



# FEDERAL HEALTH INFORMATION TECHNOLOGY RESEARCH & DEVELOPMENT STRATEGIC FRAMEWORK

*Prepared by the*

**HEALTH INFORMATION TECHNOLOGY RESEARCH & DEVELOPMENT  
INTERAGENCY WORKING GROUP**

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**COMMITTEE ON SCIENCE & TECHNOLOGY ENTERPRISE**

*of the*

**NATIONAL SCIENCE & TECHNOLOGY COUNCIL**

**MARCH 2020**

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Federal agency members of the Health Information Technology Research and Development Interagency Working Group (HITRD IWG) advance information technology (IT) research and development (R&D) for improving health by coordinating Federal health IT R&D plans and activities, providing a forum for sharing information about Federal health IT R&D programs, promoting synergies across Federal health IT investments, and articulating health IT R&D needs to policy-makers and decision-makers. The HITRD IWG reports to the NSTC Committee on Technology's Subcommittee on Networking and Information Technology. More information is available at <https://www.nitrd.gov/groups/hitrd>.

### **About this Document**

This strategic R&D Framework was developed to improve medical, functional, and public health outcomes through R&D in the use of data and IT for advanced health IT applications and improved detection of existing health concerns and discovery of emerging issues. It is expected that this Framework will help the United States capitalize on the full potential of health IT to improve the efficiency and effectiveness of healthcare and lengthen and improve the quality of American lives. This Framework will also help Federal agencies work across silos and prioritize areas for transformation by investing in tools and technologies that open new areas of discovery and better coordination of R&D activities. It does not define specific research agendas for individual Federal agencies; instead, agencies will continue to pursue priorities consistent with their missions, capabilities, authorities, and budgets, while maximizing planning, collaboration, and coordination with one another through the HITRD IWG to avoid duplicative efforts.

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## Acknowledgments

This document was developed through the invaluable contributions of the HITRD IWG members, including those who have since retired, and the staff of the NITRD NCO.

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## 1. Introduction

The rapid development of health information technology (health IT)\* has made it possible to improve human health in previously inconceivable ways. For example, imagine a world in which individuals can carry medical identification bracelets or tokens that enable them to safely and securely share their up-to-date and accurate medical record information as they wish. This will allow them to avoid the danger of not being able to remember or communicate their important health information (e.g., medications, conditions, and treatment history) in times of crisis. This vision for the future will become reality with strategic research and development (R&D) in health informatics, infrastructure, and data management, including accessibility, usability, security and privacy, validation, verification, standards, data quality, and transmission. For data to be useful, advanced analytics (e.g., machine learning, artificial intelligence, statistics, and data mining), networking, and communications are also required.

Health IT investments will do far more than facilitate ease of access for medical records. The anticipated paradigm shift within health and medicine will also allow people, including those in rural or resource-limited environments, to unobtrusively monitor their health, receive the information they want when they need it, have more control over sharing their data, and have treatments targeted to their individual profiles, while prioritizing personal preferences and culture. Modernization of health IT will also influence how the medical community prevents, diagnoses, and treats disease, as well as how it shifts its focus to wellness. These changes should have a cascading effect: people will have increased access to health services and be healthier and more productive. Because of the efficiencies afforded by advanced health IT, this enhanced healthcare quality will be realized while medical systems reduce costs and adapt more readily to changes in the population and workforce.

The Health Information Technology Research and Development (HITRD) Interagency Working Group of the Networking and Information Technology Research and Development Program developed this Health IT R&D Strategic Framework to provide an overview of salient issues, needs, and ongoing Federal investments in health IT R&D. The Health IT R&D Strategic Framework provides a clear, comprehensive, and structured description of the key R&D challenges, organized and explained in a way that facilitates understanding by all stakeholders, to support R&D coordination across Federal agencies and innovation across the health IT community to maximize impact of taxpayer funds and serve the health needs of the public in the digital age. The HITRD Interagency Working Group published a draft of this Framework in the Federal Register<sup>1</sup> and incorporated responses to public comments into this final version.

By focusing on how to maximize Federal R&D investments, the Health IT Framework aligns with the President's Management Agenda<sup>2</sup> and the draft *Federal Health IT Strategic Plan 2020-2025*<sup>3</sup> of the Office of the National Coordinator for Health Information Technology. These plans include R&D priorities at a high level focusing on modernizing the IT infrastructure, data usability, accountability, transparency and portability, development and commercialization of health IT innovation, and the use of IT to support healthcare services. It also specifies the necessary infrastructure to support and optimize the growth of health IT and develop tools for managing data and decision-making to leverage data as a strategic asset.

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\* In this framework, health IT R&D includes, but is not limited to, use of digital information, data, and technology across the human lifespan in the areas of health screening, diagnosis, treatment, and surveillance; reducing preventable medical errors; preventing disease; supporting self-management of health and wellness; providing healthcare services; and responding to disasters and emergencies, all to improve individual and community health outcomes. Health IT R&D does not include research in biological sciences (e.g., computational biology) or approaches that enhance health indirectly (e.g., technologies to enhance transportation).

This Framework supports those priorities with a comprehensive examination of Federal health IT R&D. Section 2 summarizes the high-level motivators for advancing health IT, Section 3 translates these into areas where health IT R&D is needed, and Section 4 summarizes opportunities for collaboration that will optimize the success of these R&D efforts. Section 5 outlines the HIRTD agencies' existing, ongoing research to identify gaps and allow for enhanced coordination and planning of Federal health IT R&D.

## 2. Key Motivators of Health IT Research and Development

Health IT R&D is a transformative factor in improving health outcomes and quality of life while reducing costs. The Health IT R&D Strategic Framework defines eight key health issues that motivate investment in health IT R&D:

1. Reduce the burden of disease;
2. Address health aspects of changing population demographics;
3. Reduce the economic impact of disease;
4. Enhance the safety, reliability, and quality of healthcare;
5. Facilitate health service coordination;
6. Improve the health outcomes of disaster response;
7. Address healthcare workforce changes; and
8. Effectively utilize health data, devices, and information.

