FINAL REPORT

Assessing the SHARP Experience

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List of Abbreviations

AMIA: American Medical Informatics Association

ARRA: The American Recovery and Reinvestment Act of 2009

API: Application programming interface

C-CDA: Consolidated Clinical Document Architecture

CEM: Clinical element model

CIMI: Clinical Information Modeling Initiative

CMS: The Centers for Medicare and Medicaid Services

EBAM: Experience-based access management

EHR: Electronic health record

FDA: The Food and Drug Administration

FHIR®©: The HL7 Fast Healthcare Interoperability Resources initiative

HIE: Health information exchange

HIMSS: Health Information Management Systems Society

HIPAA: Health Insurance Portability and Accountability Act

HITECH: The Health Information Technology for Economic and Clinical Health Act

GAO: General Accountability Office

HeD: Health eDecisions Initiative

I2B2: Informatics for Integrating Biology & the Bedside

IMD: Implantable medical device

mHealth: Mobile health

NCCD: The National Center for Cognitive Informatics and Decision Making in Healthcare

NIH: The National Institutes of Health

NIST: The National Institutes for Science and Technology

NLP: Natural language processing

NORC: NORC at the University of Chicago

NQF: National Quality Forum

ONC: Office of the National Coordinator of Health IT

PCORI: Patient Centered Outcomes Research Institute

PI: Principal investigator

PO: Project officer

ADM: Quality data model

RDF: Resource description framework

RUA: Rapid Usability Assessment

S&I: Standards and Interoperability Framework

SHARP: Strategic Health IT Advanced Research Project

SHARPc: SHARP on patient-centered cognitive support

SHARPn: SHARP for secondary use of electronic health record data

SHAPRS: SHARP on privacy and security

SMART: Substitutable Medical Apps & Reusable Technology

TURF: "Toward a usability framework for EHR usability"

Executive Summary

In 2010, the Office of the National Coordinator for Health IT (ONC) introduced the Strategic Health IT Advanced Research Project (SHARP), a program that funded research in priority areas identified in HITECH. SHARP awardees focused on health IT privacy and security; health IT design, and health IT functionality and capacity to use data captured using health IT for secondary purposes. The SHARP program aimed to improve the security, functionality, and design of health IT tools such as electronic health records (EHRs), and to enable broader usage of data captured through these tools including electronic exchange of clinical information. To understand the SHARP experience, ONC contracted with NORC at the University of Chicago (NORC) to conduct an independent evaluation of the program.

Awardee Background

ONC awarded $15M to each of the four SHARP awardees. Each awardee focused on one of the HITECH priority areas introduced above. In Table 1, we summarize the objectives and expected outcomes associated with each of the four awardees. Each of the awardees included multiple investigators and teams spread across several institutions.

Table 1. Summary of Research Focus and Objectives by Awardee

Awardee and PI	Research Focus	Objectives
Security of health information technology (SHARPS[1]) / Carl Gunter, University of Illinois	■ Security audit practices for health care institutions ■ Structured representation of privacy rules and regulations ■ Experience-based access management approach ■ Security technology enabling telemedicine and mobile health (including implantable medical devices)	■ 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. ■ To create 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 (SHARPc[2]) / Jiajie Zhang, University of Texas Houston Health Sciences Center	■ Barriers to use of EHRs by creating tools for assessing usability and optimizing care process workflow
	■ Cognitive load, usability and workflow issues associated with use of EHRs by:
	  o Modeling setting-specific factors affecting clinical decision support
	  o Creating a model for creating succinct summaries of data on complex patients with multiple chronic conditions
		■ To deliver short-term tools that address the urgent usability, workflow, and cognitive support issues concerning health IT.
		■ In the long-term, conduct breakthrough research that can fundamentally remove the key cognitive barriers to health IT adoption and meaningful use.
		■ 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.

Awardee and PI	Research Focus	Objectives
Health care application and network platform architectures (SMART[3]) / Ken Mandl and Isaac Kohane, Harvard University Medical School	■ Platform for development of vendor and standards neutral EHR functionality in the form of apps ■ Application programming interface (API) to allow integration of apps into EHR products ■ Specific apps to support key functions, including Meaningful Use	■ To lay the groundwork necessary to enable a tectonic shift to a flexible health IT environment that includes the SMART platform architecture. ■ To incorporate a user interface that will allow "iPhone-like" substitutability for medical applications based upon shared basic components. ■ To create a platform that will include a set of services that enable efficient data capture, storage, and effective data retrieval and analytics, which will be scalable to the national level but nonetheless respectful of institutional autonomy and patient privacy.
Secondary use of EHR data (SHARPn[4]) / Christopher Chute, Mayo Clinic	■ Applications of clinical element models (CEMs), e.g. identification of patient cohorts by phenotype ■ Structure for unstructured clinical notes	■ To assemble modular services and agents from existing open-source software to improve the utilization of EHR data for a spectrum of use cases.

Findings

The findings presented in this report describe the successes, challenges, and overall experience as understood by the SHARP awardees themselves, ONC POs, and other relevant stakeholders including health IT vendors and providers. We also drew from our own review of the program documentation provided by ONC and publicly available outputs generated through SHARP. In addition, this report reflects on cross-cutting themes and conclusions that may inform similar programs in the future.

We found evidence that the SHARP program has contributed to research, policy, and industry, both directly and indirectly. Specifically, SHARP contributed scores of new information products to our health IT knowledge base through peer-reviewed publications academic presentations, white papers, and reports. The awardees also produced tangible software applications, tools, and methods applications available for further experimentation and use. While we did not find specific evidence that the SHARP program has, to this point, led to large-scale changes in the use of health IT, it has led to some industry collaborations and pilot studies that demonstrate changes in health IT products and their use.

Additionally, we found indications that some foundational SHARP activities will affect change beyond the life of the program. For example, SHARPc's work influenced some aspects of Stage 2 Meaningful Use and several major electronic health record (EHR) vendors are now actively demonstrating capacity of their products to incorporate apps developed by SMART. SHARP may also influence the design and use of health IT in unanticipated ways. For instance, a new standard for health data exchanged emerged at a crucial time that offered a strategic benefit to one of the awardees. The application of this new standard created interest in the awardee's work among established EHR vendors and health care system across the country.

In the paragraphs below we summarize our findings related to each awardee.

Security of health information technology.
Academic publications and presentations constitute many of the tangible outcomes of SHARPS. As of our last count, the team completed at least 150 successful peer-reviewed publications, presentations, posters and reports in multiple forums including HealthSec, HIMSS, and AMIA. Additionally, we found some examples where vendors and policy makers have already found reason to focus on SHARPS findings. In the area of mobile device security, SHARPS work helped inform the policy process during a time of increased recognition of security problems. In the area of experience-based auditing (a novel way of auditing access data for inappropriate access), some vendors asked for input from SHARPS on their products.

The Principal Investigator (PI) noted that about one-third of the specific projects under SHARPS will continue even past the SHARP period of performance through a National Science Foundation program focused on trustworthy information systems for health and wellness. The PI also noted that focus on establishing a "learning health care system" through initiatives at ONC, the Patient Centered Outcomes Research Institute (PCORI), and other stakeholders could lead to the continuation of his team's work.

Patient-centered cognitive support.
SHARPc contributed to the field of clinical decision support in two fundamental areas: the science of usability and cognitive support for providers at the point of care. In the area of usability, recommendations generated from the project informed the National Institute for Standards and Technology usability guidelines. The team also helped to ensure usability requirements were included in the EHR certification criteria for Stage 2 Meaningful Use. This provided the necessary incentive for EHR

Key Accomplishments by Awardee

SHARPS completed over 170 artifacts, including 150 successful peer-reviewed publications, presentations, posters and reports in multiple forums including HealthSec, HIMSS, and AMIA. In some cases, these efforts described specific prototypes and solutions to problems. Additionally, the SHARPS team produced 20 artifacts and resources to facilitate future health care privacy and security research including a library of medical device design specifications, an advanced encryption framework, and tools for automating access policy based on computer programmable rules. SHARPs work is particularly notable in mobile device security, where their work has informed our understanding of risks, and experience-based auditing, where vendors have begun soliciting input from SHARPS.

SHARPc produced over 110 artifacts, including 75 academic presentations and peer-reviewed publications. In the area of usability, the team generated recommendations that informed the NIST usability guidelines. The team also helped to ensure usability requirements were included in the EHR certification criteria for Stage 2 Meaningful Use. This provided the necessary incentive for EHR vendors to consider applying the usability solutions developed by SHARPc. In the area of cognitive support, the team contributed to ONC's HeD effort and led the development of "Twinlist."

SMART generated over 70 artifacts, including 42 presentations and peer-reviewed publications. The team also disseminated their research through more creative channels, such as webinars, videos, and blog posts. The team successfully demonstrated the value of substitutable applications to support use cases associated with clinical care and research. The team engaged with HL7's new FHIR$^{®©}$ initiative to develop a prototype referred to as SMART on FHIR$^{®©}$, which consists of an open-source FHIR$^{®©}$ API server and Starter Applications. The team also contributed to enhancements of the Blue Button API enabling an easier workflow for patients to view, download, and transmit their medical information to providers and caregivers. Most recently, several EHR vendors and provider organizations demonstrated their use of SMART on FHIR$^{®©}$ at HIMSS 2014 Annual Meeting.

SHARPn produced over 120 artifacts, including 79 presentations and peer-reviewed publications. The team created tools and resources to facilitate effective use of electronic clinical data captured by EHRs and similar systems for broader uses. cTAKES, an open-source software that converts free text from medical records into structured data, is currently use in a number of commercial and research settings. Another promising innovation is the Phenotype Portal, a tool that uses structured patient data from EHRs to identify patient cohorts useful for multiple purposes, such as calculating quality measures or identifying individuals for clinical trial eligibility.

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vendors to consider applying the usability solutions developed by SHARPc. Without this impetus, EHR vendors tended to base product development on end-user requests rather than usability research. In the area of cognitive support, the team contributed to ONC's Health eDecision effort and led the development of "Twinlist", an innovative user-interface design to support medication reconciliation.

Health care application and network platform architectures. SMART experienced some initial challenges with vendor engagement and market buy-in. In part, this was due to their use of the resource description framework (RDF) as a standard to support the application programmer interface (API) necessary to incorporate their "apps" in different proprietary EHR systems. Due to direction from ONC, SMART shifted from focusing on an API strategy to working within ONC's C-CDA Collaborative focused on defining standards for data sharing across systems. The C-CDA Collaborative was instrumental in connecting the SMART team to HL7 leads working on the FHIR[®©] initiative. The SMART team also provided support to the FHIR[®©] initiatives, including working with FHIR[®©] community to improve the specification which is currently a draft standard for trial use and enhancements of the Blue Button API to work with FHIR[®©] server.

When SMART started this project, FHIR[®©] was not available and the team ended up using standards like RDF to fill this gap. With the emergence of the FHIR[®©] standard, the SMART team now had the standards available to meet the original goals of their project of producing substitutable medical applications. Vendors found FIHR[®©] a far easier framework to work within. This work is just gathering momentum.

Secondary use of EHR data. SHARPn demonstrated the disconnect between strategic research projects where investigators aim for long-term affects mediated by years of additional research and the goal of developing innovation applicable to the "real world" immediately. While the SHARPn team successfully demonstrated the capacity of their tools to relate to "real world" use cases, the information we gathered suggests that these tools did not translate to stakeholders outside of research.

We also gathered information that suggested the complexity of SHARPn's approach to NLP, data normalization, and phenotyping created barriers to its adoption outside of the research community. At the same time, we learned that some vendors use SHARPn tools such as cTAKES to motivate and test their own proprietary tools.

Based on the SHARP experience, several important lessons learned emerged relevant for future sponsors of similar programs. Research sponsors should:

- support the goals of highly applied, high-technology programs, such as SHARP, by asking awardees to focus on demonstrating market relevance up front as part of the proposal and initial deliverables;

- select the best mechanism for sponsoring projects and establish clear expectations;

- emphasize strategic business planning and work with industry and academic though leaders on such plans;

- recognize the differences between concept innovation, prototypes, pilots, and market (production) readiness and the time and progression required to move from one spectrum to the other;

- scope projects effectively and purposively to ensure adequate coordination and oversight; and

- encourage awardees to be flexible in order to take advantage of emerging opportunities and market needs.

Conclusions

The findings from this independent evaluation suggest that SHARP has made meaningful contributions to the knowledge base in the priority areas outlined in HITECH—including health IT privacy and security, health IT design, and health IT functionality and capacity to use data captured using health IT for

secondary purposes. Altogether, SHARP awardees produced nearly 500 artifacts—over two-thirds of these are peer-reviewed articles and academic presentation, the remaining products include applications, recommendations, portals, posters, technical reports, resources, software, testimony, videos, and workshops. In addition, they supported strategic ONC initiatives, such as SMART's involvement with FHIR$^{®©}$ and SHARPc's efforts with Health eDecision which led to the development of "Twinlist".

