FEDERAL HEALTH INFORMATION TECHNOLOGY RESEARCH AND DEVELOPMENT STRATEGIC FRAMEWORK

National Science and Technology Council

Networking and Information Technology Research and Development Subcommittee

Draft for Public Comment

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About this Document

This draft, *Federal Health Information Technology Research and Development Strategic Framework*, was developed by the Health Information Technology Research and Development (HITRD) interagency working group (IWG) under the auspices of the Networking and Information Technology Research and Development (NITRD) Subcommittee of the National Science and Technology Council (NSTC).

The purpose of the HITRD IWG is to advance information technology R&D for improving health by providing a forum for sharing information about Federal health Information Technology (IT) R&D programs, coordinating health IT R&D plans and activities, promoting synergies across Federal health IT investments, and articulating health IT R&D needs to policy and decision makers. As a part of the group's activities, a draft strategic R&D Framework was developed to examine current investments and identify opportunities and challenges in health IT R&D. When finalized, this Federal R&D Framework will help the United States capitalize on the full potential of health IT to strengthen our economy, improve our society, and result in better coordination of activities and new synergistic initiatives.

The Health IT R&D Strategic Framework does not, however, define specific research agendas for individual Federal agencies. Instead, agencies will continue to pursue priorities consistent with their missions, capabilities, authorities, and budgets, while coordinating with one another through the HITRD IWG.

Networking and Information Technology Research and Development
Federal Health Information Technology Research and Development
Strategic Framework

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1. Introduction

The rapid development of Health Information Technology (health IT) has made it possible to improve human health in ways that were previously unimaginable. For example, imagine a world in which every individual carries a medical identification bracelet or token that enables them to safely and securely share their up-to-date and accurate medical record information as they wish. This will allow people 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 data management, including data quality and transmission, accessibility, usability, security and privacy, validation, verification, standards, and infrastructure. For data to be useful, advanced analytics, such as machine learning, artificial intelligence, statistics and data mining, and networking, and communications are also required.

Health IT investments will do far more than facilitate ease of access for medical records. This paradigm shift within health and medicine will also allow people to unobtrusively monitor their health, receive the information they want when they need it, and have treatments targeted to their individual profile, prioritizing personal preferences and culture, including those in rural or resource-limited environments. Improvements in health IT will also influence how we prevent, diagnose, and treat disease, as well as how we shift the 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 quality will be realized while reducing cost and adapting to the coming changes in the population and workforce.

In this document, an R&D Framework means a clear, comprehensive, structured description of the current state of a field of research, organized and explained in a way that facilitates understanding of the field by all stakeholders, and that supports R&D coordination and cooperation by participating Federal agencies. This health IT R&D Strategic Framework will improve medical, functional, and societal health outcomes through R&D in the use of data and IT for advanced health IT applications. Health IT R&D includes, but is not limited to, the use of digital information, data, and technology across the human lifespan in the areas of screening, diagnosis, treatment and surveillance; preventable medical error reduction; disease prevention; self-management of health behavior and wellness; healthcare; and disaster and emergency response that support improved individual and community health outcomes. It does not include research in basic biological sciences (e.g., computational biology) or approaches that enhance health indirectly (e.g., technologies to enhance transportation). This Framework is designed to provide an overview of the salient issues, needs and ongoing federal investments in health IT R&D. This Framework aligns with the Office of the National Coordinator for Health Information Technology's (ONC's) *Federal Health IT Strategic Plan 2015-2020* by focusing on Federal R&D investments.[1] This Framework summarizes the motivators and challenges, needs, mechanisms of collaboration, and the ongoing research, in order to identify gaps and allow for enhanced coordination and planning of Federal agency health IT R&D.

[1] Office of the National Coordinator of Health Information Technology, F*ederal Health IT Strategic Plan: 2015 – 2020,* https://dashboard.healthit.gov/strategic-plan/federal-health-it-strategic-plan-2015-2020.php.