These key motivators are described below.

### Reduce the Burden of Disease

Disease burden is the impact of health problems on society as measured by financial cost, mortality, morbidity, disability, and other indicators. While the United States is among the most economically prosperous nations in the world, the health of the Nation falls well below that of other high-income countries in several key metrics, including rates of heart disease, obesity, disability, and infant mortality.<sup>4</sup> Innovation in health IT methods and systems has the potential to substantially reduce the burden of disease in the United States. This outcome can be achieved through a variety of methods, including but not limited to, expanding the medical community's ability to understand and predict the course of disease to facilitate prevention, diagnosis, and treatment; delaying disease progression by efficiently, effectively, and securely enhancing information exchange and communication among providers, patients,\* and caregivers; providing real-time decision and systems support to ensure early diagnosis, maximally effective treatment, and the highest possible quality of care; improving and facilitating access to healthcare services generally, and especially in rural and resource-limited environments; and creating new, and improving existing, IT tools that support patient self-care throughout the course of life. In addition, healthcare data and related information must be made accessible and usable to the extent that they can be acted upon by all users and patients, including persons with disabilities, as approved by the patients.

### Address Health Aspects of Changing Population Demographics

Innovation from health IT R&D is critical because the changing population demographics in the United States have resulted in a shift in healthcare demands. According to the Bureau of Labor Statistics, as

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\* For simplicity, the term "patient" is used in this document exclusively to mean "people pursuing healthcare". It is noted that Federal agencies use a range of terms to describe patients pursuing healthcare (e.g., clients, consumers, and patients).

the population ages, the ratio of retirees to workers in the United States goes up; it is expected to reach about 40 percent in 2020.<sup>5</sup> Furthermore, in 2015 Congress granted veterans, some of whom have significant health and healthcare challenges, access to care outside of Department of Veteran's Affairs (VA) facilities,<sup>6</sup> thus expanding the number of individuals in the general-population U.S. healthcare system. Also, U.S. Disability Statistics indicate that about 12.7 percent of non-institutionalized persons in the U.S. population, or about 41 million people (circa 2017), have a disability as defined by the Americans with Disabilities Act, where physical, cognitive, or sensory disabilities are associated with congenital, developmental, or acquired health conditions.<sup>7</sup> Persons with disabilities often have increased barriers to access, and impaired ability to understand or act upon, health information. Finally, growing diversity in the U.S. population also requires new healthcare approaches because economic, language, and cultural factors within some groups may make them less likely to effectively engage with the healthcare system early, when prevention of the worst outcomes is still possible.<sup>8</sup> Supporting open health informatics tools and services is expected to enable increasing portability of data, including seamless "translation" of medical and nonmedical terminology and capabilities to all patients regardless of ability, language, and culture, and identification of high-quality evidence related to their individual conditions, regardless of cultural background, native language, or level of health literacy.

### **Reduce the Economic Impact of Disease**

The economic impact of disease may be characterized in multiple dimensions, including direct health expenditures, the impact of disease on an individual's or household's income and thereby on market or nonmarket consumption opportunities, and the broader societal implications of lost productivity and wages due to illness.<sup>9</sup> In fact, reduced productivity due to poor health in the population is well documented, as is the relationship between health and income.<sup>10</sup> Investment in Health IT to improve transparency, oversight, and effective use of health-related data can reduce these economic costs for all sectors by enhancing the quality of care, including facilitating preventive and wellness efforts, enabling healthcare teams to coordinate more effectively, and identifying care duplication and inappropriate care options so as to intervene before patients incur additional costs and risks. A variety of mechanisms made possible from health IT information and communication technologies can support this cost reduction, including reduced burdens on the healthcare team; better data portability supported by interoperable systems; fewer days of work lost by both patients and healthcare providers; digital healthcare service delivery models (e.g., telehealth, in which providers and patients can effectively interact virtually without the costs of in-person visits); and enhanced continuity of care. These activities can reduce individual, community, and national costs and potentially produce financial benefits to healthcare organizations.

### **Enhance the Safety, Reliability, and Quality of Healthcare**

Despite established, evidence-based guidelines for care, health services research has indicated that such guidelines are only followed approximately 50 percent of the time.<sup>11</sup> This is due in part to the exponential increase of medical data in electronic health records from diagnostic tests, procedures, and visits, along with a flood of information originating from patients themselves, such as home monitoring devices and personal data from the emerging Internet of Things (IoT). As a result, AHRQ Demonstration Projects indicate that it is increasingly difficult for teams to provide consistent, evidenced-based care without the aid of robust, real-time clinical decision support (CDS).<sup>12</sup> There is a need to improve governance, access, dissemination, integration, and safety of decision-making systems in order to leverage health data assets more effectively. With targeted and actionable information, health professionals can more precisely assist patients, caregivers, and providers in effective and

efficient delivery of care, by enhancing adherence to evidence-based guidelines, by reducing preventable medical errors and incidents of misdiagnoses, and by streamlining identification of risk factors for poor outcomes. Ultimately, this should maximize the quality of healthcare decisions and allow for development of the optimal approach for each individual patient's needs.