Industry collaborations and pilot studies that occurred under SHARP created opportunities for potential changes to health IT policy and design. For example, SHARPc's work influenced some aspects of Stage 2 Meaningful Use and that major EHR vendors now actively demonstrate the capacity of their tools to incorporate SMART apps. Furthermore, the currency of some of SHARPS work in the area of data security for medical devices and mHealth applications has risen and attracted the attention of regulators in recent years. It is important to note that, in some cases, the mechanisms by which SHARP programs may influence design and use of health IT could not be anticipated. For example, SMART investigators did not know that the FIHR$^{®©}$ standard would emerge and offer a strategic benefit to their project at a critical time. Similarly, the SHARPS team did not know that medical device security would take on broader interest during the period of performance.

Overall, the SHARP program established a foundation for health IT researchers and stakeholders to build on in the future. The SHARP experience also offers lessons for future sponsors of similar highly applied, high-technology programs designed to spur important improvements in the design and use of health IT.

Introduction

NORC at the University of Chicago is pleased to present this draft summative report from an independent evaluation of the Strategic Health IT Advanced Research Project (SHARP), a program introduced by the Office of the National Coordinator for Health IT (ONC) in 2010. ONC created the SHARP program of cutting-edge research to improve the security, functionality, and design of health IT tools such as electronic health records (EHRs), and to enable broader usage of data captured through these tools including electronic exchange of clinical information. In this report, we present findings from a detailed review of materials submitted by SHARP awardees throughout the history of the program and discussions with SHARP awardees, ONC Project Officers (POs), health IT technical experts, and other stakeholders.

The SHARP program consists of four separate cooperative agreements described below. ONC awarded each agreement to a large consortium of institutions and investigators working on distinct projects related to a common theme. Due to the complexity of the work conducted by each SHARP award or program, we present our findings in two ways. First, we describe findings including the scope of activities, as well as accomplishments and challenges associated with award. We then describe themes we observed across awardees. In some cases, these themes elucidate specific lessons learned. We end the report with conclusions summarizing the findings and important takeaways stemming from this evaluation.

Before presenting findings and themes, we provide background on the program itself and the four awards. We also describe the methods used to conduct this independent evaluation and the strengths and limitations of these methods. Because the SHARP program addresses some of the most vexing technical and design challenges facing health IT stakeholders, deep understanding of the significance of their work requires some background in health IT and relevant literature. To make this report accessible to a broad audience, we offer a basic and stylized version of awardee activities and focus the analysis on explaining the accomplishments, challenges, and summative conclusions associated with the program.

Program Background

ONC initiated SHARP following the passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act as part of the American Recovery and Reinvestment Act (ARRA) of 2009. Recognizing the challenges to achieving a robust digital health information infrastructure enabling providers and consumers to improve health and care throughout the U.S., ONC dedicated significant resources towards closing the gap between the promise of health IT and its realized benefits—including the goal of a transformed health care delivery system. ONC envisioned SHARP as a research program supporting the goals of HITECH and overcoming challenges to adoption and effective use of health IT.

The SHARP Program supports advanced research activities to address key short- and medium-term challenges to the HITECH and its programs. Overall, ONC awarded $60 million evenly split across four SHARP cooperative agreements focusing on the following:

- Defining and exploring fundamental research questions within an identified set of high-priority areas addressing barriers to the nationwide 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 and findings on innovations and novel tools to developers and purchasers of health IT.

The SHARP Funding Opportunity Announcement (FOA) challenged researchers to articulate important gaps in the capacity for existing health IT functionality, standards, and policies to improve health care delivery. Successful applicants described how they would conduct original research that establishes the knowledge base necessary to address these gaps.[5] In addition, ONC asked SHARP awardees to go beyond traditional methods for disseminating academic research and actively engage relevant stakeholders to facilitate rapid application of their findings into practice. See Appendix A for the SHARP vision paper, which provides additional background on the aims of the SHARP program.

SHARP Awardees and Areas of Focus

SHARP focuses on solving currently-known and anticipated challenges to effective use of health IT by designing and testing new methods and advanced technologies. These projects focus on areas ripe for "breakthrough" advances, including: security of health information technology (SHARPS), patient-centered cognitive support (SHARPc), health care application and network platform architectures (SMART), and secondary use of EHR data (SHARPn). Each SHARP focus area addresses specific statutory goals from HITECH.

Given the nature of the research agenda and the broader context of HITECH, the FOA called for multi-disciplinary research teams and an equal focus on short-term and long-term needs. ONC awarded four separate SHARP projects addressing each of the four focus areas. Each award involved multiple investigators across multiple institutions throughout the country. A single PI-institution was responsible for overall coordination for each awardee.

Each of the SHARP investigator teams came with a long history of prior ground-breaking research in their field. In all cases, the SHARP award allowed these investigators to build upon their prior work in novel ways by refining and extending it. In some cases, investigators were collaborating with new colleagues from unfamiliar disciplines. But, in general, the teams built upon strong prior collaboration between researchers and institutions. Exhibit 1 outlines the lead investigators and institutions for each awardee and briefly describes their SHARP-related experience. Appendix B describes the awardees in further detail.

Exhibit 1: Awardee Overview by SHARP Areas of Focus

Area of Focus (Awardee)	PI and Institutions	Institutions' Background and Experience
Security of health information technology (SHARPS[6])	**University of Illinois (PI-Carl Gunter)** University of Illinois at Urbana-Champaign Carnegie Mellon University Dartmouth College Harvard University and Beth Israel Deaconess Medical Center Johns Hopkins University and Children's Medical and Surgical Center New York University Northwestern University and Memorial Hospital Stanford University University of California, Berkeley University of Massachusetts Amherst University of Washington Vanderbilt University	■ This interdisciplinary team includes experts in computer security and privacy, medical and healthcare information, and social scientists, who are attuned to social and political factors affecting widespread participation in telemedicine, clinical data repositories and registries, and other health IT advances. Each computer science investigator has had experience collaborating with at least one of the medical and health information systems experts on the team. For example, one of the security experts brings prior collaboration with an internet and an artificial intelligence learning expert. These strategic collaborations enable interdisciplinary research partnerships that will accelerate the proposed health care security and privacy research. ■ *Examples of previous work:* Development of new techniques for securing sensitive patient data and exposed faults in existing healthcare system; extensive knowledge of large-scale operational systems used at hospitals; design and implementation of early prototypes of security mechanisms for implantable medical devices.
Patient-centered cognitive support (SHARPc[7])	**University of Texas Houston Health Sciences Center (PI-Jiajie Zhang)** Arizona State University Baylor College of Medicine Baylor Health Care System (Baylor Research Institute) Harvard University/Brigham & Women's Hospital Intermountain Healthcare The University of Texas MD Anderson Cancer Center University of Washington University of Kentucky University of Maryland at College Park University of Missouri VA Palo Alto Health Care System	■ These institutions brought an elaborate, pre-established research infrastructure; a long track record of pioneers and high-impact cognitive research in healthcare; a critical mass of top researchers both locally and across the nation; a comprehensive and deep understanding of the cognitive issues in health IT; a broad coalition of stakeholders for dissemination and technology transfer; and strong institutional support. ■ *Examples of previous work:* Developed usability guidelines for integrating electronic health records at the Department of Defense and Veteran Health Administration; researched the unintended consequences of computerized provider order entry; applied human factors engineering to understand the barriers and design improvements to optimize the use of information communicated in electronic health records.

Area of Focus (Awardee)	PI and Institutions	Institutions' Background and Experience
Health care application and network platform architectures (SMART[8])	**Harvard Medical School (PI-Isaac Kohane)** **Boston Children's Hospital (Co-PI-Kenneth D. Mandl)** Children's Hospital Informatics Program at BCH Partners Healthcare MGH Laboratory for Computer Science Regenstrief Medical Informatics	■ The team brought expertise in clinical standards development and use, decision support innovations, and open-source software development and employment (including platforms for personal health records, data analytic, and electronic medical records); it has also shown a successful, rare track record of translating cutting-edge research into practice. ■ *Examples of previous work:* Created a health IT ecosystem used by more than 70 commercial and academic developers; applied standard protocols, data formats, and coding systems to connect electronic health records and personal child health records; developed a code base use by six commercial and non-profit ventures.
Secondary use of EHR data (SHARPn[9])	**Mayo Clinic (PI-Christopher Chute)** **Intermountain Healthcare / University of Utah (Co-PI-Stan Huff)** Agilex Technologies, Inc. Centerphase Solutions, Inc. Clinical Data Interchange Standards Consortium (CDISC) Deloitte Group Health Research Institute Boston Children's Hospital IBM T.J. Watson Research Center Massachusetts Institute of Technology Mirth Corporation MITRE University at Albany – SUNY University of Colorado University of Pittsburgh	■ This team had deep expertise in decision support, natural language processing, phenotype extraction systems, and data exchange systems, as well as access to necessary tools such as the Minnesota state-wide information exchange network, "supercomputers," and clinical research data. ■ *Examples of previous work:* One of the PIs chaired HL7, an international organization committed to providing standards for health information exchange; contributed to the Meaningful Use specifications; developed novel methodologies to extract information from electronic health records.

Project Characteristics and Objectives

Although each of these awards focused on different areas, they share several common features. Each award involved dozens of researchers across several institutions and disciplines. ONC awarded each team $15 million to carry-out an aggressive research and research translation scope in four years. Given this size, scope, and timeline, each SHARP awardee organized themselves into large sub-projects with their own lead investigators and institutions. This structure resulted in hundreds of individual research projects and participation from scores of institutions and key investigators across the four SHARP awards.

In each case, the awards included sub-projects with their own distinct team of institutions and experts; a senior investigator different from the PI would lead each sub-project. In addition, each awardee identified its own advisory committee to help provide direction and prioritize challenges and opportunities. The advisory committees consisted of distinguished individuals from academic institutions, leading EHR vendors, professional associations, patient groups, and hospitals. ONC also provided a Federal Steering Sub-Committee for the program, designed to advise awardees from the vantage point of the federal government.

ONC charged each awardee with ambitious objectives to address specific problems within health IT. Exhibit 2 provides a summary of the areas of focus and key objectives for each awardee. While the investigators were motivated to influence health care practice as part of the program, they also faced institutional incentives to focus on traditional academic goals, such as academic publication and training. To this end, the awardees set out to produce a range of "traditional" outputs including peer-reviewed publications, academic conference presentations, and posters. Moreover, awardees created other resources to facilitate research and product development including libraries, ontologies, and unique datasets. Awardees built and enhanced software applications that they would make available to other researchers, product developers, and providers. In addition to these outputs, ONC asked the awardees to develop concrete plans for understanding market needs in their area and engaging with market participants.

Exhibit 2. Description of the Research Focus and Objectives

Awardee	Research Focus	Objectives
Security of health information technology (SHARPS[10])	■ Security audit practices for health care institutions. ■ Structured representation of privacy rules and regulations. ■ Experience-based access management approach. ■ Security technology enabling telemedicine and mobile health (including implantable medical devices).	■ 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. ■ To create 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 (SHARPc[11])	■ Barriers to use of EHRs by creating tools for assessing usability and optimizing care process workflow. ■ Cognitive load, usability and workflow issues associated with use of EHRs by: ○ Modeling setting-specific factors affecting clinical decision support. ○ Creating a model for creating succinct summaries of data on complex patients with multiple chronic conditions.	■ To deliver short-term tools that address the urgent usability, workflow, and cognitive support issues concerning health IT. ■ In the long-term, conduct breakthrough research that can fundamentally remove the key cognitive barriers to health IT adoption and meaningful use. ■ 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.
Health care application and network platform architectures (SMART[12])	■ Platform for development of vendor and standards neutral EHR functionality in the form of apps. ■ Application programming interface (API) to allow integration of apps into EHR products. ■ Specific apps to support key functions, including Meaningful Use.	■ To lay the groundwork necessary to enable a tectonic shift to a flexible health IT environment that includes the SMART platform architecture. ■ To incorporate a user interface that will allow "iPhone-like" substitutability for medical applications based upon shared basic components. ■ To create a platform that will include a set of services that enable efficient data capture, storage, and effective data retrieval and analytics, which will be scalable to the national level but nonetheless respectful of institutional autonomy and patient privacy.
Secondary use of EHR data (SHARPn[13])	■ Applications of clinical element models (CEMs), e.g. identification of patient cohorts by phenotype. ■ Structure for unstructured clinical notes.	■ To assemble modular services and agents from existing open-source software to improve the utilization of EHR data for a spectrum of use cases.