2. Motivators of Heath IT Research and Development

Investment in health IT R&D is motivated by the following key goals of national health:

2.1 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 (U.S.) is among the most economically prosperous nations in the world, the health of the Nation falls well below that of other high-income peers. The U.S. fares worse in adult and infant mortality, as well as in the areas of low birth weight, injuries and homicides, obesity and diabetes, and heart disease.[2] Further, as the U.S. population ages, the Medicare population is projected to grow from 54 to 93 million beneficiaries, and conditions such as heart disease, cancer, arthritis, trauma-related disorders, chronic obstructive pulmonary disease (COPD) and asthma are expected to become more prevalent and costly.[3] Health disparities, caused by differential disease screening rates, shorter lifespans, and late diagnoses and thus worse outcomes, also highlight the uneven burden of disease in the United States.[4] Innovation in health IT methods and systems has the potential to transform health and substantially reduce the burden of disease in the U.S. This outcome can be achieved through a variety of methods, including but not limited to: better disease course understanding and prediction to facilitate treatment and prevention in general and for particular patients (e.g., precision medicine); delaying disease progression by efficiently, effectively, and securely enhancing information exchange and communication among providers, patients,[5] and caregivers; providing real-time decision and systems support to ensure early diagnosis, maximally effective treatment, and the highest possible care quality; improving and facilitating access to healthcare services generally, especially in rural and resource-limited environments; and creating new, and improving existing, tools that support patient self-care throughout the course of life. In addition, healthcare data and related information must be accessible and usable, to the extent that it can be acted upon by all users and patients, including persons with disabilities, as approved by the patient.

2.2 Address Health Aspects of Changing Population Demographics

The changing population demographics in the U.S. have resulted in a shift in healthcare demands. As the population ages, the ratio of retirees to workers in the U.S. is expected to reach 40 percent by 2020.[6] Furthermore, veterans are returning to the U.S. with significant health and healthcare challenges,[7] and

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[2] S.H. Woolf and L. Aron, eds., *U.S. Health in International Perspective: Shorter Lives, Poorer Health* (Washington, DC: The National Academies Press, 2013), 420.

[3] Anita Soni, *Medical Expenditure Panel Survey: STATISTICAL BRIEF #471: "Top Five Most Costly Conditions among Adults Age 18 and Older, 2012: Estimates for the U.S. Civilian Noninstitutionalized Population,"* (Rockville: Agency for Healthcare Research and Quality, 2013), https://meps.ahrq.gov/data_files/publications/st471/stat471.shtml.

[4] Agency for Healthcare Research and Quality, *2015 National Healthcare Quality and Disparities Report and the 5th Anniversary Update on the National Quality Strategy* (Rockville: Agency for Healthcare Research and Quality, 2016), http://www.ahrq.gov/research/findings/nhqrdr/nhqdr15/index.html.

[5] For simplicity, the term "patient" is used exclusively in this document 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).

[6] Mitra Toossi, "*Labor Force Projections to 2020: A More Slowly Growing Workforce*," https://www.bls.gov/opub/mlr/2012/01/art3full.pdf .

[7] Surface Transportation and Veterans Health Care Choice Improvement Act of 2015, H.R. 3236, 114th Congress (2015).

have been granted new access to non-Department of Veteran's Affairs (VA) care, expanding the number of individuals in the U.S. healthcare system. Finally, about 12.6 percent of non-institutionalized persons in the U.S. population, or about 40 million people (circa 2014), 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.[8] Persons with disabilities often have enhanced barriers to access, and ability to understand and act upon, health information.[9] Federal legislation, including Section 508 of the Rehabilitation Act as amended and Section 255 of the Telecommunication Act as amended (and derived standards), help to ensure that persons with and without disabilities have equal access to and use of information and communication technology, and telecommunications equipment and services.[10] Using the opportunities provided by health IT R&D is necessary to optimally support health and around-the-clock care needs.

Growing diversity in the U.S. population requires new 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.[11] Supporting health IT services may allow the seamless "translation" of medical and nonmedical terminology to all patients regardless of their cultural backgrounds, native languages, or levels of health literacy.

2.3 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 non-market consumption opportunities, and the broader societal implications of lost welfare due to illness.[12] Direct health expenditures affect all sectors that may, directly or indirectly, assume the financial burden, including, but not limited to, individuals, households, employers, local communities and cities, and state and Federal governments.

Health IT can reduce costs by enhancing the quality of care, including facilitating preventive and wellness efforts, enabling the healthcare team to coordinate more effectively, and identifying care duplication and inappropriate care options so as to intervene before incurring additional costs and risks to the patient. A variety of mechanisms can support this cost reduction, including: reduced burdens on the healthcare team; reduced days of work lost by both patients and healthcare providers; digital healthcare service delivery models, such as telehealth,[13] in which providers and patients can effectively interact without the cost of in-person visits; and enhanced continuity of care made possible through information and communication

[8] Cornell University, Institute on Employment and Disability, *Disability Statistics 2016*, https://www.disabilitystatistics.org/.

[9] E.W. Grabois, M.A. Nosek, and C.D. Rossi, (1999). "Accessibility of Primary Care Physicians' Offices for People with Disabilities: An Analysis of Compliance with the Americans with Disabilities Act," *Archives of Family Medicine*, 8, no. 1 (1999): 44–51.