Secure and resilient health IT applications, systems, and medical devices must also safely capture, store, and integrate data—including patient-generated and medical device data—to augment medical situational awareness with responsive, validated clinical capabilities among vendors, institutions, and manufacturers. Specifically, reliable and interoperable medical informatics tools and systems should eliminate costly and error-prone data entry through smart and efficient capture of data in a shareable, semantically consistent way; ensure the safe and accurate transfer of data from one health system to another; and facilitate data integration and decision support. To prevent medical errors, health IT systems must also automatically capture and make available the data from medical equipment (e.g., physiological monitors) and other sources that are needed to assess and improve care, identify adverse events and healthcare errors, and evaluate patient functioning and treatment outcomes. To go further to prevent medical errors and unintended patient harm while reducing the burden of reporting to state and Federal agencies, health IT systems also must allow for standardized adverse event and disease reporting that can be automated to capture and report relevant information—including context—as well as support fidelity, auditability, and traceability of medical events and transactions through enhanced real-time data logging, playback, and system-monitoring capabilities. In addition, health IT systems should actively scan data to detect outbreaks of disease and care-related problems as soon as possible so they can be quickly and appropriately addressed.

Healthcare quality will be enhanced by systems that continuously monitor health as well as the safety and the safe use of the system itself. Those data can be shared in real time with the research community to iteratively improve quality of care, care guidelines, and decision support. Coordination of Federal agencies' R&D investments is critical to building a strong evidence base and environment to scale-up clinical decision support and other health IT systems.

### **Facilitate Health Service Coordination**

The ability to appropriately share information among all participants involved in a given patient's treatment and transition through care is required to achieve safer and more effective care. The ideal healthcare system has well-organized care coordination, including timely and accurate information flowing between providers and systems. There is considerable evidence suggesting that this is *not* the current state of the U.S. healthcare system.<sup>13</sup> Health IT can facilitate provision of care that is more patient-centered, less duplicative and costly, and more coherently focused on shared goals.<sup>14</sup> To motivate and provide the technical imperative to achieve interoperable and efficient care coordination, bidirectional data sharing and testing should be a mandatory aspect of programs that regulate healthcare providers across the continuum of care.

### **Improve the Health Outcomes of Disaster Response**

Health and healthcare challenges always arise from emergency situations and natural disasters. On average, the U.S. experiences more than ten disaster events each year that have a negative financial impact of more than \$1 billion.<sup>15</sup> Integrated information from health IT systems—including connected devices and communications technology, electronic health record and clinical decision support systems, and other components of the health IT landscape—could automate data collection and analysis during a disaster or pandemic to optimize planning, speed response, improve diagnosis and care, and support caregivers.

## **Address Healthcare Workforce Changes**

The U.S. healthcare workforce is older than the general population.<sup>16</sup> For the last two decades, the average age of registered nurses has been rising, with the average age now being 50 years old.<sup>17</sup> Similarly, in 2015 more than 31% of physicians were 55 or older.<sup>18</sup> AHRQ research also suggests that older healthcare providers are leaving medical practice earlier than in previous decades, partly because of difficulties related to current health IT systems.<sup>19</sup> These trends are compounded by the need for additional providers.<sup>20</sup> This combination of an aging workforce with increased healthcare workforce requirements highlights the critical need for user-friendly health IT to reduce the burden upon providers and health-related professionals, streamline the healthcare process, and facilitate high-quality care at home using nontraditional providers.<sup>21</sup> Health IT R&D can also lead to more efficient and secure mechanisms for data and communication transmission and support effective use of assistive technologies such as decision aids that allow providers to function at the maximum level of their credentials and expertise by either eliminating or reassigning activities below that level and/or speeding the decision cycle and medical situational awareness.

Critically important is the need to develop a workforce that will support the R&D needs of health IT as it becomes an integrated and integral part of the healthcare system and healthier communities of the future. ONC supports a number of workforce development programs to keep healthcare workers current with the changing healthcare environment.<sup>22</sup> For R&D, the rapid pace of change and the cross-cutting nature of health IT highlight the need for future-focused training of the workforce in the areas of data science, privacy and security, networking, and human-computer interaction to enable healthcare workers to work across disciplinary boundaries. Training is also needed for other stakeholders, including for educating the next generation of healthcare professionals, providing IT literacy training for healthcare professionals, and providing advanced-level training for data scientists and informaticians.

## **Effectively Utilize Health Data, Devices, and Information**

Adoption of electronic health records (EHRs) is now nearly ubiquitous, and EHRs are well established as a foundation of health information for the Nation; 94 to 98 percent of U.S. hospitals had adopted EHRs as of 2015.<sup>23</sup> However, health information is not only entered into by EHRs by healthcare professionals but also by laboratory facilities, genomic analyses imaging, billing records, patient-generated data, and contextual and environmental data that impact health, as well as by medical devices that directly or indirectly monitor health (e.g., continuous glucose monitors) or deliver therapy (e.g., insulin pumps). Optimal models of future care are anticipated to emphasize reliance on real-time data, predictive algorithms, and precision delivery of diagnosis and treatment, all of which increase the need for high-integrity and high-velocity objective data. Improved collection, integration, portability, and analysis of data, combined with modular, interoperable platforms have the potential to transform health through better modeling of disease and optimization of devices and algorithms for specific patients, disease states, or practice settings. For example, in chronic diseases, both clinical informatics tools and bioinformatics will allow more accurate understanding of the real-world impacts of different treatments on symptoms over time.

While the last decades have seen enhancements in productivity and safety across a range of industries through automation, healthcare and medicine have fallen behind. This is now beginning to change as advances in analytics such as artificial intelligence, deep learning, machine learning, statistics, and data mining have resulted in health data also being used for uncovering new relationships between variables. Development of new patient and clinical decision support tools will be needed to make the enormous

amount of new data relevant and actionable to pave the way for medical advances far into the future, moving towards semiautonomous and autonomous systems in critical care. This more deterministic delivery of treatment in trauma care could improve patient outcomes. For example, in rare diseases, automated CDS using advanced analytics can rapidly search large amounts of data within a patient's record, as well as within the hospital and scientific literature, to discover new links between biology, genetics, the patient, and the environment. Bioinformatics tools can capture important information about the context within which a treatment or device is used to reliably interpret data, including identifying biomarkers that contraindicate specific therapy. In an example of more intelligent sensing in remote monitoring, blood pressure readings taken while the patient is standing will yield different results than those collected while lying down, but this position information has not been captured routinely. Information about the context of use of a device is important to reliably interpret data.