Cross-Program Collaboration

SHARP awardees did their work in the context of a broader set of changes in the adoption and use of health IT spurred by other ARRA programs. During this period, the United States experienced rapid increases in the adoption of EHRs by health care providers.[14,15] ONC asked SHARP awardees to collaborate with other concurrently launched health IT initiatives including the Medicare and Medicaid Incentives Program, a program designed to drive adoption and "meaningful use" of EHRs.[16]

In addition to collaboration across programs, ONC also facilitated collaboration among SHARP awardees themselves through the "Pan-SHARP" project initiated at the American Medical Informatics Association (AMIA) Annual Meeting in the fall of 2011.Through Pan-SHARP, ONC established a collaboration to develop a prototype that addresses the requirements necessary for medication reconciliation using contributions from across the four SHARP awardees. In an effort to focus resources on other priorities, the Pan-SHARP initiative wrapped up in the fall of 2012 and SHARPc presented their experience at the 2012 Annual Meeting of the American Medical Information Association (AMIA) meeting.[17]

Program Oversight and Management

ONC's Office of the Chief Scientist released the SHARP FOA and made awards in 2010. As Cooperative Agreements, SHARP awardees operated under the oversight of a Project Officer (PO) based at ONC. In the summer of 2012, following the departure of the program's original Project Officer, ONC assigned multiple POs to SHARP awards. In conducting this re-alignment, ONC sought to match the expertise of ONC staff with the substantive focus of each award. For example, ONC paired the SHARPS team with a PO who brought expertise in security and privacy issues. Additionally, distributing oversight across different POs enabled ONC to work more closely with each awardee to focus their work around ONC's priorities.

During this time, ONC asked awardees to prioritize different sub-projects within their area and focus remaining resources on those accomplishments that would most likely influence health IT use in the short-term. For example, during the course of the SHARPc project, ONC suggested removing one of the projects, which was large and complex in scope. While the core goals remained intact, SHARPc evolved from having six sub-projects to five.

Moreover, ONC increased their emphasis linking SHARP findings directly to ongoing policy work and industry practices. For example, ONC re-emphasized the importance of developing market engagement plans to help understand market needs in their area of focus and asked awardees to target or refine the tools and resources developed through their projects to meet those needs. As part of these re-prioritization activities, ONC also reduced its emphasis on Pan-SHARP. We discuss the impact of these shifts in greater detail in the Key Findings section.

Assessment Objectives and Approach

The purpose of this report is to characterize the SHARP experience and identify its successes and challenges as well as summative themes and conclusions. The report provides a summary for interested stakeholders and will inform the design and implementation of similar programs in the future.

Research Questions and Assessment Framework

This independent evaluation assessed successes, challenges, and lessons learned across several program dimensions and from different perspectives. For example, we describe successes and challenges in the context of:
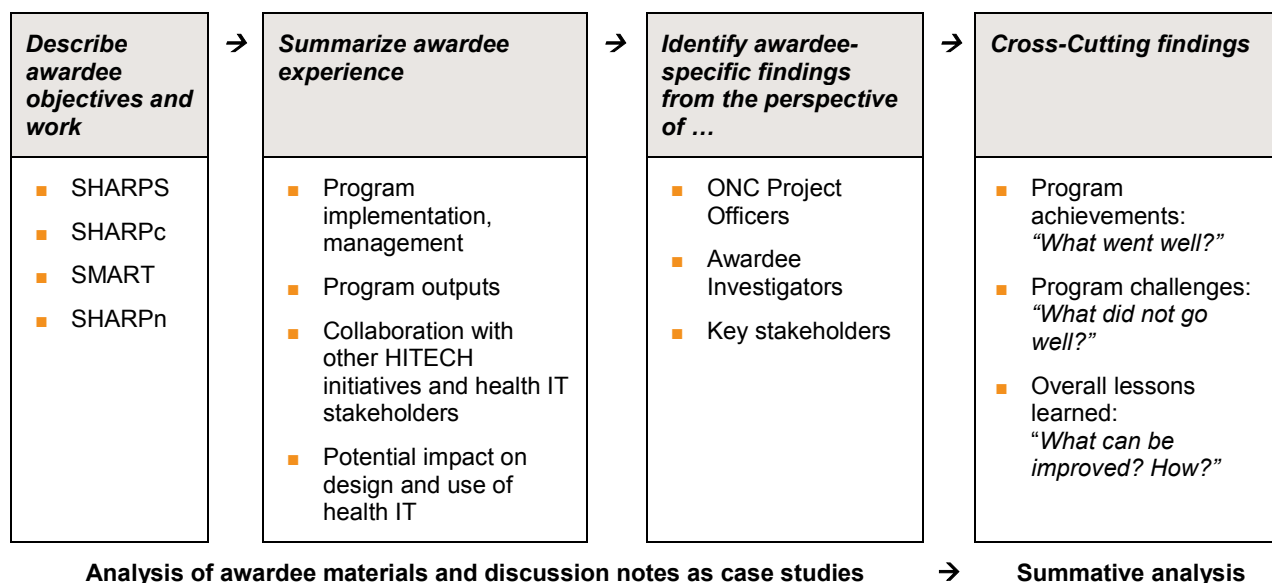
- Program implementation and management—how did program oversight affect implementation?

- Program outputs—what types of tangible product or artifacts did the awardees create? What was their applicability?

- Collaboration with other HITECH initiatives and health IT stakeholders—how did the awardees leverage other HITECH initiatives? How did collaboration with vendors and industry experts affect the awardee's work?

- Potential impact on design and use of health IT—was there impact on the research community? Was vendor engagement and uptake observed?

We consider and assess these program elements for each awardee separately. We characterize successes and challenges as understood by the SHARP awardees themselves, ONC POs, and other relevant stakeholders including health IT vendors and providers. We also draw from our own review of the program documentation provided by ONC and publicly available outputs generated through SHARP.

As an initial frame of reference for analysis, we viewed each awardee as its own case study worthy of detailed assessment. The case study framework is commonly used to address descriptive research questions.[18] For example, in this evaluation, we explore questions such as "what did the awardee accomplish?" and "what did not go well?" Moreover, the case study method allows us to present descriptions and explanations from multiple perspectives. The first set of awardee-specific findings focus on providing a more detailed overview of each awardee's activities and then on their experience related to each program component as understood by different stakeholders.

The second frame of reference for our evaluation focuses on cross-cutting themes relating to the overall program experience across awards. In presenting findings from this activity, we summarize overall successes, challenges, and lessons learned relating to program components across the awards. Exhibit 3 on page 13 depicts our research questions as well as the dimensions and perspectives considered in this study.

Exhibit 3. Assessment Framework

Describe awardee objectives and work		***Summarize awardee experience***		***Identify awardee-specific findings from the perspective of …***		***Cross-Cutting findings***
■ SHARPS ■ SHARPc ■ SMART ■ SHARPn	→	■ Program implementation, management ■ Program outputs ■ Collaboration with other HITECH initiatives and health IT stakeholders ■ Potential impact on design and use of health IT	→	■ ONC Project Officers ■ Awardee Investigators ■ Key stakeholders	→	■ Program achievements: *"What went well?"* ■ Program challenges: *"What did not go well?"* ■ Overall lessons learned: *"What can be improved? How?"*

Analysis of awardee materials and discussion notes as case studies   →   **Summative analysis**

Data and Methods

In this section, we describe the methods and tools we used to gather the information for our analysis. We conducted a series of qualitative activities to capture information required to address the questions from our research framework.

Review of program documentation. We began the project by reviewing program documentation including the FOA and proposals submitted by funded awardees. We reviewed progress reports, provided to POs by SHARP awardees on an ongoing basis, as we received these reports. We also reviewed publicly available information disseminated by awardees through their websites, peer-reviewed publications, videos, and other media.

Inventory of awardee outputs. As part of our review of program documentation and publicly available materials, we periodically catalogued outputs from the program including software, research resources, papers, presentations, and other program artifacts. See Appendices C and D for the latest inventory completed in April 2014.

Site visits to awardees. Between October 2011 and August of 2012, we conducted in-person discussions with each of the Principal Investigators and met with key co-Investigators. These two or three day site visits helped us understand awardee goals and learn about successes and challenges at that point in the project. Based on our review of awardee materials, we developed topics for discussion for these meetings in advance. We also shared these topics with discussants ahead of time. The summary of each of these site visits are included Appendices E-H.

Initial discussions with Project Officers. Following the assignment of each of the four SHARP awards to a PO whose expertise was closely aligned with its specific focus area, NORC engaged in semi-structured discussions with POs at two points. We initially conducted discussions in late 2012 and early 2013 and then conducted follow-up calls as part of a series of closing discussions described below. Through these discussions, we gained information on successes and challenges specific to each awardee from the

perspective of the POs. We also obtained the POs' ideas on areas of the project most likely to influence design and use of health IT in the short-term.

Closing discussions. Finally, we conducted a series of 12 semi-structured discussions during the last quarter of 2013 and first quarter of 2014 to gather stakeholders' final thoughts on successes, challenges, and lessons learned. See Exhibit 4 for the topics of discussion.

In all, we conducted closing discussions over the telephone with three groups of stakeholders: POs, PIs and key co-investigators, and outside stakeholders with experience working with SHARP awardees. See the Appendix I for a complete list of the individuals we spoke with, the purpose of each discussion, and the date.

Outside stakeholders included consultants, a health IT vendor, provider organizations, and a state official involved in health information exchange. PO and PI discussions took one hour. We reached out to other stakeholders only to follow-up on specific leads articulated by the PIs or POs for half-hour discussions on specific topics associated with our research framework. A description of our methods is included in Appendix J.

Exhibit 4.   Closing Discussion Topics

- Most important successes of the project
- Mechanisms by which project outputs may influence health IT adoption over time
- Key challenges, particularly with respect to transitioning the research results into practice
- Important lessons learned from all involved
- Role of ONC and other SHARP awardees
- Collaboration with ONC on non-SHARP activities
- Role of this type of funding for future health IT work

Analysis. We structured our analysis around the research questions listed in Exhibit 3. We used two overall approaches to analyzing these data. First, we crafted case studies[19] focused on explaining the trajectory, challenges, successes, and lessons learned from each project. Second, looking across projects, we took a grounded theory approach[20] to understanding successes, challenges, and lessons learned that cut across all SHARP projects.

To support analysis for both methods, we organized the information captured during the qualitative activities described above by research question and program component. These components included implementation, oversight, program outputs, collaboration, and potential impact on design and use of health IT (see Exhibit 3). In reviewing the data within this organizational structure, we identified key themes within each awardee and across awardees. The findings presented here reflect patterns related to successes, challenges, and lessons learned both within and across SHARP awardees. Our summative findings presented in this reported, established using grounded theory, include observations relevant to future programs of a similar nature.

Limitations. Based on the original scope for this project, we hoped to conduct an impact evaluation of the SHARP program. Early on, however, we realized that an impact evaluation posed serious challenges because we lacked both counterfactuals (a comparison world without SHARP) or validated measures representing SHARP's impact. After several iterations on design with ONC, we decided to pursue a qualitative and primarily descriptive approach to this report.

The intent is not to document the impact of the SHARP program, per se, but instead highlight important successes, challenges, and lessons learned. We base the characterizations in this independent evaluation report on a purposively selected group of discussants. In addition to PIs and POs, we spoke with a limited group of outside stakeholders and co-investigators to extend our capacity to make useful observations regarding the program. To account for the real-world context of this evaluation, we also considered external factors including commitment and participation from health IT vendors, timely policy levers (e.g., Meaningful Use and certification requirements), and provider engagement.

External Factors. In assessing each awardees' ability to achieve the goal of influencing changes in the behavior of health IT vendors, providers or patients, we considered factors outside of the awardees' control. The awardees largely designed and tested new technologies to address their goals or demonstrated the capacity for existing technologies to solve persistent problems. Even in cases where they successfully demonstrated innovation, there may be limited incentive for vendors, providers, or other stakeholders to adopt their findings in the short- or medium-term.

In some cases, policy levers such as EHR certification or meaningful use may facilitate adoption of SHARP findings, and we present some information on SHARP's influence in this area. In other cases, even if stakeholders recognize the benefit of an advancement, they may not anticipate enough return on investment to change or they might see broader adoption of the advance as a threat to their business model. Finally, in some cases, awardees developed technologies where an external market outside of the research community is still emerging or maturing.

As our findings and conclusions will suggest, we observed that adoption of any given SHARP finding required a beneficial set of external conditions. In some cases, awardees may have anticipated some of these conditions and considered them as part of a strategic plan to encourage adoption. However, in many cases, the direct, short-term impact of these innovations required the alignment of conditions that occur by chance and are difficult to predict.

