FINAL REPORT

Vision for the Strategic Health IT Advanced Research Projects (SHARP) Program

Presented to the Office of the National Coordinator for Health Information Technology,
United States Department of Health and Human Resources

March 2012

NORC
at the UNIVERSITY of CHICAGO

Table of Contents

Introduction

NORC at the University of Chicago, working under contract to and in consultation with expert staff of the Office of the National Coordinator for Health Information Technology (ONC) at the U.S. Department of Health and Human Services, is pleased to present this paper outlining the vision for the Strategic Health IT Advanced Research Projects (SHARP) program. The paper presents the motivation and objectives of the SHARP program both at its inception and in the current context of health care in the United States. It first offers a brief review of the history and mechanics of the program, including the research areas targeted by program funding. The paper then details the anticipated outcomes and benefits to accrue from SHARP in the current environment and reviews the approaches to program management, results dissemination, and collaboration that can help extend and accelerate benefits of the program.

Program Background

In February 2009, President Obama signed the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5) (ARRA). ARRA includes the "Health Information Technology for Economic and Clinical Health Act" or the HITECH Act. The HITECH Act authorizes unprecedented investments to advance the use of health IT to improve the quality, safety, and efficiency of health care in the United States (U.S.).

The HITECH Act authorizes a number of programs to strengthen this health information infrastructure and promote the adoption of health IT across the country. These include the Medicare and Medicaid EHR Incentives Program, the Information Technology Professionals in Health Care ("Workforce") Program, the Beacon Communities Cooperative Agreement Program, the State Health Information Exchange (HIE) Program, the Health Information Technology Regional Extension Center (REC) Program, and the Health Information Technology Research Center (HITRC).

The SHARP Program supports advanced research activities to address key short- and long-term challenges to the implementation of HITECH and its programs. Research includes:

- Exploring and defining fundamental research questions within an identified set of high-priority areas such as barriers to the nationwide adoption of electronic exchange and use of health information in a secure, private, and accurate manner;

- Providing opportunities for relevant academic and industrial researchers, health IT developers and implementers, health care providers and delivery system researchers, and other stakeholders to collaborate for the purpose of stimulating innovation and translating the results of research into health IT products;

- Creating breakthrough solutions, technologies, and services for application to health IT in the near- and long-term, and addressing significant challenges and opportunities relevant to the adoption and meaningful use of health IT;

- Identifying a range of model (proof-of-concept) systems that serve as motivating and unifying forces to drive fundamental research in health IT; and

- Encouraging effective use of health IT through rapid dissemination of research results, findings on innovations, and novel tools to developers and purchasers of health IT.

SHARP focuses on solving currently known and anticipated challenges to adoption and the meaningful use of health IT. These projects focus on areas ripe for "breakthrough" advances. For example, potential security breaches represent a major threat to public trust in the electronic maintenance and exchange of health information. SHARP research in this area seeks to identify new methods to create tools that, through their incorporation into deployed technology, will enhance data security. In doing so, the program will close the gap between the promise of health IT and its realized benefits in critical areas. The SHARP Principal Investigators have designed and dedicated the projects to supporting the goals of HITECH and overcoming health IT challenges to adoption and the meaningful use of health IT.

Thus, SHARP Awardees' work addresses fundamental research questions aimed at promoting private, secure, and accurate electronic exchange and use of health information by stimulating innovation and translating research into health IT tools and products. This requires collaboration among medical informaticists, health care researchers, health IT developers and implementers, health care providers, and other stakeholders. These efforts will promulgate the development and dissemination of previously unforeseen tools, products, and methods that will ultimately improve patient outcomes, quality of care, and catalyze additional private-sector investments in health IT.

Program Overview

ONC awarded funding to an academic institution representing a collaborative research group to conduct a four-year interdisciplinary research project. The Awardees address short- and long-term challenges within the domain area, and forge partnerships among researchers, patient groups, health care providers, and other health IT stakeholders to translate the results of their research into practice.

