FACTORS ASSOCIATED WITH THE IMPLEMENTATION AND FULL USE

OF A NATIONWIDE HEALTH INFORMATION TECHNOLOGY SYSTEM

by

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A thesis submitted to the

Faculty of the Graduate School of the

University of Colorado in partial fulfillment

of the requirements for the degree of

Doctor of Philosophy

Clinical Science Program

2013

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Factors Associated with the Implementation and Full Use of a Nationwide Health

Information Technology System

Thesis directed by Professor John S. Rumsfeld.

ABSTRACT

To date, no study has followed the complete diffusion of health IT across a large,

nationwide health care system and evaluated key factors at specific times. This

observational study evaluated the successful nationwide implementation of the

Department of Veterans Affairs (VA) Clinical Assessment, Reporting, and Tracking

system (CART) Program in all 75 VA cardiac catheterization laboratory hospitals, from

first contact with each hospital, through technical installation, and concluding with full

clinical use. The aims of this study were to: (1) evaluate variation in the durations of the

chronological stages of implementation and assess the hospital-specific characteristics

associated with the time required to achieve full implementation; (2) identify facilitators

and barriers associated with implementation; and (3) explore the association of key

factors with the time required to complete full implementation and also two time

periods within the implementation process.

The diffusion of CART implementation followed a pattern typical for innovations.

Most stages of implementation varied little in duration among hospitals; however, there

was significantly higher variation in the final stage of implementation, Clinical Use,

which began after training and concluded with full use of CART. In a survey of clinical

champions, integration of CART with the EHR, senior leadership endorsement, and the desire to improve quality were the top three facilitators noted for implementation. Contentment with current processes and VA technical support were among the top barriers noted. In multivariable analyses, research potential using CART data and CART Program technical support were key facilitators associated with significantly faster implementation times; conversely, contentment and privacy and security regulations were barriers associated with slower implementation times. Finally, initiation of implementation after endorsement of CART by senior leadership was associated with significantly faster times to install CART, and faster implementation times overall.

The results of this study reinforce that successful health IT implementation does not end with technical installation and training, and must support clinical use as part of routine care delivery. In addition, key factors may be important at various time points to support successful diffusion. Organizations should be mindful of motivational factors to move beyond installation of health IT to full use.

The form and content of this abstract are approved. I recommend its publication.

Approved: John S. Rumsfeld

DEDICATION

This work is dedicated to my parents, **Robert and Linda Box,** who, through their love, support, and example made this imaginable, and to **Sarah Lewis**, who makes the sun shine.

IT was a field. Gene, thanks for being such a stalwart supporter over the years and introducing me to Colorado. Sheri, every time I prepare a presentation, I think of your first Grand Rounds and your boundless enthusiasm for presenting data in such a way that it captivates everyone in the room; I have always tried to follow your example. And Jody, I truly wish you were still with us and I could wander into your office and tell you I finally finished. This acknowledgement section would not be complete without you in it. Your fierce passion for research was only surpassed by your devotion to your family, and your mentorship left an indelible mark on me and so many others; thank you.

To my VA and CART colleagues - especially Dr. Hans Gethoffer, Dr. Meg Plomondon, Dr. Robert Jesse, Dr. Stephan Fihn, Josie Nance, Mary McDonell, Brian Gillespie, Greg Noonan, Dr. Tom Maddox, Dr. Thomas Tsai, Dr. Paul Varosy, and Alec Arney - CART exists and has grown because of all of you and I am forever grateful. Hans, thank you for being my IT mentor and for the vision, elegance, and simplicity you built into CART. It is an honor to work with you and learn from you. Meg, you were one of the very first people I met in Colorado! Thank you so much for your friendship and mentorship over the years, and also especially for encouraging me in this process and suffering through the early draft. I owe you a lot of ice cream!

Thank you also to my friends, both near and far, who have cheered me on and supported me – my Denver Ya-Yas, Dr. Sue Greer, Stephanie Nye, and the Tour de Cure Crew.

Finally, thank you to my amazing family. To my Lewis family, especially Ann

Bishop and Mary Essay, thank you for adopting me and making my life in Colorado so

filled with love and fun! The gluten-free snacks (green chili!), theater and game nights,

and family parties helped me through the years of studying and writing. Thank you for

your love and friendship.

To Dr. Meredith Drosback, my best friend, thanks for helping me navigate the

ups and downs of the PhD process; since I taught you the Diels-Alder reaction, I guess

you owed me.   And, of course, thanks for sticking up for me, even when you know I'm

wrong.

To my sisters, Mendi Crisler and Julie Pierce, thank you for your constant

friendship and always believing in me. Now that I'm wiser, I know two things for sure:

I'll always be your bratty little sister and I'll always look up to both of you. Let's take a

Sister Trip and celebrate!

Mom and Dad, you are my heroes. You always have the uncanny ability to know

when I need an encouraging phone call or quick note. Thank you for everything you

sacrificed to help me get to this finish line. Ok… you can stop worrying now!

And to Sarah, we did this together. Thank you for pots and pots of the world's

greatest coffee, the bikes and hikes, always making me laugh, and for being *my*

champion.

Thank you to God for the blessing of all of these amazing people in my life.

TABLE OF CONTENTS

xi

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

AHRQ - Agency for Healthcare Research and Quality

AMI – Acute Myocardial Infarction

CART - Clinical Assessment, Reporting, and Tracking Program

CPOE - Computerized Physician Order Entry

CPR - Computerized Medical Records

DHCP - (VA) Decentralized Hospital Computer Program

DSS - Decision Support System

EHR - Electronic Health Record (system)

EMR - Electronic Medical Record (system)

HITECH - Health Information Technology for Economic and Clinical Health

(health) IT - Health Information Technology; used as an umbrella term to include all forms of health-related technology such as CPOE, EHR, EMR.

IOM - Institute of Medicine

MIS – Medical Information System

POMR - Problem-Oriented Medical Record

ONC - Office of the National Coordinator for Health Information Technology, Department of Health and Human Services

VA - Department of Veterans Affairs

VistA - Veterans Health Information Systems and Technology Architecture

CHAPTER I

INTRODUCTION

Since the Institute of Medicine (IOM) first proposed six domains to improve

health care quality in 2001, health care organizations have been focused on improving

outcomes in the targeted domains.[1] Most believe that health information technology

(IT), as suggested in the landmark IOM report, could be a cornerstone for a new learning

health care system, one in which information is translated to knowledge in an iterative,

innovative process in the service of quality.[2]

Government mandates established by the Health Information Technology for

Economic and Clinical Health (HITECH) Act provision of the 2009 American Recovery and

reinvestment Act created additional catalysts for health IT by incentivizing use of

electronic health records (EHR) and proposing a staged process for the "Meaningful

Use" of these systems.[3] More recently, reports of improvements in patient outcomes

through clinical decision support systems, use of health IT to conduct proactive

surveillance, and the efficiency and health care delivery gains possible through emerging

mHealth efforts provide evidence of the benefits of health IT.[4-5] Even so, recent

estimates of electronic health records installations in the United States report that

prevalence is still modest, increasing from 8.7% in 2008 to 11.9 % in 2009 to

approximately 15% in 2010.[6]

In the last five to ten years, much has been written about the diffusion of health

IT. The developing evidence base in this field primarily includes cross-sectional

assessments of prevalence, penetration, and retrospective surveys or editorial

perspectives.[7-8] Understanding facilitators of and barriers to the installation of EHRs has

been a critical area of focus, in particular due to the sense of urgency hastened through

HITECH. Key drivers of EHR installation have emerged in the last decade, such as

organizational or senior management support, adherence to standards to facilitate

evaluation and interoperability, formal training, endorsement by colleagues, and

meeting privacy and security requirements.[9-10]

Importantly, in the current conversation surrounding health IT, the terms

implementation, installation, and *adoption* have been used more or less synonymously.

None of the terms have been defined to reflect a measure of the full use of a health IT

system, nor do they reflect the entire process of achieving full use, but most often have

been used instead as a proxy for a measurement that a hospital or practice has a system

in place. Using these terms interchangeably may cause confusion and obfuscate

important characteristics of the entire process of health IT diffusion, while making it

difficult to compare research in this field.

The purpose of this observational study was to explore a nationwide health IT

implementation process, from first contact with a facility to the full use of the system,

and answer the research question: **What are the key factors associated with the**

implementation and full use of a nationwide health IT system? First, a new framework

to clarify the nomenclature surrounding health IT implementation and characterize the

stages in the implementation process was proposed. This framework was applied to

address three specific aims: (1) evaluate variation in the durations of the chronological stages of implementation and assess the hospital-specific characteristics associated with the time required to achieve full implementation; (2) identify the top facilitators and barriers associated with implementation; and (3) explore the association of key factors (i.e., hospital characteristics, facilitators, and barriers) with the time required to complete full implementation and also the periods of time to move from initiation to completed installation and the time to move from completed installation to full use of the system.

The health IT application studied in this thesis is now in full, verified use in all eligible VA hospitals nationwide. The results of this research may be helpful to hospitals and health care groups who wish to consider the stages of health IT implementation and the characteristics of a nationwide health IT diffusion. Moreover, this research extends knowledge related to key factors associated with process of health IT implementation.

CHAPTER II

LITERATURE REVIEW

Literature review introduction

While information technology is not a new field, its application in health care has

grown exponentially in the last ten years. The implementation and use of electronic

systems to document, store, and retrieve data in the US health care system has been

driven by many forces and impacted by many challenges. In order to appropriately set

the context for the work in this thesis, a thorough literature review was conducted to

illuminate the progress of health IT in the US, explore the key drivers for

implementation of health IT in hospital systems, appreciate the facilitators and barriers

related to achieving full use of health IT, and assess the current status and future

potential of health IT.