Key Findings

We organize our findings by successes, challenges, overall experience, and cross-cutting lessons learned as ascertained from across the qualitative research activities. Due to the varying nature of objectives across awardees, we describe successes and challenges for each awardee separately in the context of program components included in our research framework.

We start by presenting our findings from the case study method where we synthesize information that describes programs activities, successes, challenges, and overall experience. We draw these findings from each of the research activities described above, and focus particularly on findings from our closing interviews. In each of the sections that follow, we provide an overview of each awardee and describe their successes and challenges with respect to key program components. These components include problem implementation, program outputs, program management, and potential influence of the program on design and use of health IT.

Notably, given the vast scope and technical nature of each award, our summary of awardee activities is not comprehensive or highly detailed. Instead, we intend to provide a cogent and illustrative summary of the awardees' experience for non-technicians as well as a thoughtful assessment of their experience based on direct discussions with awardees and stakeholders.

Security of Health IT

The SHARP program awardee in the area of security and privacy (known as "SHARPS") aims to identify the most effective means to protect health care data from external breach and implement data access and management rules that prevent unnecessary disclosure of sensitive patient information. Part of this work focuses on assuring compliance with legal requirements under the Health Insurance Portability and Accountability Act (HIPAA) and other state and federal policies. Additionally, their work provides tools for providers to develop and enforce their own policies in this area. SHARPS also helps advance procedures to secure health care data housed on multiple systems, applications and medical devices (including mobile devices, implants, and sensors) using encryption and advanced network technologies.

In describing their program, the SHARPS team divides their work into four clusters, described below:

- *Telemedicine.* SHARPS work includes efforts to improve the security of data managed by devices that capture and communicate health data such as implantable medical devices (IMDs) and mobile health (mHealth) applications. Using these technologies, as well as the associated communication networks and intermediaries, presents opportunities for potential and significant security violations. This work includes the development of secure platforms and protocols for remote patient monitoring, characterizing safety risks that come from security vulnerability and similar projects. This work also includes the development of hardware prototypes in the form of new microchips and attachments for use in smart phones and amulets used for establishing a secure "network" of data for each person.

- *Audit.* SHARPS works to improve methods that audit the act of accessing patient information (i.e., "access events") through systematic and "smarter" review of data from software usage logs. Effective auditing allows stakeholders to identify of violations and analyze access patterns to safeguard privacy over time. As health information exchange (HIE) grows, the opportunity for violations increases. The audit team also aims to create systems that ensure appropriate access to medical records to support care, and guarantees that the system accurately links queries to the correct patient.

- *Automated Policy.* SHARPS also focuses on methods for helping health care institutions understand, adjudicate, and comply with complex privacy requirements mandated by federal and state law and institutional policies. The investigators contend that an important step in this process is creating formal representations of these rules to facilitate automated compliance when it is possible. The automated policy team uses existing policies and high-level modeling tools to develop a formal representation of HIPAA requirements. The developed methods will be publicly available, and subsequently used to formalize other federal, state, and institutional policies.

- *Encryption and Trusted Base.* Finally, the SHARPS team helps develop methods for securing individual components of complex systems containing medical information to ensure overall system security. The team develops strategies to encrypt or conceal data to achieve different privacy and security objectives.

SHARPS addresses both current privacy and security challenges facing health-care stakeholders (e.g., policy development) and longer-term issues that may emerge with increased use of health IT. Overall, the emphasis is on longer-term concerns and establishing platforms, approaches, and methodologies to using "real-world" data to anticipate, understand, and solve potential security problems.

As the project evolved, additional opportunities arose, leading to shifts in emphasis in some cases. Initial research conducted by the project found that regulators had largely not addressed risks associated with breach of information stored or transmitted through implantable medical devices. The researchers' work

in this area resulted in greater public understanding of these risks through Congressional testimony and media coverage. As a result, the SHARPS team was able to provide input to inform future action by regulators.

Like the other SHARP awardees, SHARPS focuses on creating an environment where researchers contribute to improving health IT and its use over time. Part of the motivation for SHARPS comes from the PIs observation of the need to develop a cross-disciplinary research community in the area of health IT application security. In the following section, we address the team's accomplishments relative to this and other goals.

SHARPS: Accomplishments and Successes

We found the SHARPS team accomplished milestones in their proposed research area. As of our last count in April of 2014, the SHARPS team produced over 170 artifacts representing their work, including over 150 peer-reviewed publications and presentations. The SHARPS team also produced artifacts and resources to facilitate future health care privacy and security research including a library of medical device design specifications. Finally, the SHARPS team produced resources that may have direct value to developers and providers, such as an advanced encryption framework and tools for automating access policy based on computer programmable rules. See Appendix C for a complete inventory of project outputs and Appendix D for a count of the outputs by type.

As with the other SHARP programs, SHARPS experienced a change in PO in 2012. In 2012, ONC also conducted a review of their projects noting ONC priorities. This ultimately led to a revised scope of work for the program. In the paragraphs below, we outline selected accomplishments as noted during PO and PI discussions and focusing on the revised scope of work.

Accomplishments in Telemedicine. As described above, under the telemedicine domain investigators aimed to identify and to address security and privacy risks associated with capture, analysis, and sharing of health data using medical devices and monitors as well as mobile devices such as smart phones. SHARPS findings in these areas have the potential to improve decision making on the part of patients, providers, health IT application vendors, and policy makers.

In many cases, the impact of the SHARPS program depends on future adoption and interest on the part of providers, developers and policy makers. Most significantly, the PI and PO both noted SHARPS' important contribution to regulation of the security of medical devices through consultation with the General Accountability Office (GAO) and the Food and Drug Administration (FDA). To support future study and regulatory work, the SHARPS team produced reports and provided testimony to Congress on the issue.[21] While it is not possible to attribute FDA actions directly to this work, the FDA has issued new guidance to manufacturers due to emerging evidence of threats to device security.

Also in the telemedicine domain, the SHARPS team helped characterize privacy risk associated with storing and using data from biometric sensors on mobile applications. This information may help consumers understand the risks associated with providing health-related information through mobile applications.

The program also completed several studies of patient preferences in the area of security and privacy relating to use of mobile devices capturing and analyzing health data. Investigators present their findings in white papers and other materials that may guide the work of providers, health IT application vendors, and policy makers in the future.

Accomplishments in the area of Encryption and Trusted base. As noted above, in this domain investigators aimed to develop security strategies to protect specific types of health information imbedded in a larger system. For example, the team developed and tested prototypes that require users (including the patient him or herself) to enter information about the patient's medical history in order to gain access to patient-specific information using an approach called Knowledge-Based Access. They also developed an automated program (called "Charm") that facilitates rapid development of processes to encrypt data in medical or health applications and provide access to appropriate providers without compromising medical care.

The team successfully created a prototype, which employed encryption using Charm, to assure the security of patient data in a free clinic started in Baltimore by students at Johns Hopkins University. The use of Charm in the EHR used in this clinic assures security without inappropriately restricting access or hampering care in a setting where many different volunteer or student clinicians treat the same patients.

Accomplishments in the area of Audit. The PI noted the promise of their modeling of schemes to implement "Experience-based Access Management" or EBAM in electronic health record applications. Most existing systems use "role" or "attribute" based access where access to information is driven by the role an individual plays on the team and their attributes as well as the attributes of data elements (e.g., social workers may receive access to only selected portions of a patients record and nurses may only receive access to information the patients they treat). Under role-based management, users still have access to much more data than they need to do their jobs.

EBAM facilitates restrictions that secure more information without denying access rights that could prevent individuals from doing their work by updating access rules over time based on ongoing, automated audits of an individual's use of data. The PI anticipated adoption of this approach by EHR vendors in the coming months. The resources provided through SHARPS facilitate the use of EBAM processes to support identity and access management by vendors and providers using their existing audit systems.

Another accomplishment in the area of audit includes SHARPS work in creating mechanisms to extract and segment sensitive information to ensure privacy. The PI noted that health information exchange organizations and EHR vendors currently struggle with this issue and anticipated that their publications would help these organizations create effective solutions. Although a separate project, the PO noted that this work could support ONC's Data Segmentation Initiative.

Accomplishments in Automated Policy. In the area of automated policy, the SHARPS program created prototypes building off of its work in other areas. For example, the program created a prototype to segment sensitive data working closely with the State of Illinois' Health Information Exchange Cooperative Agreement program. This approach was different from the ONC data segment project, which used a predicate/reducer approach. Additionally, the team worked on mechanisms to streamline provider approaches to monitoring and enforcing compliance with HIPAA and authoring provider-specific policies.

Collaboration with vendors and industry experts. The SHARPS PI considered the "unprecedented" collaboration between health care industry experts and information security experts as a major success of the award. In the area of audit, the PI notes that multiple vendors have asked to work with the SHARPS team to evaluate new experience-based audit systems. These vendors seek SHARPS' input on the extent to which their emerging audit technologies can benefit from SHARPS work. While we cannot predict the specific mechanism by which this collaboration will influence a vendor's activities, we assume that vendors see at least potential benefit to their products through this engagement. Also, vendor interest

suggests that even if industry participants do not directly use the tools created by SHARPS, the awardee's research findings may influence the direction they take with their own proprietary approaches.

In a few areas, the SHARPS team managed to secure collaboration with health IT providers and stakeholders. For example, SHARPS worked closely with the Chief Technology Officer from the State of Illinois' Office of Health IT to create a prototype application that facilitates compliance with state and local policies by blocking access to information that can reveal HIV status or other sensitive information. The prototype will help stakeholders identify options for ensuring privacy of sensitive information in health information exchange projects throughout the state.

Creating a unique research consortium. As noted in Exhibit 2, SHARPS set out to establish a consortium of researchers crossing the disciplines of computer science, information security, medicine, law, and social sciences to address complex problems in health care information privacy and security. The number of publications and coordination across sites suggests they made initial progress toward this goal. However, we can only assess the sustainability and strength of this consortium over time. We describe the potential future of this consortium later in this section.

SHARPS: Challenges

In addition to the successes outlined above, the SHARPS team faced several important challenges related to project management, engagement with stakeholders outside of the project team, and dataset acquisition.

Coordinating a large amount of sub-projects. The PO noted that the presence of 12 sub-grantees created substantial management challenges both for the lead institution PI and for ONC. From both the PO and PI perspective, the volume of sub-projects incorporated into the SHARPS award made it challenging to set priorities and achieve effective coordination between sub-projects within the SHARPS award and with other related ONC initiatives.

Heavy reliance on students. Interviews with the PO and PI revealed that SHARPS sub-projects relied heavily on contributions from students. The PI acknowledged that transitioning projects after students graduate may delay further development of research into prototypes and viable strategies for industry. Furthermore, the PO noted that the focus on supporting student projects in some cases detracted from focusing on areas most likely to achieve market impact. However, the PI observed that sowing interest and expertise among future researchers and designers represents an important medium- to long-term contribution to the field.

Engagement with outside stakeholders. Given the scope, number of sub-projects, and broad potential audience for health care security and privacy research, SHARPS faced challenges in identifying when and how to engage outside stakeholders. In some cases, SHARPS investigators felt at odds with manufacturers that did not want to share device design specifications. Engagement with stakeholders often took the form of data sharing and testing rather than encouraging adoption. For example, providers testing different approaches to data segmentation, auditing, and encryption required use of data from hospitals and other health care providers.

Dataset acquisition. Finally, as a large project team, SHARPS had difficulty with acquiring datasets to validate scientific advances; the procurement, use, and sharing of data across so many institutions was a huge challenge. Because of the number of institutions and investigators involved, the PI reported a long process for establishing data sharing agreements and beginning the flow of data necessary to accomplish their work. This was a challenge experienced by all SHARP awardees.

Overall SHARPS experience

As with the other awardees, academic publications and presentations constitute many of the tangible outcomes of SHARPS. As of our last count, the team completed at least 150 successful peer-reviewed publications, presentations, posters and reports in multiple forums including HealthSec, HIMSS, and AMIA. In some cases, these efforts described specific prototypes and solutions to problems.[22] In other cases, these publications provided background information characterizing security problems and hypothesized solutions representing the focus of the project.[23] Finally, many of these publications described strategies and methods for specific functions, such as audit, that are potentially usable by stakeholders in provider settings.[24]

While the extent to which these publications will influence the market will play out over time, there are a few examples where it is clear that vendors and policy makers already find reason to focus on SHARPS findings. The first is in the area of mobile device security, where SHARPS helped inform discussion and policy making as the security risks became well-recognized. The second is experience-based auditing, where some vendors are already asking for input from SHARPS on their products.

The PI noted that about one-third of the specific projects under SHARPS will continue even past the SHARP period of performance through a National Science Foundation program focused on trustworthy information systems for health and wellness. The PI also noted that focus on establishing a "learning health care system" through initiatives at ONC, the Patient Centered Outcomes Research Institute (PCORI), and other stakeholders could lead to the continuation of his team's work.