Through these dedicated research teams, the SHARP program will work toward specific aims, which include:

- Addressing strategic crosscutting themes that foster collaboration, consistency, and a multi-purpose technology convergence of EHR, HIE, and telemedicine;

- Developing security functions, policies and technology tools that will facilitate increasingly widespread, rapid, and sophisticated electronic use and exchange of health information while assuring and enhancing individuals' safety and privacy;

- Addressing the cognitive challenges in health IT by focusing on work-centered design, cognitive foundations for decision-making, adaptive decision support, model-based data summarization, visualization, and distributed teamwork;

- Developing, testing, refining, and disseminating models for clinical decision support that are consistent with providers' natural cognitive reasoning processes;

- Establishing a series of pipelines using a powerful computing engine (UIMA) and state of the art techniques to support secondary uses ranging from quality measurement and health information exchange to disease surveillance and genomics research;

- Assembling modular services and agents from existing open-source software to improve the utilization of EHR data for a spectrum of use-cases; and

- Developing a user interface that will allow "iPhone-like" substitutability for medical applications based upon shared basic components and a set of services that enable efficient data capture, storage, retrieval, and analytics, which will be scalable to the national level but nonetheless respectful of institutional autonomy and patient privacy.

The SHARP Program funds four competitively awarded cooperative agreements over the course of four years, each of which focuses on a distinct research domain. Although each domain addresses different areas, all projects revolve around the development and diffusion of health IT innovation and share the following key features:

- *Establishing a Research Agenda*: Each Awardee implements a research agenda addressing the specific goals of HITECH, the challenges to adoption and meaningful use of health IT that are critical to closing the gap between its reality and promise, and achieving the goal of a transformed health care delivery system.

- *Using a Multidisciplinary Approach:* Each Awardee works with multiple disciplines, as appropriate, such as health informatics, computer and information science, and health services research.

- *Using Subject Matter Expertise:* Addressing the different domain areas within the SHARP program requires advanced subject matter knowledge. Each Awardee develops and implements plans to use internal and external expertise, and help lead nationwide coordination efforts relevant to their research focus.

- *Developing Relationships with Other ONC Programs:* Where it is of benefit to overall efficiency and effectiveness of the HITECH program, SHARP Awardees collaborate with other programs making strategic contributions in the same or closely related aspects of health IT, such as the State Cooperative Agreement Programs for Health Information Exchange (HIE) and the Beacon Communities.

- *Generating Short- and Long-Term Results:* Each Awardee project generates intermediate products, tools and/or research, in addition to making longer-term contributions to the overall field of health IT.

- *Developing Multi-Sector Partnerships:* Each Awardee develops partnerships with the vendor community and other private-sector health IT, healthcare, consumer, and other relevant stakeholder organizations to enable the productive exchange of information. Relevant stakeholders that are highly engaged with a project may vary across projects and time. In general, they include a variety of perspectives such as those of healthcare professionals and/or their associations, hospitals and other organizational providers of health services (e.g. home health agencies, community health clinics) and/or their associations, consumers and consumer organizations, and/or federal, state, and local government entities.

- *Demonstrating an Institutional Commitment to the SHARP Program*: Each Awardee demonstrates institutional commitment to the project by making equipment, facilities, and laboratory space available to the Project's activities. This is significant because it shows that the Awardee institution or organization, and not merely the Principal Investigator or project team lead, is committed to the project and its success.

- *Conducting an Internal Project Evaluation*: Each Awardee uses formative and summative evaluation strategies to conduct (at a minimum) an annual evaluation to measure and report on progress toward achieving its mission and goals. This provides for and informs adjustment of project plans and activities based on the observed progress and contributing factors.

- *Using a Project Advisory Committee (PAC)*: Each Awardee forms a multi-stakeholder project advisory committee (PAC), including members of industry and representatives of professional organizations and institutions. The PAC meets regularly (typically quarterly) to help align the work of the Project with external concerns and interests.