Literature search methodology

This literature review was conducted on two search platforms, PubMed and

Google Scholar. PubMed was selected because it is the predominant database used to

index scientific publications, particularly in medicine. Google Scholar was selected to

augment the results of the PubMed searches, beyond traditional academic research

publications.   Due to the relative immaturity of the field of health IT and consequently,

the formal evaluation of health IT, some important publications and discussions in this

arena are not found in traditional academic journals.

Much as the literature base in health IT has grown over the last several decades. The nomenclature surrounding the field of health IT has also been in flux, making a comprehensive search of all related terms challenging (e.g., "electronic" versus "computerized" health records). As part of their "References and Web Services" resources, PubMed maintains several topic-specific queries, including a comprehensive query on "Electronic Health Records." This PubMed comprehensive query, therefore, was taken as the nidus for this literature search and edited, updated, and recoded to encompass the appropriate terms relative to this thesis. The full code and additional methodology for the PubMed master literature search is provided in Appendix A.

The scope of the literature review was limited primarily to the United States and the research published since 2000. The PubMed master search was adapted to accommodate a similar review in Google Scholar and the code for the Google Scholar master search is provided in Appendix B. These master searches were each, then, combined with key topic areas, summarized in Table 1, on the next page. Some additional articles were added to the final results, primarily through the review of the results of the primary searches, and also through review of key works in this field which were outside the timeframe of the search strategy (e.g., some historical publications related to health IT in the US and the Department of Veterans Affairs) or related to development of the conceptual model. The literature searches were last updated in April 2012. The PubMed and Google Scholar results were lastly merged to eliminate duplicates.

Table 1. Literature search results

SEARCH TOPIC	TOTAL CITATIONS		ABSTRACTS REVIEWED*	ARTICLES REVIEWED*
	PubMed	Google Scholar		
Master Search	31,889	About 16,700	259	165
Master Search Combined with Topic Area:				
Progress	32	112	27	12
Importance	85	69	10	7
Implementation or Adoption or Diffusion	266			
Implementation		543	65	56
Adoption		322	42	30
Diffusion		66	3	3
Success or Failure	61			
Success		121	21	10
Failure		35	12	8
Facilitators or Barriers	87			
Facilitators		43	23	11
Barriers		221	42	18
VA or Veterans Affairs	115	435	14	10

*Abstracts were reviewed after results from both platform searches were completed, results merged, and 74 duplicate publications resolved.

Brief history of health information technology in the United States

Electronic health records 1950 - 1999

Since the mid-20th century, computers and information processing have quickly become mainstays of all industries. In the 1950's and 1960's, computer programming languages began to gain popularity and use and by the early 1970's, the first kernel of

what we now consider the Internet was created in the form of a series of connected

computers capable of exchanging data across geographic space. This early network, the

Advanced Research Projects Agency Network (ARPANET), was quickly adopted by the US

Department of Defense and used to connect research laboratories and universities. It

was not long after these landmark advances in computing languages and networking

that innovators in all industries began to adopt these technologies. In many ways,

simple curiosity and passion for innovation promulgated adoption of technology. More

importantly, innovators quickly envisioned the use of the new technology to more

rapidly and efficiently store and retrieve large amounts of data and to solve complex

problems.

The American health care industry was not far behind the curve in its initial

embrace of computers and networking. There are many examples, dating back to the

1960's, of computerization of health care records; certainly, the burdens of

documentation, volumes of paper-based notes, and complex decision-making required

of physicians made health care a prime target for computer-based innovation. Three

early developments in health care computing stand out as launching points for the

health IT industry. These developments and other major milestones described in this

chapter are depicted in Figure 2 on page 25.

First, Lockheed, infused with grant funding from the brand new, progressive US

space program, created a "medical information system" which went live in 1973 in

Mountain View, California, at El Camino Hospital. The Lockheed-produced system is

popularly regarded as the first computerized physician order entry (CPOE) system. While ownership changed hands many times over the years, the core of this system is now managed by Eclipsys, currently part of Allscripts. A version of this system, in fact, is still in use by a few hospitals.[11]

Second, across the country at University Hospital in Burlington, Vermont, Lawrence L. Weed and collaborators began the Problem-Oriented Medical Information System (PROMIS) project in 1967, which evolved into a functioning problem-oriented medical record used in two wards of the University Hospital by 1978. This system included a small network of computer terminals which processed information through disease-based algorithms and were used as early decision support tools at the patient's bedside. In addition, the system permitted progress notes to be entered as part of a patient record.[12]

Third, the early history of computerization in health care would not be complete without mention of the Department of Veterans Affairs (VA). In 1968, the VA established a centralized governing office to manage and develop laboratory and pharmacy information systems, but these were very slow to be developed and even slower to be distributed, due to lengthy life cycle and organizational requirements. In 1969, the first computers were purchased by individual VA medical centers, and by 1978, the number of computers was finally greater than the number of medical facilities (182 computers in 172 medical centers). As computers became more prominent in VA facilities, facility-based developers who were not part of the centralized organizational

office began to organize and innovate in a much more "grassroots" manner and these developers soon became known as the VA's "Underground Railroad." The Underground Railroad developers at local facilities also engaged clinical experts and together, agreed upon architectural principles and common data and coding standards in the late 1970's. They convened a meeting in Oklahoma City to present and disseminate this work amongst their colleagues, but the centralized governing office responded to this grassroots effort strongly, and demanded all development cease. With their jobs in peril, however, the "secret" and decentralized development continued. In 1981, a successful prototype of the VA's early information system, the Decentralized Hospital Computer Program (DHCP), was demonstrated at the Washington DC VA Medical Center to the VA's Chief Medical Director and soon embraced. By 1985, the core DHCP applications were implemented at all VA facilities. [13]

Since the 1980's, DHCP has evolved considerably into the internationally-recognized electronic health record (EHR) system known as the Veterans Health Information Systems and Technology Architecture, or VistA.[14] VistA remains the platform for the VA's Computerized Patient Record System (CPRS), the provider-facing graphical user interface in use in every VA facility nationwide. Moreover, as the VA looks to their next generation health management platform, and begins to integrate patient data and services across the continuum of a Veteran's care - from active duty within the Department of Defense to care and health management through the VA, the

tens of billions of structured free text data elements and billions of free-text notes in VistA will remain the foundational data sources.

These three examples demonstrate early adoption of computers and networking in health care, specifically: an early version of CPOE at El Camino; a precursor to decision support systems (DSS) at University Hospital in Vermont; and a nationwide, networked full EHR in the VA hospital system. In the 1970's and 1980's, other major hospital systems were also developing and embracing medical information systems, notably Mayo Clinic, Harvard, and Duke. In addition, the companies now recognized as leading EHR vendors, e.g., Cerner, EPIC, McKesson, and Siemens, were all emerging, purchasing smaller companies and components, and developing. Despite the early momentum during the latter part of the twentieth century, widespread adoption of computerized record systems by most of the health care industry began to lag behind other industries. In particular, smaller hospitals and systems, practice groups, and individual practices found it difficult to tolerate the disruption to workflow, the often overwhelming capital investment, introduction of new IT staff, and lack of a measurable return on their investments which implementing computerized systems would require.[15]

Computers in medical research at the end of the twentieth century

At the time widespread adoption of health information systems seemed to lag, a "perfect storm" to alter this slowdown began to brew at the intersection of medical research and rising health care costs. Health care providers have long been engaged in research and invested in exploring the best methods by which to care for patients; even

though modern peer-reviewed research most often necessarily focuses on populations of patients, the goal of any single physician must be to improve the outcomes for any one patient at any one moment. Computing and processing capabilities expanded exponentially throughout the latter half of the twentieth century, and medical researchers embraced this inherent potential with alacrity, knowing it could facilitate more robust research and evaluation, and more rapidly translate to care. In the 1990's, investigators from McMaster's University harnessed the ever-increasing computing power to aid in christening a research field they termed *evidence-based medicine*, the "systemic approach to analyze published research as the basis of clinical decision making."[16] It may be argued that without the rapid data aggregation and processing power computers provided, the field of evidence-based medicine would not have become so immediately prominent in the 1990's.

Indeed, utilizing computers in research to assimilate and assess data and evidence has been very formative in the development of other research disciplines, such as genomics research, outcomes-based research, and more recently, comparative effectiveness research. The improved ability to process scientific inquiries likewise helped foster the development of national organizations, such as the National Library of Medicine, which is responsible for the rich database of medical literature known as PubMed, and also the Agency for Healthcare Research and Quality (AHRQ), for example. While broad adoption of health information systems still faced steep challenges, the use

of computers in the health care setting nevertheless became ubiquitous through the explosion of the medical research community.

Health care spending at the end of the twentieth century

The medical research community in the 1990's was heavily focused on basic science, clinical trials, and research to improve the quality of health care. Soon, however, attention began to focus on soaring health care spending. The exponential and oft-discussed "cost curve" of the American health care system was purported to be due to in large part to skyrocketing Medicare expenditures brought by rapidly increasing numbers of uninsured Americans. The projected steepness of the curve, in which 20% of the gross domestic product was anticipated to be consumed by health care costs by 2016, held disastrous implications for public health programs.[17] However, even a cursory glance beneath the surface of the health care cost discussion revealed many other potential determinants, beyond coverage issues for the uninsured, which required careful evaluation.