Patient Centered Cognitive Support

The SHARP awardee that focused on clinical decision support (called "SHARPc") established the National Center for Cognitive Informatics and Decision Making in Healthcare (NCCD). The NCCD investigates methods to make EHRs easier for clinicians to use. The idea is to enable clinical decision support technologies that integrate with and enhance clinicians' reasoning and decision-making within the context of their daily work.

The SHARPc team has two major goals for their projects. In the short-term, the team aims to address the urgent usability, workflow, and cognitive issues of health IT systems. The team developed tools that enable EHR designers to quickly identify and prioritize usability problems and resources for resolving usability problems in existing systems. In the long-term, the team hopes their work leads to design processes focused on usability and supports adoption and effective use of health IT. Five research areas constitute the SHARPc project, include:

- *Work-centered design of health IT applications*: to generate a set of EHR-specific metrics which foster usability, best practices, and guide certification; provide tools to increase health IT adoption and cost effectiveness by integrating functions and reducing risks associated with variegated user behavior.

- *Cognitive foundations for decision-making relevant to health IT applications*: to form a new approach to clinical decision support (CDS) based on the cognitive constructs of accurate decision-making and develop the theoretical basis for clinical summarizations of key clinical conditions; develop and pilot a CDS in an EHR system that evolves, adapts, and proactively reacts to patient and provider needs.

- *Modeling of site specific factors to enhance clinical decision support functionality associated with health IT*: to develop methodologies which improve the efficacy and applicability of CDS

by integrating patient and environmental specific factors; tailor CDS by incorporating evidence-based guidance and workflow optimization techniques into EHRs.

- *Model-based data summarization*: to develop a stand-alone automated clinical summarization engine that yields condition specific, actionable, 1-2 page summaries which can be integrated into existing EHRs.

- *Cognitive information design and visualization with the goal of facilitating use of data from health IT to support better clinical decisions*: to construct an interface which supports the integration of clinical understanding, decision making, and problem solving.

SHARPc: Accomplishments and Successes

SHARPc investigators made contributions to research by publishing approximately 119 artifacts (see Appendix C). These artifacts were largely traditional research products such as publications, presentations, posters, and abstracts (see Appendix D). SHARPc also produced other resources and products including tools that software developers or providers can use to evaluate EHR usability and document how users interact with EHRs. The SHARPc award represented a new opportunity to improve EHR usability and facilitate systems design that matched cognitive workflows and offered effective decision support at the point of care.

Advancements in EHR usability research. SHARPc advanced the field of EHR usability research by developing several resources, including a framework for EHR usability (TURF – "toward a usability framework for EHR usability"). This framework represents a method for objectively evaluating, testing, and measuring ease of use of EHRs. SHARPc also produced assessment tools including a Rapid Usability Assessment (RUA) tool designed to identify critical usability issues. Research conducted under SHARPc contributed to the development of the National Institutes for Science and Technology (NIST) EHR usability guidelines. These usability guidelines, referred to as Safety Enhanced Design, were included under Meaningful Use Stage 2 certification requirements for EHR vendors.[25] Through Medstar, their vendor liaison, SHARPc assisted vendors preparing to certify their products to meet the requirements of Safety Enhanced Design and assessed current vendor usability practices, as well as vendor knowledge needs to improve user centered design processes.

In closing interviews, discussants emphasized SHARPc's role in increasing the profile of usability in health IT design. They also noted the inclusion of usability requirements for Stage 2 Meaningful Use certification created a useful incentive for the vendor community to focus on usability.[26] Though consulting with individual vendors was not a goal of the program, SHARPc worked with a small number of vendors on improving usability of their EHR design. The SHARPc team provided feedback on vendor adherence to User Centered Design Processes and technical assistance to vendors on how to conduct usability testing using the TURF software tool.

Establishing a usability center. The SHARPc team also established a usability center. In the short-term, the center makes tools that health IT vendors can use and plans to provide support to the vendor community. In the long-term, the center aspires to become a center of excellence in usability, conducting research, and offering a range of services in usability design, testing, and certification.

Automated clinical summarization. SHARPC developed and released large knowledge bases to support various aspects of clinical summarization. For example, they developed a "problem-medication" knowledge base that EHR vendors can use to summarize clinical information. In this way, each EHR vendor would not "re-invent the wheel," but rather leverage an open-source knowledge resource within their own EHR.

Some vendor uptake with cognitive support products. SHARPc made progress in the area of cognitive information design and visualization. Specifically, the team's work on "Twinlist," which provides cognitive support of medication reconciliation through a user interface design, helps providers review and reconcile different medication lists for the same patient on the same screen. Discussants noted that "Twinlist" has a potential impact on EHR design and use over time. Exhibit 5 provides screenshots of the "Twinlist" software.

Exhibit 5. Screenshots from a Demonstration of Twinlist[27]

This is a screenshot of the two medication lists, side-by-side. The one on the left was created when the patient was admitted to the hospital. The one on the right is the medication list from the hospital. When a user clicks on a drug name, the selected drug name becomes highlighted in green.
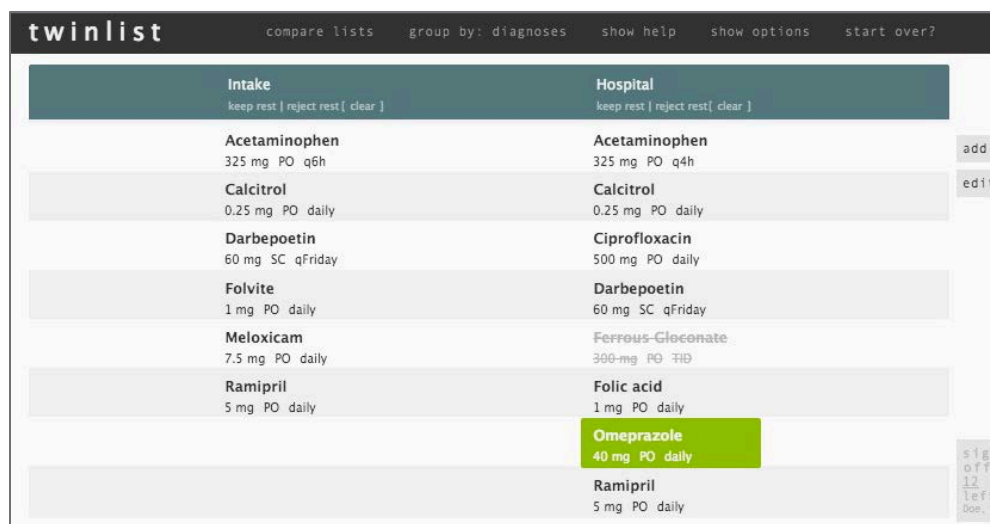
This is a screenshot of the reconciled medication list. The overlapping drugs are listed under the middle column titled "Identical." Similar drugs are listed under "Intake similar" and "Hospital similar." Unique drugs are listed under "Intake unique" and "Hospital unique." The user can then choose to accept or reject each drug.
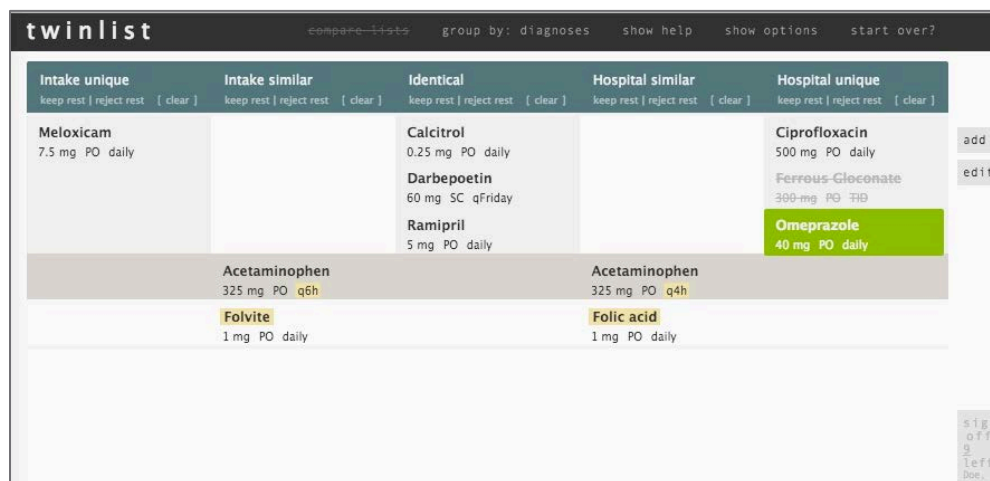
A few EHR vendors are now actively integrating elements of the design into their own EHR user interfaces. While still early on in the process, discussants noted commercial vendor uptake of these artifacts suggests early translation of SHARPc's work into practice.

Contribution to the Health eDecisions Initiative. In the area of modeling site specific factors to enhance clinical decision support (CDS), SHARPc began to work with ONC's Standards and Interoperability (S&I) Frameworks' Health eDecisions (HeD) Initiative in June 2012.[28] HeD is a public-private sponsorship to develop and validate standards to enable broader uptake of CDS standards and services by the health IT community. The SHARPc project contributed by developing an authoring and editing (HeD editor) tool to create, import, and customize CDS components for the EHR. Users do not need extensive technical skills to use the editor. This "first of its kind" tool can provide value in advancing knowledge in the area of developing CDS and incorporating CDS in the EHR.

HeD is working on two primary use cases for important CDS components across systems. In the first case, stakeholders share CDS components across different systems using standard knowledge artifacts. In the second use case stakeholders share CDS through a service.[29] For this initiative, SHARPc contributed to the first version and subsequent updates of the HeD schema, which include components on triggers, conditions, actions, and metadata for decision support rules. SHARPc has also been working on the user interface for the HeD editor.

SHARPc: Challenges

The SHARPc team faced a number of challenges related to vendor engagement, maintaining partnerships in an evolving and innovative project, and compensating for staff turnover in specialized areas.

EHR vendor engagement. SHARPc experienced ongoing challenges garnering commercial vendor participation. When SHARPc initially engaged with the vendor community, vendors did not express interest focusing instead on Meaningful Use 1 requirements. They also felt that vendors generally did not acknowledge the science of usability.[30] As part of a mid-program re-assessment and prioritization effort in 2012, SHARPc brought on an outside organization—MedStar Health (National Center for Human Factors in Healthcare)—to assess vendor needs. Market research conducted by Medstar in 2013 showed vendor interest in usability topics varied across vendors depending on their size and market penetration.

According to the market research, some of SHARPc's work did not benefit large EHR vendors who claimed to have established processes for usability. Mid-sized EHR vendors, who did not have established processes and tools for usability, showed interest in using SHARPc tools. Finally, the MedStar analysis showed that smaller EHR vendors seemed more focused on increasing market share and so usability was a lower priority at this time. In order to meet the vendor needs as identified by Medstar, SHARPc developed standardized scenarios and scripts for vendors to conduct summative user testing required for EHR certification.

Producing strategic research with short-term impact. The team experienced a natural tension between the traditional timeline for strategic research and the need to create usable tools and products in the short term. The SHARPc project team anticipated working on a longer timeframe to produce strategic results. They experienced challenges in meeting ONC's expectation to produce intermediate artifacts with direct impact. ONC redirected the team to focus on identifying usability needs of the EHR vendor community. ONC also encouraged the SHARPc team to integrate their CDS work with standards being developed under the HeD initiative and to disseminate their work via channels familiar to health IT developers. The SHARPc team was responsive to these changes in direction.

Maintaining project leadership and partnerships in the process of an evolving project. The project experienced changes in senior leadership. Notably, one of the co-Project Directors changed positions and a member of the SHARPc Project Advisory Committee moved to ONC. At ONC, a change in POs in 2012 also led to a re-assessment of project activities, which were accommodated by the SHARPc team.

Overall, the team has worked hard to compensate for market movement and staff turnover in areas requiring highly specialized skills while still meeting evolving project goals and adhering to timelines. The team has hired new staff as needed, in some cases contracting with outside entities.

Overall SHARPc experience

SHARPc contributed to the field of clinical decision support in two fundamental areas: the science of usability and cognitive support for providers at the point of care. In the area of usability, recommendations generated from the project informed the NIST usability guidelines. The team also helped to ensure usability requirements were included in the EHR certification criteria for Stage 2 Meaningful Use. This provided the necessary incentive for EHR vendors to consider applying the usability solutions developed by SHARPc. Without this impetus, EHR vendors tended to base product development on end-user requests rather than usability research. In the area of cognitive support, the team contributed to ONC's HeD effort and led the development of "Twinlist."

