 730 warnings and 269 requests for corrective action plans to hospitals and has imposed civil monetary penalties on six hospitals for noncompliance.[163,164]

Moreover, there are still barriers hindering consumers' ability to obtain this information. While the CMS rules require hospitals and payers to publish rates, it leaves the choice of how to bundle rates up to the implementer. For consumers, this can create confusion if the prices they are comparing are not for comparable services. In February 2023, Project Clarity, a private sector collaboration of experts from across the health IT industry, announced it would create 100 standardized care bundles to be used by consumers for comparison healthcare shopping.[165]

Health IT Infrastructure Gap Analysis

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

Balancing the Potential Risks and Benefits of Artificial Intelligence

AI holds significant promise in solving healthcare challenges, yet research and regulations are necessary to ensure that bias and harm are not implemented in the design and use of new technologies. DSIs and predictive models lack the patient and caregiver perspective.

While AI has the potential to provide significant breakthroughs in healthcare, research, regulations, and policies are needed to ensure that algorithms and AI tools are not compounding bias and are not discriminatory by design. AI that furthers inequities and bias is a significant concern that must be balanced with the potential benefits. As researchers and policymakers seek to better understand how to mitigate algorithmic bias, standardized representative data collection can be utilized to better train AI algorithms to not perpetuate racial and other health disparities. Patient and caregiver perspectives should be considered in the design of DSIs and predictive models. A key concern with AI is that policymaking will hinder the proliferation of AI; however, industry coalitions, federal agencies, and researchers agree that transparency and education are key to addressing the practical and ethical concerns of using AI tools in clinical and research settings.[166]

Reducing the Digital Divide

Further requirements and initiatives are needed to reduce the digital divide, including encouraging health equity to be a core design feature and component in health care.

Digital and health literacy are important to keeping individuals healthy and enabling them to find, understand, and use information. Digital literacy varies widely by educational attainment and age. For instance, 64 percent of college graduates can identify an example of two-factor authentication while only 31 percent of those with a high school diploma or less education can.[167] Nearly nine out of 10 adults have difficulty using the everyday health information that is routinely available to them. Such people are more likely to skip necessary medical tests and may also end up in the emergency room more often.[168]

The lack of broadband connection can have significant health impacts. Forty-three percent of adults with annual household incomes under $30,000 did not have a home broadband subscription in 2021, while only eight percent of adults with incomes of more than $75,000 reported not having a home broadband subscription.[169] Some Americans rely only on their smartphones, with 15 percent relying on wireless broadband without any traditional home broadband service.[170] Areas with lower rates of broadband access are correlated with worse patient health and public health outcomes, highlighting the urgency of providing people with adequate broadband access. The digital divide hinders health IT adoption, as the lack of broadband connection or technical knowledge can deter patients from accessing patient portals and other key health information.

Increasing Access to and Accessibility of Telehealth Services

Telehealth continues to bridge access gaps but still poses risks of exacerbating disparities.

While the use of telehealth is beneficial for many patient groups, significant issues remain to make telehealth truly accessible for others, including patients with limited English proficiency or health literacy, those who are deaf or hard of hearing, and visually impaired patients. Although interpretation services are often offered in person, telehealth services may not offer as robust interpretation services. Patients may also under-utilize video telehealth services and only feel comfortable using telehealth services with family or an interpreter present. As telehealth continues to be a care modality, design considerations should be taken into account to ensure compatibility with assistive technology and devices to ensure ease of use for people with disabilities.

Accessibility for visually impaired patients is particularly challenging, as telehealth services may not include accessibility tools, like screen readers and alternative texts. Additional consideration must be taken to make telehealth more accessible.

Missing Health IT Infrastructure for Health Equity and SDOH Data

The collection of health equity and SDOH data remains inconsistent due to a lack of standardization, the infrequency of the recording of this data, and the lack of adoption of IT tools by CBOs, public health organizations, and social service providers.