Thus, as data accumulate at increasing rates, health IT R&D can improve the interoperability, privacy, security, and development of advanced analytics and visualization across different vendors' EHRs, medical devices, and other systems. The increasing volume, velocity, and variety of data creates a complex system of data flows that will demand R&D in new areas, including adaptive, personalized models to promote behavior change; development of real-time, multiscale models of public health; and dynamic decision support for efficient allocation of resources.

### 3. Cross-Cutting Health IT R&D Needs

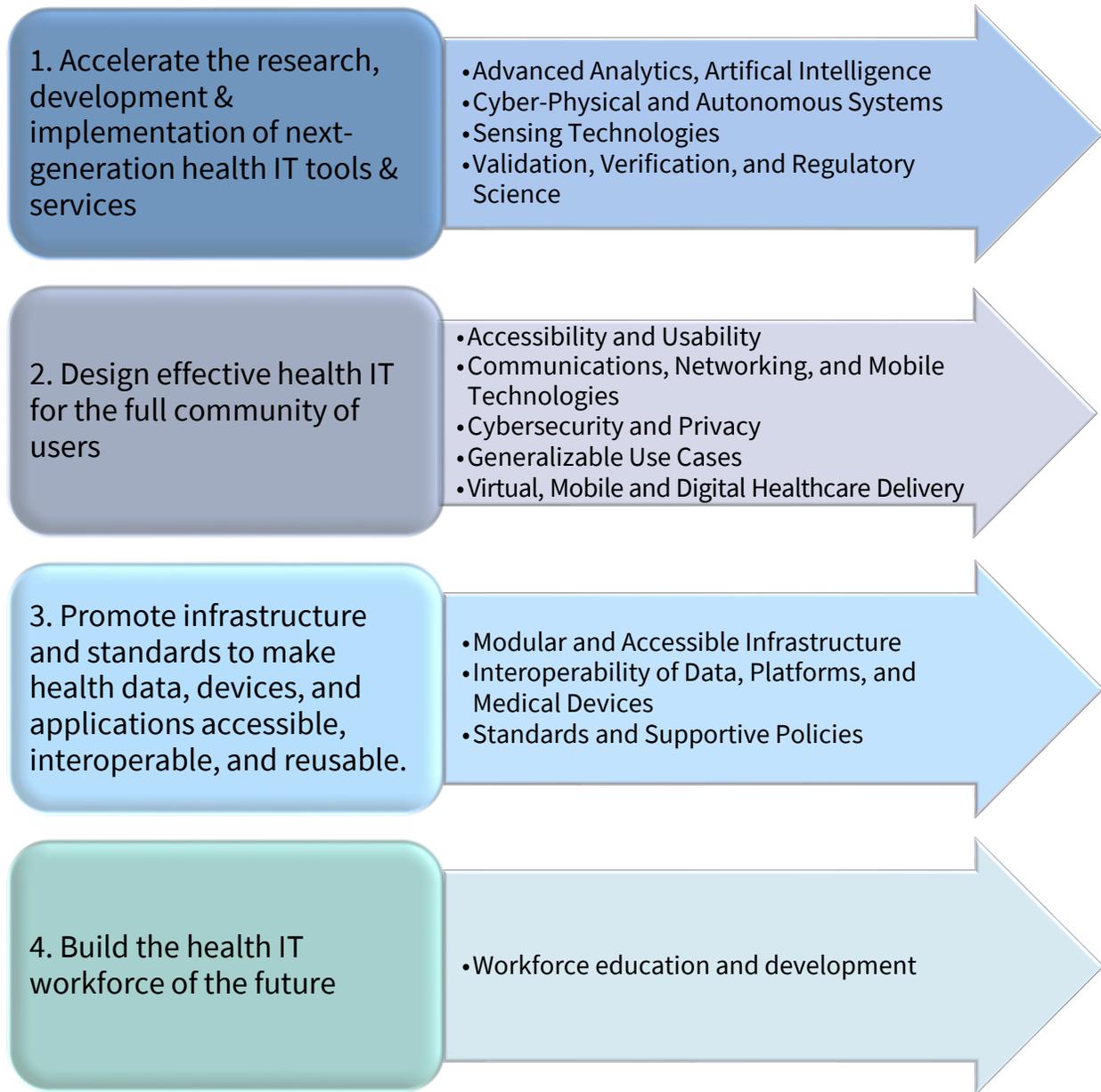
The motivators of health IT R&D described in Section 2 highlight a common set of fundamental challenges. Overcoming these challenges and accelerating the development of health IT will require R&D investments in key cross-cutting needs areas, which are summarized in this section.

These challenges highlight some key themes of health IT R&D. What is also clear and perhaps most important, health IT R&D is, by its very nature, multidisciplinary. Many of the areas of need have been tackled by single disciplines or domains and yet remain challenging problems. To address these issues, recent reports have suggested the criticality of bringing together traditional biomedical and clinical researchers with scientists from computer, statistical, engineering, social, behavioral, and economic sciences, as well as others. A second key theme is that establishing collaborative R&D in health IT is not a "quick fix." Rather, collaborative health IT R&D affords an opportunity to achieve increased impact, with use-inspired R&D challenges surfacing in clinical implementation to reveal new needs for fundamental science R&D. These needs and the solutions they generate can be evaluated and implemented, leading to whole new series of iterative scientific advancements. A clear example right now is in the areas of health IT analytics, which are progressing rapidly to leverage current data, while also preparing for the onslaught of new medical, environmental, and personal data arising from the IoT.

To address the motivators described in Section 2, health IT R&D investments are needed in four broad cross-cutting needs areas:

1. Accelerate the R&D and implementation of next-generation health IT tools and services;
2. Design effective health IT for the full community of users;
3. Promote infrastructure and standards to make health data, devices, and applications accessible, interoperable, and reusable; and
4. Build the health IT workforce of the future.