Moving forward, the team seeks to further align their research with the needs of the EHR vendor market. The team continues to engage the vendor community working through partners like Medstar, presenting their work at vendor conferences such as HIMSS, and building one-on-one relationships with vendors. Future work of the SHARPc team will build off these initial successes and focus on usability science with the goal of ensuring the next generation of health IT incorporates usability science into software design. The PI expressed interest in keeping the Center's work active by pursuing funding through different channels.

Health Application and Network Platform Architectures

The Substitutable Medical Applications & Reusable Technology ("SMART") program focused on the areas of health application and network platform architectures. The SMART program enabled developers to use a common platform for creating "apps" that can be used across health IT applications including different EHR products. Investigators developed a new architecture to support rapid development and dissemination of substitutable applications that share common basic components. The team also established an environment in which developers can continually design and disseminate new applications. Overall, the SMART team envisions an environment of substitutable apps constructed around shared core components similar to the Apple or Android "app stores." They believe this approach would reduce technology costs, support standards evolution, accommodate differences care workflow, foster competition in the market, and accelerate innovation.

The SMART program included four areas of focus:

- Developing networked services required for national implementation of the SMART platform;
- Investigating the SMART platform architecture that includes testing a small number of apps such as medication-management transactions among multiple stakeholders;
- Investigating how to retrofit existing commercial and non-profit, open-source health IT platforms to be SMART-ready; and
- Laying-down the sustainable infrastructure for a SMART ecosystem whereby apps can be rapidly tested, shared, and substituted in a SMART exchange.

As a first step towards allowing substitutability of EHR functionality, the team developed a SMART application programming interface (API). The SMART API specifies how apps can "plug" into an EHR or other system. The API allows integration of "read only" apps enabling the EHR user to view, but not manipulate, data from apps. While this is a limited API, the team decided this approach would work best to rapidly establish a stable API with important benefits for providers.

SMART also engaged with standards development efforts, including the SMART Consolidated Clinical Document Architecture (C-CDA),[1] the Blue Button Community, and the HL7 Fast Healthcare Interoperability Resources (FHIR®©) initiative. Similar to the other SHARP awardees, SMART generated numerous artifacts.

SMART: Successes and Accomplishments

According to the latest inventory, the SMART team produced 77 artifacts (see Appendix C). Many of these artifacts include presentations at academic and industry conferences (e.g. AMIA and Health 2.0). The team also disseminated their research through more creative channels, such as webinars, videos, blogs, and toolkits designed for the developer community (see Appendix D for a distribution of artifacts by output type). Furthermore, SMART worked with ONC to set up a challenge in 2011[31] that invited software developers to build an app using the SMART platform. The first-place winner built an app—called Meducation[32]—that takes medication lists from the patient record and turns them into simplified medication instructions, viewable in multiple languages. Developers are currently working on an iPhone version of this application.

SMART accomplishments fall under three different categories. First, SMART successfully demonstrated the value of substitutable applications to support uses cases associated with clinical care and research. Second, they contributed to standards development to demonstrate how providers and vendors could implement popular standards to support use of SMART applications. Finally, SMART applications have recently experienced penetration into commercial vendor products.

Successful app development for clinical use cases and commercial vendor uptake. The SMART team developed several applications, including Pediatric Growth Charts,[33] BP Centiles,[34] and Cardiac Risk.[35] They continue to support and enhance the Pediatric BP Centiles app used at Boston Children's hospital. Most recently, the SMART team developed an API to make clinical imaging data stored in provider systems available to app developers.

In addition, Cerner—a commercial EHR vendor with significant market share—developed an in-house prototype integrating Pediatric Growth charts with their Millennium EHR. Marand Corp, another EHR vendor, incorporated the SMART API and two apps (BP Centiles and Pediatric Growth Charts), into its OpenEHR-based health record system. With significant EHR adoption among ambulatory providers and hospitals, commercial vendor uptake holds promise for SMART's ongoing efforts in app development.[36,37] Moreover, the SMART team has successfully implemented the SMART API with open-source EHR companies such as WordVista and OpenMRS.

Standards development and refinement. ONC encouraged SMART to integrate with other ONC initiatives to extend the work of the project beyond a research effort. As a result of these collaborations, the SMART team made progress in three key standards development efforts spanning transport, clinical content, and data models.

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[1] Consolidated Clinical Document Architecture (CCDA)—is an Hl7 standards that combine various documents to create a standard vocabulary and a minimum data set to govern all forms.

Through their work on the C-CDA collaborative, the SMART team engaged with HL7's new FHIR[®©] initiative. FHIR[®©] is a next generation standards framework that builds off existing HL7 messaging and document standards. Stakeholders designed FHIR[®©] as a developer-friendly specification with a focus on implementation. By supporting granular data exchange, more flexible custom workflows, and exchange of data with mobile applications and medical devices, FHIR[®©] addresses a major industry need.

The SMART team's work in support of FHIR[®©] includes:

- Working with FHIR[®©] community to improve the specification which is currently a draft standard for trial use;

- Development of a prototype referred to as *SMART on FHIR*[®©], which consists of an open-source FHIR[®©] API server and Starter Applications (e.g., Patient Selector, Pediatric Growth Charts, BP Centiles, and Cardiac Risk);

- Enhancements of the Blue Button API to work with FHIR[®©] server. This will facilitate an easier workflow for patients to view, download, and transmit their medical information to other providers and caregivers; and

- Future development efforts that includes participation in the HL7 measure selection (or "balloting") process for the FHIR[®©] standard and ongoing development of the FHIR[®©] API server.

Most recently, the SMART team reported dissemination of their *SMART on FHIR*[®©] activities at the HIMSS 2014 Annual Meeting.[38] Here, vendors such as Hewlett Packard and Cerner, as well as providers, including Intermountain Healthcare, demonstrated their use of *SMART on FHIR*[®©] by making available their EHR data through standard APIs. *SMART on FHIR*[®©] has important implications for the health care industry as it allows for the development of platform agnostic apps in a way that major vendors find feasible.

In addition, SMART project staff launched the SMART C-CDA collaborative to assess the quality of real-world C-CDA documents. The team observed that the C-CDA standard could produce the consistency and granularity required to enable SMART applications, but that vendors rarely implemented the standard in this fashion. Multiple vendors noted that provider database set-ups affect their C-CDA and therefore the C-CDAs produced by a single EHR product may lack consistency across different provider organizations. Other reasons for variation in C-CDAs included incorrect use of standard terminologies; for example, incorrect uses were found in LOINC (terminologies used for lab results) and RxNorm (terminologies used for medications).[39]

As part of the collaborative, the SMART team assessed vendor C-CDA documents and recommended changes to individual vendors to improve the quality and consistency of the structured data transmitted via this document type. Several vendors participated in one-on-one discussions with the SMART and Lantana teams to improve their C-CDA. Ultimately, six vendors decided to place their final C-CDA documents into a public library for use by industry participants.[40]

SMART also successfully collaborated with ONC on the Blue Button initiative, which gives patients the ability to access and share their own medical data. Specifically, SMART developed an API specification giving consumers the ability to easily share their health record data with mobile device apps. Under Stage 2 Meaningful Use, consumers have the ability to view, download, and transmit their healthcare data.[41] However, the workflow for providers to download and share their data with providers, caregivers, or other healthcare applications is cumbersome. The Blue Button API enables the exchange of the same data,

using a simple and familiar workflow.[42] SMART has also produced a reference implementation of a Blue Button API and Clinical API Server, and pre-loaded them with clinical content.

These resources offer guidance for both data holders (such as health care providers and insurers) and third-party application developers seeking to add this functionality to their products and services. Ongoing activities include completing the reference implementation and initiating a pilot workgroup to demonstrate the real-world use of the API and the flow of data.

Making the SMART architecture more accessible. SMART has successfully developed a framework and APIs which enable others in the industry to start building applications. The BP Centiles app is currently being applied at Boston Children's Hospital. Software developers and innovators can now use this platform to connect with EHR vendor products. As discussed above, proprietary and open-source EHR vendors are integrating the API and apps into their products.

SMART: Challenges

While SMART achieved important accomplishments, investigators and ONC faced a number of challenges in the course of the project. Many of these challenges focused on making their work relevant to the health IT vendor community. While we found some evidence that SMART addressed many of these challenges, some of them may persist.

Difficulty translating their innovation into tangible engagement with health IT. At different points in the project, the SMART team had difficulty translating their innovation into tangible engagement with health IT vendors and providers. For example, the SMART API initially delivered data in a format known as the resource description framework (RDF). Health IT developers struggled with use of RDF to manage the data that a SMART app can extract from an EHR. The team noted that many developers lack familiarity with this tool. To address this, the SMART team explored more intuitive ways to express RDF data and settled on the REST API which is a format health IT developers have greater familiarity with.

Obtaining market buy-in. SMART's entry in the market relies largely on working with open-source EHRs and smaller start-up companies, which typically have a smaller market share. Large commercial EHR vendors have a vested interest in "locking" data into their proprietary systems and are not open to collaborations that require them to share their proprietary systems. Consequently, the uptake of SMART products has a limited reach. However, Stage 2 Meaningful Use will require vendors to exchange and share data with other systems. EHR vendors, in their desire to drive down costs, may develop greater interest in the SMART platform and apps produced to extend their EHR's functionality and facilitate exchange. Recently, SMART has engaged with a major commercial vendor who is interested in integrating their Pediatric Growth Charts into their own custom app.

Meeting the Pan-SHARP expectation in addition to existing partnerships. Discussants noted the time and resources required for initiating Pan-SHARP was substantial and took away from the research. The SMART team already managed dozens of partnerships and subcontracts. The management of additional relationships became an administrative burden. For example, the project had to undergo a fairly substantial re-budgeting exercise; an activity that is not typical for an academic institution. To further confound matters, ONC experienced changes in project leadership and the importance of Pan-SHARP evolved over time. From a grantee perspective, adjusting to new project leadership and evolving expectations of Pan-SHARP stretched available resources. Given the short timeframe of four years to accomplish ambitious, market-altering goals, investigators did not feel additional cross-awardee collaboration (e.g., Pan-SHARP) was feasible.

Producing strategic research with short-term impact. The team experienced a natural tension between the traditional timeline for strategic research and the need to work on an accelerated timeline to translate research into practice. The SMART team initially anticipated working on a longer time frame for industry uptake of their products. However, ONC clarified their need to have usable tools and products in the short-term that would have more immediate impact to the provider community. To meet ONC's expectations, the SMART team refocused their project efforts around the Standards & Interoperability (S&I) Framework development and increased engagement with the vendor community through efforts like the C-CDA collaborative. The team also disseminated project artifacts in venues frequented by the health IT developer community—such as the HIMSS and Health 2.0 conferences—where the team engaged with smaller EHR start-up companies.

In many cases, EHR vendors did not see benefits from facilitating the creation of the necessary APIs necessary to incorporate the SMART apps. EHR vendors have traditionally not supported open APIs as this would allow easier access to vendor data. In an effort to demonstrate value, the SMART team used a "sidecar strategy": instead of developing functionality compatible with a specific EHR, SMART developed a platform that allows SMART apps to access EHR data stored in a registry or database separate from the EHR itself. In this way, SMART apps can support clinicians in their daily tasks without direct integration into their EHR system.

Overall SMART Experience

SMART may be beginning to overcome their challenges of vendor engagement and market buy-in. Initially, the SMART team was hesitant to participate in the C-CDA Collaborative. However, the C-CDA Collaborative was instrumental in connecting the SMART team to HL7 leads working on the FHIR[®©] initiative. When SMART started this project, FHIR[®©] was not available and the team ended up using standards like RDF to fill this gap. With the emergence of the FHIR[®©] standard, the SMART team now had the standards available to meet the original goals of their project of producing substitutable medical applications. This work is just gathering momentum. The SMART team acknowledges that we will learn much more about the trajectory of their project and the concept of substitutable functionality for EHRs in the months and years to come.

Secondary Use of EHR Data

The "SHARPn" award focused on making EHR data usable for secondary purposes, including clinical research, quality reporting, population health interventions, or even simply health information exchange. Investigators, led by the Mayo Clinic, created tools and resources to facilitate effective use of electronic clinical data captured by EHRs or similar systems for broader uses. The project created and refined tools that structure data captured by clinical software in order to facilitate data sharing and secondary uses.

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 using the original EHR. SHARPn investigators fall into three distinct teams with interrelated objectives and cross cutting dependencies. The first focuses on Natural Language Processing (NLP) and includes investigators working on processing free text entered into EHRs to catalog and structure clinical attributes that describe the patient characteristics, events, diagnoses, and procedures documented in the free text. This task ranges in methods and complexity depending on the nature of the free text; for example, free text entered by a clinician in specifically defined fields (e.g., "chief complaint") is more straightforward to process than a completely unstructured clinical note.