[10] U.S. Department of Justice, *A Guide to Disability Rights Laws*, *https://www.ada.gov/cguide.htm.*

[11] World Health Organization, *Adherence to Long Term Therapies, Evidence for Action* (Geneva: World Health Organization, 2003), http://www.who.int/chp/knowledge/publications/adherence_full_report.pdf.

[12] World Health Organization, *WHO Guide to Identifying the Economic Consequences of Disease and Injury* (Geneva: World Health Organization, 2003), http://who.int/choice/publications/d_economic_impact_guide.pdf?ua=1.

[13] "*What is Telehealth?",* Center for Connected Health Policy, http://www.cchpca.org/what-is-telehealth.

technology. These activities can reduce individual, community, and national costs, and also potentially produce financial benefits to healthcare organizations.

2.4 Reduce the Productivity Impact of Poor Health

Reduced productivity due to poor health in the population is well documented.[14] Workplaces are increasingly concerned with the direct loss in productivity and revenue resulting from employee illness. Workers may miss work or be less productive during work because of their own or family health issues. Persistent illness can cause people to drop out of the workforce, resulting in additional productivity loss due to retraining replacement employees. Health IT has a key role to play in prevention and treatment to reduce the frequency of poor health and increase the speed at which patients are treated and able to return to the workplace.

Health IT also has a role to play in better productivity of the healthcare work force. Enhancing healthcare workflows, providing better mechanisms for data and communication transmission, and supporting effective assistive technologies, such as decision support systems, should allow providers to function at the maximum level of their credentials and expertise by either eliminating or reassigning activities below that level.

2.5 Enhance the Safety, Reliability, and Quality of Healthcare

Despite established, evidence-based guidelines for care, recent health services research indicates that these guidelines are only followed approximately 50 percent of the time.[15] With the exponential increase of medical data in electronic health records from diagnostic tests, procedures and visits, along with the flood of information from patients themselves, such as home monitoring devices and the emerging Internet of Things (IoT), it is increasingly difficult for teams to provide consistent, evidenced-based care without the aid of robust, real-time clinical decision support (CDS).[16] CDS brings together patient-specific information with different treatment options in a way that allows clinicians and patients to choose the most appropriate care. To support the implementation of CDS across a range of healthcare settings, the Agency for Healthcare Research and Quality (AHRQ) has funded demonstration projects that have created processes and tools for translating clinical knowledge and narrative guidelines into formats that can be used by multiple electronic health record (EHR), claim management, and procedure-ordering systems. These systems are being used by the ONC as the basis for standards to facilitate shared CDS.[17] According to the ONC, a systems integration and safety approach to CDS must provide decision support to health professionals to assist patients, caregivers, and providers in avoiding missed diagnoses and enhance adherence to evidence-based guidelines, as well as streamline identification of risk factors for

[14] John Hadley, "Sicker and Poorer—The Consequences of Being Uninsured: A Review of the Research on the Relationship between Health Insurance, Medical Care Use, Health, Work, and Income," *Med Care Res*, 60 (2003): 2S 3S-75S.

[15] Elizabeth A. McGlynn, Steven M. Asch, et al., "The Quality of Healthcare Delivered to Adults in the United States," *New England Journal of Medicine*, 348 (2003): 2635-2645.

[16] R. Mardon, B. Mercincavage, M. Johnson et al., "Findings and Lessons from AHRQ's Clinical Decision Support Demonstration Projects," AHRQ Publication No. 140047EF (Rockville: Agency for Healthcare Research and Quality, 2014).

[17] A. Wright, D.W. Bates, B. Middleton et al., "Creating and Sharing Clinical Decision Support Content with Web 2.0: Issues and Examples," *J Biomed Inform* 42, no. 2 (2009): 334-46, http://medicine.yale.edu/cmi/glides/index.aspx.

other poor outcomes. Ultimately, this should maximize the accuracy of healthcare decisions and allow for the development of the optimal approach for each individual patient's needs.

Secure systems must also safely capture, store, and integrate data, including that from patient self-reporting, personal devices, and sensor data, for decision support across vendors, institutions, and manufacturers. Specifically, reliable and interoperable health IT 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 further medical errors, health IT systems must also automatically capture and make available the data from medical equipment (e.g., physiological monitors) and other sources needed to assess and improve care, identify patient harm and healthcare errors, and evaluate patient functioning and treatment outcomes. To prevent further medical errors and unintended patient harm, while reducing the burden of reporting to state and Federal agencies, health IT systems must allow for standardized adverse event and disease reporting that can be automated to easily capture and report relevant information, including context. In addition, health IT systems should actively scan data to detect outbreaks of disease and care-related problems as soon as possible, so that they can be quickly and appropriately addressed. Healthcare quality will be enhanced by systems that continuously monitor and enhance health safety and reliability. Those data can be shared in real-time with the research community to iteratively improve the quality of care, care guidelines, and decision support.