The Institute of Medicine landmark reports

In 1999, the Institute of Medicine (IOM) published an astonishing report entitled *To Err is Human: Building a Safer Health System.* This landmark report combined rigorous research with thoughtful, policy-focused commentary and quickly brought to the attention of the health care and medical research communities the alarming statistic that potentially as many as 100,000 people die each year as a result of preventable

medical errors. Equally dismal, these errors led to additional costs of between $17-29 billion, annually.[18]

To Err is Human was quickly followed by another Institute of Medicine report in 2001, entitled *Crossing the Quality Chasm: A New Health System for the 21st Century.* Beyond the efforts of the first report in describing the costly errors replete in our heath care system, the 2001 report pushed readers to acknowledge that our health care system was far from where it could, and should be, with respect to quality. The new report suggested that caring for the uninsured was only one piece of the cost puzzle. Moreover, a "quality chasm" in our health care delivery system, according to the Institute of Medicine, had formed in large part because of our failure to keep up with the pace of technology and research. According to the authors, "Faced with such rapid changes, the nation's health care delivery system has fallen short in its ability to translate knowledge into practice and to apply new technology safely and appropriately."[1]

Crossing the Quality Chasm put forth six domains of improvement to bridge the gap between where US health care was at the end of the twentieth century and where it could be in the twenty-first. The six domains of improvement encompassed aims to make health care *safer,* more *effective, patient-centered, timely, efficient,* and *equitable.* These domains are described in Figure 1, on the next page.   By greatly improving in these six areas, moreover, health care systems could reach the end goal of providing the highest possible quality of care to their patients. To make the substantial changes

required, the Institute strongly endorsed both the application of evidence to health care delivery and the use of information technology.

Safe	• avoiding injuries to patients from care that is intended to help them
Effective	• providing services based on scientific knowledge to all who could benefit, and refraining from providing services to those not likely to benefit
Patient-Centered	• providing care that is respectful of and responsive to individiual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions
Timely	• reducing waits and sometimes harmful delays for both those who receive and those who give care
Efficient	• avoiding waste, including waste of equipment, supplies, ideas, and energy
Equitable	• providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status

Figure 1. The six domains for health care improvement.

The 2001 IOM report, combined with the shocking statistics of the 1999 report, created a turning-point in the collective attitudes of the US health care system and sharpened the focus of the delivery system toward improving outcomes in the six domains. By addressing errors and waste and applying evidence from medical research,

many began to believe there were additional ways to bend the cost curve. But, as the IOM suggested, much of the improvements would need to be facilitated by computers and more robust adoption of health information technology.

In 2002, Ash, et. al., conducted a national survey of 964 randomly selected US hospitals to determine adoption of CPOE - only one component of electronic health records - and found that only 9.6% of the hospitals had CPOE completely available.[19] The most recent national survey to document adoption of electronic health record systems, including CPOE capabilities, found that in 2010 still only 15% of hospitals had adopted even a "basic" EHR.[6] Thus, in the decade since the IOM reports, adoption of health IT has remained slow, despite acknowledgment and endorsement by much of the industry. Substantial progress, however, has been made to understand the reasons for lagging adoption and address these issues.

Implementation of health information technology in the United States

Progress and drivers of health information technology adoption

After the publication of *Crossing the Quality Chasm,* many US hospitals and practice groups did, indeed, begin to look toward implementing health information technology as a way to improve quality and safety in their organizations in the early 2000's.[4,29-33] The desire to improve in the six IOM domains produced a slight increase in health IT adoption rates. In a large, national survey of electronic health record use in 2005, Jha et. al. reported that as many as 23.9% physicians in ambulatory settings were using some form of electronic documentation.[20] Other surveys at this time found

similar percentages, depending on features specified in the survey, in pediatric practices (21.3%)[21], physician practice organizations (9 - 29%)[22], community health centers (26%)[23], and emergency departments (16.1 - 30.4%)[24].

Some components of health IT did see a more substantial increase in use. For example, electronic laboratory results, some electronic documentation, and retrieval of radiographic images and electrocardiograms were in use at greater than 50% of Massachusetts emergency departments surveyed in 2005.[25] Adoption of CPOE in emergency departments in four states (Colorado, Georgia, Massachusetts, and Oregon) nearly tripled from 2005-2008, though in 2008, still only approximately 30% of the emergency departments in these states reported adoption of CPOE.[26]

In 2004, President George W. Bush issued an executive order establishing the Office of the National Coordinator for Health Information Technology.[27] The new Office of the National Coordinator (ONC) was established to coordinate the nationwide effort to promote implementation and adoption of health IT. Although the role of the ONC was not legislatively mandated until five years later, the creation of the office did provide some structure and direction to these efforts, particular in the planning for health information exchange and leadership in health IT policy and standards.

In 2007-2008, another national survey of US physicians was conducted to determine adoption of electronic health records. This time, the investigators more strictly characterized an electronic health record system beginning with a framework specified by the International Organization for Standardization and adopted by the

IOM[28]. Through a consensus process, the investigators determined an EHR qualified as fully-functioning if it possessed functionality in four areas:

> Recording patients' clinical and demographic data, viewing and managing results of laboratory tests and imaging, managing order entry (including electronic prescriptions), and supporting clinical decisions (including warning signs about drug interactions or contraindications). [7]

By this more strict definition, which by application would require CPOE, documentation, and a host of other features for an EHR to qualify as "fully functioning," investigators estimated that only 4% of physicians in the US truly had a full EHR, even though as many as 13% had EHRs with some of the four functional areas.[7] Using similarly strict definitions, similar results were found in children's hospitals (2.8% full EHR and 17.9% basic).[29]

Thus, in the time period from the release of the landmark IOM reports and even after the establishment of the Office of the National Coordinator for Health Information Technology, rates of adoption of full EHR systems in US hospitals improved only marginally, with less than one-fifth of American physicians using even basic EHRs. Despite the promise of efficiency gains, improvements in quality and safety, and the potential for health information exchange, the US health care system at large still faced challenges and obstacles in embracing and investing in health IT. To improve this situation, it has been important in the last decade to fully understand the barriers to health IT adoption.

Facilitators and barriers to the adoption of health information technology

IT projects fail at estimated rates between 12-40% across all industries. [10,30] In

health care, there have been some spectacular examples of partial implementations and

complete failures, such as the aborted installation of a national financial suite in the VA

at Bay Pines[31] or the failed implementation of a large clinical information system at

Kaiser Permanente Hawaii[32].[45] When considering the complexities of the US health care

enterprise, from small physician offices to large practice groups to large private and

public hospital systems, it is logical to consider that facilitators and barriers to adoption

of health IT might fall into very specific and specialized domains, depending on the

environment or any number of other variables. A tremendous number of editorials,

surveys, and books have been written in the last decade to describe facilitators and

barriers to health IT adoption and to categorize findings. Perhaps surprisingly, the

themes and categories of these findings across nearly all literature sources are quite

similar. Edward Shortliffe wrote a policy paper in 2005 for the journal *Health Affairs* and

categorized the primary factors in health IT adoption as cultural, structural, and financial

(i.e., "the business case" for health IT).[15] For convenience, the following discussion will

adopt Shortliffe's categorizations, and apply them to the explanation of facilitators and

barriers of health IT adoption.

First, organizational and cultural facilitators and barriers have appeared to

outweigh technical constraints. As Bates, et.al, astutely point out, "The main barriers

are not technical, because adoption rates in other countries are high."[33]. Key

organizational and cultural factors center on the acceptance and leadership of both

senior management and local leaders, the ability of the organization to make it

worthwhile for users to adopt, and the overall readiness of an organization, whether

small practice or large system, to change.

Senior leadership and collaboration of high-level stakeholders is paramount to

empowering selection of health IT.[15,17,47,48] Many studies have pointed out that the

organization must feel the products being implemented are endorsed by leadership.

Moreover, it is important that senior management support and will accommodate the

changes and additional workload collaboratively across departments to ensure all

stakeholders are engaged at the appropriate times.[16,19,49-55] Senior leadership is also in

part responsible for creating an environment and culture which is prepared to embrace

the change which health IT adoption will bring, from changing roles of staff, changing

workflows, and new requirements placed on the enterprise. Indeed, organizational

culture and readiness to change have emerged as powerful factors in the adoption of

health IT.[52,55-57]

Beyond senior management and top-level leadership, facility- and practice-based

leadership is equally essential to guide adoption. The role of "clinical champions," or

clinical leaders who have endorsed a product and are able to train others in its use, have

been particularly successful in facilitating adoption. The support and acceptance of

colleagues and peers is also instrumental in driving acceptance.[16,19,35,49,51,58] In addition,

sometimes incentives such as less direct care hours during training or additional

financial incentives for users have been shown to be successful. Sometimes an incentive is simply the belief that adoption of health IT will improve outcomes such as safety and quality of care, or contribute to research.[9,33-35]

The second category of factors relates to the structural realities of the US health care system at large, the composition of personnel and staff, and the impacts to workflow and efficiencies. In the US, our health care data has been fragmented over the last few decades, primarily because of locally-based IT solutions which lack interoperability. Understandably, practices and organizations which rely on community resources may be reticent to invest in non-interoperable solutions if those solutions will only result in duplicative work.[29,33,35-37-61] To complicate the barriers of interoperability, health information exchange nationally, or even across systems in the same facility, has also been virtually impossible due to a lack of standards, both technical standards and clinical standards.[21,38-40] Amongst the technical standards, privacy and security issues have been noted as occasional barriers in adoption of health IT.[33,41] Thankfully, with the establishment of the ONC and the work of many clinical professional groups, some of the barriers surrounding standards are subtly decreasing.

At the facility or system level, other structural realities such as personnel composition can be barriers. Prior to 2000, many organizations simply did not have IT staff in place to support health IT adoption and maintain IT products.[33,36,42-44] Some organizations had IT support, but it was not internal to the organization and therefore removed from the time and emotional commitments being faced by the organization.

