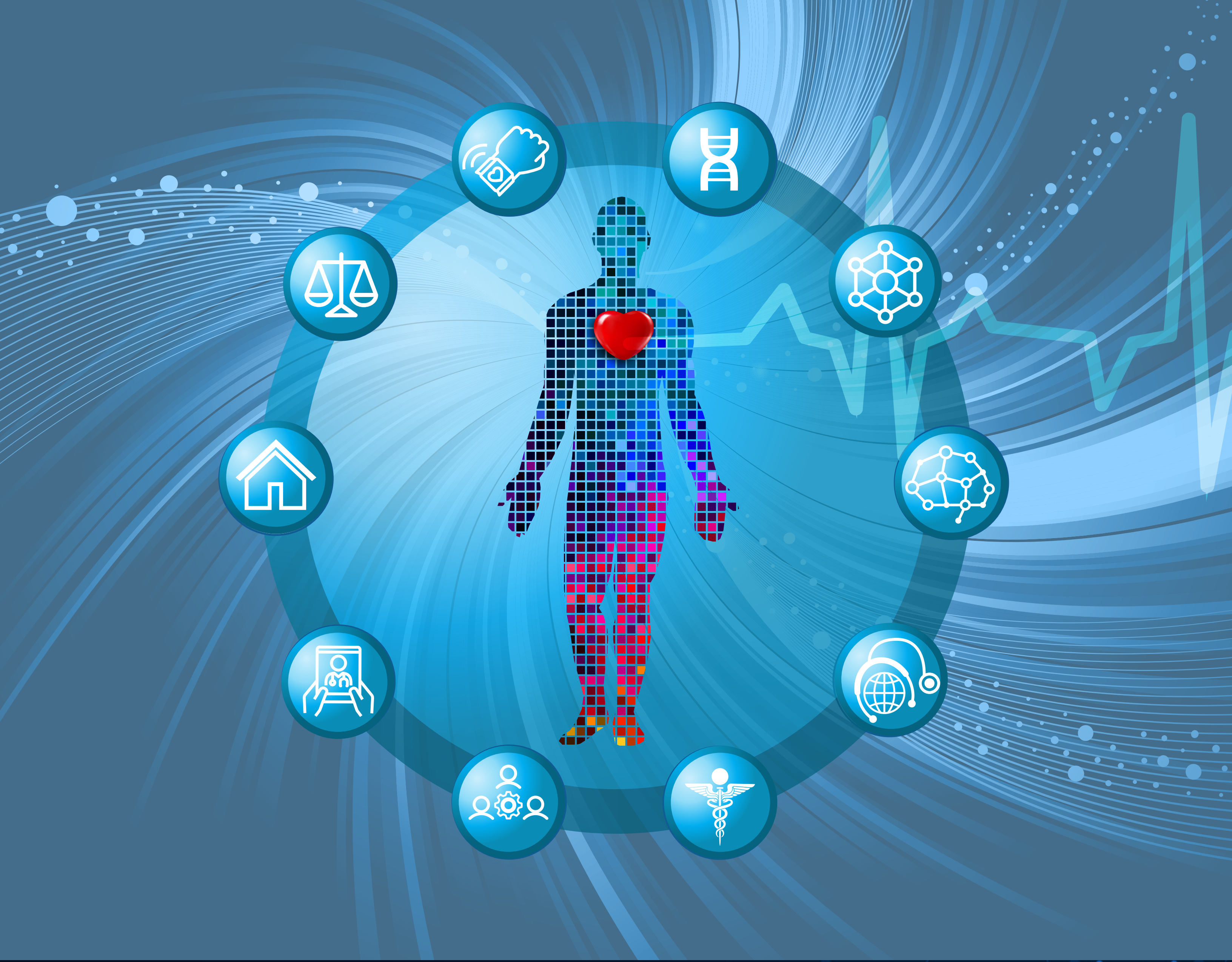

A NATIONAL STRATEGY FOR DIGITAL HEALTH

February 2022

SOLVING PROBLEMS FOR A SAFER WORLD®

Executive Summary

The nation needs a comprehensive strategy for bringing innovation and new technologies to bear.

The technologies referred to collectively as "digital health" are disrupting the status quo of healthcare and well-being, in this country and beyond. In this regard, the COVID-19 pandemic appears to be a watershed. Circumstances drove a surge in use of telehealth, in the process yielding data and potential lessons regarding its delivery, impact, value, and sustainability. The pandemic may yield a transformation that positively affects individuals, families, and communities. The alternative—simply layering digital technologies on top of the current system—will not merely maintain the status quo. It will worsen conditions for those who are already behind in terms of connectivity, digital literacy, and access to care, and will further open the door to abuse, fraud, and waste. That result, in a nation of such wealth and innovative capacity, is unacceptable. The nation needs to act strategically, with full consideration of the distinctive challenges and opportunities that digital health presents.

This strategy offers a framework for guiding the development of the U.S. digital health ecosystem. The strategy comprises six goals, each with recommended actions. Altogether, the goals are aimed at realizing the vision of **improved health and well-being of the nation powered by a digital health ecosystem.**

Goal 1. Form a connected health ecosystem defined by timely, secure data exchange. Semantic interoperability of health data is essential to advancing digital healthcare delivery. A connected U.S. ecosystem will securely and reliably move actionable data on demand to those who need it when they need, which will improve health outcomes. Success in achieving this vision will depend on standardizing formats for patient identification, health data, and health architecture, as well as building a safe, secure, and resilient digital health ecosystem.

Goal 2. Empower individuals to take charge of their health and well-being. Digital technologies and tools should enable individuals to better manage their health and access health information, anywhere and anytime, without special effort. The foundation for achieving this goal is individual ownership of personal health data, complemented by deploying resources to strengthen digital literacy. Digital devices and systems must equip individuals and providers with meaningful and shareable information and enable greater engagement of individuals in maximizing their health and well-being.

Goal 3. Establish artificial intelligence (AI) as a trusted cornerstone of digital health. AI can strengthen digital delivery of healthcare in multiple ways. It can increase the productivity and efficiency of care delivery, allow healthcare systems to provide more and better care to more people, improve the experience of healthcare practitioners, and grow recipients' trust in their care. Harnessing AI requires that its application be trustworthy, characterized by transparency, equity, fairness, and reliability.

Goal 4. Institutionalize rapid sharing of integrated data for public health. Public health authorities and their partners need access to complete, timely data to support decision making. Digital technologies can enable information flow throughout the federated public health ecosystem. Of critical importance is bringing together person- and provider-generated data from the primary care and public health domains. Adopting an integrated and interoperable systems approach to funding public health can sustain these changes.

Goal 5. Build a workforce skilled in application of digital health. A sustainable health workforce will use new technologies to deliver person-centered, integrated quality care. Digital health technologies will enable individuals to receive coordinated and collaborative home and community-centered health services supported by a digitally empowered workforce, across healthcare and social services.

Goal 6. Grow digital equity to achieve health equity. Digital technologies are now foundational for obtaining health services, support, and information. Individuals must be able to access and adopt affordable broadband-enabled technologies and be sufficiently familiar with digital systems to use them for meeting their personal and family health-related needs.

A final component of the strategy is governance. Widespread reform of fragmented and out-of-date governance structures is needed. Strategic investments that avoid duplication, harmonize efforts, and represent a whole-of-nation approach will reap the benefits of digital health. This strategy details the key components of the governance structure required and recommends steps for achieving effective governance mechanisms.

This document is designed to provide leaders with a framework for effecting change. The kind of change involved is wide-ranging—not merely technological, but also political, social, and cultural. Implementation of ideas herein will require a substantial investment of time, money, resources, and—most important—leadership. Other nations are making those investments, guided by national planning. The U.S. must move judiciously, but without delay, to realize the vision for a digital health ecosystem.[1]

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[1] A draft of this strategy was released in May 2021 with the intent of starting a conversation. Throughout 2021, we shared the draft with experts and solicited their feedback and ideas. The 2022 version, no longer marked draft, includes a number of significant changes that reflect the insightful feedback we received and the evolution of our thinking. The Overview now includes a detailed vision for the nation's digital health ecosystem. Goal 1 includes more discussion of needs relating to data and device security and to information integrity. Goal 2 now includes an objective focused on digital health literacy, as well as deeper specification of the objective for individual data ownership rights. Goal 3 is new, addressing needs related to making Artificial Intelligence a trustworthy component of the digital health ecosystem. Goals 4 and 5 have been both streamlined and more thoroughly referenced. Goal 6 has been expanded from a relatively tight focus on broadband access to a broader treatment of health equity. Finally, the Strategy now includes a conclusion that discusses considerations related to implementation and recommends some near-term next steps.

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1. Purpose

Digital health is the convergence of health-related sciences and digital technologies that empower people and populations to manage their health and well-being [1].

An explosion of new consumer- and enterprise-focused technologies has become a disruptive force in how the U.S. population experiences healthcare and well-being. These technologies—referred to collectively as "digital health"—have the potential to transform the current healthcare system, improving outcomes while reducing costs and strengthening each person's experience with healthcare. That potential was illustrated during the COVID-19 pandemic, which created a surge in the use of telemedicine and other forms of digital health. The nation's healthcare providers can draw lessons from that experience regarding, for example, digital health's accessibility and its impact on health outcomes, equity, and costs. The nation can apply those lessons to drive transformation of healthcare, but also must recognize that the transformation will be more than technological; simply layering digital technologies on top of the current system will not lead to large-scale improvement. Success also calls for cultural, political, and social change. The nation needs a strategy for bringing innovation and new technologies to bear thoughtfully, with full consideration of the distinctive challenges digital health presents.

The framework offered here is intended for leaders in the digital health community who are positioned to make change happen—including federal and state government, care providers, community champions, academia, and technology developers. Based on analysis of the current and desired future state, the strategy is organized around six goals and associated objectives to aid in determining priorities and laying the groundwork for change. Strategic action now—while lessons from COVID-19 remain fresh—can transform the health-related experience of individuals, families, and communities. By contrast, delay will allow current problems to persist

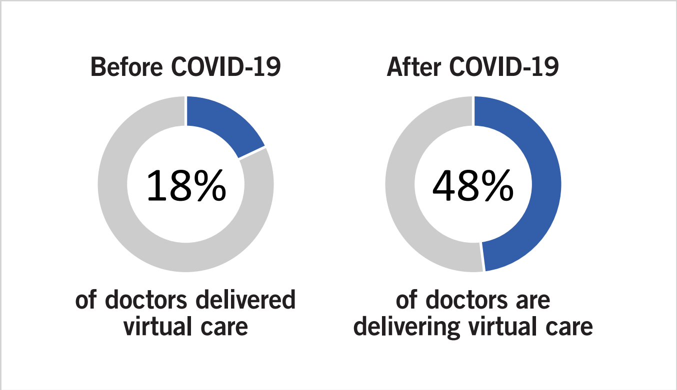


FIGURE 1. DELIVERY OF VIRTUAL CARE

Source: Survey: "Physician Practice Patterns Changing As A Result Of COVID-19," Merritt Hawkins press release, April 22, 2020.

https://business.kaiserpermanente.org/insights/telehealth/covid-19-accelerated-telehealth and possibly worsen. Ultimately, the decision to act or hesitate will have ripple effects that could extend to U.S. national and global security [2] [3] [4].

The MITRE Corporation authored this document, with guidance from the Health Advisory Committee. MITRE established the Health Advisory Committee to engage visionary senior-level executives to guide MITRE and the six federally funded research and development centers (FFRDCs) it operates in identifying innovative solutions to transform the national health and human services enterprise. MITRE addresses healthcare and public health issues through its FFRDC work for multiple agencies, including the Department of Health and Human Services, the Department of Veterans Affairs, the Department of Defense, and the Department of Homeland Security.

2. Strategy Overview

The strategy framework is a set of six broad goals. Section 3 describes each goal in greater detail and specifies objectives that will guide achievement of each. Achieving these goals requires widespread reform of fragmented and out-of-date governance structures, and leveraging the strengths of the public and private sectors. Section 4 provides a thorough discussion and recommended steps for achieving effective governance.