Administration of the SHARP Program

Coordination and collaboration among experts from multiple institutions is essential to the development of innovative research. To create an organizational structure that facilitates the necessary level of collaboration, ONC established and coordinated a federal steering committee (FSC) while each site established and maintained a project advisory committee (PAC). The FSC and PACs provide guidance to the Awardees; the FSC supports ONC's oversight of the program and facilitates coordination among Awardees, while the PACs help each Awardee monitor its status and develop its plans.

FSC members include health IT leaders from various government agencies, including the Department of Veterans Affairs (VA), the Centers for Medicare & Medicaid Services (CMS), and the Health Resources and Services Administration (HRSA). The FSC monitors Awardees' progress and status, provides expert guidance and direction, and helps to shape research agendas and identify dissemination methods for Awardees.

Each Awardee has formed a multi-stakeholder PAC to review and provide input on its research methods and results. PAC membership includes industry experts, representatives from professional organizations and associations, and ONC-identified liaisons. ONC-identified liaisons have extensive subject matter expertise relevant to each project. These members regularly report on projects' progress (including successes and issues) to ONC. Other than the ONC liaisons, each project's leadership team selected the additional members of their PAC. Each PAC meets quarterly to discuss progress and ensure the alignment of project work with external concerns and interests. Each Awardee's PAC directly advises and supports the Awardee. None of the PACs provides advice or recommendations to HHS.

Consistent collaboration among the Awardees and their PACs, as well as between the FSC, Awardees, and ONC play a critical role in ensuring beneficial project results. This ongoing collaboration enables the dissemination of results and contributes to the Awardees' development of technology transfer strategies and sustainability models. This ensures that results reach the market and that productive research continues after the completion of the award.

SHARP Awardees and Research Domains

The following sections present a description of each program, its affiliated organization and research domain. Awardees implement collaborative, interdisciplinary research projects that address short- and long-term, well-documented challenges to the adoption of health IT related to four priority domains:

Security of Health Information Technology. This research area addresses the challenges of developing security and risk-mitigation policies and the technologies necessary to build and preserve the public trust as health IT systems become increasingly ubiquitous. The project goes beyond the need to establish systems to maintain compliance with legal and regulatory challenges in the current context. It looks for opportunities to incorporate sophisticated methods

that define guidelines addressing a more nuanced understanding of the objectives of security policy. It then attempts to employ these policies consistently and effectively to the context of EHRs, health information exchange, and telemedicine.

The University of Illinois at Champaign-Urbana received program funding in the area of Security of Health IT and looks to advance the requirements, foundations, design, development, and deployment of security and privacy tools and methods. This project focuses on three major health care environments: EHRs, Health Information Exchange (HIE), and Telemedicine (TEL). A multidisciplinary team of computer security, medical, and social science experts are developing security and privacy policies and technology tools to support electronic use and exchange of health information. The objective of this SHARP project is to address strategic crosscutting themes that foster collaboration, consistency, and a multi-purpose technology convergence of EHR, HIE, and TEL.

The first anticipated outcome of the Security of Health IT project is to improve the maturity of security and privacy technologies and policies to remove a key range of security and privacy barriers that prevent current health IT systems from moving to "higher" stages of meaningful use of health IT. The second anticipated outcome of the project is the creation of an integrated multidisciplinary research community in security and privacy for health IT that will facilitate progress beyond the scope and duration of this project.

Patient-Centered Cognitive Support. This research area addresses the challenge of harnessing the power of health IT to produce clinical decision support models that integrate with, enhance, and support clinicians' reasoning and decision-making. It seeks to do this by offering information at points and in manners consistent with how clinicians approach decision-making in the context of their daily work. The goal is to develop methods to improve the relevance and, thus, the effectiveness of decision support to facilitate patient-centered care across different health IT tools used by providers.