The second focuses on data normalization. The team worked to create a series of tools taking data coded using different EHR formats and transforming those data into a consistent structure. The data

normalization team developed a "pipeline" of normalization tools allowing users to extract and transform structured and unstructured EHR data into a common set of clinical element models (CEMs). The CEMs consist of a series of attributes that, taken together, represent a specific patient characteristic, diagnosis, procedure, or event. These CEMs are then stored in a queryable database. The infrastructure for supporting this "pipeline" of tools and generating CEMs is the Unstructured Information Management Architecture (UIMA) processing engine, the same technology underlying IBM's Watson computer. Investigators tested a prototype of the overall pipeline and CEM creation exercise by taking data from Intermountain Health, a project collaborator in Utah, along with Mayo's own clinical data to populate CEMs using both institutions' data.

The third team focuses on phenotyping. The team worked with the output of the NLP team and data normalization team. Namely, they populated CEMs to identify cohorts of patients to support secondary uses. For example, one of the phenotyping sub-projects aimed to identify the CEMs relevant to the numerator and denominator of National Quality Forum-endorsed quality measures to facilitate reporting. To identify patients or encounters meeting specific criteria, the phenotyping team defined processes for users to query a CEM database and apply Drools, a forward-chaining rules based language, to isolate the data needed to generate quality measures and identify a research cohort or similar patient grouping tasks.

SHARPn: Successes and Accomplishments

The SHARPn team and PO identified several important accomplishments related to research contributions and real-world applications.

Important contributions to natural language processing research. Our research activities revealed several areas where SHARPn has contributed to research and health IT design. By our last count, the team had produced over 120 artifacts including peer reviewed publication and presentations, as well as a series of resources applicable to research, quality reporting, or other secondary uses (see Appendices C and D). Discussants noted the importance of SHARPn's contribution to NLP by developing software that converts free text from medical records into structured data.

This software, known as cTAKES, is open-source. It is an independent tool that is part of the data normalization process. Investigators and other stakeholders note the use of cTAKES in a number of commercial and research settings. Notably, cTAKES is the NLP tool employed by the i2B2[43] (Informatics for Integrating Biology & the Bedside) system used by Partners Healthcare and other academic medical centers to identify cohorts for clinical trials using EHR data. An industry expert also noted that many vendors, including the expert's company, use cTAKES in their design and testing work when creating their own proprietary NLP technologies.

Clinical element modules were applied in real-life scenarios. The SHARPn program also demonstrated the usefulness of clinical element modules (CEMs) to describe and document the specific components clinical concepts such as diagnoses, treatments, and symptoms. For example, a CEM might identify all of the factual elements that establish a specific treatment provided or symptom described in a clinical encounter.

SHARPn investigators used data organized in CEMs to calculate quality measures accredited by the National Quality Forum (NQF). Investigators undertook this project as a means to test the usefulness of their model to accomplish a "real world" use case. More broadly, the team demonstrated the capacity to use JBoss® Drools (a pre-existing language used to represent business rules) to translate quality data model (QDM) specifications developed by NQF to rules that can be applied to EHR data in multiple formats. This project demonstrated use of the tools created by SHARPn for a secondary purpose of interest to many provider organizations.

Phenotyping portal demonstrated as a real-word application. Among the most promising SHARPn innovations is a phenotyping portal (dubbed "Phenotype Portal"[44]). This portal uses a "QDM to Drools" translator to take structured patient data from EHRs and identify patient cohort useful for multiple purposes. For example, this tool and other algorithms developed through SHARPn can help group patients to calculate quality measures or to identify individuals eligible for clinical trials. The Portal is currently used by clinical researchers, particularly in the area of genomics.

Ultimately, the PIs emphasized the overall use case that the program demonstrated—"cohort definition" —was the primary contribution of the project. Each of the components from NLP to data normalization to phenotyping helps users isolate cohorts of patients or visits for secondary analysis. Once identified, providers and researchers can use these cohorts or patient groups to drive alerts or other clinical decisions support applications, populate quality measures, or identify individual candidates for clinical research.

SHARPn: Challenges

While SHARPn made important contributions to research, investigators and other stakeholders noted important challenges that slowed broader impact of the project.

Applicability of the clinical element models varies by use case. CEMs reflect a specific approach to organizing clinical data that facilitates detailed characteristics of patients and their experiences as captured in medical records. While SHARPn advanced the possibility for research and design activities using CEMs, discussants noted that CEMs may not take hold as a predominant approach to modeling clinical data moving forward. One of the PIs noted that the idea of normalizing to CEMs may not present the optimal approach. He noted that his team developed CEMs as a prototype to motivate the Clinical Information Modeling Initiative (CIMI), a collaborative effort to create detailed data models for clinical concepts. It is likely that this group will ultimately replace CEMs with a more refined approach.

According to the closing discussions, many stakeholders believe that it may not be necessary to use complex modeling techniques such as CEM normalization to achieve routine secondary uses of EHR data. They note that advanced clinical research in a field such as genomics may require the level of detail included in CEMs, but that less complex and easier to implement normalization techniques may suffice for other uses such as quality reporting, clinical decision support, and even some research projects. The investigators partially addressed this issue by attempting to make the Phenotype Portal agnostic to the data model. So far, investigators have successfully tested use of the Phenotype Portal with CEMs as well as two other non-CEM data models.

Dissemination and communication were an ongoing challenge. Some discussants expressed regret that the Phenotype Portal is not more widely used by health IT stakeholders and attributed its underuse to difficulty in communicating its value to non-research audiences. Although investigators noted some interest in the Phenotype Portal by commercial entities such as a vendor of clinical data analytics software, they felt limited in their ability to both conduct technical aspects of the project and market effectively to outside entities. In some cases, they felt they lacked the expertise and contacts to effectively communicate the relevance of their advances to industry.

Investigators expressed a similar regret regarding what they perceived as underuse of CEMs. Some discussants noted that the project would benefit from greater collaboration with ONC on dissemination and engagement with market stakeholders. Multiple investigators acknowledged that the complexity of their work creates barriers to effective communication and collaboration.

Difficulty meeting industry standards. One industry stakeholder noted that SHARPn contributions to cTAKES did create new opportunities for research and development and testing of prototypes, but did not

meaningfully contribute to the design of EHRs for commercial use. This stakeholder noted the slow throughput and processing time as a hindrance to using cTAKES outside of the research and experimental arena. As with CEMs, some stakeholders noted that cTAKES structures data and creates a logic with a very high degree of validity and reliability that is important for research but not essential for other uses. The same stakeholder noted the challenges with using the UIMA processing engine developed by SHARPn in the "real world." In both cases, the complexity of the applications and infrastructure that make them ideal in a research setting present a liability when they are used directly to address the everyday needs of health care providers, who will most likely not be able to accommodate lengthy processing times in their workflow.

Finally, SHARPn investigators, like other SHARP awardees noted challenges associated with accessing "real" clinical data for testing tools and processes. They echoed the difficulty of sharing data (even in de-identified form) across institutions, such as Mayo and Intermountain Health, to design and test their innovations. One of the PIs noted that the legal challenges involved in avoiding HIPAA concerns on the part of provider stakeholders rivaled the technical and scientific challenges associated with the project.

Overall SHARPn Experience

Overall, SHARPn demonstrated the disconnect between strategic research projects where investigators aim for long-term affects mediated by years of additional research and the goal of developing innovation applicable to the "real world" immediately. While the SHARPn team successfully demonstrated the capacity of their tools to relate to "real world" use cases, the information we gathered suggests that these tools did not translate to stakeholders outside of research.

We also gathered information that suggested the complexity of SHARPn's approach to NLP, data normalization, and phenotyping created barriers to its adoption outside of the research community. At the same time, we learned that some vendors use SHARPn tools such as cTAKES to motivate and test their own proprietary tools.

Some of the SHARPn work will continue through NIH funded research grants. However, investigators felt that their non-SHARP funding sources would not adequately support dissemination and continued refinement of the SHARPn products. The PIs noted that the team unsuccessfully applied for a Health Care Innovation Award from the Centers for Medicare and Medicaid Services (CMS) and expressed skepticism about the prospect of funding outside of traditional sources of pure research funding such as the National Institutes of Health (NIH).

Cross-Cutting Lessons Learned

Having highlighted awardee-specific successes and challenges, we provide cross-cutting lessons learned reflecting themes articulated by multiple stakeholders. Some of these potential lessons represent positive results from SHARP, while others present options for addressing challenges represented by the program.

> I feel we did reasonably good work in terms of developing an open-source platform and trying to make it accessible and available. However, we were left to our own devices in terms of identifying consumers. We could have benefited from more help and advice on the promotion aspect. ONC's assistance may have led to slightly higher rate of adoption.
>
> *-- SHARP Investigator*

Funders can support goals of programs such as SHARP by asking awardees to focus on demonstrating market relevance up front as part of the proposal and initial deliverables. For programs aiming to influence the design and use of technology applications in a short time frame, sponsors might require proposals to demonstrate market relevance and a plan for market entry. One approach would be creating a requirement that the project conduct a rigorous assessment of the market environment and stakeholder needs

as a first step. In addition to helping understand how to refine research topics, such an assessment could include a description of the processes relevant market stakeholders use to make design, policy, and purchasing decisions.

This point came up in discussions with SHARP POs that took responsibility over the program in the summer of 2012. For example, the SHARPc PO and program stakeholders noted that the project team experienced had scientific expertise in usability and cognitively optimized processes for facilitating decision making, but initially they lacked a basic understanding of marketplace needs and the pace and process for EHR design in industry. The SHARPS PO made a similar observation regarding the vast number of projects pursued under SHARPS and the lack of a coherent link between many of these projects and a market need. In a similar vein, one of the investigators on the SHARPn team noted that their group was best suited to do the "heads-down" programming and research rather than make connections in industry.

> This [SHARP] is a different type of grant. It's a research grant that asked researchers to move the market forward. They did not have assistance on how to do that until the summer of 2012.
>
> *-- SHARP Project Officer*

Select the best mechanism for sponsoring projects and establish clear expectations. In initiating similar programs, government sponsors might consider the benefits and costs associated with using grants, contracts, or cooperative agreements as a funding mechanism. Typically, contracts imply heavy oversight and direction from sponsors where permission is required to use project resources outside of documented boundaries. Under contract, awardees produce deliverables described in a request for proposal. Conversely, grants imply very limited oversight, leaving investigators to explore different avenues as research progresses. In some cases, cooperative agreements can serve as an effective middle ground, between contracts and grants.

Academic institutions receive funding predominantly through grants. Therefore, it may be important to ensure investigators and sponsors share a detailed understanding of expectations at project inception when working under other arrangements. In the case of SHARP, ONC logically used a cooperative agreement mechanism to make awards. Because of the nature of the research and technical expectations set forth in the funding opportunity announcement (FOA), successful applicants came from academia. Also, instead of collaboration with a PI from a single institution, the project required awarded PIs to work across multiple institutions with co-PIs leading significant program channels and awardee resources.

> ONC should appreciate the importance of the student training that is being done. It is an unrealistically short path to application [to go straight from research to vendor implementation]. The students are being trained, and then will work for industry. And the kind of things they can do for industry will make an important impact on the future… This would be an area where programs like SHARP can be improved.
>
> *-- SHARP Investigator*

We found evidence in our interviews that awardees did not fully appreciate the different expectations associated with the cooperative agreement (vs. grant) mechanism at the start of the program. One PI noted initial surprise at ONC's focus in staying on top of the evolution of specific tasks and sub-projects. He noted that in academic work, the research questions and methods typically evolve in the course of the project.

Emphasize strategic business planning. Following from the needs assessment, participants may be required to establish a business plan demonstrating the path (or potential paths) in which their innovations will take from research to the marketplace. Such a plan would need to account for economic, policy, and programmatic elements affecting the market. Recognizing the difficulty in predicting these paths, awardees and sponsors may consider several potential paths and their likelihood of success working with industry and academic thought leaders.

In the SHARP program, awardees sometimes did not focus on the path to market adoption early in their programs. For example, the SMART project sought to establish a proof-of-concept on their development platform that relied on the RDF data format. This format allowed for necessary flexibility and granularity, but posed challenges because of its lack of common usage among health-care programmers. Similarly, some awardees took on a number of research projects driven primarily by student or investigator interest. For example, investigators acknowledged that security researchers often focus on categories of security breaches that are not currently industry priorities by may represent vulnerabilities in the future.

> Traditionally, when you have academics trying to develop products, the goal is do really good research [but] this doesn't always meet the immediate needs of vendors in practice. The first thing [that] would need to happen is a clear delineation of whether the goal of the program is for long-term research or industry consumption.
>
> *-- Industry Expert*

SHARP stakeholders discussed the risks associated with an approach focused exclusively on needs articulated by the market at a particular point in time. For example, these needs that can shift abruptly may focus on needs associated with maximizing short-term gains rather than optimizing functionality. In emerging areas such as health IT, there is substantial overlap between market stakeholder needs and optimization. However, as evident from this evaluation, SHARP awardees and POs must be diligent in keeping their focus on this overlap. An overly market-based approach may be inappropriate for public investment because of its emphasis on short-term gains for market participants. Conversely, an approach that does not adequately address market needs may not be able to demonstrate a viable path to affecting the use of health IT.