For each of these areas, this strategic framework identifies and describes specific target areas for R&D, as shown in Figure 1 (on the next page). Also included are examples of how advances in health IT R&D in these areas are expected to translate to improvements in health and in healthcare efforts.



**Figure 1.** The four major cross-cutting health IT R&D needs areas and the specific targets in each.

**Accelerate the Research, Development, and Implementation of Next-Generation Health IT Tools and Services**

This area focuses on health IT R&D to support methods and tools to generate high-quality information (extracted from either existing records or new sensing or other devices) that can be analyzed rapidly and effectively. This health IT R&D should also prioritize R&D on enhancing the validation and verification processes that can support the efficiency and effectiveness of the regulatory process. By addressing this needs area and implementing these tools to modernize health IT, there is the potential to transform health services by effectively using all data assets to improve decision-making and productivity.

### ***Advanced Analytics***

Key targets for health IT R&D include developing an understanding of new patterns and relationships between diverse risk and protective factors spanning detection, prediction, treatment, and prevention from the individual through the population levels. Analytic advances to merge, fuse, match, and analyze different types of health data include R&D in artificial intelligence, classification and clustering, data mining, deep learning, modeling of complex data and interactions, statistics, natural language processing, image processing, and analysis and visualization. These analytics tools will allow development of more accurate diagnosis, treatments, illness trajectories, and preventive methods, as well as a better understanding of the complex relationships between genes, the environment, and health.

Further, as data increases across systems and become central to how we manage health, improved methods are needed to ensure high data quality, extraction methods, and document provenance, as well as appropriate sharing of data (especially asynchronous data). These methods will be supported with standards and transparency models that will support the flow of information while ensuring quality and privacy.

While novel data and analytic methods have transformed other industries, medicine and healthcare have lagged in developing new methods to understand and explore the data relationships and inferences necessary to advance discovery and cutting-edge applications in health data sciences. This work also should encompass new efforts to explore data biases and fairness in algorithmic work, as well as reproducibility of results.

**Example Outcomes:** The Million Veteran Program, launched by the VA Office of Research and Development, is an important partnership between the VA and veterans to learn more about how genes affect health, aiming to improve healthcare for veterans by establishing one of the largest databases of genetic, military-exposure, lifestyle, and health information. This program is leading to new ways of preventing and treating illnesses in veterans.

### ***Cyber-Physical and Autonomous Systems***

The IoT, intelligent sensors, and real-time machine-based learning and intelligent software will support building both closed-loop and human-in-the-loop evidence-based systems. These systems can range from identifying anomalies in the data that require professional attention to fully closed-loop controls that adjust treatment based on incoming data and current health status. These systems will provide accurate information flows to ensure that people and systems are functioning properly, resulting in more consistent care of patients, even when they are at home, and more actionable information for providers when it is needed.

**Example Outcomes:** Ubiquitous home monitoring will allow patients, their caregivers, and healthcare providers to support ongoing care and be notified and intervene early before a crisis. Data on symptoms, treatment, and response will all naturally cycle information back into the system. Further, trauma care can be enhanced through use of more deterministic, intelligent applications and medical devices for more precise delivery of inpatient treatment.

### ***Sensing Technologies***

The development of sensing, including conventional biomedical sensing, environmental and behavioral sensing, newer lab-on-a-chip sensing, and contextual sensing with the IoT, will allow for earlier detection of disease and better health monitoring and disease prevention. R&D is needed to ensure the appropriate sensors are developed and validated that target the full range of health, behavior, and environmental variables with usable form factors and interfaces.

**Example Outcomes:** With sensors monitoring for early changes in health status, it will be possible to reduce risk and unchecked development of disease. Sensors that monitor such actions such as sleep, activity, gait, or social interactions may predict changes in health status, and when paired with other health information and family history, could be predictive of the development of a disease.

### ***Validation, Verification, and Regulatory Science***

Methods are needed to speed up the R&D design cycle for bringing innovations into practice while ensuring high user confidence in system safety and functionality. This includes addressing pre- and post-marketing regulatory requirements, where applicable.

**Example Outcomes:** Safe and reliable innovations will rapidly become available for medical and personal use. For example, analytic simulations of new treatments based on existing data of components could speed the time from intervention creation to trials.

### **Design Effective Health IT for the Full Community of Users**

For health IT to maximally support patients, caregivers, providers, administrators, and policy-makers, R&D efforts are required for usability and accessibility in both remote and in-person settings. This is equally important for healthcare providers where it has been shown that electronic health records have had negative effects on patient-centered communication while increasing the burden on healthcare providers.<sup>24</sup> Health IT R&D on user-centered design and human-computer interaction in non-health areas has fueled the “digital revolution,” but user-centered work in medical and healthcare settings is in its infancy. Health IT R&D can support this transformation in health and healthcare while still preserving privacy and security. By addressing this needs area, there is a real potential to significantly improve access, capabilities, transparency, and security while reducing risks and errors that will lead to better data governance.

### ***Accessibility and Usability***

For health IT to perform optimally, the needs of diverse users should be understood and bridged with the appropriate health IT tools so that information can be effectively accessed, comprehended, and acted upon. Accessibility and usability design issues impact all health IT users, from providers to patients and caregivers, but in very different ways. Accurate knowledge needs to be developed of the sociotechnical system that affects how providers, patients, and caregivers use and understand technology and its diffusion—including their beliefs about its value—to facilitate adoption and use of new health IT tools. Health IT R&D in accessibility and usability would result in providers spending less time searching for and explaining data to patients. The development of mobile systems would provide patients greater access to their own health data in an understandable format. The greatest benefits may be to the users with the fewest resources and whose primary support will be from information delivered electronically. Thus, health disparities can be reduced by designing and implementing accessible, trustworthy, and value-based systems for all individuals. Usable and accessible health IT will support all users in making better decisions about health.