Vision

Improved health and well-being of the nation powered by a digital health ecosystem.

A digital health ecosystem with a highly interoperable infrastructure will promote responsive, data-driven decisions and, ultimately, better health outcomes for the nation. The application of digital technologies will also lead to improved individual and provider experience and reduced costs. The envisioned ecosystem will have the following behaviors:

- Systems containing data related to health and well-being connect and coordinate to make sharing of that data routine, reliable, and secure, whether for care delivery, improved population health, or emergency response. Thoughtful use of standards, including a unique national patient identifier, make interoperability real.
- Individuals have the option to engage fully in managing their health and well-being, empowered by the ability to store, aggregate, and share their electronic health information, and access information and care, anywhere and anytime.
- Patients and providers routinely trust applications that rely on artificial intelligence (AI) to make care decisions; those applications are developed using methods that are non-biased, valid, and well-documented.
- Interventions to promote population health, prevent disease, and respond to emergencies occur earlier and are more effective as public health officials and researchers integrate enormous volumes of highly diverse data, coming from clinical, public health, climate, social determinants of health (SDoH), genomic, and social media sources.
- Members of the health workforce have programs they can use to acquire skills needed to make safe and effective use of digital technologies, while patients, providers and others have confidence that they can access real-time expert care in any setting, including the home or community, even if they live in rural or remote areas.
- The research, design, and development of health-related resources take SDoH fully into account, and integration of SDoH data into clinical and public health systems contributes to reducing long-standing disparities in health and healthcare.
- An equity perspective permeates all facets of the development and implementation of a digital health ecosystem, leveraging digital technologies to ensure positive health outcomes for all.

Vision

Improved health and well-being of the nation powered by a digital health ecosystem

Collaborative Governance

Goals and Objectives

Form a connected health ecosystem defined by timely, secure data exchange

- Standardize patient identification
- Standardize health data
- Standardize the health architecture
- Secure the connected health ecosystem

Empower individuals to take charge of their health and well-being

- Provide individuals with ownership of data relating to their health
- Create a national action plan to improve digital health literacy
- Develop a framework for reasonable use of digital health
- Assess options for reimbursing use of digital modalities
- Analyze impact of restrictions on use of telemedicine
- Further mature the nation's precision medicine capability

Establish artificial intelligence as a trusted cornerstone of digital health

- Create governance for reliable, transparent and ethical AI development
- Apply a maturity model to guide AI development and use
- Support practices that will ensure AI integrity
- Conduct rigorous AI evaluations and establish performance metrics
- Foster informed AI users through certification and continuing credit training

Institutionalize rapid sharing of integrated data for public health

- Develop funding strategies to encourage a systems approach to investment in public health workforce and infrastructure
- Establish a representative governance entity to drive modernization of digital public health infrastructure
- Partner to expand available data and improve reporting to public health agencies

Build a workforce skilled in application of digital health

- Support the National Health Care Workforce Commission
- Invest in upskilling workforce
- Modernize post-secondary accreditation requirements
- Support model programming for continuing education in digital health and data science
- Establish a newly defined digitally-enabled workforce

Grow digital equity to achieve health equity

- Create a new National Broadband Plan
- Ensure community engagement in digital health development and research
- Improve measurement, monitoring, research, and practice to account for inequities and varying levels of access

FIGURE 2. OVERVIEW OF STRATEGY

3 Goals and Objectives

Goal 1. Form a Connected Health Ecosystem Defined by Timely, Secure Data Exchange

> **Health data in the 21st century is too important to remain siloed.**

Health data interoperability is essential to advancing digital health. Section 4003 of the 21st Century Cures Act defines interoperability as “the ability of systems to exchange and use electronic health information from other systems without special effort on the part of the user” [5] [6]. Creation of interoperable systems depends on stakeholder agreement regarding how data is represented and exchanged, as well as assurance that the data is confidential, available, and not corrupted. The outcome is a connected digital health ecosystem that puts data into the hands of those who need it, when they need it, reliably and securely. Such an ecosystem will:

- Allow individuals to access, aggregate, and control their own health data, generated by multiple providers, institutions, and other data sources, to obtain a more complete picture of their health.
- Support coordination of care among a diverse set of family caregivers, clinicians and multiple health and social service providers, across time, and geography, based on comprehensive and current information.
- Enable innovation involving health monitoring devices and patient-generated data that could lead to faster, more personalized care.
- Facilitate robust observational data studies based on larger collections than most traditional clinical trials, including clinical data, SDoH data, and data generated or reported by patients.
- Help achieve faster, more complete, and transparent integration of clinical care data with data used for public health reporting and monitoring.

Current and Future State

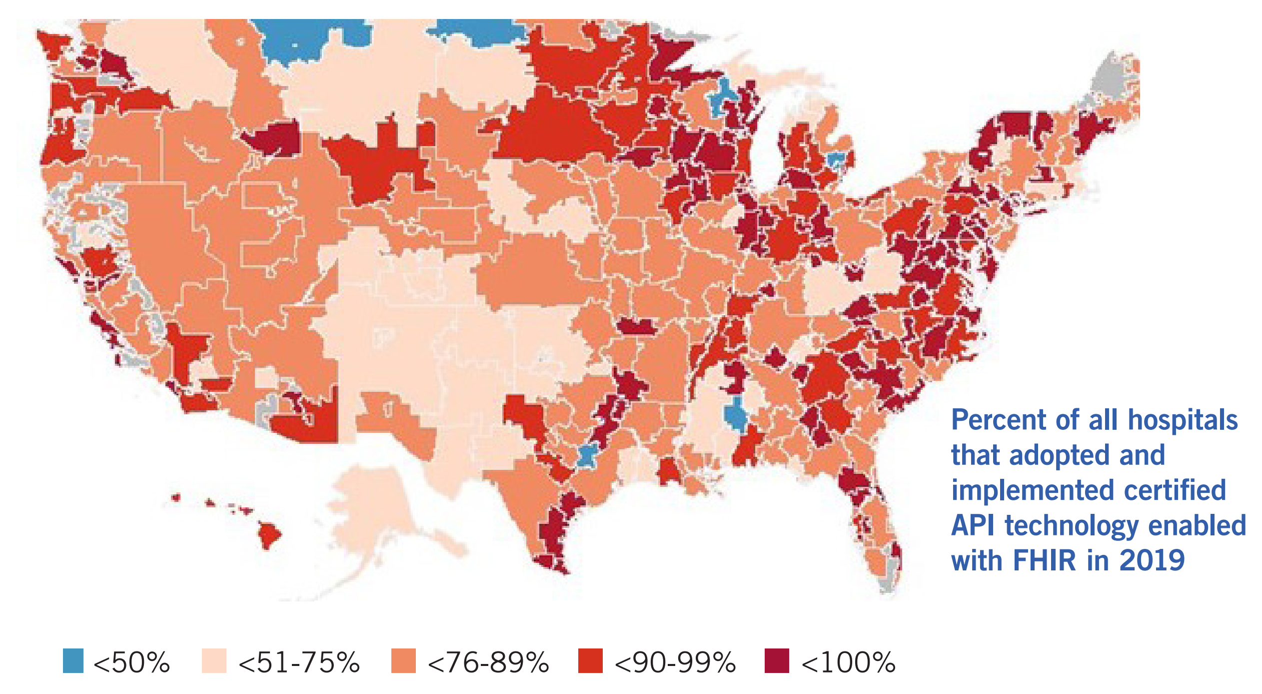
The COVID-19 pandemic revealed the costs resulting from information gaps among individuals, providers, public health officials, payers, researchers, and government agencies. Lives were put at risk because the nation navigated the crisis largely without real-time data on the number and location of cases, availability of hospital resources, or the effectiveness of treatments. Health data in the 21st century is too important to remain siloed.

Many market sectors benefit from common standards, from the shape of electrical plugs to universal airline booking systems. Healthcare also uses standards, but tends to confine them to narrow areas, such as common billing codes and electronic prescribing. Healthcare information is often held within closed proprietary systems, so even though standards exist to represent and exchange information, the data may remain sequestered in practice. Providers and electronic health record (EHR) vendors have incentives to perpetuate this status quo. A tight hold on patient data allows health systems to retain “customers.” Proprietary data formats make it difficult and costly for providers to change EHR and health information technology vendors. Unlocking patient information requires counteracting disincentives for sharing, improving—or in some cases creating—incentives for sharing, and overcoming mismatches between proprietary information systems.

There are signs of progress from the current, fragmented state. Recently, healthcare interoperability has received strong bipartisan support, as demonstrated by the passage of the 21st Century Cures Act [6]. The Cures Act advances data standardization and establishes prohibitions against information blocking: the practice of restricting or limiting the use and exchange of data contractually, through excessive fees, or use of non-standard technology. U.S. government payment incentives for reporting Electronic Clinical Quality Measures (eCQMs) and digital quality measures (dCMS) along with U.S. government regulations requiring the adoption of open standard Application Programming Interfaces (APIs) have provided another impetus for interoperability improvements.[2] Additional pressure has come from value-based programs that provide incentives for coordinated care and penalties for readmissions and other poor outcomes that result from uncoordinated care, poor data management, and exclusive data ownership [7].

The Office of the National Coordinator for Health Information Technology (ONC) reports that as of 2019 most hospitals (84 percent) and clinicians (61 percent) had adopted API technology enabled with Health Level Seven (HL7) ® Fast Healthcare Interoperability Resources (FHIR)®[3] (See Figure 3).

A portion of U.S. residents theoretically have API-enabled access to their data on their smartphones. Still, overall, little has changed for patients and providers. Patients are not informed that they



Percent of all hospitals that adopted and implemented certified API technology enabled with FHIR in 2019

FIGURE 3. IMPLEMENTATION OF FHIR-ENABLED API

Source: HHS Office of the National Coordinator for Health IT, *The Heat Is On: The US Caught FHIR in 2019.* *https://www.healthit.gov/buzz-blog/health-it/the-heat-is-on-us-caught-fhir-in-2019*

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[2] See Objective 1-3 for more information on APIs.

[3] "The HL7® FHIR® standard defines how healthcare information can be exchanged between different computer systems regardless of how it is stored in those systems." FHIR-based APIs are a required part of certified electronic health information technology pursuant to ONC's 2015 Edition Health IT Certification Criteria. Source: *What Is FHIR*, Office of the National Coordinator for Health IT. https://tinyurl.com/2phd7hc7.

can access their health records through apps that use FHIR. Also, organizations do not use these FHIR APIs to exchange records between organizations. Currently, no infrastructure supports, for example, service discovery or grants access to clinicians from other organizations. Creating standards, developing technology, deploying systems, updating regulations, and migrating providers to new technology all take time.

Decisive action on several fronts can accelerate progress toward a connected digital health ecosystem: achieving standardized, interoperable health data; establishing a unique national patient identifier; and ensuring accessibility for patients, providers, and public health systems. Taking advantage of standardized data, researchers and developers will converge to common, best practice queries, which will also increase reliability and validity of the resulting data analysis. Standardization will result in common metrics designed both at a system level (e.g., average mortality rate resulting from a surgical procedure) and at the patient level (e.g., average patient out-of-pocket costs for a particular procedure).

Standardized data and APIs allow standardization of quality and performance measurement and consistent public health reporting (e.g., using dynamic queries composed of Clinical Quality Language, HL7 FHIR, and standardized data elements). Putting core infrastructure data elements in place should drastically reduce the burden of annual eCQM definition. The use of national standard data elements should also significantly simplify and improve traditional public health reporting. In addition, standard data elements used across the nation should make detecting emerging public health threats easier and more reliable. Goal 4 contains a detailed discussion of public health data.

It is important to address the algorithms that power much of essential digital technology. Today's health algorithms are expensive, proprietary, and often trained on the data of a single institution, with little direct portability. Clinical decision support (CDS) systems, eCQM calculators, eligibility and prior-authorization algorithms, claims processing decisions, and AI and machine learning models are often non-transferrable due to foundational layers (i.e., terminologies, data, and APIs) rather than standardized across the nation. In addition, the underlying measures and rules (e.g., payer rules for prior authorization) are often owned by a specific organization and are not shared across institutions. Once the nation standardizes data and APIs (or considerably extends deployment and exchange), the design, development, testing, innovation, and proliferation of open algorithms can flourish and spread rapidly. This will result in more innovation, greater competition, lower prices and cost, and improved workflows.