While public and private efforts are underway to better collect and standardize SDOH and health equity data, more education is needed to encourage the consistent use of screening tools and collection of data. The COVID-19 pandemic illustrated the urgency of collecting race, ethnicity, and language data in order to better identify disparities and evaluate the impact of interventions. Gaps in race and ethnicity data continue to exist, necessitating policy action and training for healthcare workers to emphasize the importance of the collection of race and ethnicity data.

Organizations that collect SDOH data report that integrating SDOH data into EHRs is a significant challenge. In one survey, 80 percent of respondents collected SDOH data on homelessness, language, and social isolation, but only half reported trying to integrate the data into EHRs. Policy efforts can be undertaken to create a set of standardized, clinically valid, and actionable SDOH data elements so the data can be collected consistently across different domains.[171]

Another key barrier is the lack of health IT infrastructure to collect, send, and receive SDOH data with CBOs and social service providers. While many healthcare providers make electronic referrals to CBOs, social service providers, or other referral partners, there are not many closed-loop referral processes. This leads to a lack of interoperability necessary to help healthcare organizations that identify social needs communicate and understand the impact of the intervention that CBOs and other resource programs have.[172] Furthermore, public health organizations largely lack the IT infrastructure to support collecting, sending, and receiving SDOH data, necessitating additional standards and infrastructure to ensure secure and private exchange and use of SDOH data. Incentives at the federal level, including funding, technical resources, and infrastructure, are necessary to create connectivity and coordination among healthcare organizations, public health organizations, CBOs, and social service providers at both the local and state levels.

TARGET AREA: USE OF TECHNOLOGIES THAT SUPPORT PUBLIC HEALTH

Gaps in Infrastructure and Standards to Support Data Sharing for Public Health Purposes

There is a need for infrastructure to support data sharing that promotes coordination and standardization across different systems and data sources.

The COVID-19 pandemic highlighted the importance of public health surveillance systems and their limitations. While these systems have been essential in tracking the spread of the virus and informing the public health response, they have also faced challenges related to data completeness, timeliness, and accuracy. The pandemic has additionally revealed disparities in data collection and reporting, with some communities and populations being underrepresented or excluded from data collection efforts.[173]

There are significant gaps in the public health surveillance system. One example is the need for interoperability between different systems and data sources. This can lead to data silos, duplication of efforts, and delays in data sharing and analysis. Another challenge facing public health surveillance systems is the increasing complexity and volume of data. The growth of digital health technologies and the proliferation of data sources have created new opportunities for surveillance and new challenges related to data management, quality control, and analysis. There is also a need to better integrate SDOH data into public health surveillance systems. SDOH data can provide valuable insights into the health needs and disparities of different communities. However, these data are often fragmented and difficult to access. Finally, there is a need for increased investment in public health surveillance systems at all levels. This includes not only funding for data collection and analysis but also for training and capacity building of public health professionals.[174]

Public health surveillance systems need to be improved to be more effective in tracking the spread of diseases and informing public health responses. This includes addressing the challenges of data completeness, timeliness, accuracy, interoperability, and data volume.

TARGET AREA: INTEROPERABILITY

Lack of Consistent Use of Standards by Laboratories and Lack of Pharmacy Connectivity

The lack of consistent use of standards by laboratories and pharmacies creates a barrier to interoperability. There is a lack of infrastructure to support the connectivity of pharmacy data with the broader health IT ecosystem.

Laboratories and pharmacies are two key healthcare actors that face varying challenges to fully participate in the HIE ecosystem.

Laboratory data currently moves through different data systems, creating risk of the loss of meaning of data if the result does not contain consistent or sufficient information. For example, laboratories and health systems often use local codes for laboratory tests that then must be mapped to common terminology standards (e.g., LOINC, SNOMED-CT). In addition, laboratory results are produced from a variety of

instruments and methods which can have different formats or scales.[175] The lack of standardization increases costs and complexity and limits interoperability.[176]

To support their increased role in supporting patient care and participating in new care models, pharmacies need access to relevant patient health information and the ability to share data. Like laboratories, pharmacies were not eligible for incentive funds under the HITECH Act. As a result, their IT systems are relatively fragmented compared to those that received the incentive funds and sometimes are not connected to national or local HIE initiatives.[177]

Information Blocking — Infeasibility Exception

With regard to the information blocking rules, an actor's ability to comply with requests for access, exchange, or use of EHI is sometimes limited.