The University of Texas Health Science Center at Houston won the Patient-Centered Cognitive Support SHARP award to establish a National Center for Cognitive Informatics and Decision-Making in Healthcare (NCCD) with eight member institutions. The purpose of these institutions is to respond to the urgent and long-term cognitive challenges in health IT adoption and its meaningful use. NCCD's vision is to become a national resource providing strategic leadership in research and applications for patient-centered cognitive support in health care. NCCD's mission is three-fold:

1. To bring together a collaborative, interdisciplinary team of researchers (from the fields of biomedical and health informatics, cognitive science, computer science, clinical sciences, industrial and systems engineering, and health services research) across the nation with the highest level of expertise in patient-centered cognitive support research;

2. To conduct short-term research that addresses the urgent usability, workflow, and cognitive support issues concerning health IT, as well as long-term, breakthrough research that can fundamentally remove the key cognitive barriers to health IT adoption and its meaningful use; and

3. To translate research findings to the "real world" through a cooperative program involving researchers, patients, providers, health IT vendors, and other stakeholders that maximize the benefits of health IT for health care quality, efficiency, and safety.

NCCD leads six research projects to address the cognitive challenges in health IT identified by ONC, focusing on work-centered design, cognitive foundations for decision-making, adaptive decision support, model-based data summarization, visualization, and distributed teamwork. NCCD will deliver short-term tools within the first two years and longer-term breakthroughs in four years. It will translate them into real-world health care settings through an elaborate and coordinated effort to support and accelerate the adoption and meaningful use of health IT.

Health Application and Network Platform Architectures. This research area focuses on the development of new and improved architecture to support rapid development and dissemination of substitutable applications that share common basic components. In addition to establishing an environment in which developers can continually design and disseminate new applications, the project envisions a graphical user interface where providers can select and download these applications, similar to "app selection" interfaces used by smartphones and other mobile-computing devices. The project also provides applications that facilitate the capture, storage, retrieval, and analysis of data, scalable up to a national level, while maintaining the security and integrity of data from each particular institution.

Harvard University created the Substitutable Medical Applications Reusable Technologies (SMArt) project to bring together researchers, industry partners, clinicians, and other stakeholders to lay the groundwork necessary to enable a tectonic shift to a flexible health IT environment. This incorporates a user interface that will allow "iPhone-like" substitutability for medical applications based upon shared basic components. Additionally, the platform will include a set of services that enable efficient data capture, storage, retrieval, and analytics, which will be scalable to the national level but, nonetheless, respectful of institutional autonomy and patient privacy.

Four specific projects address a number of these goals. Project 1 focuses on the networked services that are required for the SMArt platform and how they scale from the practice to the nation. Project 2 is an investigation of the SMArt platform architecture that includes testing a small number of apps such as medication-management transactions among multiple stakeholders. Project 3 investigates how to retrofit existing commercial and non-profit, open-source health IT platforms so that SMArt apps can be substituted as needed. Project 4 lays down the sustainable infrastructure for a SMArt ecosystem whereby apps and platforms can be rapidly tested, shared, and substituted in a SMArt exchange.

Secondary Use of EHR Data. This research area focuses on strategies for linking disparate sets of data generated by EHR systems and other tools to allow new monitoring and research capabilities. In doing so, it hopes to generate new knowledge in support of quality of care and population health objectives.

The Mayo Clinic generated a framework of open-source services dynamically configurable to transform EHR data into standards-conforming, comparable information suitable for large-scale analyses, inferencing, and integration of disparate health data. The project expands upon evolving methods for using EHR data captured and maintained in disparate formats to create cogent, structured information for uses outside of the primary function of supporting clinical care through the original EHR. Secondary uses addressed by the project include structuring data for health information exchange (HIE), public health applications, quality reporting and clinical research.

The project assembled a federated informatics research community committed to open-source resources that can industrially scale to address barriers to the broad-based, facile, and ethical use of EHR data for secondary purposes. The goal of this project is to make these artifacts available to the community of secondary EHR data users, manifest as open-source tools, services, and scalable software. In addition, the project considered partnerships with industry developers who can make these resources available with commercial deployment.