Standardization of data and APIs is necessary, but not sufficient, to realize the innovations, cost savings, and public health benefits of a connected digital ecosystem. In recent years, the healthcare system has been a target of ransomware attacks that have made data and systems unavailable, caused procedures to be rescheduled and patients diverted, and potentially impacted the integrity of data with patient safety implications. More recently, ransomware actors have engaged in double extortion attacks in which data is stolen as well as encrypted, leading to loss of privacy.

The Cybersecurity Information Sharing Act (CISA) of 2015 recognized the emerging cyberthreat to healthcare and established an industry task force, which delivered its final report to Congress in 2017 [8]. The Healthcare Sector Coordinating Council stood up an industry and government Cybersecurity Working group to implement the recommendations from this report. In addition, CISA 2015 Section 405(d) required the Department of Health and Human Services (HHS) to strengthen the cybersecurity posture of the healthcare and public health sector, which led to the creation of a collaborative effort between industry and the federal government to develop consensus-based guidelines, practices, and methodologies to strengthen the cybersecurity posture of the healthcare sector [9]. The Food and Drug Administration, through a "whole-of-community approach," has taken a leading role in securing medical devices through premarket and post-market cybersecurity guidance, encouraging the adoption of threat modeling, promoting software transparency through software bills of materials, and recognizing the shared responsibility between healthcare delivery organizations and device manufacturers in preparing for and responding to cybersecurity incidents [10]. In addition, the National Institute of Standards and Technology Cybersecurity Center of Excellence collaborates with healthcare, technology, and industry partners to develop practice guides to improve the cybersecurity posture of healthcare delivery organizations [11]. These efforts provide the foundation for building a safe, secure, and resilient connected digital ecosystem.

Objectives

Objective 1-1. Standardize Patient Identification

The U.S. should support the development of a standard national patient identifier for every individual. Sharing information among providers, institutions, and public health agencies requires the ability to track the same person across multiple systems. As simple as this sounds, in practice it has shown a high failure rate, because of variability in the ways of reporting information such as names, addresses, and dates of birth [12]. While provider organizations and clinicians have unique national identifiers, patients do not. Today, matching patient identity across disparate systems requires algorithms that weigh multiple factors and assign degrees of confidence to one or more possible matches. A unique identifier will help ensure patient records can be reliably discovered, matched, and merged across settings, which is crucial to reducing medical errors and facilitating the exchange and matching of patient data. Experience with other identification records, including Social Security numbers, passports, and Medicare beneficiary IDs, and other identifiers (such as credit card numbers) enables the nation to issue a unique and enduring identifier securely and safely.

Objective 1-2. Standardize Health Data

Creating health data standards would ensure data is computable across different repositories and would drive more effective and efficient care and transformation. The U.S. effort to standardize health data centers on the ONC's United States Core Data for Interoperability (USCDI), v1 and v2. The USCDI defines a set of health data classes (e.g., problems and allergies) that are available for exchange [13]. However, someone knowing only what class of health data should be represented would not know how to record specific health data. The current process for dealing with this challenge involves creation and standardization of HL7 FHIR Implementation Guides (IGs), takes years to complete, and yields inconsistent results. Leaders of efforts such as USCDI and US Core, ONC's FHIR at Scale Taskforce initiative, and the new HL7 Implementation Division should agree on a systematic, prioritized, and expedited process. An organized effort will result in the creation of a set of robust, well-defined, and reusable data items at the level of detail needed for semantic interoperability.

Health data standardization should also tackle the challenge of medical terminology. Current practice requires mapping between different terminology systems, which introduces inaccuracies and prevents sharing of health information. If possible, standard practice should be to use open terminologies free of proprietary licensing fees; otherwise, the federal government should provide nationwide licenses for proprietary terminologies.

Advancing the use and interoperability of SDoH data as well as traditional health data is important to improve the health and well-being of individuals and support interventions to protect public health. Data standardization initiatives must continue to build on ONC's current efforts to support the electronic exchange and use of SDoH data by: advancing standards development and adoption for SDoH; disseminating approaches and support for implementation of the needed infrastructure at state and local levels; and exploring electronic data tagging capabilities and clinical guidelines with SDoH for electronic clinical decision support [14].

Objective 1-3. Standardize the Health Architecture

The information architecture for any system is vital to digital health because it provides a blueprint for planning and implementing solutions, and for organizing the sharing of information among systems. Standardizing the health architecture involves two primary actions. First is designating HL7 FHIR as the API architecture for the interoperable exchange of health data for clinical status, workflow, and business processes. Second is standardizing a national Health Information Technology Architecture, to cover service discovery, service brokering, data discovery, data exchange, and other services.

Future success of the digital health system will depend on reliable discovery of and access to a broad range of data via APIs. Therefore, the government should require a common open API architecture for all health use cases—throughout patient, provider, payer, public health, and other health and social services. Additional funding and development must continue to address ongoing scenarios (e.g., prior authorization and provider directory) and expand to those that are unaddressed or unfinished (e.g., patient cost transparency, patient data ownership, patient data use agreements, medical devices). Standards development organizations for APIs should aggressively design efforts to focus on core workflows—not every edge case—to accelerate standardization and adoption. Additional funding and development of improved tooling for IG development, system testing, client and server technology, and app development to facilitate more plug-and-play adoption of FHIR and the standardized health architecture could accelerate adoption of a standardized health information technology (IT) and API architecture.

Objective 1-4. Secure the Connected Health Ecosystem

The transformative promise of a connected health ecosystem will not be realized without ensuring the security and privacy of its operations and data. Patients, clinicians, public health officials, payers, researchers, and government agencies need to be able to trust the integrity and be assured of the availability of the data and services provided.

In this complex ecosystem there is a "digital divide" between poorly resourced and better resourced institutions. Since the ecosystem as a whole is only as strong as its weakest link, to realize the benefits will require resources, training, and technical approaches to ensure the design, development, and operations of a secure and resilient health architecture. This health architecture must be developed in a risk-informed way that balances the trade-offs between safety, security, and privacy.

Interoperable health data standards are key to realizing the ecosystem. To enable secure and reliable data exchange and operational use, these standards must include security, vendors need to implement these secure standards, and there need to be incentives to encourage adoption.

Goal 2. Empower Individuals to Take Charge of Their Health and Well-Being

A critical step in the path toward empowering individuals is ensuring they have the right to own as complete a copy of their information as possible.

The World Health Organization (WHO) defines empowerment as "a process through which people gain greater control over decisions and actions affecting their health" [15]. Empowerment is at the heart of person-centered care (PCC), an approach that emphasizes accounting for the whole person, ensuring individuals can be fully engaged in decisions about their health, and being respectful of each individual's preferences, beliefs, and values. Among the principles of person-centered care are access to care when needed, coordination and integration of care, continuity of care, and full information to use as a basis for making decisions [16]. The person-centered care approach is grounded in the belief that when the individual is respected and empowered to participate in carerelated decisions, satisfaction and health outcomes will improve.

Digital technologies have the potential to empower the individual as part of PCC in a variety of ways. Mobile and other devices allow the individual to self-monitor and manage their health and behaviors that impact their health. The flexibility of care modalities afforded by telemedicine can help ensure access to care when needed, matched to the individual's circumstances. Data interoperability should make coordination among care providers increasingly focused on prevention and more effective and can help make continuity of care reliable and seamless. Finally, the ability to acquire tailored information supported by decision-making tools can provide individuals the ability to better participate in and make decisions about their health and well-being.

Research has already demonstrated that digital technologies are effective in delivery of PCC, with measurable impacts on outcomes [17] [18]. Still, success in harnessing digital technologies to empower the individual as part of PCC requires a strategic approach, consisting of:

- Giving individuals more control over their personal health data, including directing the sharing and exchange of their health data[4]
- Providing individuals with information needed to determine when to apply digital health as part of a holistic plan that includes conventional delivery approaches
- Supporting the individual's ability to use digital health options, through programs to strengthen digital health literacy, as well as policy and law regarding delivery, access, and reimbursement of care
- Advancing the state of precision medicine, which offers individuals a powerful mechanism for tailored care

Current and Future State

Synchronous and asynchronous digital health capabilities are redefining the delivery of healthcare and the experience of managing one's well-being. In the future, individuals will have wide-ranging options to see, compile, and use increasingly complete health information. This will give them the option to build a full picture of their health and well-being, identify patterns, ask informed questions, and generally have more evidence for making decisions.

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[4] See https://www.carinalliance.com/about-us/.

At present, deriving that "full picture" can be difficult, in part because current law and regulations do not consistently enable individuals to control their health data. People unknowingly sign away their rights to data, medical record data is only partially accessible in portals, and information on individuals is routinely aggregated and sold. The ONC Cures Act Final Rule seeks to enable consumers to store, aggregate, use, and share electronic health information without special effort using APIs and apps of their choice. Individuals will be more fully empowered when they have the same rights over their health data as other entities that currently use and benefit from their health information [5] [19] [20] [21] [22].

Today's institution-centric infrastructure will need to give way to a person-centered highly distributed infrastructure, to orchestrate care across time, settings, and geographies. New distributed care models will engage both consumers and providers to direct and evaluate care interventions [23]. Architectural models will be needed to bridge consumer and provider directed care, in person and virtual care. These models will radically reframe the control of health data, its use, reuse, and exchange.

The advent of digital health may bring lower associated healthcare costs, such as reduced travel, less time away from work for the patient, and generally improved efficiency. However, the net cost associated with implementation of digital health—and therefore the overall return on investment—is not yet well understood. The costs for development, integration, training, operations, and maintenance, as well as costs associated with expansion of visits that may be driven by use of telehealth, comprise an important part of the overall picture. The digital health community needs methods and data for building a full understanding of the economics and net costs. In addition, the government must update reimbursement models to account for the role and impacts of digital health technologies and tools.

A key concern regarding digital health devices and services is their safety and security. Virtual visits must maintain patient privacy, Remote Patient Monitoring (RPM) devices must collect and transmit personal health data securely, and devices that deliver therapy must be protected against integrity-related attacks. Second, trust and confidence in digital technologies, devices, and their generated data vary among both individuals and providers. Personal commercial wearables—which have seen enormous growth—are generally identified as "educational" and some providers do not trust the data they contain [24]. Additionally, not all providers have access to liability protection regarding digital health data.

Another concern centers on the individual's capacity and competence for utilizing the digital health devices and other tools, and for processing the volume and variety of data being generated in this digital health era. As with other facets of health and healthcare in this country, digital health literacy differs sharply among various population groups, with negative implications for the health of underserved populations [25]. Research indicates that low health literacy is more prevalent among the elderly, men, racial/ethnic minorities, and low socioeconomic status groups [26]. Higher levels of health literacy reflect higher levels of educational attainment.

Finally, precision medicine (also called precision health) will play a prominent role in the future state for the empowered individual. Precision medicine allows targeted medicines for disease as well as approaches to address individual comorbidities, genetic predispositions, and preventive care. It can empower healthcare providers and individuals to tailor prevention and treatment strategies to individuals' unique characteristics [27]. There is also considerable innovation and growth in digital therapeutics (DTx), which deliver evidence-based therapeutic interventions that are driven by high-quality software programs to prevent, manage, or treat a medical disorder or disease. They are used independently or in concert with medications, devices, or other therapies to optimize patient care and health outcomes [28].

Objectives

Objective 2-1. Provide Individuals with Ownership of the Data Relating to Their Health

Healthcare's primary focus, the patient, has often been denied a seat at the table in the healthcare system.[5] A critical step toward empowering individuals to take charge of their health is securing ownership rights that enable them to store, aggregate, use, and share their electronic health information, including copies of their clinical records, in any way they want.