In particular, for rural hospitals and small practices, finding and supporting IT staff to manage health IT adoption and maintenance can be a tremendous challenge.[43,45]

At the level of the individual user, many organizations have reported significant difficulties in adoption of health IT if the structure and processes of normal clinical routines are disrupted, either by required training on new software or by software which is not suited to enhance or fit into workflow. The software and hardware being implemented must be designed to fit into clinical and administrative workflows, and even improve the time to perform some tasks, such as documentation. Some of the most successfully reported software, in fact, has been designed with careful consideration and direct input of the users, to maximize efficiency. Without careful attention to usability and design, health IT adoption can be met with significant resistance.[9,36,46-53]

Insufficient training or the lack of clinical or technical champions to support the training of others has also been reported as a major structural barrier. Inadequate training on the maintenance of health IT systems can compound this problem. However, training time supported by leadership and led by clinical champions and enthusiastic, supportive technical staff can more smoothly guide the transition for all staff, including providers, nurses, and administrators.[9,22,35,49,50,54-57]

Many of the cultural and structural factors related to health IT adoption also relate to the final category of factors, the financial or "business case" for health IT. Despite the potential for improvements in the IOM domains and the possible reduction

in expenditures, errors, or unnecessary procedures, it has been financially untenable for many health care practices and organizations to implement health IT. Larger facilities have been quicker to adopt, mostly because these facilities are better able to absorb the initial capital investment. Likewise, urban and tertiary health care organizations and organizations which are non-profit or federally funded have also been more likely to adopt health IT. [21,58-60] However, rural practices and hospitals have been very slow to adopt for a variety of reasons, including lack of capital or financial incentives, lack of IT staff support, and distance from academic or teaching facilities which could encourage a more outcomes-based culture.[20,23,24,33,43,61,62] There has been significant concern voiced by all sectors of the health care community, including the government and policy-makers, that disparities in the adoption of health IT based on facility size and location could create even deeper disparities in the care delivered to lower socioeconomic or minority populations.

Incentivizing health information technology implementation

Although improving the health care system in the six IOM domains remains a tangible goal through the adoption of health IT, the pressure to adopt health IT by 2014, as laid out in the executive order by President George W. Bush during the establishment of the ONC[40], has proven very challenging financially for many organizations. Nearly all of the previously referenced literature sources on facilitators and barriers also make mention of the significant financial challenges faced by organizations wishing to adopt health IT. Most critically, it is unrealistic for many organizations to make the investment

in health IT when the initial costs are so steep, the impacts to the business functions of

the organization so significant, and the benefits of such an investment so difficult to

measure.   As David Bates succinctly notes, "The biggest barrier is reimbursement,

because physicians must pay for EHRs, but most of the benefits accrue to payers and

purchasers."[33] Acknowledging this, countless experts and researchers strongly

suggested that, in order for the rate of health IT adoption to improve, financial

incentives would need to be provided, ostensibly through federal funding and legislative

initiatives.[7,29,33,37,42,58,59,63-70]

As a part of the American Recovery and Reinvestment Act of 2009, or "the

stimulus bill" as it came to be known, $19 billion were included to promote the adoption

and full use of health IT, particularly fully-functioning EHRs. This portion of the Act, the

Health Information Technology for Economic and Clinical Health (HITECH) Act, makes

clear that the reason to adopt health IT should be improving the quality of health care,

and achieving the improvements of the IOM domains described in *Crossing the Quality*

Chasm. The HITECH Act codified the establishment of the Office of the National

Coordinator for Health Information Technology and expanded its resources to be able to

form and support committees on health IT policies and standards. Most importantly,

the law created new financial incentives for the adoption of health IT, and will

eventually impose penalties for those who do not adopt.[3] Specifically, in 2011,

physicians could begin to receive extra payments or even subsidies through Medicare

and Medicaid for adopting EHRs which meet a core set of requirements and

functionality. Likewise, hospitals which adopt qualified EHRs can also receive financial incentives. To receive any of the financial incentives, however, the physicians or hospitals must demonstrate "meaningful use" of the health IT system in measurable ways.[38] Thus, the financial model for health IT adoption does not rely solely on installing a system, but requires the system to be applied to the direct purpose of improving health care and health care delivery. Meaningful Use criteria have been outlined in three stages.[3] In brief, in the first stage of Meaningful Use, facilities which have certified EHRs must demonstrate use of the EHRs through basic reporting of health care information, such as number of visits and percentages of, demonstrate the use of tools such as clinical reminders, and share patient information. The Office of the National Coordinator Final Rule for Meaningful Use Stage 2 was in September 2012 and includes requirements for health information exchange and e-prescribing, and additional use of clinical quality measures, for example.[71] Stage 3 of Meaningful Use has not been officially decided, but is anticipated to require clinical decision support, interoperability with personal health records, and efforts to improve population health are the anticipated targets.

Current rates of health information technology adoption

ARRA and Meaningful Use criteria have only recently been enacted and is difficult to measure their immediate impact on overall health IT adoption. As mentioned previously, the most recent national survey to document adoption of certified EHRs found that in 2010, 15% of hospitals had adopted a "basic" EHR, which

represents 75% growth from the investigators' previous survey in 2008. Unfortunately, only 4.4% of the hospitals had implemented all of the qualifying Meaningful Use criteria for Stage 1. [6] In a separate analysis of office-based physicians, Hsiao, et.al. found that only 11% of those surveyed intended to apply for financial incentives and had EHRs which met even two-thirds of the Stage 1 requirements.[72]
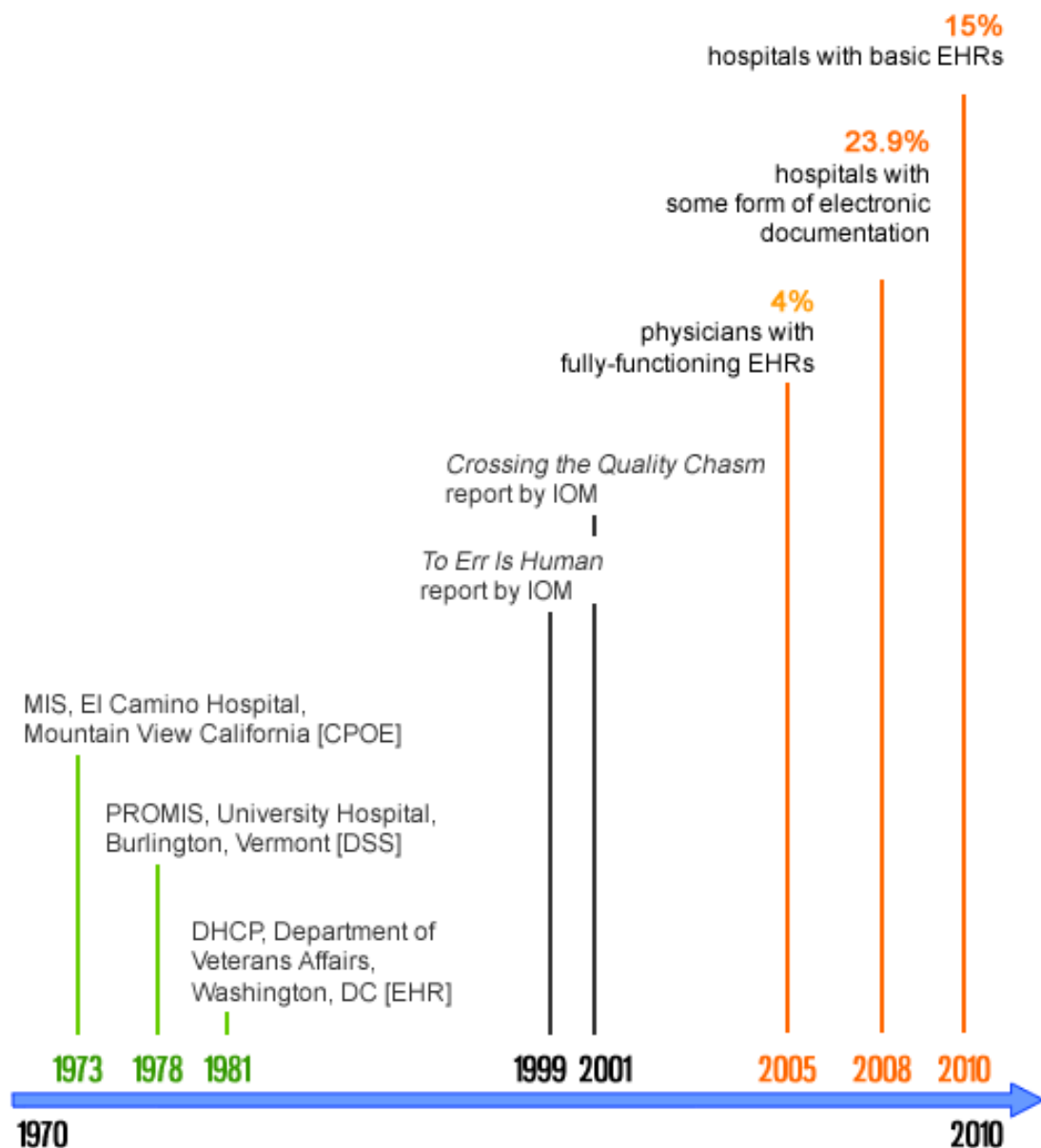
Figure 2. Major milestones in health information technology.