2.6 Facilitate Health Service Coordination

Healthcare comprises a wide range of services, and healthcare coordination is the deliberate organization of patient care activities. Sharing information among all participants concerned with a given patient's treatment and transition through care is required in order to achieve safer and more effective care.[18] Broad care coordination approaches include treatment and care management, coordination of medical management, coordination of health IT workflows, and operation of patient-centered medical homes.[19] While 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.[20] Health IT systems are needed to aid in care and service coordination, which are crucial to maintaining a working healthcare system, curbing healthcare spending, enhancing the continuity of care, and improving patient outcomes. Health IT can be used to facilitate care coordination activities, which can in turn facilitate care that is more patient-centered, less duplicative and costly, and more coherently focused around shared goals.[21] To motivate and provide the technical imperative to achieve interoperable care coordination, bidirectional data sharing and testing should be a mandatory aspect of programs that regulate care providers. This interoperability standard is already required by law for the Department of Defense (DoD) and the VA.[22] Further, health IT systems

[18] Agency for Healthcare Research and Quality, "Care Coordination," last revised July 2016, http://www.ahrq.gov/professionals/prevention-chronic-care/improve/coordination/index.html.

[19] Ibid.

[20] Institute of Medicine, *The learning health care system in America,* (Washington, DC: Institute of Medicine, 2012), http://www.iom.edu/Activities/Quality/LearningHealthCare.aspx.

[21] "Care Coordination"

[22] Review of Military Health System Modernization Study, Pub. Law No. 113-66, Sec. 713 (2015).

should employ standard language and conceptual frameworks (e.g., such as provided by the International Classification of Functioning Disability and Health) to create a knowledge transaction space for system users and to improve the efficiency and fidelity of longitudinal and interdisciplinary communication to support coordination in clinical practice and research.[23] An example of this approach comes from the DoD's Healthcare Management System Modernization: Health Readiness Concept of Operations.[24]

2.7 Improve the Health Outcome of Disaster Response

Health and healthcare challenges arise from emergency situations and natural disasters. Approximately 700 disasters occur each year with annual worldwide impact of over $100 billion dollars per year.[25] Integrated information from health IT systems—including connected devices and communications technology, EHRs, CDS systems, and other components of the health IT landscape—during a disaster or pandemic could automate data collection and analysis to optimize planning, speed response, improve diagnosis and care, and extend caregiver resources.

2.8 Address Healthcare Workforce Changes

The U. S. Census Bureau predicts that by 2050 nearly 20 million workers or about 20 percent of the national workforce will be 65 or older.[26] In fact, the healthcare workforce in the U.S. is already older than the population.[27] By 2020, nearly half of all registered nurses will reach the traditional retirement age of 65. Currently, the average age of a nurse in the U.S. is 50.[28] Nearly one-quarter of physicians in a 2007 nationwide survey were 60 or older.[29] Research suggests that these older healthcare providers are leaving medical practice earlier because of issues with current health IT systems.[30] These issues are compounded by the need for additional providers. The National Academy of Medicine reports that by 2030, the Nation will need an extra 3.5 million formal healthcare providers just to maintain the existing ratio of providers to the total population, representing a 35 percent increase from current levels.[31] This combination of an aging workforce with increased demands highlights the critical need for health IT to reduce the burden

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[23] "International Classification of Functioning, Disability and Health," World Health Organization, last updated July 2016, http://www.who.int/classifications/icf/en/.

[24] Laurie Harrington and Maria Heidkamp, "The Aging Workforce: Challenges for the Healthcare Industry Workforce," *Issue Brief of the National Technical Assistance and Research Center*, Rutgers University, March 2013, https://www.dol.gov/odep/pdf/ntar-agingworkforcehealthcare.pdf.

[25] "IMF Survey: National Disasters Hitting More People, Becoming More Costly," International Monetary Fund, Posted October 10, 2012, http://www.imf.org/external/pubs/ft/survey/so/2012/new101012a.html.

[26] Vincent K. Grayson and Victoria A. Velkoff, "The Next Four Decades, The Older Population in the United States: 2010-2050," (Washington DC: U.S. Census Bureau, 2010), https://www.census.gov/prod/2010pubs/p25-1138.pdf.