Research has shown that individuals who have more complete information ask better questions, engage in their care more effectively, and at times may even identify mistakes in their records [29] [30] [31] [32]. Patient data ownership does not mean owning the medical record maintained by a provider, as providers have distinct responsibilities for medical records under state law and payer policies. Ownership rights for the patient can be specified, however, by building on existing laws and regulations to ensure that individuals are empowered while still maintaining the integrity of the provider medical record for treatment and payment purposes [33]. Although patients should be able to incorporate their copies of provider-maintained medical records into their longitudinal personal records, they cannot make any changes to the provider's medical record outside of the Health Insurance Portability and Accountability Act (HIPAA), which allows patients to request corrections. The patient's aggregated record could be annotated without risking the integrity of the underlying clinical records. The key actions needed to achieve this objective include:

- Engage consumer protection agencies and patient advocacy organizations in the development of model plain language terms of service for personal health record applications [34].
- Incentivize the immediate push of a copy of the information gathered in the medical record during a clinical encounter to the patient's destination of choice to ensure the individual's record always remains current with aggregated information from all providers [35].
- Draft federal legislation that harmonizes existing federal data protection laws with recently enacted state data protection laws.[6]
- Explore the risks and benefits of patients being able to license the use of their personal health data, including shared revenue.

Objective 2-2. Create a National Action Plan to Improve Digital Health Literacy

Access to and control over one's data are important features of an effective digital health ecosystem. But individuals will benefit only if they have sufficient knowledge and skills to understand how to use the data they receive—along with fully understanding their rights as consumers of such data. There should be public education and training programs and resources that school systems can adopt to ensure that a minimum level of digital literacy, math and scientific terms or relationships are core to education. These should be supplemented by tools for adults already out in the world. Initiative to accomplish these ends should be part of an action plan for health and digital health literacy, akin to

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[5] See, generally, the Society for Participatory Medicine, https://participatorymedicine.org/

[6] See, e.g., the California Consumer Privacy Act of 2018 (Cal. Civ. Code §§ 1798.100 et seq.) and the California Consumer Privacy Rights Act (Proposition 24, approved Nov. 2020); the Virginia Consumer Data Protection Act (2021 VA SB1392/2021 HB 2307); and the Colorado Privacy Act (Colo. Rev. Stat. § 6-1-1301 et seq.).

the National Action Plan to Improve Health Literacy developed in 2010 [36]. The plan should guide engagement with healthcare professionals, policymakers, consumers, individuals, and families in a multisector effort to identify and address needs for health and digital health literacy.

Objective 2-3. Develop a Framework for Appropriate Use of Digital Health

Part of empowering individuals is enabling them to form an approach to their care and well-being that works for them, based on best available evidence. Virtual care and digital health will not replace conventional care. The healthcare industry will benefit from having a framework it can use to adjust its delivery of care models, to integrate virtual care with traditional in-person care and harness technology to support more and increasingly advanced care in the home and community by a digitally interconnected and empowered community care workforce.[7]

- The increased integration of digital health tools in care will require research to demonstrate their safety, efficacy, feasibility, reproducibility, and sustainability.[8] Analysis is needed to evaluate the use of digital health technologies in multiple care settings (including home and community-based), comparing the experiences of those who have and have not adopted digital health, and assessing barriers to use. Coordination across federal agencies, states, and others is needed to support a cost/benefit analysis of digital health impacts.
- Leverage ongoing efforts of quality organizations to assess if virtual care/digital health supported by home- and community-based providers can deliver the same or better level of quality as traditional in-person care at a similar or lower cost.
- Establish best practices for securing digital health technologies. These practices must ensure confidentiality and privacy, integrity, and availability of these technologies.
- Identify how technology can be harnessed to support the shift away from a "brick and mortar" medical care system to an upstream health promotion approach that meets more of the health and social needs of individuals in the communities where they live.

Objective 2-4. Assess Options for Reimbursing Use of Digital Modalities

The pandemic-driven surge in telehealth usage (see Figure 4) underlines one of the biggest barriers to the greater adoption of digital health technologies—reimbursement. The Centers for Medicare & Medicaid Services (CMS) has eased some of these challenges with the introduction of new Current Procedural Terminology codes to cover telehealth and RPM services [37]. However, the digital health community needs additional regulations and changes to develop a path for greater reimbursement for the use of digital technologies. It will be important to create data-driven models of the effect of reimbursement changes on access, quality, and cost within fee-for-service and value-based care delivery and payment models for digital modalities. The community should also identify new business models to support outcomes that a digital health ecosystem can achieve. For digital services already reimbursed, options assessment should include exploring the impact of different approaches for transitioning payment to value-based care models. For digital services not always reimbursed, the assessment should examine the impact of introducing payment on access, quality, and cost.

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[7] See work supported through the Patient Centered Outcomes Research (PCOR) Trust Fund, including by the PCOR Institute, along with efforts by the Agency for Healthcare Research and Quality to generate evidence on digital health.

[8] Examples of work underway include DIME digital health playbook (playbook https://www.dimesociety.org) and Xcertia, recently purchased by HIMSS (https://www.himss.org/news/himss-continues-improving-health-app-effectiveness-and-safety)

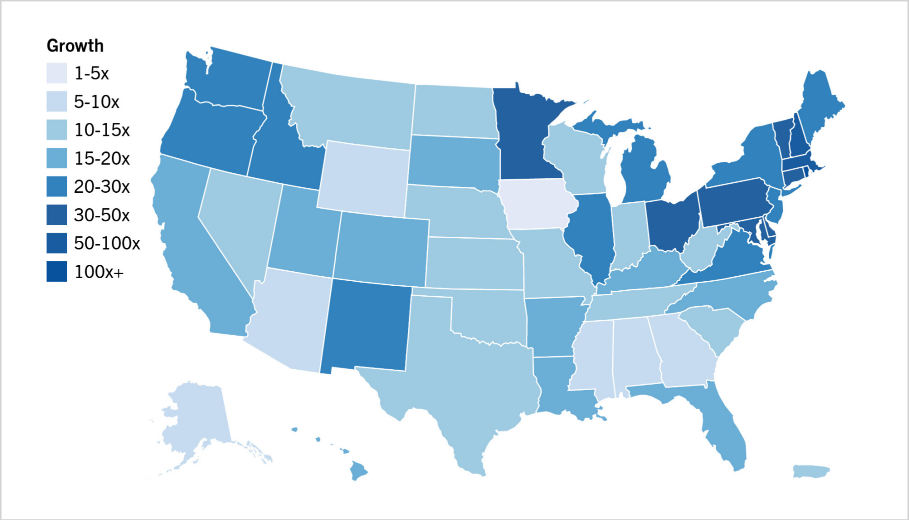

FIGURE 4. GROWTH OF TELEHEALTH CLAIMS

Source: The COVID-19 Healthcare Coalition, *COVID-19 Telehealth Impact Study, https://c19hcc.org/telehealth/,* updated May 2021

Objective 2-5. Analyze Impact of Restrictions on Use of Telemedicine

For synchronous delivery of care via telemedicine, state licensure statutes and other requirements such as state scope of practice laws and facility privileging processes can inhibit care delivery and increase costs, especially for rural providers. In general, providers must have a license from the state of the originating (patient) site and must additionally conform to the scope of practice for that state. Each state requires a given health facility to review its providers' qualifications before granting them privileges to practice in that facility. Analysis of the impact of restrictions should include exploring the effectiveness of interstate licensure compacts agreed to by state licensing boards, in terms of cost, quality, and access impacts to provide data that guides future approaches. In addition, analyzing changes in cross-state licensure, scope of practice, and emergency privileging approaches during the COVID-19 pandemic will build understanding of the impact on cost, quality, and access to provide data that guides future approaches.

Objective 2-6. Further Mature the Nation's Precision Medicine Capability

The country is still in the very early stages of developing a robust capability for precision medicine. Enabling advances and use of precision medicine will depend in part on building key research programs. Examples include the Department of Veterans Affairs Million Veterans Program[9] and the National Institutes of Health All of Us Research Program[10] that create repositories of genetic,

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[9] https://www.mvp.va.gov/pwa/

[10] https://allofus.nih.gov/

clinical, lifestyle, military experience, and other data to advance this capability and ensure that it can be used for diverse populations. Key actions to support achieving this objective include:

- Support the exploration of mathematical and computational techniques that can apply genomic and phenotypic insights to the achievement of an individual's health goals.
- Support programs aimed at increasing genomics literacy and emphasizing the individual and environmental context that is useful to care providers and individuals.
- Ensure security standards, regulations, and processes provide appropriate privacy, confidentiality, and integrity—the lack of which would hamper participation.
- Ensure high-speed networks and interfaces support the transfer of vast volumes of data for collaboration among researchers and clinicians, industry, academia, laboratories, and pharmaceutical and healthcare organizations.

Goal 3. Establish AI as a Trusted Cornerstone of Digital Health

> **We need to make strategic choices about AI, the data we use to support it, the humans creating and using it, and its role in the broader ecosystem.**

AI, particularly in the form of machine learning (ML), can support improvements in care outcomes, patient experience, and access to healthcare services. It can increase productivity and the efficiency of care delivery and allow healthcare systems to provide more and better care to more people. AI can help improve the experience of healthcare practitioners, enabling them to spend more time in direct patient care and reducing burnout. However, successful outcomes rely on the quality and completeness of the data used to develop the algorithms, standardized and repeatable data curation, and an approach that addresses transparency, bias, and trust before the first model is built or the first line of code is written.

Current and Future State

The HHS AI Strategy defines AI as "… the theory and development of computer systems able to perform tasks normally requiring human intelligence, in order to deliver solutions that can automate routine tasks, draw data-based insights, or augment human activities" [38]. Even though AI intersected with healthcare applications long before ML became common, AI, through ML, has recently established a real presence in health [39]. Individual health and healthcare, population health, and public health have realized AI benefits. Individual health and healthcare use of AI can encompass clinical decision support, predictive risk models, more automated claims processing, and capture of the electronic health record [40].

Population health has benefited from the use of smart health devices such as vital sign trackers to predict disease onset prior to more overt symptom manifestation. In public health, AI systems have addressed the tracking and spread of disease since the early 2000s [41] and have experienced a recent resurgence in the form of modeling the COVID-19 outbreak [42].

The digital health community anticipates this trend will increase as AI/ML algorithms and models become increasingly integrated into data workflows to empower more precise diagnoses, better patient outcome prediction, risk assessment for population health, treatment plan management, and payment integrity improvement through fraud, waste, and abuse reduction.

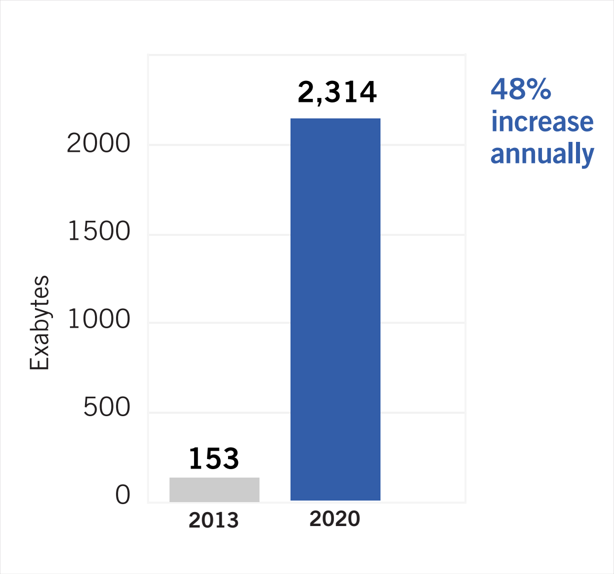

FIGURE 5. EXPLOSIVE GROWTH OF HEALTH DATA

Source: Stanford Medicine, *Harnessing the Power of Data in Health.* *https://med.stanford.edu/school/leadership/dean/updates/healthtrends2017.html*

In general, the digital health community can expect dramatic growth in the volume—and variety—of healthcare and related data (see Figure 5). Application of AI to this data will simultaneously fuel both deeper understanding of the individual and more insights derived from populations [43]. Notably, the digital health community can gainfully apply AI capabilities to unstructured data. This includes analysis of SDoH data to improve identification of risk factors for chronic diseases and outcomes, and address health disparities among underrepresented populations [44].