*Example Outcomes:* Patients, caregivers, and providers will have tools that meet their needs. These tools will make information more usable and actionable, so users are more effective in managing their health.

### ***Communications, Networking, and Mobile Technologies***

R&D investments in communication and networking technologies are needed to enable flexible, reliable, and high-performance information flows that enable time-aware and time-critical functionality. While other service industries have been transformed through mobile and networked capabilities, medicine

and healthcare have lagged. Networked technologies allow information to flow in real time and to inform critical decisions of providers, patients, caregivers, and communities. These technologies are especially central to healthcare services delivered to remote and rural areas, which suffer from a shortage of medical providers and local facilities. Mobile and networked devices will allow these services to be distributed throughout the community using state-of-the-art, evidenced-based information tools.

**Example Outcomes:** Information will be accessible in real time to support just-in-time, mobile, and remote interventions (e.g., telehealth and mobile health, clinical decision support, and shared decision-making).

### ***Cybersecurity and Privacy***

Health datasets are among the most sensitive and high-value information that is stored on network systems, making them prime targets for theft and misuse. Health records include data that are identifying (e.g., addresses, dates of birth); financial (e.g., social security and credit card numbers); and potentially stigmatizing (e.g., diseases, behavior). Thus, methods are needed to safeguard privacy while facilitating secure patient-directed sharing and to guard against loss of, and malicious attacks on, the personal health information of individuals, providers, healthcare systems, and insurers. Effective cybersecurity requires monitoring and logging of data to establish baselines and monitor for change. Data-based risk management strategies are also needed to combat vulnerabilities and attacks against individual devices as well as networks, considering patient safety, legacy systems, and user preferences. Further, R&D investments in software are needed as a key to supporting both security and quality of systems.

**Example Outcomes:** Patients, healthcare providers, and researchers will safely, securely, and easily share data as needed. At the same time, health data are safe, secure, and protected from cyber-attacks and privacy threats.

### ***Generalizable Use Cases***

While there are many pressing clinical scenarios that motivate health IT R&D, a prioritized set of use cases is needed with the concomitant provision of clinical repositories to support rapid expansion of knowledge. Development of health IT needs scenarios, both inside and outside of traditional clinical settings, should take into consideration the needs and abilities of patients, caregivers, healthcare providers, and communities.<sup>25</sup> This will allow comparisons of health IT R&D across a wide spectrum of contexts. These common use cases will allow comparisons of solutions and support aggregation of diverse knowledge.

**Example Outcomes:** There will be rapid advances in knowledge as funders and researchers focus on agreed-upon priority areas.

### ***Virtual, Mobile, and Digital Healthcare Delivery***

Methods are needed that enable remote participation or healthcare delivery through a virtual presence or through using intelligent systems that allow distributed and specialized knowledge to be utilized in real time to support more accessible and efficient delivery of healthcare. While telemedicine and remote consultation with software and cameras is available today, R&D is needed in other remote clinical modalities, including virtual and augmented reality.

**Example Outcomes:** Healthcare providers and patients throughout the country will be efficiently and effectively supported by experts and systems, regardless of location.

## **Promote Infrastructure and Standards to Make Health Data, Devices, and Applications Accessible, Interoperable, and Reusable**

This cross-cutting need area focuses on prioritizing health IT R&D infrastructure. Infrastructure investments can help support the creation of data and knowledge networks to share best practices, tools, and data more effectively and efficiently within a distributed healthcare ecosystem. By addressing this need area to break down silos between digital services and build flexible, scalable systems that respond to demand, there is the potential to dramatically improve the customer experience and the efficiency and effectiveness of services, such as those provided by the VA or the Center for Medicare and Medicaid Services (CMS).

### ***Modular and Accessible Infrastructure***

Appropriate infrastructure is needed to enable rapid, efficient development of informatics tools, as well as the collecting, handling, de-identifying, secure storing, exporting, moving, transitioning, and integrating of data, and to leverage these data and the resulting knowledge. The infrastructure should enhance portability of structured and unstructured data between systems to support innovations in R&D and healthcare.

**Example Outcomes:** Aggregating and sharing of data, databases, and tools will be enabled so that information can securely move seamlessly between systems, platforms, and medical devices within the distributed healthcare ecosystem to avoid expensive duplication of effort and reduce errors and risks.

### ***Interoperability of Data, Platforms, and Medical Devices***

Section 4003 of the 21st Century Cures Act (2016) defines the term “interoperability” with respect to health information technology as health information technology that, “(A) enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user; (B) allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and (C) does not constitute information blocking\* as defined in section 3022(a).”<sup>26</sup> Medical devices are a part of the many digital inputs and outputs within the medical system that require interoperability so that data can move seamlessly between devices and systems and generate new knowledge and innovation. Interoperability can also facilitate new models of healthcare delivery and automation by promoting the availability and sharing of information across systems even when products from various manufacturers are used.

**Data and Systems Interoperability:** Clear requirements for minimum standards and data sharing must be provided to those who implement and operate systems, to ensure that data are both freely available and semantically consistent for the health IT R&D and clinical communities across a distributed ecosystem. This requires R&D on data and metadata specifications and common data elements that enhance reuse and quality assessment for high-fidelity medical records. Implementation guidance must accompany the requirements of standards and bidirectional exchanges to explain how to deal with variability and workflow limitations.

**Medical Device Interoperability:** Medical device interoperability is not limited to unidirectional patient data but includes more complex interactions such as exerting command and control over a medical device. It is important to establish and implement appropriate functional, performance, and interface

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\* Information blocking is a practice that is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.

requirements for devices with such interactions. Current nonstandard interface requirements do not allow interoperability. Interoperability is essential to realizing advanced medical systems that can function autonomously to reduce medical errors and to prevent harm. R&D is needed on interoperability standards and reference implementations to limit security vulnerabilities and enhance compatibility with existing software and/or hardware. This should foster a culture of support for “plug-and-play” device interoperability that can enable the creation of complete and accurate electronic health records and development of innovative medical applications to enhance knowledge and safety.