Recognize differences and progression between concept innovation, prototypes, pilots, and market (production) readiness. Sponsors and program stakeholders should carefully balance the desire for projects to innovate and think beyond existing boundaries with the need for short-term applications. Awardees may achieve this by developing and implementing a business plan and timeline that anticipate specific contributions, but also allow for more open-ended research that may result in longer-term gains. As noted above, many awardee efforts involved translation of new ideas into prototypes and attempting to find "real world" data and institutions for pilot testing and refining these prototypes.

Awardees and stakeholders from industry noted that this work is markedly different than working out market entry and "production readiness" of an idea. For example, many of the open source applications developed in academic setting require more processing time and complexity than feasible for vendors and providers, but, nonetheless created examples and resources for industry to leverage over time. One industry representative noted "you don't care [as much] about processing speed when you are doing research."

Scope projects effectively and purposively. Many SHARP projects were very broad and ambitious in terms of their scope, number of participants, and sub-projects. It may be useful to fund projects with a narrower scope in order to manage complexity in coordination and oversight. PIs and POs across projects noted the difficulty in managing coordination and collaboration across complex domains. In some cases, given the scope of coordination required even within projects, awardees felt that it was unrealistic to expect awardees to collaborate among themselves through the Pan-SHARP initiative. In other cases, investigators understood the value of coordinating across SHARP awards but anticipated more help from ONC in making this coordination bear fruit.

Encourage flexibility to take advantage of emerging opportunities. Over the course of the project, ONC began to encourage awardees to focus their work more. As part of their oversight, ONC encouraged some awardees to shed projects that did not complement related ONC programs or did not initially follow market-relevant paths. Some awardees set out looking for analyses that were not possible due to lack of

data, but this finding in itself identified a market need. For example, the SHARPS program sought to understand how the FDA adjudicated security breaches involving data stored and transmitted though medical devices. They found almost no FDA investigation of instances of security breach involving devices. This finding, in part, led to greater engagement with the FDA, Congress, and GAO team in reviewing medical device security to provide scientific input to inform future regulation in this area. This topic became increasingly important in the course of the project as health IT stakeholders began, for the first time, to recognize risks associated with tampering with data transmitted to and from medical devices.[45]

> In general, a lot of this comes down to timing. A great idea, one year earlier, can go ignored. There was really good work done with SHARP grants – some will go places but others will dissipate because the timing is wrong. This is the nature of research; you invest because you are hoping something valuable might come out of it, not because of the guarantee.
>
> *-- Industry Expert (in the context of explaining "SMART on FIHR®©")*

Other examples from the SHARP awardees further illustrate the importance of flexibility and openness to shifting to accommodate concurrent changes in technology and standards. In the case of SMART, the prototype app development interface relied on the RDF platform, which was not familiar to health IT vendors, was quickly re-purposed to be able to accommodate a detailed specification of the CDA document standard. Ultimately, the FIHR®© standards platform offered a solution to making the SMART app development platform accessible to major vendors. As described earlier in the report, this led to a substantial breakthrough revealed at the 2014 HIMSS Annual Meeting—several vendors and providers demonstrated their use of *SMART on FIHR®©* by making their EHR data available through standard APIs.

Conclusions

By funding the SHARP program in 2010, ONC intended to create a test bed for innovation to accelerate improvements in the design and use of health IT to achieve goals outlined in HITECH. Even as providers, vendors, and government officials began programs to rapidly increase health IT adoption, important challenges remained. ONC recognized the importance of funding advanced research in priority areas to spur innovation and motivate short-, medium-, and long-term changes in functionality afforded to providers and patient safeguards. Specifically, SHARP funded research in priority areas identified in HITECH, including health IT privacy and security, health IT design, as well as health IT functionality and capacity to use data captured using health IT for secondary purposes.

The SHARP program overall has contributed to research, policy, and industry, both directly and indirectly. Across the entire program, SHARP created over 300 peer-reviewed publications, research reports, and white papers. Taking approval by peer-review as a proxy for creating significant new knowledge, we can conclude that the awardees made significant contributions to foundational knowledge base for health IT.

Our inventory demonstrates that SHARP awardees produced nearly 500 artifacts, presenting new knowledge or introducing tools and resources for product development, testing, and new research. These artifacts include over 60 examples of open-source software applications or knowledge resources produced by SHARP that represent potential value to developers and researchers.

The accomplishments by each awardee are summarized below.

- **SHARPS** completed over 170 artifacts, including 150 successful peer-reviewed publications, presentations, posters and reports in multiple forums including HealthSec, HIMSS, and AMIA. In some cases, these efforts described specific prototypes and solutions to problems. In other cases, these

publications provided background information characterizing security problems and hypothesized solutions representing the focus of the project. Finally, many of these publications described strategies and methods for specific functions, such as audit, that are potentially usable by stakeholders in provider settings. Additionally, the SHARPS team produced 20 artifacts and resources to facilitate future health care privacy and security research including a library of medical device design specifications, an advanced encryption framework, and tools for automating access policy based on computer programmable rules. SHARPS' work is particularly notable in the area of mobile device security and the area of experience-based auditing.

- **SHARPc** produced over 110 artifacts, including 75 academic presentations and peer-reviewed publications. The team contributed to the field of clinical decision support in two fundamental areas: the science of usability and cognitive support for providers at the point of care. In the area of usability, the team generated recommendations that informed the NIST usability guidelines. The team also helped to ensure usability requirements were included in the EHR certification criteria for Stage 2 Meaningful Use. This provided the necessary incentive for EHR vendors to consider applying the usability solutions developed by SHARPc. Without this impetus, EHR vendors tended to base product development on end-user requests rather than usability research. In the area of cognitive support, the team contributed to ONC's HeD effort and led the development of "Twinlist."

- **SMART** generated over 70 artifacts, including 42 presentations and peer-reviewed publications. The team also disseminated their research through more creative channels, such as webinars, videos, and blog posts. The team successfully demonstrated the value of substitutable applications to support use cases associated with clinical care and research. Moreover, SMART contributed to standards development to demonstrate how providers and vendors could implement population standards to support use of SMART applications. For example, the team engaged with HL7's new FHIR®© initiative develop a prototype referred to as *SMART on FHIR®©*, which consists of an open-source FHIR®© API server and Starter Applications. The team also contributed to enhancements of the Blue Button API to work with the FHIR®© server. This enables an easier workflow for patients to view, download, and transmit their medical information to other providers and caregivers. Most recently, SMART applications experienced penetration into commercial vendor products; several EHR vendors and provider organizations demonstrated their use of *SMART on FHIR®©* at HIMSS 2014 Annual Meeting.

- **SHARPn** produced over 120 artifacts, including 79 presentations and peer-reviewed publications. Using techniques, such as Natural Language Processing (NLP), data normalization, and phenotyping, the team created tools and resources to facilitate effective use of electronic clinical data captured by EHRs and similar systems for broader uses. One of the team's key accomplishments is the creation of cTAKES, an open-source software that converts free text from medical records into structured data. cTAKES is currently use in a number of commercial and research settings, including i2B2 (Informatics for Integrating Biology & the Bedside) system used by Partners Healthcare and other academic medical centers to identify cohorts for clinical trials using EHR data. Other vendors also use cTAKES in their design and testing work when creating their own propriety NLP technologies. Another promising innovation is the Phenotype Portal, a tool that uses structured patient data from EHRs to identify patient cohorts useful for multiple purposes, such as calculating quality measures or identifying individuals for clinical trial eligibility.

While SHARP achieved important accomplishments, the findings also highlight a number of challenges during the course of the project. The key challenges include: 1) coordination of partnerships and subcontracts; 2) obtaining market buy-in; 3) engagement with outside stakeholders; and 4) producing strategic research with short-term impact.

Coordination of partnerships and subcontracts. In order to accomplish ambitious, market-altering goals within a four-year timeframe, SHARP awardees included many institutions and subcontracts. In turn, the main institution managed dozens of partnerships and subcontracts. At times, this made it difficult to set priorities and achieve effective coordination between the sub-projects within the SHARP award and with other related ONC initiatives. In fact, one awardee had several sub-projects that were overlapping in goals and the PO worked with the awardee to create an inventory to align the sub-projects and ensure resources are optimized. Another awardee noted the Pan-SHARP initiative required substantial time and resource and took away from the research. ONC's expectation of Pan-SHARP stretched available resources and the awardee did not feel additional cross-awardee collaboration (e.g., Pan-SHARP) was feasible.

Obtaining market buy-in. SHARP awardees experienced ongoing challenges garnering commercial vendor participation. They noted limited capacity to both conduct technical aspects of the project and market effectively to outside entities. In some cases, they felt they lacked the expertise and contacts to effectively communicate the relevance of their advances to industry. ONC's expectation of open-source products also presented barriers for market entry. For instance, the uptake of SMART products has had a limited reach because SMART relies largely on working with open-source EHRs and smaller start-up companies, which typically have a smaller market share. Large commercial EHR vendors have a vested interest in "locking" data into their proprietary systems and are not open to collaborations that require them to share their proprietary systems. However, Stage 2 Meaningful Use will require vendors to exchange and share data with other systems. In their desire to drive down costs, EHR vendors may develop greater interest in the SMART platform and apps produced to extend their EHR's functionality and facilitate exchange. Recently, SMART has engaged with a major commercial vendor who is interested in integrating their Pediatric Growth Charts into their own custom app.

Engagement with outside stakeholders. Each awardee was conducting research in highly specialized areas, which at times had some disconnect with the vendor or developer communities' priorities and interests. For example, when the SHARPc team initially engaged with the vendor community, vendors did not express interest in usability but instead were focusing on Meaningful Use 1 requirements. The PI also found that that vendors generally did not acknowledge the science of usability. Findings from a needs assessment, conducted by an external consultant, showed that vendor interest in usability topics varied across vendors depending on their size and market penetration. This exercise redirected SHARPc toward developing standardized scenarios and scripts for vendors to conduct summative user testing required for EHR certification. In SHARPn's case, a few of their prototypes have shown slow throughput and processing time. One industry stakeholder noted the complexity of the applications and infrastructure that make the prototypes ideal in a research setting but the lengthy processing times present a liability when they are used directly to address the everyday needs of health care providers, who will most likely not be able to accommodate long processing times in their workflow.

Producing strategic research with short-term impact. SHARP awardees also experienced a natural tension between the traditional timeline for strategic research and the need to create usable tools and products in the short-term. For instance, the SMART team initially anticipated working on a longer time frame for industry uptake of their products. However, ONC clarified their need to have usable tools and products in the short-term that would have more immediate impact to the provider community. To meet ONC's expectations, the SMART team refocused their project efforts around the Standards & Interoperability (S&I) Framework development and increased engagement with the vendor community through efforts like the C-CDA Collaborative. The team also disseminated project artifacts in venues frequented by the health IT developer community—such as the HIMSS and Health 2.0 conferences— where the team engaged with smaller EHR start-up companies. Similarly, to meet ONC's expectation to produce intermediate artifacts with direct impact, SHARPc was redirected to focus on identifying usability needs of the EHR vendor community. ONC also encouraged the SHARPc team to integrate their

CDS work with standards being developed under the HeD initiative and to disseminate their work via channels familiar to health IT developers. The SHARPc team was responsive to these changes in direction.

Based on the SHARP experience, several important lessons learned emerged relevant for future sponsors of similar programs. Research sponsors should:

- support the goals of highly applied, high-technology programs, such as SHARP, by asking awardees to focus on demonstrating market relevance up front as part of the proposal and initial deliverables;

- select the best mechanism for sponsoring projects and establish clear expectations;

- emphasize strategic business planning and work with industry and academic though leaders on such plans;

- recognize the differences between concept innovation, prototypes, pilots, and market (production) readiness and the time and progression required to move from one spectrum to the other;

- scope projects effectively and purposively to ensure adequate coordination and oversight; and

- encourage awardees to be flexible in order to take advantage of emerging opportunities and market needs.

According to our findings, the SHARP awardees conducted original research that made new contributions to the knowledge base in their respective research areas. While we did not find specific evidence that the SHARP program has, to this point, led to large-scale changes in the use of health IT, it has led to some industry collaborations and pilot studies that demonstrate changes in health IT products and their use. The program also produced findings relevant to stakeholder achievement of meaningful use with the potential to influence health IT use and design in the near future. This body of work will leave an important legacy for future researchers and other health IT stakeholders.

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