AI confers many benefits, but also creates many challenges, as recently well documented by the Government Accountability Office [45]. Unlike applications of AI for commercial purposes such as a movie recommendation service, the stakes of errors and bias are high in healthcare uses. The mistakes and inequities that resulted from ill-advised AI development and use have been well documented in recent years, leading to mistrust, confusion, and tragic outcomes [46] [47]. Common forms of misuse include failing to account for historical inequity in the data, capture sufficient data, or understand how outcomes should be defined from the data.

Ethical concerns are also a significant factor, as when testing a model's effects on a population without informed consent, without offering education, opportunity to provide input, or avenues to easily correct erroneous information and outcomes [46]. Properly designed data collection, free of system bias, is imperative for application of AI that is effective, safe, and trustworthy.

Employing any technical approach in the belief that a simple solution will work in a highly complex space presents dangers. High-stakes risks combined with uncertainties in performance lead to mistrust and misuse of AI systems. The digital health community needs to move forward deliberately and collaboratively, making strategic choices about AI, the data used to support it, the humans creating and using it, and AI's role in the broader ecosystem. Future AI systems can and must learn from these costly lessons to lead to higher quality of life for patients, reduced burden on healthcare providers, a whole-patient view of health, and improved population health. As AI systems are applied to the tasks they perform well, such as organizing large, disparate data sets into meaningful information and automating repetitive tasks, they empower health stakeholders to focus their attention, intelligence, knowledge, and skills on improving health outcomes across the ecosystem.

Establishing trustworthy AI systems will require adherence to ethical norms for data quality, data integrity, careful data selection, and model evaluation. Stakeholder engagement and co-creation are critical to successful outcomes and support from the community that AI will affect. That means nurses, doctors, hospital administrators, patients, community members, and patient advocates representing different populations should be full and ongoing participants in the design process. As the field develops, health systems and government agencies will benefit from appropriate AI adoption strategies that help them determine when and how to deploy AI appropriately in daily operations and research. Data scientists and health specialists need to ensure the data quality, coverage, and integrity long before the first model is built.

Objectives

Objective 3-1. Create Governance for Trustworthy AI Development

Establishing norms and processes for trustworthy AI algorithm development ensures that, as the use of AI in digital health proliferates, the possibilities for instability, misuse, unreliability bias, unfairness, or inequity are revealed and evaluated. Such norms and processes encourage more responsible system development prior to training algorithms and prior to their using them within health settings. Governance will provide guidance on determining when an algorithm performs "accurately enough" and how to look for elements of data and implementation that could have adverse outcomes. Specific needs include:

- Develop policies, define standards, and establish norms for trustworthy AI algorithm development.
- Make convening a specialized AI Institutional Review Board (AI IRB) at the organizational level standard practice. This can uphold the norms and define AI system development and use prior to data collection, algorithm selection, training, testing, and fielding of the systems. It may be helpful to link this to an IRB that typically accompanies Protected Health Information/Personally Identifiable Information (PHI/PII).
- Standardize descriptions of AI algorithms and maximize use of plain language. This will enable clinicians and policymakers to know which information is being used to support decisions and identify other possible outcomes to enable informed choices regarding the utility of algorithmic recommendations [48].

Objective 3-2. Apply an AI Maturity Model to Guide Development and Use

An AI maturity model is a framework used to assess an organization's ability to create, use, and manage AI capabilities, ranging from low/immature to high/fully mature.[11] Organizations can apply a model to help determine the best path for developing, governing, and deploying AI. Applying a maturity model will assist government agencies and health systems in determining when to use AI to address challenges to the digital health ecosystem. In addition, it will provide a method for building a roadmap from current practices to the future state that facilitates improved AI development and adoption. Using a strategy that identifies use cases and fosters building systems to fit those uses will enable focused utilization of AI. It also provides the opportunity to address responsible and ethical development of AI-based systems prior to use in health settings.

Objective 3-3. Support Practices That Will Ensure AI Integrity

Applying AI accurately while minimizing bias and ensuring equity depends on the quality and completeness of health-related data sets. In the context of AI and health systems, bias has been defined as "the instances when the application of an algorithm compounds existing inequities in

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[11] As an example, Gartner employs a five-level maturity model for AI: awareness, active, operational, systemic, transformational. https://www.gartner.com/smarterwithgartner/the-cios-guide-to-artificial-intelligence

socioeconomic status, race, ethnic background, religion, gender, disability or sexual orientation to amplify them and adversely impact inequities in health systems" [48] [49]. The sources of data-induced inequity can stem from historical inequities captured in the data; algorithmic bias due to data set imbalance between over-represented and under-represented populations; missing, incomplete, or ill-defined feature values; or inappropriate feature selection. Granting individuals greater rights of ownership to their personal health data (see Objective 2-1) could have implications for data quality, especially completeness, if individuals have wide latitude to restrict use of that data. To overcome these challenges and ensure higher quality AI outcomes requires focusing on data quality through creating, curating, and safeguarding data sets. Specific types of actions include:

- Develop models and enforce governance policies to detect the stability, completeness, and consistency of health-related data sets.
- Facilitate access to high-quality real-world data and synthetic data.
- Institute policies and safeguards such as de-identification techniques for the protection of health-related data sets.

Objective 3-4. Conduct Rigorous AI Evaluations and Establish Performance Metrics

The effectiveness of AI solutions encompasses everything from algorithmic performance to understandability of the presented results. To know if a system is ready for use, performance and effectiveness criteria must specify the minimally acceptable performance thresholds across all relevant populations, such as percentage of false positives or false negatives and handling of unexpected input. Enacting rigorous evaluations will entail creating methods to evaluate the accuracy, dependability, equity, and effectiveness of AI algorithms used for healthcare clinical decision making and public health preparedness. For each use case, the digital health community must establish testing criteria that specify minimal standards for acceptance. These criteria must include performance metrics for the algorithm itself as well as criteria for the user experience, such as the ability to understand algorithmic explanations of results. As part of governance, AI practitioners should be held accountable for smart development practices, whether a system is a clinical decision support tool or software in a medical device.

Objective 3-5. Foster Informed AI Users Through Certification and Continuing Credit Training

Inequitable outcomes or adverse consequences of AI use can be a function of users not understanding the AI outputs or using the system in an unintended way. Continuing education will lead to more responsible AI use by enabling users to understand ways in which the AI-based system should and should not be used and how to recognize when the outputs are not trustworthy. Placing an obligation for providing appropriate training on AI providers enables AI stakeholders to use AI responsibly. Encouraging the AI community to adopt a data science or AI oath will engender the ideal of accountability for capability development [50].

Goal 4. Institutionalize Rapid Sharing of Integrated Data for Public Health

To modernize public health workforce and technology infrastructure, the White House and Congress should pivot to a new way of funding public health.

The digital health community must build an ecosystem that facilitates timely and complete information flow throughout the federated public health ecosystem. Public health authorities and their partners must have timely access to the complete, integrated data they need to promote health, prevent disease, and respond to emergencies. This calls for bringing together data from the primary care and public health domains, as well as other sources of health information. Public health action must leverage and reuse existing standards in a systematic and cohesive way that facilitates data sharing across sectors, jurisdictions, and government. Additionally, effective public health actions require access to widely varying types of data. These changes can be sustained by basing funding for public health on an integrated and interoperable systems approach.

Current and Future State

Typically, public health data flows from local public health departments to state and then federal public health agencies. Assistance provided by federal agencies occurs at the invitation of state and local public health agencies. Due to a lack of federal Constitutional authority for state coordination of public health measures and the absence of any other state-based coordinating entity, the implementation of public health functions is disjointed and distributed, leading to many challenges. These challenges span a wide range of workforce and technical capabilities, as well as variations in the implementation of standards across the country and within states.

Although the U.S. spends more than $3 trillion on healthcare annually, less than three percent of that is directed to public health functions, and that proportion has declined since 2000 [51]. Adjusting for inflation, the Centers for Disease Control and Prevention (CDC) budget—from which the more than 3,000 state, tribal, local, or territorial (STLT) public health agencies receive approximately 75 percent of their funding—has remained almost unchanged since 2008 [52]. As a result, many federal and STLT public health departments lack the resources to maintain or upgrade their informatics infrastructure to leverage new technologies and analytic techniques [53].

In addition, congressional appropriation of funds to HHS agencies does not take a systems approach; rather, it provides project- or condition-specific funding. In 2018 CDC reported that it had more than 100 different surveillance systems and programs receiving data from STLT jurisdictions [54], not including separate reporting to other federal public health agencies that also fund public health activities. Additionally, funding is inequitably distributed among jurisdictions, ranging from $69.25 per person in Alaska to $18.44 per person in New Jersey [55]. This inequity results in different technical and informatics capacity for public health surveillance, preparedness, and response across the country [56]. It also presents challenges for recruitment and retention of highly skilled IT staff, data scientists, and informaticists to support public health agencies' use of their data in new and innovative ways.

Similarly, the lack of a coordinated approach results in differences in how standards are adopted and used across public health jurisdictions. For example, regulatory reporting requirements vary across jurisdictions [57]. This leads to significant burdens on health IT developers to accommodate jurisdiction-specific customizations of EHR systems that will trigger a report when certain conditions are detected in a given record and generate standard messages to accommodate reporting requirements.

Moreover, while the government has devoted much effort to establishing electronic connectivity with healthcare entities, healthcare/primary care and public health are often seen as separate, and consequently the "chasm between primary care and public health" [58] persists. As indicated by the Institute of Medicine:

> Public health and primary care should function as one system … two groups as part of a single system and members of a collaborative team with common objectives—improving population and community health, sharing the same information systems, and serving the same patients and populations at the same time [59].

Primary care data is not the only type of data that has value for public health. The digital health community can derive insights and leading indicators from data related to, for example, SDoH, climate, or agriculture. Such data is likely to be stored in other systems or maintained by other sectors, such as community-based organizations, that are not connected electronically to public health agencies. Data sharing across jurisdictions, with federal partners, and across health-related settings and sectors, is further complicated by a lack of understanding by data-sharing partners of the regulatory scope of public health reporting and HIPAA [60], state-specific privacy laws, and inconsistent data governance rules and data-sharing agreements.

To advance the digital public health ecosystem, the government must base funding for public health on an integrated and interoperable systems approach that leverages whole-of-nation approaches and focuses on population health outcomes [61]. Public health STLT staff should receive training so they can become informed and active participants in the standards development process and in data science communities. This would allow all 3,000+ jurisdictions to leverage the best innovations and data-interoperability practices for rapid and comprehensive public health preparedness and response.

Finally, a governance structure will need to be developed and implemented to realize the potential of a digital health ecosystem for public health. The governance structure will need to unify efforts to modernize the ecosystem, address issues such as the use of standards, and streamline and clarify procedures regarding privacy-focused data sharing and use [62]. It will require that health-related sectors be educated on the new governance strategies to foster best practices during data-sharing activities.

Objectives

Objective 4-1. Develop Enduring Funding Strategies That Encourage a Systems Approach to Investment in the Public Health Workforce and Technology Infrastructure

To modernize the public health workforce and technology infrastructure, the White House and Congress should shift to a new way of funding public health that would include providing funding for execution of a long-term strategy; discontinuing line item-, condition-, or project-specific funding for public health agencies; and funding of a governance entity (see Objective 4-2). HHS agencies should fund STLT health departments in the same systems-oriented way. Finally, MITRE recommends that the White House and Congress also incentivize the timely, bidirectional exchange of complete data between clinical and public health entities. Incentives can encourage electronic information exchange between clinical organizations and public health entities [63], as CMS has done in its Promoting Interoperability program.