The infeasibility exception, one of the eight ONC-defined information blocking exceptions, recognizes that legitimate practical challenges may limit an actor's ability to comply with requests for access, exchange, or use of EHI. For instance, an actor may not have—and may be unable to obtain—the requisite technological capabilities, legal rights, or other means necessary to enable access, exchange, or use. To use this exception an actor must, among other things, provide a written response to the requestor within 10 business days of receipt of the request with the reason(s) why the request is infeasible. Some actors have requested more consideration about whether the exception provides enough time for actors to review complex requests and respond in a way that is consistent with the Infeasibility Exception of the information blocking rules.

Information Blocking — Registries

There is some confusion in the health IT industry about if and when organizations that operate disease or patient registries are considered actors under the information blocking rules with respect to providing access to registry data.

The information blocking definition of HIN or HIE is a single, functional definition. The definition does not specifically exclude any particular entities from the definition, nor specifically identify particular entities in the definition. As a result, organizations have to assess whether their functional activity meets the HIN/HIE definition in the ONC Cures Act Final Rule. The health IT industry would benefit from more clarity about if and when organizations that operate disease or patient registries are considered actors under the information blocking rules with respect to providing access to registry data.

Solving Data Linking and Patient Matching Challenges*

The lack of standardized health data linking has resulted in a disparity of interoperability across systems and states. Patient matching when sharing data needs to be improved, especially for vulnerable populations.

Standardizing data linking can improve interoperability across health systems and states by creating richer data combined from multiple sources. No national standard currently exists for data linking, leading to disparities in interoperability. Steps are being taken to address this through the White House OSTP National Strategy to advance privacy-preserving data sharing and analytics. Additional insight from government

agencies that have utilized data linking to connect clinical and claims data and PPRL initiatives can inform the national strategy and the development of standards to improve interoperability between healthcare organizations.

Patient matching continues to present administrative and cost burdens on the healthcare system, with some organizations spending between $250,000 to $1 million per year on identification resolution.[178] Hospitals have also noted that a barrier to sending patient health information is the difficulty of matching or identifying correct patient data between systems.[179] There is significant work that must be done to ameliorate incorrect and missing patient data. Under-resourced 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.[180]

Limited Inclusion of LTPAC in Interoperability

Interoperability needs to be increased across the broader care continuum to include LTPAC providers.

LTPAC providers face challenges in participating in interoperable health data exchange, creating silos between these providers and the rest of the healthcare continuum. LTPAC providers are less likely to use interoperable health IT systems compared to acute and ambulatory providers. This lack of interoperable IT systems and data can lead to issues in coordinating transitions of care and negatively impact patient outcomes.[181] One barrier for LTPAC providers is the cost of adopting and implementing interoperable health IT systems. While periodic inconsistent measurement has occurred regarding the adoption and use of health IT by LTPAC providers a uniform view into the state of health IT adoption and use by LTPAC providers is lacking.[182]

Streamlining of Health Information Exchange*

Gaps in interoperability remain when health organizations rely on multiple methods of electronic data exchange and must coordinate across multiple health systems, health IT systems, and health information networks to enable exchange.