[27] "The Aging Workforce"

[28] "The Nursing Workforce in 2014: Growth, Salaries, Education, Growth and Trends," American Nurses Association, posted August 2014, (http://www.nursingworld.org/MainMenuCategories/ThePracticeofProfessionalNursing/workforce/Fast-Facts-2014-Nursing-Workforce.pdf.

[29] "The Aging Workforce"

[30] R. Jan Gurley, "Whether Retiring or Fleeing: Doctors Are Leaving Healthcare," Center For Health Journalism, Annenberg School for Communications and Journalism, University of Southern California, March 27, 2014, http://www.centerforhealthjournalism.org/2014/03/10/whether-it%E2%80%99s-retire-or-flee-doctors-are-leaving-health-care.

[31] "The Aging Workforce"

upon providers and health-related professionals, streamline the healthcare process, and facilitate high quality care at home with non-traditional providers, such as aging in place.[32]

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.[33] For R&D, the rapid pace of change and cross-cutting nature of health IT highlight the need for more training of the workforce in the areas of data science, privacy and security, networking and human-computer interaction to enable them to work across disciplinary boundaries.

2.9 Effectively Utilize Data, Devices, and Information

EHR adoption is now nearly ubiquitous, and EHRs are established as a foundation of health information for the Nation (94 to 98 percent of U.S. hospitals have adopted EHRs to date).[34] However, health data arise not only from EHRs, but also from laboratory facilities, genomics, imaging, billing records, patient-generated data, and contextual and environmental data that impact heath, as well as medical devices that directly or indirectly monitor health (e.g., continuous glucose monitors). Data collection, integration, and analysis have the potential to transform health through better modeling of disease, and optimizing devices and algorithms for specific patients, disease states, or practice settings. For example, in chronic diseases, these tools will allow us to more accurately understand the real-world impacts of different treatments on symptoms over time. Advanced in analytics, such as deep learning, machine learning, statistics and data mining, have resulted in health data also being used for uncovering new relationships between variables, where development of new patient and CDS tools will be needed to make these data actionable. In rare diseases, for example, automated CDS using machine learning and/or artificial intelligence can rapidly search large amounts of data not only within a person's record, but also within the hospital and scientific literature, to discover new links between biology, genetics, the patient, and the environment. Finally, blood pressure readings taken while the patient is standing will yield different results than those done while lying down, but this information is rarely captured. Thus, information about the context within which a treatment or device is used is important to reliably interpret data. As data accumulate at increasing rates, R&D challenges in health IT adoption and use include interoperability; privacy and security; and development of advanced analytics (e.g., machine learning, statistics and artificial intelligence) and visualization across different vendors' EHRs, medical devices, and other systems.

3. Cross-Cutting Health IT R&D Needs

These diverse motivators of health IT 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 need areas, which are summarized in this section.

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[32] Trans-NIH/Interagency Workshop on the Use and Development of Assistive Technology for the Aging Population and People with Chronic Disabilities, February 2015, http://cra.org/ccc/wp-content/uploads/sites/2/2015/06/CCC-AiP-White-Paper.pdf.

[33] https://www.healthit.gov/providers-professionals/workforce-development-programs.

[34] "Percent of Hospitals, by Type, that Possess Certified Health IT," Health IT Dashboard, Office of the National Coordinator for Health IT, 2015, http://dashboard.healthit.gov/quickstats/pages/certified-electronic-health-record-technology-in-hospitals.php.

These cross-cutting need areas also highlight some key themes. First, and perhaps most importantly, is that health IT R&D is, by its very nature, multidisciplinary. Almost all of the cross-cutting areas 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 science, systems engineering, social, behavioral, and economic sciences, as well as others.[35] Another observation is that collaborative R&D in health IT is not a quick fix. Instead, health IT R&D affords an opportunity for achieving increasing impact, with use-inspired R&D challenges surfacing in clinical implementation to reveal new needs for fundamental science. These needs and the solutions they generate can be evaluated and implemented, leading to whole new series of iterative scientific advancements. This is very clear right now in the areas of health IT analytics, which are progressing rapidly so as to leverage current data, while also preparing for the onslaught of new medical, environmental, and personal data arising from the IoT. Finally, these themes highlight the fact that continuing health IT R&D is supporting the shift from healthcare to preventative medicine to expand our understanding of the origins of health and disease.