Objective 4-2. Establish a Representative Governance Entity That Drives Modernization of the Infrastructure Supporting the Digital Public Health Ecosystem

Given the federated nature of the public health ecosystem and the lack of a federal regulatory public health agency, the digital health community must establish a governance entity that represents all key public health stakeholders. This entity would coordinate the strategic decision-making process required to modernize the digital public health ecosystem. The governance process should ensure appropriate balancing among public health needs under normal and extreme conditions. The digital health community could implement the proposed approach to governance by either expanding the scope of the Digital Bridge Initiative [64] or by establishing a larger, separate entity. Digital Bridge includes the appropriate partners to influence positive change but is limited to advancing small initiatives, such as electronic case reporting, several jurisdictions at a time, and focuses on the connection between public health and healthcare. In either case, enhanced governance should leverage previous recommendations from the Public Health Community Platform [65]:

- Work to build consensus around the use of standards.
- Develop guiding principles to ensure equitable access to health IT among all jurisdictions.
- Highlight opportunities to create system efficiencies.
- Convene data partners and legal experts (e.g., experts in privacy and public health law) to develop strategies for reducing variation in data-sharing agreements.

The digital health community must coordinate implementation of this objective with efforts to establish an overall governance approach for this strategy, as described in Section 4.

Objective 4.3: Partner to Expand Data Available for Public Health Action and to Improve Completeness and Timeliness of Reporting to Public Health Agencies

This objective focuses on ensuring that public health agencies get data needed for them to take steps proactively. Of critical importance is integrating data from the primary care and public health domains, which can be accomplished in part using federal policy and funding levers [59]. Important lines of activity include the following:

- Expanding the volume and variety of data for public health applications is important but may create burden on those who are primary data sources—such as state Medicaid agencies—and on providers expected to process that increased data flow. Multiple public agencies (human services, education, public health) want claims and other health-related data; that demand needs to be managed, such that the right data gets to those who need it. HHS should work with state agencies and providers to specify use cases that drive demand for rapid, timely exchange and interoperability of data. This activity should be supported by analysis from the scientific and policy communities.
- HHS should work with academic institutions, large health systems, and physician associations to incorporate education about appropriate data-sharing practices into accredited clinical training programs and continuing education. HHS can also develop messaging to address misperceptions among public health reporters related to HIPAA and support timely and relevant knowledge transfer among public health and clinical and community partners.
- Finally, the CDC and public health authorities at state, local, tribal, and territorial levels should collaborate to identify options for mandating electronic and complete data reporting via legislation and incentives for CMS Eligible Professionals and Eligible Hospitals.

Goal 5. Build a Workforce Skilled in Application of Digital Health

A diverse, trained, and engaged workforce is the foundational infrastructure for a digital health ecosystem.

Digital health technologies will have an impact on traditional approaches to health occupations, tasks, and functions. These technologies will also enable individuals to receive interconnected and collaborative home- and community-centered health services supported by a digitally empowered workforce, integrated across healthcare and social services. This workforce will provide a broad spectrum of services to meet the health and social needs of individuals in the communities where they live and address SDoH before they lead to or exacerbate chronic illness. These services will include disease prevention measures, caregiving and personal care, nursing, therapy provided in the home, clinical care, home-based primary care, hospital level (acute) care in the home,[12] and hospice at home. As indicated in Objective 4-3, the nation also has a great need to build a public health workforce skilled in the application of digital health, especially in the areas of data science, informatics, IT, and digital communications. Ultimately, a diverse, trained, and engaged workforce serves as the foundational infrastructure for a digital health ecosystem. "Workforce" in this strategy is taken to encompass clinicians; clinical technicians; clinical technicians; clinical program managers; community health workers providing medical, non-medical, and preventive services; and public health, software development, and data science professionals.

Current and Future State

The digital transformation of health and public health systems is underway. The delivery of health education and health services will be driven by increasingly advanced technologies. From EHRs, robot-augmented surgery, the Internet of Things (IoT), and virtual reality, to decision-making supercomputers, technology will play an increasingly important role in healthcare delivery for individuals and populations in the future. In addition, large amounts of data (e.g., clinical, social health, public health, genomic, climate) will be leveraged for better individual and population health.

However, the current workforce is insufficiently prepared to use technology and big data to improve outcomes. Healthcare organizations are moving to address emerging needs (see Figure 6). Studies on the many health workforce disciplines report 30 to 70 percent of health workers lack adequate skills to use digital technology and fully engage with digital information [66] [67]. This has already become a recognized need in both high- and low-resourced countries across the globe, and many countries address it by a call for formalized standards for enhanced training in health information technology [68].

The health workforce comprises a diverse set of occupations and industries. Currently, the demand for all types of health workers in the United States—physicians, nurses, allied health professionals (e.g., medical technologists, occupational therapists, respiratory therapists, physical therapists), home and community-based health workers, and the multidisciplinary workforce of public

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[12] Hospital at Home® provides hospital-level care in a patient's home as a full substitute for acute hospital care. VA hospitals, health systems (including Presbyterian Health System), home care providers, and managed care programs currently implement Hospital at Home® at numerous sites around the United States as a tool to treat acutely ill older adults cost-effectively, while improving patient safety, quality, and satisfaction.

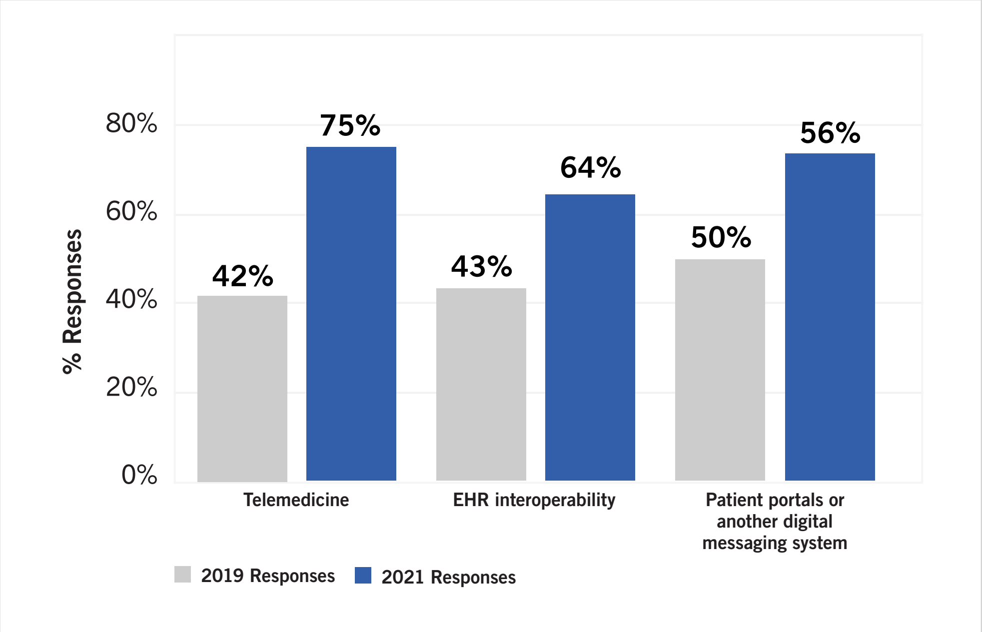

FIGURE 6. WHERE HEALTHCARE ORGANIZATIONS ARE INVESTING TO IMPROVE PATIENT EXPERIENCE

BDO 2021 Healthcare Digital Transformation Survey.

https://www.bdo.com/BDO/media/Report-PDFs/Digital%20Transformation/2021-Healthcare-Digital-Transformation-Survey_web.pdf

health—has far outpaced the supply, and the disparity is expected to worsen with an aging population, increasing numbers of people with chronic illness, and large numbers of retirements. Recent studies show that America will face a shortage of up to 122,000 physicians by 2032 and will need to hire at least 200,000 nurses per year to meet increased demand and to replace retiring nurses. The U.S. healthcare system also has critical shortages of allied health and behavioral health professionals, especially in vulnerable rural and urban communities [69].

As digital technologies continue to be integrated into healthcare delivery and public health, the mix of skills required changes. One essential skill is digital health literacy, the "ability to seek, find, understand, and appraise health information from electronic sources and apply the knowledge gained to addressing or solving a health problem" [70].

All health professionals need a baseline level of digital health literacy, supported with access to continuing education in the knowledge, use, and application of digital technologies. Without an appropriately skilled workforce, the nation will not be able to realize the full potential of digital innovations. In fact, technology may interfere with work, having unintended consequences leading to burnout and early retirement [71]. Barriers to technology use within the existing workforce include:

- Resistance to new ways of working.
- Very limited funding opportunities for existing public health staff to take advantage of academic or fellowship training programs in informatics or data science.
- Absence of digital health literacy skills from existing core and discipline-specific competencies [72].

Clearly, it takes time and effort to learn how to employ new technologies. The capacity and competence of the health workforce cannot be created in a matter of months, but the process must start immediately, focusing on both a pipeline of new health professionals as well as improving the skills of the current healthcare workforce.

Higher education institutions and professional associations must lead the transformation of the health workforce, continually updating and expanding their curricula to include discipline-relevant digital health skills and competencies. This can begin by building on the Workforce Development Workgroup of the EU*U.S. eHealth Work Project, which developed a digital health competency framework to inform required changes in the education of health workers [73]. Specific materials from this project are now available in the Health Information Technology Competencies open-source repository [74]. This work started as a joint effort of the European Union and ONC in 2013. The Applied Public Health Informatics Competency Model, updated in 2016 by the Public Health Informatics Institute, provides excellent competency guidance with working recommendations for the public health community [75]. Applied informatics training programs for public health workers and anyone in a public health informatics role should be certified to ensure a base level of expertise among those filling informatics roles in governmental health agencies.

HHS should collaborate with education and training communities to support expansion of the availability of high-quality courses, programs, and training materials at progressive levels for each professional group. Attention should be given to adapt job descriptions, provide on-the-job training and staff development, and address the acceptance, trust, and useability of the technologies [76].

Following the model of the HITECH Act, which prepared the workforce for EHR implementation, the federal government should evaluate incentives and opportunities to upskill the current workforce for digital health. The HITECH Act funded two distinct health IT workforce training programs: the University-Based Training Program and the Community College Consortia Program, which supported training of more than 20,000 working professionals and students between 2010 and 2013 [77].

Finally, the health workforce should routinely integrate professional and ethical considerations into their daily work. As the volume and movement of personal health data grows, healthcare and public health workers must understand the human and technological aspects of HIPAA, privacy, and data integrity. Training in health IT competence should include the ethical and legal issues of digital technologies and use of data, including privacy, security, liability, and intellectual property.

Objectives

Objective 5-1. Support the National Health Care Workforce Commission

The Patient Protection and Affordable Care Act (ACA) established the National Health Care Workforce Commission, a multi-stakeholder committee to advise Congress and the Administration on how to align federal healthcare workforce resources with national needs [69]. However, the Commission has never become operational. In September 2021, the Bipartisan Policy Center recommended that Congress allocate appropriate funding for the National Health Care Workforce Commission and that the Commission should [78]:

- Perform an analysis of the national healthcare workforce to identify the most critical workforce gaps.
- Quantify the comparative effectiveness of federal workforce recruitment and retention programs.

- Consider how the non-physician and public health workforce, as well as technology, can expand workforce capacity, provide ongoing training, and enable the integration of health and healthcare.
- Make recommendations for addressing workforce shortages, adequate training of faculty, and consolidation of the currently siloed federal workforce programs.

Objective 5-2. Invest in Upskilling Current Members of the Health Workforce

Prioritizing the upskilling of the current workforce is critically important now as HHS develops strategies for creating a pipeline of new employees with the right skills to work in the era of digital health. Any efforts must take care that those new skills and the use of technology do not lead to increased burden on the existing staff. In addition to providing health professionals with knowledge and skills to use and apply digital technologies, training in maintaining privacy and security will be critical. The digital health community should consider any existing incentives and opportunities to upskill the current workforce.

Objective 5-3. Modernize Post-secondary Accreditation Requirements for the Health Workforce, to Include Digital Literacy and Skill Development

Health professionals must possess digital literacy in order to implement digital solutions successfully and ethically. Accreditation requirements must keep pace with evolving digital health technologies. Modernizing post-secondary accreditation requirements must include engaging with professional associations and accrediting bodies to evaluate existing curricula and identify gaps in digital health; developing discipline-specific and appropriate knowledge, skills, and abilities in digital health; and incorporating new knowledge, skills, and abilities into the curriculum of institutions and programs that train the health workforce.