Importantly, medical device interoperability standards are already required by law for the Department of Defense and the VA.<sup>27</sup> There is still a need for R&D to develop standard language and conceptual frameworks—such as provided by the International Classification of Functioning, Disability and Health<sup>28</sup>—to create a knowledge system for users and to improve the efficiency and fidelity of communication that supports coordination in clinical practice and research. Early examples of this approach come from the Office of the National Coordinator for Health Information Technology’s *2018 Interoperability Standards Advisory*<sup>29</sup> and the DoD Healthcare Management System Modernization “Health Readiness” concept of operations.<sup>30</sup>

**Example Outcomes:** Interoperable healthcare systems, platforms, and medical devices will ensure that systems and devices behave safely and securely when processing real-time data and scenarios; enable the creation of complete and accurate electronic health records; and foster the development of innovative third-party medical “apps” for diagnosis, treatment, research, safety and quality improvements, equipment management, and adverse event detection and reporting. Closed-loop systems, where devices can interact with each other semiautonomously or autonomously, will intelligently analyze patient changes and reduce medical errors and preventable harm to improve patient safety and the quality of medical care.

### ***Standards and Supportive Policies***

Technological health solutions, such as imaging, laboratory, consumer mobile health, and medical devices, need Federal health IT R&D investments to identify standards, supportive policies, and incentive structures that allow the most appropriate technologies to be adopted and used.

These R&D-informed standards and supportive policies and incentives are needed to capitalize on data and knowledge and to support development of efficient, reliable, interoperable systems that can be integrated with legacy systems. Such work could build upon past Federal investments in open standards for the integrated clinical environment.\* Standardized approaches need to be developed for conformance and interoperability testing of systems that will allow the use of shared resources and ensure consistent, high-quality testing, and continuous functioning, even as components of the systems are updated.

**Example Outcomes:** Data- and knowledge-sharing systems will be developed so that data can move, as needed, to enable coordinated care and develop a learning health system. Information, once captured, will be shared, translated to the appropriate level of detail and vocabulary, and made accessible to downstream stakeholders.

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\* Examples are the American Society for Testing and Materials ASTM F2761, *Integrated Clinical Environment*; the Association for Advancement of Medical Instrumentation AAMI-UL 2800 family of medical device interoperability standards; the National Library of Medicine-based terminology services and code systems; and standards developed by Health Level-Seven International and Integrating the Healthcare Enterprise International.

## **Build the Health IT Workforce of the Future**

To develop and optimize health IT, a well-trained workforce is needed. This includes education and training of professionals from both medical and non-health disciplines such as computer science, informatics, and engineering. There is a critical need to build a sustainable health-IT-literate workforce for the 21<sup>st</sup> Century that can efficiently and effectively develop, implement, and innovate tools and infrastructure that will enable the country to thrive.

### ***Workforce Education and Development***

New models are needed for training people in the interdisciplinary skills needed to advance the field. Training in developing and effectively utilizing data science, privacy and security methodology, networking, and human-computer interaction techniques are all critical to developing the 21<sup>st</sup>-century health IT workforce. These new education models need to include skills to ensure health IT R&D is responsive to the changing health IT landscape and the resulting workforce needs. These new models also should include health IT training for healthcare professionals.

**Example Outcomes:** Students spanning different ages and different skillsets will be trained in the R&D skills necessary for health IT to become central to health and wellness in our Nation in the continuous advancement of discovery, clinical science, and medical care.

## **4. Collaboration Opportunities in Health IT R&D**

Although several Federal agencies have efforts to address health IT research challenges, many gaps remain in the Federal R&D portfolio for health IT. Technical barriers arise throughout each stage of technology development, from fundamental science and engineering challenges through applied R&D (including efficacy and effectiveness trials) and deployment. A comprehensive multiagency, multisector focus on the difficult cross-cutting R&D challenges in health IT offers many benefits and synergies while also avoiding duplication of effort, missed lessons learned, and general inefficiencies. For example, establishing shared architectures for secure data use and reuse will facilitate advances in healthcare diagnosis and treatment, and in fundamental R&D on computational methods to extract new knowledge from these data.

### **Partnerships for Innovation**

Addressing the health IT R&D needs described in this Framework will require close partnerships across Federal agencies, state and local governments, the private sector, academia, and international partners. Strong partnerships will be critical to maximizing the efficacy of Federal funding. Public-private partnerships will empower the private sector to accelerate research discoveries from the laboratory to the marketplace and should be designed to support economic growth and create jobs and new industries.

These partnerships can also optimize the movement of people and intellectual capital across organizational and sector boundaries, and they should be structured to ensure that intellectual property concerns do not impede progress or result in duplicate efforts.

Partnerships to reinvigorate the healthcare workforce by promoting education and training about health IT will also be necessary. Further, the healthcare workforce should participate in studies on the design, implementation, use, and reliability of health IT to result in better, more usable, and more useful systems. Healthcare workers have a good understanding of the common problems and good ideas for solutions, but there are currently limited pathways for incorporation of their insights. Inclusion of multidisciplinary expert communities, including healthcare professionals, computer scientists,

engineers, and health IT professionals, could result in innovative technical solutions and analysis for both medical care and technical infrastructure. Hardware and software components could be crowd-sourced for development or for evaluation and refinement prior to widespread adoption. The community that can be engaged through crowdsourcing of medical solutions can include diverse expertise to help address complex system challenges such as cybersecurity risk mitigation.