To address the motivators and challenges summarized in the previous section, health IT R&D investments are needed in the key cross-cutting areas listed below:

Cross-Cutting Health IT R&D Needs		
Area	**Description**	**Outcomes**
Accessibility	Bridge the needs of diverse users with the appropriate health IT tools so that information can be effectively accessed, understood, and acted upon.	*Patients, caregivers and providers will have tools that meet their needs, so they are more effective in managing health.*
Advanced analytics	Merge, fuse, match and analyze different types of health data to develop understanding of new patterns and relationships between diverse risk and protective factors spanning detection, prediction, treatment, and prevention from the level of the individual through the population. These analytic advances target artificial intelligence, classification and clustering, data mining, machine learning, modeling complex data and interactions, natural language processing, statistics, image processing and analysis and visualization.	*Precision medicine will be enabled by advanced analytics that take into account a wide range of diverse data, and allows for the development of treatment and prevention programs that are personalized for the individual.*
Communications, networking, and mobile technologies	Communication and networking technologies are needed to enable flexible, reliable, and high performance information flows that enable time-aware and time-critical functionality. These technologies also are central to healthcare services delivered to remote and rural areas.	*Information will be accessible in real-time as needed to support just-in-time, mobile, and remote interventions (e.g., tele- and mobile health, clinical decision support, and shared decision-making).*

[35] President's Council of Advisors on Science and Technology Advisors, *Report on Federal Information Technology R&D*, August 2015, https://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST/nitrd_report_aug_2015.pdf.

Cross-Cutting Health IT R&D Needs		
Area	**Description**	**Outcomes**
Cyber-security and privacy	Methods to safeguard privacy by facilitating secure patient-directed sharing and guarding against loss and malicious attacks on the personal health information of individuals, providers, healthcare systems and insurers need improvement. Effective cybersecurity requires secure monitoring and logging of data communication to establish baselines and monitor for changes.	*Sharing data securely will be easy and safe. Patients, healthcare providers, and researchers will have the data that they need.*
Cyber-physical systems	The IoT and sensors will support building both closed-loop and human-in-the-loop evidenced-based systems that provide accurate information flow to ensure that people and systems are functioning as they should.	*Home monitoring will allow patients, their caregivers, and providers to support ongoing care and be notified before a crisis, and will naturally cycle information back into the system.*
Data quality	Improved methods to facilitate high data quality, extraction methods, and document provenance, as well as appropriate sharing of data (especially those data that are asynchronous).	*Data collected across a range of sources will be combinable to facilitate real-time clinical research and analytics.*
Generalizable use-cases	A prioritized set of use cases and clinical scenarios is necessary to support rapid knowledge expansion in health IT.	*Funders and researchers will more easily focus on agreed upon priority areas to rapidly advance knowledge.*
Human-technology interaction/ usability	Accurate knowledge of how people use and understand technology, including as part of a socio-technical system, as well as their beliefs about its value, needs to be developed, to facilitate adoption and use of new health IT tools.	*Health IT will leverage interactions between people and technology and between our complex infrastructures and human behavior. The information will be usable and actionable to maximize effectiveness.*
Infrastructure for sharing and storing data and tools	Appropriate infrastructure is needed to enable rapid, efficient development of health IT tools, as well the collecting, handling, de-identifying, securely storing, moving, transitioning and integrating data, and to leverage these data and the resulting knowledge.	*Aggregating and sharing of data, databases, and tools will be enabled so that information can securely move between systems to avoid expensive duplication of effort and reduce errors and risks.*

Cross-Cutting Health IT R&D Needs		
Area	**Description**	**Outcomes**
Interoperability and implementation guidance	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. Implementation guidance must accompany the requirements of standards and bidirectional exchange to explain how to deal with variability and workflow limitations.	*Implementation of systems and integration of data will be nearly seamless. Data transformation and reuse will be automated and provide real-time feedback.*
Medical device interoperability	Medical devices are essential to the practice of modern medicine, but most devices are not designed to interconnect with other devices. Medical device data standards and guidelines, security vulnerabilities, and compatibility with legacy software/hardware are needed. "Plug-and-Play" device interoperability can enable the creation of complete and accurate electronic health records and the cost-effective development of innovative third-party medical applications to enhance knowledge and safety.	*Devices will be interoperable, ensuring that devices behave safely and securely when processing real time data and scenarios. Closed loop systems, where devices can interact with each other autonomously, will intelligently analyze patient changes and reduce medical errors.*
Sensing	The development of sensing, including conventional biomedical sensing, newer Lab-On-a-Chip sensing, and contextual sensing of the IoT, will allow for earlier detection of disease and better health monitoring and disease prevention.	*With sensors monitoring for early changes in health status, it will be possible to reduce risk and unchecked development of disease.*
Standards and terminology	Appropriate standards and infrastructure are needed to enable development of efficient, reliable, interoperable systems, as well as integration with legacy systems. This infrastructure is necessary to move, integrate, and capitalize on data and knowledge. Such work could build upon past Federal investments in open standards for the integrated clinical environment (e.g., ASTM F2761, Integrated Clinical Environment, or "ICE"); the AAMI-UL 2800 family of medical device interoperability standards; standards promoted by HITECH and foundational Cyberphysical System Standards; National Library of Medicine-based terminology services and code systems; and others (e.g., HL-7 and IHE international). Tooling needs to be developed that will allow the use of shared resources to ensure consistency, high-quality testing, and continuous movement from version to version.	*Data and knowledge sharing will be enabled so that data can move among systems, 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 sharable with all downstream stakeholders.*
Supportive policies	Technological solutions need the development of supportive policies and incentive structures	*Innovations will be developed and disseminated*