Objective 5-4. Support Model Programs for Continuing Education in Digital Health and Data Science

Model programs must be agile, adaptable, and ready to respond to rapid changes in digital health and focus on ways to reduce staff burnout. All efforts to support model programs for continuing education should inclusive of learning needs for intra- and interdisciplinary training in clinical and public health informatics, software development, and data science, to build team-based practices. Both upskilling and continuing education efforts should seek to seamlessly integrate digital health into patient care for improved health outcomes. Efforts should include:

- Support discipline-specific assessments of the health workforce with respect to digital health knowledge, skills, and abilities and perceived level of IT-related burdens.
- Engage professional associations, licensing, and accrediting bodies to create a compendium of model continuing education programs to address gaps in knowledge and skills as well as implement methods to improve efficiency, reduce burdens on the workforce, and mitigate provider burn-out.
- Promote these programs through health workforce organizations as well as organizations devoted to digital health, such as the Healthcare Information and Management Systems Society and the American Telemedicine Association.
- Develop public health data science, informatics, and IT certification boards, like those that exist for other public health disciplines such as infection prevention and control and healthcare epidemiology, to ensure that domain experts stay at the forefront of advances in the field, as the American Medical Informatics Association has done.

Objective 5-5. Establish a Newly Defined Health Workforce Representing Diverse Backgrounds and Communities

Health informaticians and data scientists integrated into healthcare teams can leverage their expertise with health data to address complex issues, and improve quality, safety, and patient outcomes. They can mine and interpret data to give clinicians and providers key insights that help them make informed decisions on the delivery of care, create evidence-based individualized care plans, realize operational and managerial efficiencies, and develop IT-based innovations. Closing the gaps between technology and processes may help decrease the provider burden that often accompanies adoption of new technologies and reduce burn-out and turnover [79]. In addition, a digital health ecosystem must have a diverse workforce that includes health staff who address preventive factors "upstream," as well as in-home and community-based health workers. These staff will be integrated with healthcare providers to form a care team that can work together with support of digital technologies that facilitate interdisciplinary communication [78] [80]. The efforts that will help to attain this objective include:

- Create employment vehicles for data scientists and informaticians working in traditionally under-resourced healthcare and public health organizations.
- Create scholarship and loan forgiveness programs to make health and public health organizations attractive employment opportunities, while addressing much-needed increases in capacity.
- Provide direct federal and state grants to public health organizations so they can foster this expertise in their organizations.
- Establish and scale a universal home care worker family of jobs with career ladders and associated training.
- Scale the engagement of community health workers and peer providers through certification, training, and reimbursement.

Goal 6. Grow Digital Equity to Achieve Health Equity

Focusing on health equity in the digital era is non-negotiable if we are striving to leave no one behind.

As the COVID-19 pandemic powerfully illustrated, digital technologies have become foundational for obtaining health services, support, and information. Individuals must be able to access affordable technologies and possess the digital literacy to use them for their personal and family health-related needs. The literature has called both broadband connectivity (which, per the Federal Communications Commission [FCC], includes access to and adoption of high-speed internet services) and digital literacy "super social determinants of health" [81] [82] [83] [84].

The pandemic also highlighted that access and digital literacy are not equitably distributed. Digital equity—described as "a condition in which all individuals and communities have the information technology capacity needed for full participation in our society, democracy and economy"—is a core component to achieving health equity [85]. The pandemic underscored the strong link between digital and health equity. As the digital health community implements this strategy, it should consistently view development and implementation through the lenses of race/ethnicity, gender, age, disability, class, and social justice to ensure it creates a new system that does not increase health inequities, but instead eliminates them.

Current and Future State

The current state is one in which access to digital resources varies along several different socio-demographic dimensions, including income, race/ethnicity, rurality, Veteran status, disability status, age, and identity. Wealthier families are ten times more likely to own computers and have access to high-speed internet than lower-income families [86]. The role of income disproportionately affects LGBTQ+ people, who have a poverty rate of 21.6 percent, which is much higher than the rate for cisgender people of 15.7 percent [87].

Disparities by race and ethnicity persist, with a recent study showing 80 percent of White adults reported owning some type of computer, compared with 69 percent of Black and 67 percent of Hispanic adults [88]. Similar gaps are driven by age [89]. For LGBTQ+ elders, connectivity is critical as these adults are less likely to have partners or children, and connectivity is a critical way of getting support [90].

Despite narrowing of the digital divide over the past decade, a gap persists between rural, urban, and suburban areas. Rural residents are least likely to have broadband connectivity, though much larger numbers of urban residents lack it [91] [92]. Some 41 percent of people living on tribal lands in the U.S. lack access to high-speed internet [93].

Persons with disabilities have approximately half the rate of internet access compared with people without a disability. Some 62 percent of adults with a disability say they own a desktop or laptop computer, compared with 81 percent of those without a disability [94]. A substantial number of Veterans suffer from a disability, reside in rural areas, or are older than the general population. The combination of these demographic factors means that many in the Veteran population have lower rates of access to and adoption of broadband services [95].

The digital health community must also understand that the technology research and development process has often excluded vulnerable and underserved communities. This impedes the ability to generalize study results and make medical advancements in effective therapies. It also prevents some populations from experiencing the benefits of research innovations and receipt of high-quality care [96].

To have a positive impact on health equity, the digital health community must first make it a priority, and current activity by the federal government plays a large part in that step. Advancing a comprehensive approach to "equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality" is now a major emphasis for the federal government as well as a broad range of public and private sector stakeholders [97]. New executive orders require that every federal agency assess whether its programs and policies perpetuate systemic barriers that affect people of color and other underserved groups [98]. In addition, President Biden charged the U.S. Domestic Policy Council with coordinating across federal agencies to identify underserved communities and create policies supporting equity. Also, the director of the Office of Management and Budget and agency leaders must conduct assessments to classify barriers to obtaining access to federal benefits, services, and contracts and measure equity based on race, ethnicity, religion, income, geography, gender identity, sexual orientation, and disability. At the agency level, an initiative of the FCC's Connect2Health Task Force will foster further research and increase recognition of broadband connectivity (i.e., access and adoption) as a social determinant of health.[13]

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[13] https://tinyurl.com/2p8ev5pf

Increasing evidence shows a strong relationship between broadband connectivity, internet adoption, and health status or improved health outcomes.

The future needs to bring more inclusive research paradigms. The digital health community should accord priority to analysis of the uptake of, use of, and reaction to digital health by groups that have historically not benefited from medical innovation. That analysis should be grounded in culturally responsive methodologies and support the creation of appropriate policy recommendations and strategies to advance the use of digital tools to achieve equity.

Moving forward using evidence-based approaches, digital health offers an unprecedented opportunity to help reduce disparities in healthcare access, quality, and outcomes. Focusing on health equity in the digital era is non-negotiable if the United States seeks to enable all individuals, families, and communities to achieve their full potential for health and well-being [99] [100] [101].

Objectives

Objective 6-1. Create a New National Broadband Plan

The FCC developed the most recent broadband plan (Connecting America: The National Broadband Plan) in 2010 [102]. Given the reliance on broadband by all individuals and communities, the nation needs a new plan to:

- Consider the expanding needs and widening digital health disparities among U.S. communities while also recognizing significant technological advancements over the past decade and opportunities to ensure universal access to broadband and other infrastructure.
- Provide opportunities for all communities to participate in a broadband-needs assessment and proposed interventions.
- Create an accurate mapping of broadband availability and speed.
- Include broadband capability as part of a larger plan to develop “smart” communities [103].
- Create a government-wide approach to broadband adoption and affordability that replaces the current approach to broadband infrastructure, which is fragmented across the government and sometimes not aligned across federal agencies.

Objective 6-2. Ensure Community Engagement in Digital Health Development and Research

Engagement of diverse populations is essential in designing, evaluating, and adapting technology-based interventions aimed at improving health. Engagement with affected populations must occur at all stages of intervention design, implementation, and evaluation. Community engagement is an evidence-based and critical means to bring overlooked communities into the development of the digital ecosystem [99]. To this end, the digital health community should:

- Ensure standards-based development and design of digital tools.
- Involve diverse and inclusive teams that have firsthand community knowledge and lived experience in developing digital solutions.
- Implement community-based participatory design principles to create digital solutions with rather than for the community [104] [105].
- Ensure that digital health teams consider all access issues as they develop digital tools, including the language needs of the population, literacy levels, and accessibility, as well as solutions that do not require a smartphone [106].
- Support the implementation of “digital clinical trials” that leverage digital technology to improve participant access, engagement,

trial-related measurements, and or interventions; enable concealed randomized intervention allocation; and provide for participation by underrepresented communities in research.

Objective 6-3. Improve Measurement, Monitoring, Research, and Practices to Account for Health Inequities and Varying Levels of Digital Access

Tracking progress toward health equity requires continual capture of indicators to monitor access to digital technology, use of that technology, and skills of diverse populations. Multiple stakeholders share this responsibility, including federal program leaders, community leaders, technology developers, and researchers. Actions should include:

- Enhance measurement of successes and failures in digital access and equity and diffuse areas of learning.
- Identify and apply a systematic approach for assessing equity impacts of digital health interventions [107].
- Design health equity metrics appropriate to enhancing measures of digital health.
- Ensure that analysis includes a focus on different populations that have faced unique historical barriers and appropriately customize solutions and design targeted initiatives to meet the unique needs of these different populations and communities.
- Take steps to minimize bias in AI and the underlying algorithms. See discussion in Goal 3.

4 Governance Designed for the Complexities of Digital Health

Declaring digital health a national priority would be a valuable first step to establish momentum for a national strategy.

Organizations and health consumers must decide how to best integrate digital technologies and use large amounts of data to drive better health decisions and outcomes. The volume, variety, and sources of data generated are complex and change constantly as the ecosystem comes to encompass new resources, innovative technologies, and previously overlooked users. In the face of this rapidly changing and highly complex environment, the digital health community must have a governance mechanism to guide the many decisions that must collectively support an effective, safe, secure, ethical, and equitable ecosystem. Strong governance makes the specific roles and responsibilities of each actor explicit; ensures collaborative development of legislation, policy, and standards across the digital health enterprise; promotes good coordination mechanisms and decision making; and incorporates incentives to use digital health solutions. The need for good governance spans all levels—federal, state, local, and tribal levels as well as the private sector. Cohesive policies are required to (1) address data protection, privacy, information security, and patient rights and responsibilities; (2) establish protocols and standards to ensure interoperability of systems and alignment of quality measures; and (3) ensure our national health security.

Need for a New Governance Structure

Multiple challenges and opportunities for health delivery, resource planning, and national response systems demonstrate the need for implementing an updated governance structure.

Fragmented, Outdated, and Competing Regulations on Data Privacy, Data Security, and Data Sharing for Users

Different agencies currently are responsible for regulating different aspects of digital privacy and security, different industries that use and generate data, and different types of data, creating gaps in oversight and confusion about how to interpret and apply the rules. For example, separate federal privacy laws govern different aspects of data privacy. HHS enacted the HIPAA regulations that contain a data-breach notification requirement, which requires that covered entities notify the affected individuals within 60 calendar days after discovering a breach of "unsecured" PHI [108].

The Federal Trade Commission (FTC) also has implemented a rule mandating notification of a health data breach, but it is reactive only and to date has produced no meaningful consequences [109]. State laws add to the complexity of the regulatory framework governing data, particularly regarding data breaches and the recognition that widespread collection of personal information can endanger individuals' privacy and security. Starting with California in 2003, 49 states have passed laws requiring government agencies or commercial organizations notify individuals if their information has been compromised. These laws contain different, and often incompatible, provisions regarding the type of information protected, the entities covered, and the definition of "breach."