This project proposes to assemble modular services and agents from existing open-source software to improve the utilization of EHR data for a spectrum of use-cases. It consists of three major projects with interrelated objectives and cross cutting dependencies: Natural Language Processing (NLP), Data Normalization, and Phenotyping. The NLP project works on processing free text entered into EHR systems to catalog and structure clinical attributes that describe the patient characteristics, events, diagnoses and procedures.. The Data Normalization team works to create a series of tools taking data coded using different EHR formats and transforms those data into a consistent structure allowing users to extract and transform structured and unstructured EHR data into a common set of clinical element models (CEMs), which are then stored in a queryable database. The Phenotyping project works with the output of the NLP team and Data Normalization team, namely populated CEMs, to identify cohorts of patients to support secondary applications.

Evaluation of the SHARP Program

In addition to Awardees' internal self-evaluations to assess the progress of their research domain, ONC has funded a separate independent evaluation of the program as a whole. This program-wide evaluation seeks to:

1) Understand and document how each individual Awardee pursues their research objectives, noting any changes from the original proposal and the evolution of methods and key research activities during the course of the project;

2) Document and describe the nature of the outputs being produced within each research domain, including actual methods, tools and products, dissemination activities, knowledge resources (e.g., peer-reviewed publications), and collaborations with experts, ONC, and the Awardees themselves to characterize the potential long-term impact of the program as a whole.

The evaluation uses primarily qualitative methods, stemming from a review of Awardee deliverables and outputs as well as a series of discussions (conducted in-person and by phone) with Awardees and other stakeholders with knowledge of the relevant domains. The evaluation also stays abreast of emerging trends within each research domain and assesses how they may affect the relevance and potential impact of the SHARP program. ONC's Office of Evaluation and Economic Modeling leads the evaluation under contract with NORC at the University of Chicago, which a Technical Expert Panel (TEP) advises.

The Potential of the SHARP Program

While it is very likely that the program will yield quantifiable outputs such as peer reviewed publications, open-source software tools, technology platforms, methodologies and presented abstracts, the stakeholders will only achieve the overall vision for this program over time through the effective use of outputs in health care delivery, research, and related enterprises. The broader objective may be for some of the lines of investigation initiated by SHARP to help identify additional areas of inquiry that lead to new domains of research.

It may be difficult in a short time span to assess this type of impact or to determine the extent to which these new lines of inquiry would have been pursued even in the absence of SHARP funding. However it is possible (and useful) to communicate, underscore, and reach consensus within ONC and the SHARP programs on a common vision of what can and should be achieved within each SHARP domain. In the sections below, we highlight the potential components of this vision as they relate to each of the specific SHARP domains.

Security of Health Information. While vendors and providers continue to establish systems for maintaining compliance with Federal and State security and privacy requirements, the ultimate success of health IT as an effective vehicle for transforming health care delivery likely requires more than basic compliance with regulation. A sense of trust among patients and providers in the ability of electronic systems to manage health care information is critical as well. Furthermore, as the level of trust in electronic systems changes, and as the science of systems security evolves, it is likely that privacy and security requirements will be a moving target for the health IT industry.

The short-term success of the SHARP domain focused on security may be assessed by understanding the extent to which concepts derived from the program are reflected in upgrades to vendors' telemedicine, EHR, and HIE solutions. For example, whether the project motivates changes in access-based service models, approaches to encryption, or formalized paradigms for risk management. Over time, the program may create consistent policies that can be applied across EHRs, HIE, and telemedicine and that can evolve in-step with advances in security

science. The project might also lead, directly or through derivative research, to the better alignment of the principles underlying technical models, policy, and regulation so that vendors and providers can seamlessly adapt to changing requirements as public trust and preferences evolve.

Patient-Centered Cognitive Support. A core benefit of EHRs and other forms of health IT used at the point of care is the ability to provide clinicians with better information to guide more effective decision-making related to treatment, diagnosis, and assessment (e.g., with respect to the ordering of screening tests). Today, many providers hesitate to adopt clinical decision support (CDS) because methods to deliver the information (e.g., alerts or templates) may challenge their natural cognitive processes or interrupt their workflow during a clinical visit or the documentation thereof. In addition, because effective decision support requires the provision of the "right information for the right patient at the right time," CDS applications that have difficulty meeting this high standard consistently are likely to invite skepticism from many providers.