Promise and potential of health information technology adoption

In the past decade, some strong examples of how health IT can facilitate improvements in quality, safety, efficiency, and patient outcomes have been published. The VA, in particular, has seen improvements in both quality and efficiency since investments in the late 1990's in re-engineering their health IT systems and placing a greater emphasis on quality initiatives. Overall, the introduction of CPRS, the graphical user interface of VistA, created a 6% improvement in productivity.[73] The re-engineering effort also resulted in a substantial improvement in quality, as measured by quality-of-care indicators and compared to similar indicators in Medicare's fee-for-service system. After the re-engineering efforts, the VA outperformed Medicare in 12 of the 13 measured areas.[74] More recently, the VA has also been a leader in efforts such as proactive device surveillance[75,76], telehealth[77], and has recently invested in exciting new mobile health initiatives.[78,5]

Outside the VA, other examples have emerged of health IT being used as an infrastructure to support health care improvements. For example, in a study of 98 hospitals, Menachemi et. al., describe an association between the adoption of health IT applications (though not specifically Meaningful Use-certified EHRs) and AHRQ inpatient quality indicators; hospitals which had adopted health IT were more likely to have better outcomes on the quality indicators.[79] In another example, McCullough et.al., examined a national sample of hospitals from the Centers for Medicare and Medicaid's Hospital Compare database which had implemented health IT in the form of CPOE or a

basic EHR and found improvements in two of six measured process-quality measures.[80]

As investigators begin to explore the returns on investment of health IT, however, it is

important to note that health IT often acts as a facilitator or moderator in the process of

care and delivery improvements, and it is sometimes difficult to see a direct causal

benefit. With health IT adoption increases, new measures will need to be developed to

determine direct and indirect impacts of technology on health care outcomes.

Importance and limitations of previous research

For such a relatively new field, the literature base in health IT has grown rapidly.

Particularly in the last two decades, as adoption efforts have increased, so have the

number of published accounts examining rates, progress, facilitators and barriers, and

potential of health IT. In response, new peer-reviewed and online journals have been

created specifically to support this burgeoning evidence base.

The vast majority of the research on the progress of health IT adoption to date

has relied upon cross-sectional primary and secondary national survey data from large

professional organizations such as the American Hospital Association and Health

Information Managements Systems Society. While this can provide a reasonable picture

of penetration in the US health care system, these types of studies do not permit close

examination of the granularity of the process involved, from identification of a need for

health IT, through the full adoption and verified use of the technology. Indeed, in 2007,

Davidson and Heineke published a perspective in the Journal of the American Medical

Informatics Association which proposed an early framework for conceptualizing health

IT diffusion as a staged process. At that time, they argued:

> We believe that the full impact of IT has not been realized because of the failure
> to recognize both that the availability of applications to anticipated benefits
> passes through a series of discrete steps and that progress can be stopped at any
> one of these steps.[81]

The published work describing facilitators and barriers also hints much more

directly at a staged process for the adoption of health IT. To date, the only longitudinal

studies of this process are in single hospitals or small systems.[47,55,56,82-85] Much of this

work is the result of retrospective surveys, case studies, and qualitative evaluation and

often is reported as a perspective article or editorial, and less often as structured,

scientific research.

Despite these limitations, the research to date has been vital toward

understanding the overall penetration of health IT and identifying key factors which

might be important to adoption of health IT. To date, however, no empiric study

identified has followed the diffusion of health IT across a large, nationwide health care

system from the initial engagement of stakeholders through the full adoption and

clinical use of the system and associated that process with key factors at specific times.

CHAPTER III

METHODOLOGY

Study design

An observational, retrospective cohort study was conducted to describe the

discrete stages of a nationwide health IT implementation and identify hospital-specific

factors which might impact the overall implementation process, as well as key

facilitators and barriers which potentially impact each stage. First, a logical framework

for conceptualizing health IT diffusion was developed to clarify the stages required to

reach full use of a health IT system. This framework was then applied to explore three

primary questions:

1. Are there hospital-specific characteristics associated with the time required to reach
    full use of health IT?

2. What are the facilitators and barriers associated with implementation of health IT?

3. Of the hospital characteristics and top facilitators and barriers, what characteristics
    or facilitators or barriers are associated with the time required for each of the two
    periods of the implementation process and for full implementation?

Study population[9]

Nearly two decades ago, the VA was charged by a Congressional mandate to

provide care at least equivalent to care at non-VA facilities and to make comparisons

between VA and non-VA care to ensure the high quality of VA care. However, no direct

VA and non-VA clinical data were available to make these comparisons, apart from VA

internal quality improvement programs which generally relied on expensive, retrospective chart review processes.[86] Although the VA's EHR is one of the oldest and most robust, the VA EHR is limited because it does not provide standardized data entry for all types of patient care. Few discrete, standardized data entry fields existed in the EHR to support the mandated comparisons.

In initial studies comparing VA and non-VA patients after acute myocardial infarction (AMI), Veterans were shown to have more comorbidities, worse overall health status, and had lower socioeconomic status than non-Veterans[87-90]. Veterans were also reported as having a higher one-year mortality rate after AMI than non-Veterans [90], and were less likely to receive guideline-recommended procedures such as coronary angiography.[89] To address these reported disparities in the quality of cardiovascular care received by Veterans, the VA introduced a multi-layered plan to improve cardiovascular care by opening new catheterization labs, adopting national VA performance measures, and developing a national quality improvement program for cardiac catheterization procedures. Through this quality improvement initiative, the VA Clinical Assessment, Reporting, and Tracking (CART) Program for cardiac catheterization labs was conceived.

The CART Program includes a customized clinical application which primarily provides standardized report generation for catheterization lab procedures. The application is integrated within the VA's EHR and accessible through the graphical user interface, thereby facilitating single sign-on and encouraging providers to document

care as part of routine clinical work. CART supports data capture for all cardiac

procedures performed in catheterization labs, including diagnostic catheterizations and

interventions such as the placement of balloons, stents, or pacemakers. CART also

serves as a national data repository and is the centerpiece of a national quality

improvement program for VA catheterization labs. CART tracks all catheterization lab

procedures to accomplish workload capture through CPT/ICD-9 coding. Summary data

(e.g. procedures, complications) are provided to each VA catheterization lab facility to

support local quality improvement. Real-time monitoring of major adverse events and

device surveillance are also facilitated through CART.   Finally, CART enables

participation by all VA catheterization labs in the American College of Cardiology

National Cardiovascular Data Registry for national benchmarking.

This study describes the health IT diffusion process of the VA Clinical

Assessment, Reporting, and Tracking system for cardiac catheterization labs.

Implementation of CART began in 2004 and by January 2011, CART was in full use in all

75 VA catheterization labs, nationwide. All CART facilities were included in this study.

(Figure 3, next page)

Conceptual model

Diffusions of innovations theory [91]

In 1964, Everett Rogers pioneered the theory in the field of implementation

science known as *diffusions of innovations* to describe the temporal flow of how

innovations achieve critical mass and full use in a population. This theory has been

applied successfully toward diffusion research in many industries, and more recently, to

the diffusion of technological innovations.[92,93] As described in this section, diffusions of

innovations theory can also be extended as a framework for health IT implementation.

San Juan, Puerto Rico ●

Figure 3. VA cardiac catheterization lab locations and CART hospitals, 2004-2011.

In his seminal work Rogers defines diffusion as "the process by which an

innovation is communicated through certain channels over time among members of a

social system." According to Rogers, the typical "S-curve" of a diffusion graphs the

cumulative adoption of an innovation over time, beginning with the first 2.5% of

adopters, called "Innovators", and ending with the "Laggards", the last 16% of adopters.

Rogers' "adopter categories" are identified along the X axis. This S-curve graph,

illustrative of many diffusions of innovations, resembles a logistic function, as shown in

Figure 4, below, in yellow. The normal population distribution curve of a diffusions of innovation is also presented in blue, for reference, in Figure 4.
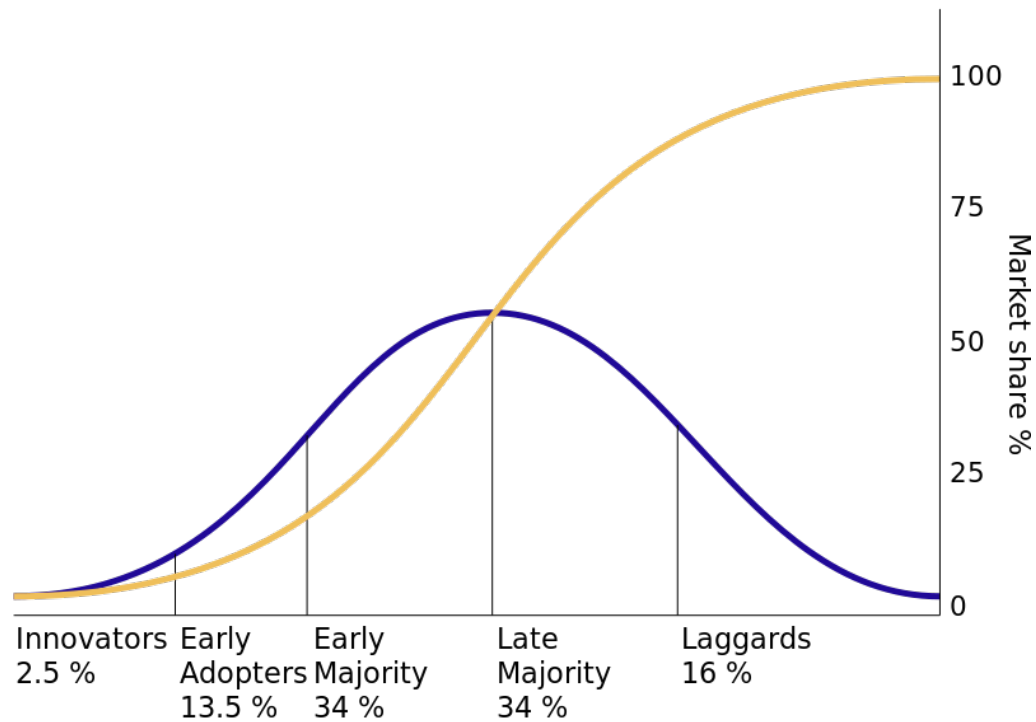
Figure 4. Diffusions of Innovations cumulative adoption "S-curve", according to Rogers.