While significant progress has been made in all aspects of interoperability for providers, certain groups are still trailing behind. Small physician practices with less than 50 physicians are two times less likely to participate in HIE and three times less likely to use information from outside sources.[183] Barriers to adoption and use include additional costs, complexity, and administrative burden involved with HIE adoption, workflows, and technology. Rural and small hospitals are not querying, searching, or sending data at the same frequency as their more urban and larger counterparts.[184] Barriers continue to exist even for hospitals that have tried to utilize HIE to send, receive, or find health information to or from other care settings and organizations. Fifty-two percent of hospitals surveyed reported that exchange partners did not have an EHR or other electronic system to receive data and 64 percent reported partners whose EHR systems lacked the capability to receive data.[185]

TARGET AREA: PRIVACY AND SECURITY

Protecting Gender and Reproductive Health Data

The inconsistent legal landscape governing gender and reproductive health data combined with the difficulty in segmenting this data regularly creates barriers to its exchange.

In the changing political landscape with a variety of health data privacy rules, health IT does not sufficiently protect sensitive health data, particularly gender and reproductive health data, putting it at risk of being compromised.[186] As health data move more seamlessly between providers and across state borders due to improved interoperability, they are at risk of being used in criminal and civil legal action against patients, providers, and others in states that ban or severely restrict abortion or gender-affirming services.[187,188] There is a lack of a consensus-based standardized terminology value set to define reproductive health data in alignment with federal and state laws.

Addressing Consent for Sharing Sensitive Health Data

There is a lack of consensus on the key use cases, the definition of sensitive health data, and the path forward to support improved electronic patient consent.

The issue of consent regarding sharing sensitive data is complex, resulting in the need for close collaboration among standards-developing organizations, policymakers, providers, and health IT developers to define key use cases, set standard definitions of sensitive health data, and define a path forward to support improved electronic patient consent capture and exchange.[189,190] Data segmentation, using FHIR® or other standards, offers the ability to choose on a more granular level which information to share but no standard has been widely adopted and proven at scale to enable data segmentation.

Lack of Accounting of Disclosures

Today patients have limited transparency into how their identified and de-identified health data are shared.

With the growth of national networks and the coming expansion of exchange purposes beyond treatment for which data can be exchanged, driven by the implementation of the TEFCA, the transparency afforded by a full accounting of disclosures is likely to become more important to individuals.[191] However, there is currently no widespread adoption of technology designed to provide patients with a full accounting of both identified and de-identified data disclosures.

Improving Cybersecurity Across the Healthcare Infrastructure*

Cybersecurity events continue to block access to health records which can impede patient care.

Cyber-attacks in healthcare are growing in terms of size and damage.[192] Ransomware attacks have doubled from 2016 to 2021.[193] An entire hospital IT system can be rendered offline through an attack on a third-party medical device, which can potentially end life-saving services for patients. In a 2023 study of hospital cyber resiliency, fewer than 50 percent of hospitals segregate their primary networks from third-party device networks, making the larger networks vulnerable to ransomware attacks through third-party

devices.[194] In the healthcare industry, cybersecurity attackers' skills are outpacing those of cybersecurity professionals, and there remains a lack of resources to gain an advantage over cybersecurity criminals.

TARGET AREA: PATIENT ACCESS TO INFORMATION

Limited Guidance for Safety and Security of Mobile Health Apps*

The lack of a uniform public or private approach to oversee the mobile health app field results in inconsistent quality of apps and widely varying privacy and security protections.

Today, there is a siloed regulatory approach to the mobile health app field.[195] While various private sector app vetting efforts exist, there is no authoritative source providing guidelines on the quality of health apps including their privacy and security, clinical validity, and usability.[196] A trusted source for vetting mobile health apps could improve the mobile health app experience, resulting in higher digital health app engagement, more valid clinical recommendations, and better health outcomes for consumers.[197]

Interoperability Concerns about Use of Patient-Generated Health Data*

PGHD can be challenging to transfer into EHRs and time-consuming for providers and patients to access, requiring special effort. PGHD device and software developers are not subject to health IT certification but play a critical role in the ecosystem.

PGHD collected from health apps, wearable devices, and other sources exist in various digital forms that often do not conform to EHR data structures. Updated standards are needed for seamless interoperability between digital devices and EHRs.[198] PGHD sources are regulated by a number of federal agencies but are not subject to health IT certification. In order to access PGHD, providers sometimes may need to access several different portals, which adds time to often overbooked schedules.[199]

Burdensome Electronic Patient-Report Health Record Update Processes*

Transparency about the accuracy of patient data and an easy electronic mechanism to update incorrect data are still lacking.