The Patient-Centered Cognitive Support research domain seeks to develop, test, refine, and disseminate models for CDS that are consistent with providers' natural cognitive reasoning processes. Ideally, these models would allow for CDS that providers perceive as being in their "flow" and that makes the information they wished they had, but often do without, more accessible in a timely manner.

The outputs of this particular program area could potentially change the design of CDS applications and functionality available in EHRs and computerized physician order entry (CPOE) applications on the market. A broader vision for this project may involve its potential to dramatically improve provider buy-in for the concept of computerized CDS and thus increase take-up and compliance with CDS in the process.

Health Application and Network Platform Architecture. A growing trend in IT system development and delivery is the movement toward the application-centric paradigm (e.g., the Apple store and devices that consume such applications such as smartphones and tablets). Using a similar paradigm, the SMArt project is building the network platform infrastructure that consists of core services and substitutable applications. By uncoupling the core system from the applications and ensuring that they are substitutable, health care providers can replace one application with another of similar functionality without having to incur huge costs, make changes to other applications, or be beholden to the vendor that provided the previous application. Furthermore, this model has the potential to drive innovation by encouraging vendors, large and small, to be more agile and drive innovation from the bottom up.

This project also has the potential to alter fundamentally how vendors design and develop applications for the health care system, driving modular, highly targeted applications in the process. In addition, vendors that have found it difficult if not impossible to enter the health care market will now be on a more level playing field in terms of opportunities to demonstrate their ability to design and develop applications that truly address complex health care needs. For instance, hospital and ambulatory providers will have the ability to select modular applications

that meet specific needs and potentially move away from monolithic, single-vendor systems and toward a 'best of breed' environment. This type of access, coupled with the broad range of apps available, can then help providers meet meaningful use requirements beyond Stage 1.

Secondary Use of EHR Data. The capture and storage of clinical data in standard and consistent formats is necessary for many other applications of health IT such as CDS, quality reporting, and population health. However, data liquidity, which relies on converting non-standard patient data into a standard, consistent format, remains a significant issue. Even with the growing adoption of EHRs spurred on by HITECH, today's health care system still relies heavily on scanned documents and reports. As a result, relevant clinical information is often not immediately accessible or usable for informing decision-making processes. Given these challenges, secondary uses of the data collected by EHRs have been limited.

The Mayo Clinic's project could potentially produce software tools and resources that will reduce the complexity of converting data into standard formats and integrating previously free-text and non-electronic data into standard electronic formats. This will in turn help establish a critical infrastructure to more effectively exchange, analyze, and mine data for patient and population health. A very important contribution of this project will be the data linkages among patient characteristics and disease conditions and the implications for enhancing understanding of the causes of and risks for various disease conditions.

Ultimately, this project is likely to demonstrate how to use data more effectively at the point of care for a variety of health care purposes. The services created will also greatly enhance the ability for researchers to apply a wide range of data from clinical encounters to advanced research projects in clinical effectiveness research and genomics.

Conclusions

SHARP is a collaborative, interdisciplinary program focusing on well-documented impediments to EHR adoption and its meaningful use. The design of the program is to create a comprehensive research infrastructure that will continue to encourage breakthrough advances that support EHR adoption even after the completion of the program. In the short term, SHARP Awardees' tools, products, and methods will be disseminated to developers and vendors and help stimulate greater private-sector investment. In the longer term, Awardees' projects will drive novel approaches to encouraging the meaningful use of health IT and fundamental improvements in care delivery and outcomes. By targeting the gap between understanding of the potential impact of health IT and the implementation of solutions that realize its benefits, the SHARP program can help accelerate nationwide progress toward meaningful use and subsequently facilitate dramatic improvements in the U.S. health care system.