The diffusion period, illustrated in Figure 4 as the x axis, is the full amount of time required for a social system (e.g., a group of individuals, a company, a hospital system, country, etc...) to fully adopt the innovation. The *rate of diffusion,* therefore according to Rogers, is the speed with which an innovation is adopted by the entire population or group being examined. While diffusion describes the uptake of an innovation by a group over time, the adoption of the innovation for each unit of the overall group follows a specific, staged process. Of note, Rogers was not the first to describe adoption in a staged process and the notion of discrete stages in adoption has

been proposed in many industries, including health care, as illustrated by the Davison and Heineke JAMIA paper quoted on page 28 of this thesis.

Rogers' adoption model is called the "Innovation-Decision Process" and consists of five successive stages, which are described in Table 2, on the next page. The titles of the stages have changed over subsequent editions of *Diffusions of Innovations*, and the original titles are also provided in Table 2 as well, for semantic comparison. The descriptions of the stages in the process, however, have remained consistent.

Several hallmarks of the Innovation-Decision Process bear additional description. First, at any stage in this process, the decision may be made to reject the innovation. Second, the Trial/Implementation stage is the first stage in which actual "hands-on" testing of the innovation occurs. During this stage, Rogers also describes a common process of "re-inventing" in which the innovation is not wholly accepted nor rejected and may go through a process of re-invention. Lastly, the Adoption/Confirmation stage is characterized by a decision to either reject the innovation or fully adopt the innovation. Moreover, Rogers defines *adoption* of an innovation as "a decision to make full use of an innovation." According to Rogers, full use of an innovation is the endpoint of adoption, and therefore, the endpoint of the entire process.

There are many semantic subtleties and various interpretations of the details of the theory of diffusions of innovations. A rigorous analysis of these is beyond the scope of this thesis. However, the conceptual framework provided by Rogers' theory, including the staged Innovation-Decision Process, provide a meaningful and appropriate

34

construct by which to evaluate health IT implementation. Most critically, by adapting

the Innovations-Decision Process to the implementation of health IT, we may begin to

appreciate and elucidate both the impact of factors - those which drive or delay - on

each stage in the process, as well as the potential linkages between stages.

Table 2. Stages of the Innovation-Decision Process

Stage Name (Original)	Stage Name (Current)	Occurs when an individual or other decision-making unit:
Awareness	**Knowledge**	*is exposed to an innovation's existence and gains some understanding of how it functions.*
Interest	**Persuasion**	*forms an opinion about the innovation.*
Evaluation	**Decision**	*engages in activities which will lead to a choice to accept or reject the innovation.*
Trial	**Implementation**	*makes a decision to try the innovation.*
Adoption	**Confirmation**	*chooses to fully adopt, or make full use, of an innovation.*

Current nomenclature for health information technology

Over the last two decades, the nomenclature surrounding the field of health IT

has been in flux. Even the term *health IT,* which has been broadly defined as "the

application of computers and technology in health care settings"[94] has begun to be used

synonymously with the term *health informatics*. In general, health informatics, a subset

of the broader field of biomedical informatics, may be considered conceptually as the

application and use of the products of health IT.[95] In this thesis, the definition of health

IT, above, is applied; although health informatics is not the direct topic of the work

described in the following chapters, in many ways it is alluded to and certainly a critical output of fully adopted health IT.

In addition, through much of the literature cited and described in the previous chapter, the *implementation* of health IT is depicted as more or less synonymous with *adoption,* and adoption is more or less synonymous with simply having an electronic record system *installed*. In fact, the ONC supports a national survey to measure health IT "adoption." In this national survey, adoption is defined according to the characteristics of the electronic records system installed, not through a discrete measurement of the use of that system.[7] In an important 2010 report on EHR progress in the US, Jha et. al. acknowledge in the study limitations that "we focused on whether hospitals adopted electronic health records rather than on how they are using the systems. As a result, this report may overestimate how much clinical care the records are supporting."[96]

The lack of clear or consensus definitions for these terms is understandable, due to the immaturity of the field of health IT research; the health care industry has been more engaged in the actual diffusion of health IT than it has been in defining the terms by which health IT diffusion is assessed. Moreover, one might argue that to date, concise definitions of implementation and adoption have not been necessary, as both terms speak to an overall process. However, in research which describes adoption and implementation processes, it is unclear whether the beginnings and, more importantly, endpoints of each term are applied universally, making comparison difficult.

Beyond the challenges of making correct comparisons when assessing the

research in health IT, there is an additional, important issue this lack of semantic clarity

causes: Using the terms *implementation* and *adoption* interchangeably and

synonymously with *installation*, with the only burden of evidence being the existence of

a system within an organization, may potentially obfuscate important characteristics of

the full process. Recall that Rogers defines *adoption* as "a decision to make full use of

an innovation."[91] Completing installation of a system, commonly called "go-live", is not

the same as fully using that system; if it were, there would be very few reports of

"health IT failures." To finally achieve the potential of health IT to improve outcomes,

such as the six domains of the IOM report , it must first be demonstrated that complete

uptake of the system has occurred, or *full use.*

Comprehensive model for health information technology diffusion

Through extensive literature review in the previous chapter and from empiric

evidence gleaned from the CART process, a four-stage process for health IT diffusion is

proposed, which begins with the first contact made with a facility and concludes when

the health IT is fully used. In the CART model, and to maintain relevance to the current

terminology of health IT, the terms *implementation* and *adoption* are defined as follows:

- **IMPLEMENTATION** = the full process of diffusion of a health IT system

- **ADOPTION** = the state of achieving full use of a health IT system

Therefore, full adoption is the final endpoint of the implementation process, as

evidenced by a metric of full use of the system. Full use of health IT indicates that the

system is being used by all providers to document all episodes of care; in other words, the system has become the official record of source, mirroring, enhancing, and eventually replacing all other means of documentation.

The proposed CART framework is presented in Figure 5 on the next page, and encompasses four stages. Implementation begins with an *Initiation* stage, in which first contact is made with a hospital and clinical and technical champions are identified to support installation. The start of installation of the system marks the completion of the *Initiation* stage and beginning of the technical *Installation* stage of the system. Once the system is installed, the *Training* stage begins. And finally, once the users are trained, they may begin the process toward fully *adopting* that system in the *Clinical Use* stage. The *Clinical Use* stage concludes when full use of the system is documented, or full adoption. The period from first contact with a facility to completion of installation is termed the *Activation Period* and the period from completed installation to demonstrated full use of the system is termed the *Use Period.* Concise definitions for each component of the framework are defined in upcoming "Data Sources" section.

The CART Health IT implementation framework is adapted from Rogers' *Diffusions of Innovations*, though the first two stages of Rogers' model have been consolidated. Figure 6 on page 40 presents the proposed CART framework for health IT implementation approximated to Rogers' model. Both the original stages and updated stages are presented. In addition, to help clarify current health IT nomenclature, both the American Medical Association's guide for EHR implementation and the ONC's

measurement of EHR uptake are also approximated on this figure. [7,91,97] Of note, the

stages of Meaningful Use are provided on this figure, with completion of Stage 1 used to

approximate full adoption, simply as a reference point. A different interpretation might

include completion through Stage 3 as full adoption.

     A hallmark of the CART Health IT implementation framework is that the stages of

implementation are mutually exclusive and exhaustive; a hospital cannot be in two

stages at the same time and no other intermediate stages exist. Finally, it should be

noted that the proposed framework is constructed to describe the implementation of

health IT, in this case a clinical application, within a health care system. In terms of

Rogers' definition of diffusion, the social system is equivalent to the scope of all VA

hospitals which operate a cardiac catheterization laboratory, and the members of the

social system in this framework are the individual hospitals.
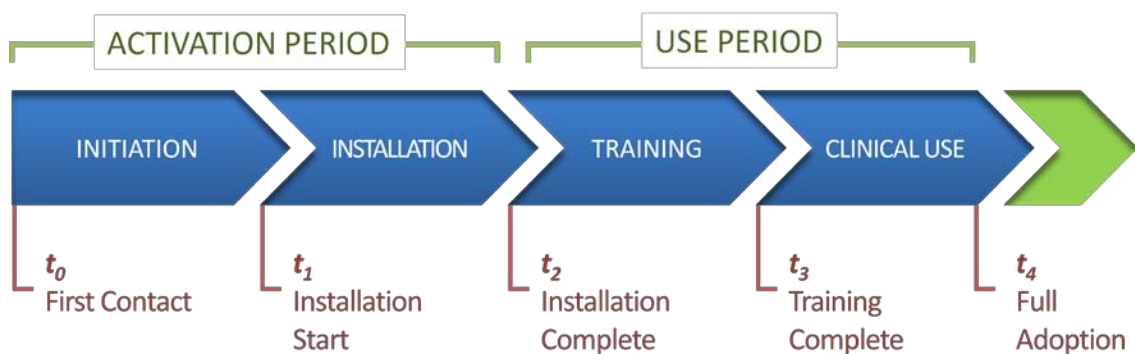
Figure 5. Periods and stages of CART Health IT implementation framework

AMERICAN MEDICAL ASSOCIATION EHR Implementation

Prepare → Select → Implement → Maintain

OFFICE OF THE NATIONAL COORDINATOR for Health IT

Adoption → Stage 1 Meaningful Use → Stage 2,3

EVERETT ROGERS Innovation-Decision Process (Diffusions of Innovations)

Knowledge/Persuasion → Decision → Implementation → Confirmation
(4th ed., 1995)

Awareness/Interest → Installation → Training → Adoption
(Original, 1962)

CART FRAMEWORK Health IT Implementation

INITIATION > INSTALLATION > TRAINING > CLINICAL USE

First Contact ⋯ Installation Start ⋯ Installation Complete ⋯ Training Complete ⋯ Full Adoption

40

Figure 6. Approximation of semantic differences in models for the health IT diffusions process.