Increasing numbers of patients access their health records but experience challenges when seeking to correct errors in their records.[200] Accurate medical records are a factor in increasing patient safety and trust. To date, there is no simple technology to update patient records easily or to disseminate updates to those who received the incorrect data.

Need for User-Friendly Price/Cost Data Transparency*

Price and coverage data provided for transparency can be difficult to understand.

Price/cost transparency data provided by hospitals and payers varies widely in how it is displayed and can be unwieldy for consumers to wade through and make sense of.[201] In November 2022, CMS issued a standardized set of data elements that hospitals could elect to adopt for displaying their pricing information. However, there is no current CMS mandate on how this data should be displayed which creates less useful information for consumers.[202] While most health insurers have complied with the Transparency in Coverage

Rule, initial indications suggest the data are unwieldy in size and lack standardized information for providers and drug dosage details across insurers. This lack of standardized data also creates challenges for researchers, employers, employees, and legislators.[203]

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 FY23. However, work remains in these target areas to achieve the full potential of using health IT tools to help transform the healthcare sector. In FY24, 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 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 that 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 Drivers 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.

ABBREVIATIONS

ACO REACH – Accountable Care Organization Realizing Equity, Access, and Community Health

AI – artificial intelligence

AI RMF – NIST AI Risk Management Framework

API – application programming interface

CBO – community-based organization

CDA – clinical document architecture

CDC – Centers for Disease Control and Prevention

CDS – clinical decision support

CIRCIA – Cyber Incident Reporting for Critical Infrastructure Act

CMS – Centers for Medicare & Medicaid Services

CMMI – Center for Medicare and Medicaid Innovation

CURES Act – 21st Century Cures Act

DEA – Drug Enforcement Administration

DMI – Data Modernization Initiative

DSI – decision support interventions

eCR – electronic case reporting

EHI – electronic health information

EHR – electronic health record

ELR – electronic laboratory reporting

FDA – Food and Drug Administration

FHIR® – Fast Healthcare Interoperability Resources

FTC – Federal Trade Commission

FY – fiscal year

HBNR – Health Breach Notification Rule

Health IT – health information technology

HHS – 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

HITECH – Health Information Technology for Economic and Clinical Health

HL7® – Health Level Seven International

HTI-1 – ONC Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing

IIS – Immunization Information System

IZ Gateway – Immunization Gateway

LTPAC – long-term and post-acute care

MIPS – Merit-based Incentive Payment System

National Coordinator – National Coordinator for Health Information Technology

NBS – National Electronic Disease Surveillance System Base System

NIST – National Institute of Standards and Technology

NPRM – Notice of Proposed Rulemaking

NSSP – National Syndromic Surveillance Program

OCR – HHS' Office for Civil Rights

OIG – HHS' Office of Inspector General

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

OSTP – White House Office of Science and Technology Policy

PGHD – patient-generated health data

PHI – protected health information

PPDSA – privacy-preserving data sharing and analytics

PPRL – privacy-preserving record linkage

QHIN – Qualified Health Information Network

RCE – Recognized Coordinating Entity

SAMHSA – Substance Abuse and Mental Health Services Administration

SDOH – social drivers of health

SNF – skilled nursing facility

SOP – standard operating procedure

STLT – state, tribal, local, and territorial

TEFCA – Trusted Exchange Framework and Common Agreement

USCDI – United States Core Data for Interoperability

RESOURCE LIST

ONC Publications

2020-2025 Federal Health IT Strategic Plan

2022 Report to Congress: Updates on the Access, Exchange, and Use of Electronic Health Information

21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking

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

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

Health IT Buzz

Health IT Data Briefs

Health IT Playbook

Information Blocking FAQs

Trusted Exchange Framework and Common Agreement

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