Cross-Cutting Health IT R&D Needs		
Area	**Description**	**Outcomes**
	that allow the right technologies to be adopted and used in the appropriate circumstances.	*faster and more efficiently.*
Validation, verification, and regulatory science	Methods are needed to speed up the design cycle for bringing innovations into practice, while ensuring high confidence in system safety and functionality. This also includes addressing pre- and post-market regulatory requirements, where applicable.	*Systems will be developed that support safety and reliability, but do not discourage rapid innovation.*
Virtual support/digital healthcare delivery	Methods are needed that enable remote participation or healthcare delivery through a virtual presence or through the use of intelligent systems that allow for distributed knowledge to be utilized in real-time. Currently, technologies that enable this capability include telemedicine and remote consultation of software/cameras. These solutions often include a wireless component, allowing for medical care or monitoring in remote locations.	*Healthcare providers and patients throughout the country will be efficiently and effectively supported by experts and systems regardless of where they are.*
Workforce development, education and training	New models are needed for training the health IT R&D community in the necessary interdisciplinary skills 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 21st century health IT work force. With minimal lag time, these new models will be responsive to the changing health IT landscape, the resulting workforce needs, and include skills for fully leveraging health IT R&D. These new models include traditional professional training, as well as K-12 and undergraduate education.	*Students across the age span, and with different skillsets, will be trained in the R&D skills necessary for health IT to become central to health and wellness in our Nation.*

4. Collaboration Opportunities in Health IT R&D

While a number of Federal agencies have begun independent efforts to address health IT research challenges, many gaps remain in the Federal R&D portfolio. Technical barriers to rapid, predictable development and deployment of health IT arise throughout the stages of technology development, from fundamental science and engineering challenges through applied R&D (including efficacy and effectiveness trials) and deployment. Trying to address one at a time the gaps of one agency, sector, or company may result in duplication of effort, difficulties in learning from previous efforts, and general inefficiencies. Instead, a multi-agency, multi-sector, comprehensive focus on the difficult cross-cutting R&D challenges in health IT offers many benefits and synergies. For example, attempts to establish architectures for secure sharing of data use and reuse will not only facilitate advances with healthcare

diagnosis and treatment, but also in fundamental R&D on computational methods to extract new knowledge from these data.

4.1 Collaboration within NITRD

The Networking and Information Technology Research and Development (NITRD) Program provides the R&D foundations for assuring continued U.S. technological leadership by sharing information and facilitating coordination on current and future Federal IT efforts.[36] The Health IT Research and Development (HITRD) Interagency Working Group (IWG), which has developed this Framework, is the primary body for coordinating Federal health IT R&D, including assisting Federal agencies in achieving the goals of national health (see Section 2). The HITRD IWG also shares R&D challenges with other NITRD working groups, including the Big Data, Cyber-Physical Systems, Software Productivity Sustainability and Quality, Cybersecurity and Information Assurance, and Privacy IWGs. The HITRD IWG will work closely with these, and other IWGs to share with them valuable information in the health IT realm.

4.2 Partnerships for Innovation

Addressing the health IT R&D gaps described herein will require close collaborations among industry, academia, and government contributors. Public-private partnerships are expected to play a central role in bringing these stakeholders together. Such partnerships should be designed to optimize the movement of people and intellectual capital across organizational and sector boundaries, and should be structured to ensure that intellectual property concerns do not impede progress. For example, collaboration with the Industrial Internet Consortium, a group led by the private sector seeking to accelerate the advancement and adoption of the IoT, could bring together stakeholders from across the ecosystem and provide access to testbeds and user groups. Models for strategic management of intellectual property rights (IPR) will need to be developed by each agency consistent with its mission and authorities. Mechanisms to reinvigorate the healthcare workforce by including 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.