CART implementation process[9]

A descriptive manuscript on the process of CART implementation was published

in the *Journal of General Internal Medicine* in 2010. [9] In that publication, the basic

stages of the CART implementation were described, including general strategies

employed for each stage. The following stage descriptions of the CART implementation

process are taken largely from that manuscript. Of note, the Initiation stage in the 2010

paper was called a Collaboration stage and the Training and Clinical Use stages were

consolidated into one Adoption stage.

Initiation

At each CART hospital, clinical champions were identified to provide local

support and momentum in the implementation process. These clinical champions were

typically directors of the catheterization lab at their hospital, though administrative

titles vary across VA hospitals. Champions, throughout all phases of CART

implementation, were encouraged to provide feedback and suggestions for

improvement in future versions of CART. Where possible, technical champions were

also identified at each hospital. In some cases, a technical champion to endorse and

help propel the installation of CART was not identified, but support through the facility's

local IT office, prompted by the clinical champion, was sufficient to move

implementation forward.

Installation

The Installation stage of CART implementation was predominantly technical. CART software passed all of the rigorous VA and National Institutes of Standards and Technology privacy and security requirements for federal software. The CART installation was streamlined to require very little personnel hours from local IT departments. All installation was conducted remotely; no site visits were required to install CART. Local IT staff needed to supply the CART technical staff with an accessible (ability to read and write data) location for installation of the CART application and create several access keys within the VA EHR to accommodate single sign-on. The CART transactional and longitudinal data repositories are stored outside the VA EHR data repositories, but linked. Installation was considered completed when CART was available via the VA EHR and able to be used to document episodes of care in VA cardiac catheterization labs.

Training

The CART implementation utilized a "train the trainer" method with the clinical champion at each hospital. The initial CART training was conducted over a one and half hour conference call between the clinical champion at a hospital and the CART Clinical and Technical Directors. During this in-service call, the clinical champion was trained to use CART through a sample patient exercise. Clinical champions were strongly encouraged to provide feedback and suggestions for improvement; in short, they were encouraged to take part in CART development. While CART was a fully-developed

application by the time national installation took place, it was still understood that

modifications and updates would continuously be required in subsequent versions.

Clinical Use

After the Training stage of CART implementation, any episodes of care

documented in the cardiac catheterization labs through CART were monitored. Monthly

benchmark reports were provided to each facility which included the number of

episodes of care documented within the CART system. These reports also document

information regarding complications and any major adverse events, so that these data

may be used in local quality and safety efforts.

Summary

The CART implementation process is very similar to accounts of health IT

implementations in the literature. In the construct of a four-stage delineation of

diffusion, some observations are important to consider when assessing potential factors

which may impact the rate of completion for each stage and overall. First, the Initiation

and Clinical Use stages are very much propelled through collaboration and human

interaction. In both, momentum is driven by decisions of people, not technical

components. In contrast, the Installation stage is driven far more by technical

components and resources. Second, in a large-scale implementation such as the CART

implementation, technical issues related to hospital-based access, local privacy and

security policies, or even equipment incompatibilities may negatively impact the rate of

installation of health IT. Finally, as mentioned previously in development of the

conceptual model, each stage is successive; while different factors may drive or delay

the completion of a stage, it is not possible, for example, to be trained on a system

which is not installed, and likewise, it is not possible to install a system without first

identifying individuals to collaboratively facilitate installation, training, and use.

Specific aims and hypotheses

As stated at the beginning of this chapter, the CART Health IT Implementation

framework was applied to investigate the following three questions:

1. Are there hospital-specific characteristics associated with the time required to reach

   full use of health IT?

2. What are the facilitators and barriers associated with implementation of health IT?

3. Of the hospital characteristics and top facilitators and barriers, what characteristics

   or facilitators or barriers are associated with the time required for each of the two

   periods of the implementation process and for full implementation?

These three questions are explored through the following specific aims and

hypotheses. Data sources are fully defined in the next section, and variable definitions

in the section after that. Where appropriate, both the null hypothesis and the alternate

hypothesis are provided in each aim, for convenience; however, the hypothesis

anticipated by this research is identified with an asterisk (*).

Aim one. To assess hospital-specific characteristics with the time required to reach full implementation (i.e., full use) of CART.

The purpose of this aim was to examine hospital-specific characteristics and determine if they are associated with the time it takes for a hospital to achieve full use of health IT. In several surveys exploring health IT adoption, such as the ONC-sponsored survey, hospital characteristics such as urban location, academic affiliation, hospital size, and geographic region have all been associated with faster adoption.[7] These characteristics, as appropriate, were explored with respect to the CART implementation.

In addition to these characteristics, the National Directive is an analogue to "support of senior leadership." The association of this senior leadership statement of support on the time to full use for hospitals beginning implementation before and after this endorsement was issued was also explored.

Finally, in Aim One, potential associations between the Activation Period, the time from first contact to the time of technical installation completion, and the Use Period, the time from technical installation completion to full adoption, were assessed. As illustrated on Figure 6, this comparison would be similar to an ONC comparison of time to "adoption" and time to complete Meaningful Use (i.e., end of Stage 1, 2, or 3, depending on how the reader wishes to interpret Meaningful Use). Because the activities required to complete these periods are performed within the same organization, it might be logical to deduce that the time required to complete one period will be associated with the time required to complete the next. Conversely, the

activities in the two periods are generally performed by different individuals (e.g., technical installation vs clinical use), so it might be just as logical to assume that there is no association. Understanding the presence or absence of an association may be important for organizations for purposes of time and staffing needs, and concomitantly, costs associated with each of these.

Primary specific aim one

To determine if there is a difference in the time required to reach full implementation based on individual hospital-specific characteristics (i.e., hospital size, teaching vs non-teaching hospital classification, geographic region, and implementation initiation with respect to the timing of the senior leadership support statement). Each hospital characteristic assessed in this aim was selected due to its importance in the health IT literature and relevance to this study.

Null hypothesis 1A: There will be no difference in the time required to reach full implementation based on any individual hospital characteristic.

Alternate hypothesis 1A: There will be a difference in the time required to reach full implementation based on hospital size.

Secondary specific aim one

To evaluate if any hospital characteristics were associated with faster or slower full implementation times.

Null hypothesis 1B: There will be no association between any hospital characteristics and the overall time to reach full implementation.

Alternate hypothesis 1B: Larger hospitals will be associated with faster overall full implementation times.

Tertiary specific aim one

To describe the relationship between the Activation Period, the duration of time between first contact with a hospital and completion of technical installation, and the Use Period, the duration of time between completion of the technical installation and full adoption.

Null hypothesis 1C: The Activation Period and Use Period will not be correlated.

Alternate hypothesis 1C: The Activation Period and Use Period will be highly, positively correlated.

Aim two. To assess facilitators and barriers of the CART implementation.

The purpose of this aim was to describe facilitators and barriers identified in a survey of CART clinical champions from the CART hospitals. The survey is described more in the section on data sources. In brief, the survey was administered to clinical champions after full implementation in a hospital was achieved. Clinical champions were asked to first rank their top facilitators and barriers in CART implementation and then indicate their overall agreement with specific statements regarding key factors in implementation.

Primary specific aim two

To determine the top five facilitators and top five barriers clinical champions at each hospital ranked as important during CART implementation.

*Hypothesis 2A(Facilitators): Integration with the VA EHR, the senior leadership support memo, and desire to improve quality will be the most important facilitators noted by CART clinical champions.

*Hypothesis 2A(Barriers): Contentment with current processes and lack of interoperability with other cardiology-specific software (e.g., hemodynamic systems) will be the most important barriers noted by CART clinical champions.

Secondary specific aim two

To determine key factors which clinical champions felt were important to overall implementation. Additionally, to determine which factors clinical champions agreed were strategic for CART implementation.

*Hypothesis 2B(Importance): CART clinical champions will indicate that integration with the VA EHR and desire for standardized reporting were very important factors related to implementation.

*Hypothesis 2B(Agreement): CART clinical champions will most strongly agree that the ability to identify an appropriate clinical champion and the belief that CART will improve quality were important to CART implementation.

Aim three. To evaluate if hospital characteristics and top facilitators and barriers were associated with the time required to complete either of the two periods of the implementation, or were associated with the full required for full implementation.

The purpose of this final aim is to evaluate whether key factors identified through the previous two aims (i.e., hospital characteristics or top facilitators or top barriers) might be associated with the duration of time to complete full implementation. In addition, these key factors will also be assessed with respect to the times required to complete the Activation Period and the Use Period. Recall that the Activation Period most closely approximates the time period currently assessed in the health IT literature to represent "adoption." (Figure 6, page 40) Therefore, assessing the possible associations between key factors and these two periods will help to elucidate whether specific factors are important for only certain portions of health IT implementation.

Primary specific aim three

To understand if the top five facilitators and the top five barriers indicated in the Clinical Champions Survey were associated the times to overall implementation.

Hypothesis 3A(Facilitators): There will be no association between any facilitators and the overall time to reach full implementation.

Hypothesis 3A(Barriers): There will be no association between any barriers and the overall time to reach full implementation.

Secondary specific aim three

To understand if significant hospital characteristics from Aim One or the top five facilitators and the top five barriers from Aim Two were associated the times to complete the Activation and Use Periods.