### Mechanisms for Implementation

The diverse capabilities and communities represented by the NITRD Program’s member agencies and other NITRD Interagency Working Groups (IWGs)—including the Artificial Intelligence; Big Data; Computing-Enabled Networked Physical Systems; Cyber Security and Information Assurance; Privacy R&D; and Software Productivity, Sustainability, and Quality IWGs—could enable a range of mechanisms for addressing the R&D challenges described here. These mechanisms include partnerships to:

1. Continue participation and engagement of funding agencies in the HITRD IWG to facilitate coordination of R&D investments and activities;
2. Joint and coordinated solicitations, with a mix of intramural and extramural funding;
3. Coordination of multiagency workshops and other meetings that bring together researchers to understand progress, identify best practices, and grow the research community, including by fostering new collaborations; and
4. Periodic implementation plans.

### Opportunities for Collaborative Funding

One way that partnerships among government agencies could be supported is collaborative funding. By way of illustration, three possible funding mechanisms that offer multiagency coordination and collaboration are outlined below; they should enable synergies among agencies and reduce potential duplication of efforts in health IT R&D:

1. **Joint Solicitations:** This tightly coupled mechanism provides for joint solicitations that address the identified R&D challenges and technology needs of multiple funding agencies. The agencies would define appropriate mechanisms for joint review and shared investment.
2. **Independent Solicitations with Collaborative Research:** All solicitations would be independent, but program managers would identify synergistic research projects, facilitated by this Framework, providing Principal Investigators (PIs) funded by one Federal agency with the awareness and opportunity to collaborate with PIs funded by other Federal agencies.
3. **Other Transaction Authority (OTA):** Transactions other than contracts, grants, or cooperative agreements could be entered into in certain circumstances for prototype projects for basic, applied, or advanced R&D when it has been determined that it is in the Government’s best interest. OTAs are a highly flexible business tool, the use of which requires application of astute business acumen to ensure smarter, more efficient acquisition of prototype systems. Federal and non-Federal participation is enabled in an OTA, and a rapid turnaround from time of public announcement to award can be as little as six months, which is particularly useful in the rapidly advancing health IT environment.

All three models could include a mix of intramural and extramural funding. Through the HITRD IWG, agencies would be able to pursue other models that would make sense for desired forms of cooperation and co-funding. In joint or coordinated solicitations, it may be desirable to consider requiring grantees to attend common investigator-led information exchange forums and to disseminate their research results through common mechanisms. Further, funding agencies could have access to proposals to allow for supplementary funding by one agency for projects selected by another agency.

## 5. Current Federal Investments in Cross-Cutting Health IT R&D

Table 1 provides a summary of Federal agency health IT R&D activities in FY2020, allowing identification of potential collaborations as well as gaps in the Federal health IT R&D investment portfolio.

**Table 1. FY2020 Federal Health IT R&D Investments, by HITRD IWG Member Agency\***

Cross-Cutting Health IT Needs Areas Receiving Federal R&D Investments	AHRQ	DoD	FDA	NIDILRR	NIH	NIST	NSF	ONC	VA
<b>Accelerating the research, development, and implementation of next-generation health IT tools and services</b>									
Advanced analytics	X	X	X	X	X	X	X	X	X
Cyber-physical and autonomous systems		X	X		X	X	X		
Sensing technologies	X	X			X		X		
Validation, verification, and regulatory science	X	X	X		X				
<b>Designing effective health IT for the full community of users</b>									
Accessibility and usability	X	X	X	X	X	X	X	X	X
Communications, networking, and mobile technologies	X	X	X	X	X		X		X
Cybersecurity and privacy		X	X	X		X	X	X	
Generalizable use cases	X	X	X					X	X
Virtual, mobile, and digital healthcare delivery	X	X		X	X			X	X
<b>Promoting infrastructure and standards to make health data, devices, and applications accessible, interoperable, and reusable</b>									
Modular and accessible infrastructure		X	X	X	X		X	X	X
Interoperability of data, platforms, and medical devices	X	X	X		X	X	X	X	
Standards and supportive policies	X	X	X	X	X	X		X	
<b>Building the health IT workforce of the future</b>									
Workforce education and development	X	X	X	X	X		X	X	

\* Member departments and agencies are **AHRQ**–Agency for Healthcare Research and Quality, Department of Health and Human Services (HHS); **DoD**–Department of Defense; **FDA**–Food and Drug Administration, HHS; **NIDILRR**–National Institute on Disability, Independent Living, and Rehabilitation Research, HHS; **NIH**–National Institutes of Health, HHS; **NIST**–National Institute of Standards and Technology, Department of Commerce; **NSF**–National Science Foundation; **ONC**–Office of the National Coordinator for Health Information Technology, HHS; and the **VA**–Department of Veterans Affairs.

## 6. Conclusions

The HITRD Strategic Framework was developed to identify key cross-cutting IT R&D needs, highlight the need to prioritize Federal funding across these areas, and drive future advances that improve the quality of American lives. The table above highlights two situations for cooperation, coordination, and collaboration across the Federal R&D portfolio: (1) coordination in areas that are broadly supported by multiple agencies (e.g., advanced analytics or workforce development), and (2) gaps where cooperation and collaboration across the Federal health IT R&D investments might be valuable. Areas such as accessibility and usability, cyber-physical systems, cybersecurity and privacy, and validation and verification are possible candidates for cross-agency information sharing and collaboration. This analysis also points to opportunities to identify specific programs and projects supported by Federal agencies that support shared learning and value. The Strategic Framework also highlights models for collaboration available to Federal agencies to support the important areas of health IT R&D.

This vision for the future of health IT will become reality with strategic R&D in health informatics, data management, accessibility, usability, security and privacy, validation, verification, standards, and infrastructure. Further, advanced analytics (e.g., machine learning, artificial intelligence, statistics, and data mining), networking, and communications also are required. By improving coordination and planning across the Federal health IT R&D communities, agencies will move another step closer to improving medical, functional, and societal health outcomes through R&D in the advanced use of data and IT for health applications.

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