4.3 Mechanisms for Implementation

The diverse capabilities and communities represented by the different HITRD IWG member agencies could enable a range of mechanisms for addressing the R&D challenges described here. These include: (a) continued participation and engagement of funding agencies in the HITRD IWG to facilitate coordination of R&D investments and activities; (b) joint and coordinated solicitations, which may include a mix of intramural and extramural funding; (c) coordination of multi-agency 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 (d) periodic implementation plans.

4.4 Opportunities for Collaborative Funding

By way of illustration, three possible funding mechanisms that offer multi-agency coordination and collaboration are outlined below, starting from a tightly coupled mechanism (Joint Solicitation) to a

[36] https://www.nitrd.gov/.

loosely coupled mechanism (Independent Solicitations with Collaborative Research) to Other Transaction Authority (OTA) mechanisms. These funding mechanisms enable synergies among agencies and reduce potential duplication of efforts in the area of health IT R&D.

1. **Joint Solicitations**: Applications are made to joint solicitations that address the identified R&D challenges and technology needs of multiple funding agencies. The agencies would work out appropriate mechanisms for joint review and shared investment. (Peer review would be desirable for at least some of the investment). Panelists might include agency/sector-specific reviewers, as necessary.
2. **Independent Solicitations with Collaborative Research**: All solicitations will be independent, but program managers will 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 by another Federal agency.
3. **Other Transaction Authority (OTA)**: Transactions other than contracts, grants or cooperative agreements are 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 (industry/academia) 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 can include a mix of intramural and extramural funding. Through the HITRD IWG, agencies are able to pursue other models that would make sense for desired forms of cooperation and co-funding.

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

The following table provides a summary of federal agency health IT R&D activities, allowing identification of gaps in the federal health IT R&D portfolio.

Current Research and Development Investments	**NSF**	**NIH**	**ONC**	**AHRQ**	**FDA**	**NIST**	**VA**	**DOD**	**NIDLRR**
Cross-cutting Research and Development Need Areas									
Accessibility and usability	***X***	***X***	***X***	***X***			***X***		***X***
Advanced analytics	***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***
Cyber-physical systems	***X***	***X***				***X***			
Data quality	***X***	***X***	***X***	***X***	***X***		***X***		
Generalizable use-cases			***X***	***X***			***X***	***X***	
Human-technology interaction/Usability	***X***	***X***	***X***	***X***	***X***	***X***	***X***	***X***	
Infrastructure for sharing and storing data and tools	***X***	***X***	***X***				***X***	***X***	***X***
Interoperability and implementation guidance			***X***	***X***	***X***	***X***		***X***	
Medical device interoperability		***X***		***X***	***X***	***X***		***X***	
Sensing	***X***	***X***		***X***				***X***	
Standards and terminology		***X***	***X***	***X***	***X***	***X***			***X***
Supportive policies	***X***			***X***	***X***				
Validation, verification, and regulatory science		***X***		***X***	***X***				
Virtual support/digital healthcare delivery	***X***	***X***	***X***	***X***			***X***	***X***	***X***
Workforce development, education, and training	***X***	***X***	***X***	***X***	***X***			***X***	

Abbreviations

AAMI	Association for the Advancement of Medical Instrumentation
AHRQ	Agency for Healthcare Research and Quality
ASTM	American Society for Testing and Materials
CDS	Clinical Decision Support
COPD	Chronic Obstructive Pulmonary Disease
COT	Committee on Technology
DoD	Department of Defense
EHR	Electronic Health Record
FDA	Food and Drug Administration
HITECH	Health Information Technology for Economic and Clinical Health
HITRD	Health Information Technology Research and Development
HL-7	Health Level 7
IT	Information Technology
IoT	Internet of Things
IHE	Integrating the Healthcare Enterprise
IWG	Interagency Working Group
NCO	National Coordination Office
NIDLRR	National Institute on Disability, Independent Living, and Rehabilitation Research
NIH	National Institutes of Health
NITRD	Networking and Information Technology Research and Development
NSF	National Science Foundation
NSTC	National Science and Technology Council
ONC	Office of the National Coordinator for Health Information Technology
OSTP	Office of Science and Technology Policy
OTA	Other Transaction Authority

PI	Principal Investigator
R&D	Research and Development
STEM	Science, Technology, Engineering and Mathematics
VA	Department of Veterans Affairs