Burdensome Reporting and Impractical Payment Models

Existing regulations and reporting mechanisms fail to align requirements between agencies, and reimbursement models do not meet the needs of a digital health ecosystem. This creates burdensome reporting requirements, leads to inefficient operations, increases liability, and decreases consumer confidence. As discussed in Goal 1, siloed information systems and lack of interoperability or data standardization between systems exacerbate these impacts and reduce interoperability.

Dated Models and Processes

Out-of-date funding models do not account for healthcare provided in a digital society. Similarly, the digital health community lacks business models and processes that support self-management and ethical practices. Similarly, the nation lacks an appropriate legal framework for the complex intersection of sensitive data, electronic records, information security, system interoperability, patient rights, user responsibilities, contractual provisions and arrangements, and accepted risks.

Future State

The state envisioned for the nation's digital health ecosystem will require a sustainable and robust governance structure that encompasses a whole-of-nation approach. This structure will establish a collaborative regulatory framework led by federal agencies in partnership with state, tribal, and local governments, the private sector, professional associations, academia, and others. A collaborative structure will foster cohesive policies that safeguard data, support data stewardship, and ensure privacy while providing ethical data access and usage for timely data-driven decisions and planning. Robust governance will promote technology that supports high-quality PCC and the quadruple aim of improving population health, increasing patient satisfaction, reducing per capita healthcare spending, and enhancing the job satisfaction of clinicians and staff. Key actions that the federal government must take include [110]:

- Ensure that consumers are protected, including ensuring the privacy, safety, and security of data and digital health tools.
- Develop and recommend standards and promote their adoption through policy levers that incentivize their adoption and use and support educational efforts in their use.
- Bring together stakeholders and experts to identify digital health-related issues and strategies to address them.
- Fund research and development to continually assess the implementation of digital health, key challenges, and strategies to address them, and best practices.

Lessons learned from the COVID-19 pandemic can shape a framework to identify and clearly define specific roles and responsibilities of each actor within the digital health governance structure, allowing for effective oversight and enabling the government to address gaps. A new framework should also provide for the integration of non-clinical data to enable decision making for individual and population health. Consumers, clinicians, and organizations using health and SDoH data will benefit from a more comprehensive regulatory approach. Clearer guidelines dictating when and how organizations can use data and inform consumers about the use or transfer of their data, how that data should be handled and maintained, and what should be done in the event of a data breach will improve consumer confidence. Such guidelines will also benefit clinicians by alleviating concerns regarding individual responsibility.

Path Forward

Step 1: Declare Digital Health a National Priority

Declaring digital health a national priority would represent a valuable first step to establish momentum for a national strategy. The declaration would serve as a meaningful political and policy tool, signaling a national commitment to digital health and to aligning government and private sector priorities.

Step 2: Establish an Entity to Create a Governance Structure Applicable Across the Digital Health Enterprise

The federal government should establish a multi-stakeholder entity responsible for creating and managing a comprehensive governance structure. It would comprise representatives of multiple government agencies, including HHS, ONC, Food and Drug Administration, FCC, Veterans Administration, and Department of Defense; state and local agencies; and non-government stakeholders from the private sector, academia, and professional associations. Lessons learned from the pandemic response would inform this entity's actions. Its responsibilities would include:

- Develop a task force or consortium to inform and coordinate efforts across the federal government, perhaps as a White House Executive Office initiative.
- Capture and apply feedback about the governance process.
- Advise on regulatory, legislative, and policy initiatives.
- Define obstacles to the application of a trusted digital health ecosystem.
- Inform decisions on health priorities and resource planning.
- Establish a Center of Excellence to embed best practices, regulatory recommendations, and ethical guidance and to support governance processes.

Step 3: Define Explicit Roles, Responsibilities, and Rights That Promote Accountability, Ethical Use of Data, and Appropriate Protection of Data

Congress enacted HIPAA in the late 20th century when the health information environment was primarily paper based and before the explosion of digital health tools; it has not made any major updates in the past 20 years The current privacy laws, including HIPAA, the Genetic Information Nondiscrimination Act, and the HITECH Act, require revisions to meet the privacy and security challenges created by digital health, including the protection of data. In developing new laws and regulations protecting the privacy and security of data, the digital health community must:

- Convene stakeholder groups and define roles, responsibilities, and rights of stakeholders within the ecosystem.
- Take a whole-of-nation approach, including private citizens as well as stakeholders beyond the healthcare sector such as providers addressing SDoH, researchers and digital tool developers.
- Ensure patients, caregivers, and health decision makers actively provide input into the governance model and remain at the center of the governance conversation.

Step 4: Develop Actionable Guidelines That Create a Culture of Respect and Responsibility and Drive Ethical Stewardship of Technologies and Data Use

Timely and reliable data drives decisions that impact health. Governance must address conventional data derived from the clinical context as well as emerging types of health data, including patient-generated health data (e.g., derived from wearables), data from medical devices, data generated outside clinical settings (e.g., transaction/browsing histories, social media, and environmental data (climate and SDoH). Governance also must include a framework for overseeing the responsible application of AI and its impact on all relevant stakeholders, and ongoing monitoring of its use to determine effectiveness, risk, trustworthiness, and return on investment. The following actions will develop an evidence base to drive policies and standards regarding the use of digital technologies:

- Establish consensus-based, comprehensive foundational principles that provide a strong, transparent, and inclusive governance process. Principles currently included in the “Ethical Framework for the Use of Consumer-Generated Data in Health Care” could serve as a starting point for development and consensus [111].
- Leverage the consensus-based principles to write guidelines that drive actionable stewardship of digital health and include ethical use of health data in technologies such as AI, predictive modeling, and big data analytics.
- Enhance consistency in standards in algorithm development. The underlying data must be accurate, complete, free from bias, and not otherwise flawed. See detailed discussion of governance for AI in Section 3-1.
- Establish guidelines for the development of digital health tools to ensure the tools meet feasibility and usability requirements for diverse populations (e.g., those with mental or physical disabilities).

Step 5: Support Operationalizing Digital Health Guidelines

As guidelines are developed, putting them into practice will involve several steps:

- Establish a collaborative environment for policy and investment management discussions based on the Federal Data Strategy [112] and built on the commonality of stakeholder organizations.
- Establish ethical and business approaches, processes, and practices for data sharing, data exchange, and analytics to enhance interoperability.

- Empower users of health and SDoH data through education and transparency about the potential implications and consequences of data use, so they can make informed decisions about sharing, disclosing, using, and stewarding data.
- Establish collaborative structures to preserve, disseminate, and build on institutional knowledge, improving accurate interpretation and ethical use of data.

Step 6: Incrementally Incorporate Governance Structures into Law

The legislative process at both the federal and state levels takes time. Prior to drafting and moving to enact legislation, policy leaders in the digital health community must evaluate and understand the economic impacts and outcomes that the legislation is intended to achieve. The institutionalization of a governance structure for a digital health ecosystem should include several steps:

- Draft model legislation that aligns and harmonizes governance structures at all levels—local, state, and national, as well as within tribal nations and territories to reduce conflicting processes, guidance, and regulations and improve oversight functions, while remaining mindful of federalism issues and jurisdictional differences.
- Develop a coordinated federal/state policy framework to support use of digital technologies, agree on appropriate uses of health data, and articulate requirements for data sharing, quality and accuracy of health information, data ownership, ethical use of data, and use of data for public health needs.
- Ensure an appropriate balance between public health needs under normal and crisis or emergency conditions. Systems must maintain steady resourcing and response during normal public health operations; those same systems also must trigger and support "surge" conditions in times of crisis or national response.
- Empower tribal, state, and federal agencies and private sector organizations to adopt practices consistent with the guidelines and standards recommended by the entity tasked with creating them.

5 Initial Thoughts on Implementation

> **We need to move thoughtfully, but without delay, to realize the vision of improved health and well-being of the nation powered by a digital health ecosystem.**

This strategy identifies the components necessary for a robust and effective digital health ecosystem. It also describes the key actions to be taken to ensure that those components are well-established and sustainable. The kind of change contemplated with this framework is more than technological—it is cultural, political, and social. It will originate from multiple sources, involve varying sets of stakeholders, and be driven by a diverse community of leaders—from federal government, state agencies, care providers, community champions, technology developers, and academia. Though unlikely to be "owned" by any one organization, the change needs to be coherent, and oriented to a shared vision. That is the purpose of this strategy, to be a resource that all leaders can consult and apply to guide their actions.

Regarding implementation of any ideas provided herein, a vital consideration is resourcing. Along with incentives for achieving the goals, the digital health community must take into consideration current policies and economic structures that may disincentivize digital health.

Successful implementation will depend on identifying and addressing:

- **Where funding/reimbursement have fallen short before.** Through various initiatives, federal and state governments have provided incentives for numerous digital health tools and technology. In some instances, these incentives have achieved exactly what they intended; in others, they failed to achieve their intended outcomes, or they left out certain sectors and actors. To attain these goals, stakeholders cannot simply throw money at the problem but should begin by evaluating what incentives have and have not proved successful in the past, identifying best practices and lessons learned.
- **What policies and economic incentives currently represent barriers to the goals and how to overcome these barriers.** Both explicit and implicit disincentives also impact the use of digital health tools and technologies. Thus, along with examining incentives, stakeholders should also explore economic disincentives for data sharing.[14]
- **Any additional financial or resource burden placed on providers, payers, and public health entities, and the policies and funding mechanisms to alleviate these burdens.** To determine the appropriate incentives, stakeholders must evaluate the relative and collective burden of any digital health requirements and the associated incentives, which may vary. Thus, incentives should not be a "one size fits all" solution but should be tailored to the burdens and pain points of specific stakeholders.
- **Ongoing funding and reimbursement policies.** Finally, when evaluating the policies described above, the digital health community should create corresponding policies and investments, not one-time activities, based on the ongoing needs of stakeholders. Stakeholders should implement robust monitoring and evaluation and continuing improvement plans to glean lessons learned and adjust policies, incentives, and disincentives accordingly.

Another implementation consideration is the need to track progress toward the vision. One function of a governance apparatus should be developing and operationalizing an evaluation framework to identify a myriad impacts, cost-effectiveness, and benefits of all portions of a digital health ecosystem. The community must use an iterative, interdisciplinary, user-centered design approach in developing this framework [113]. It must also examine the returns on investment from the perspectives of individuals and of providers, and across each of the goals of this strategy. It must develop key performance indicators—metrics used to measure processes and outcomes—for each goal and its respective objectives and across the overall strategy as individual goals are integrally linked to the others [114].

Finally, as a first step for acting on the ideas offered here, MITRE recommends a series of roundtable conversations, each centered on a core challenge. Each roundtable would bring together a cross-section of stakeholders and, using the strategy goals and objectives as a framework, identify specific actions for addressing the challenge. The roundtables should be cross-agency, involve the public and private sectors, and prioritize identifying collaborative, whole-of-nation solutions.

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[14] As an example, the 21st Century Cures Rule explicitly prohibits information blocking because of health IT vendors' unwillingness to share patient information with competitors.

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Appendix A Acronyms

Term	Definition
AI	Artificial Intelligence
API	Application Programming Interface
CDC	Centers for Disease Control and Prevention
CDS	Clinical Decision Support
CMS	Centers for Medicare & Medicaid Services
CoAg	Cooperative Agreement
eCQM	Electronic Clinical Quality Measure
EHR	Electronic Health Record
EU	European Union
FAIR	Findable, Accessible, Interoperable, Reusable
FCC	Federal Communications Commission
FFRDC	Federally Funded Research and Development Center
FHIR	Fast Healthcare Interoperability Resources
FTC	Federal Trade Commission
HHS	U.S. Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HITECH	Health Information Technology for Economic and Clinical Health
HL7	Health Level 7
IG	Implementation Guide
IRB	Institutional Review Board
ISP	Internet Service Provider
IT	Information Technology
ML	Machine Learning
NPI	National Patient Identifier
ONC	Office of the National Coordinator for Health Information Technology
PHI	Protected Health Information
RPM	Remote Patient Monitoring
SDOH	Social Determinants of Health
STLT	State, Tribal, Local, or Territorial
USCDI	United States Core Data for Interoperability

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