Hypothesis 3B(Hospital Characteristics): There will be no association between any hospital characteristics and the times for the Activation and Use Periods.

Hypothesis 3B(Facilitators): There will be no association between any facilitators and barriers and the times for the Activation and Use Periods.

Hypothesis 3B(Barriers): There will be no association between any barriers and barriers and the times for the Activation and Use Periods.

Data sources

CART tracking database

Data for this study came from two primary sources. First, as CART was being implemented in the 75 VA facilities, detailed information was stored in the CART tracking database, including all dates depicted in Figure 7, on the next page. The data in the CART tracking database was collected as a routine function of the CART national clinical quality program.

t_0, the month and year first contact was made with a facility, was documented when a hospital contacted the CART Program or vice versa. Early in 2004, at the onset of the VA cardiology community, announcing the CART application. Although this

listserv was believed to include all VA cardiology members, it was found to be deficient.

Consequently, hospitals with catheterization labs were made aware of CART through

direct contact with the CART Program Director, through other VA communications

channels, or through word of mouth. The CART Operations team held at least monthly

briefings to review progress and note additional hospitals which had begun the Initiation

stage.

t_0	First contact with a catheterization lab hospital
t_1	Technical installation of the CART application began
t_2	Technical installation of CART was completed
t_3	CART training inservice conducted
t_4	First month of evidence that ≥90% of all catheterization lab procedures were being entered into the CART application
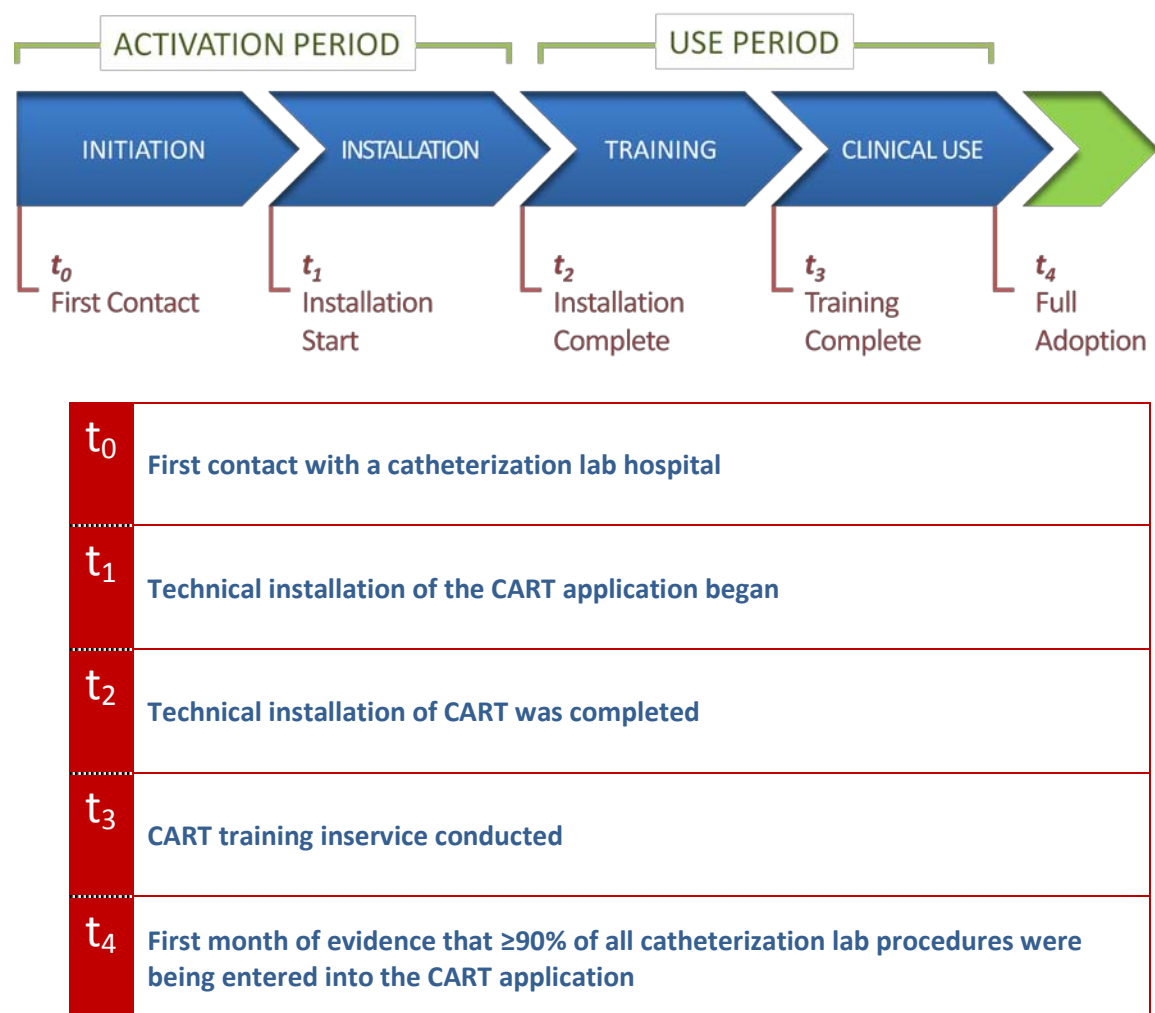
Figure 7. Time points of the CART Health IT Implementation framework.

t_1, the month and year installation began, and t_2, the month and year installation

was completed, were both documented by the CART Technical Director. The start of

installation was identified as the month the CART Technical Director began

communicating directly with the IT department at a hospital. The first steps of technical

installation were marked by receiving appropriate data and system access to facilitate

installation of the CART application. As described previously in this chapter, once access

was provided, technical installation of the application was conducted remotely.

Installation was noted as complete when the CART application was visible in a menu

selection from the VA EHR and could be successfully launched from one's account in the

EHR.

Training on the CART application included an inservice, and was described in

detail in the previous section entitled "Implementation Process." Once CART technical

installation completed, the application was available for testing by members of the

catheterization lab. Training was considered complete after an inservice by the CART

Program Director and the CART Technical Director was conducted with the clinical

champion at the hospital.

t_4, or full use (i.e., full adoption) represents the month and year ≥90% of all

catheterization lab procedures by a given hospital were being entered into CART as

opposed to pre-CART means. Prior to the implementation of CART, cardiac procedures

in the VA were recorded primarily via paper-based logs or local, non-interoperable

solutions (e.g., spreadsheets or local databases) and reported in the health record

through non-standardized, unstructured dictated or manual reports. During

implementation of CART, from 2004 through January 2011, three data requests were

made to CART hospitals to assess their level of use. Catheterization labs were asked to

submit their paper or electronic logs of procedures and these logs were checked with

reports entered in CART to assess how fully each facility was using CART. Records were

verified based on patient identifiers, procedure types, procedure dates, and operator

(i.e., physician performing the procedure). This catheterization lab procedure volume

per hospital is a predominantly stable quantity over time. Therefore, using the three

data requests per hospital and comparing it with three concomitant CART-based

assessments, the date at which a hospital achieved full use of CART, or t_4, was identified;

the month and year when a hospital demonstrated that greater than or equal to 90% of

all cases were completely entered into CART was noted as t_4, or the time when full use

was achieved. The level of greater than or equal to 90% was selected as the cut-off for

full use to allow for slight monthly procedural volume variation.   Each of the CART

hospitals have now fully adopted CART and the volume of procedures each

catheterization lab completes monthly and annually is easily calculated through CART.

Survey of CART hospital clinical champions

The second data source for this study was a survey of facilitators and barriers of

implementation. Once a hospital demonstrated full use, a clinical champion at that

hospital was asked to complete the CART implementation survey. This survey was

constructed to assess, using Likert-type scaled questions, the facilitators and barriers of

implementation. Survey items were derived primarily from documented facilitators and barriers in the literature, and secondarily, from VA- and CART-specific potential facilitators and barriers. The survey contained two main sections. The first section asked respondents to rank their top five facilitators and top five barriers throughout implementation of CART. The second section of the survey asked respondents to assess how strongly they felt key factors impacted the implementation of CART. Each section contained similar factors, such that the overall importance of the factors could also be assessed in terms of their overall rank against other factors. The survey was administered through SurveyMonkey.com. Responses were provided anonymously and later linked to hospital data from the CART Tracking Database through a crosswalk.

Portions of the research in this thesis were supported by a grant through the VA Quality Enhancement Research Initiative Rapid Research Protocol funding. This protocol is found in Appendix C. The protocol was approved as exempt research through the Colorado Multiple Institutional Review Board (Appendix D). The survey instrument developed through part of the grant proposal and is included in Appendix E.

Statistical analysis plan

All statistical analyses were performed using IBM Statistical Package for the Social Sciences (SPSS, version 20). Because of the retrospective design of the study and a study population which included all VA hospitals with cardiac catheterization labs, considerations of sample size and power were addressed in the context of the results.

Primary specific aim one

To determine if there is a difference in the time required to reach full implementation based on individual hospital-specific characteristics (i.e., hospital size, teaching vs non-teaching hospital classification, geographic region, and implementation initiation with respect to the timing of the senior leadership support statement).

Outcome variable: The duration of time from t_0 through t_4, noted in Figure 7, was used to calculate the number of months required for full implementation (i.e., an endpoint of full adoption) per hospital.

Predictor variables: Five individual predictor variables were created to represent the various hospital-specific characteristics: (1) Hospital size was coded as a tertiary variable, based on operating bed size in fiscal year 2011 (Large ≥ 180 beds, Medium 121-179 beds, Small ≤ 120 beds); (2) Academic affiliation was coded as a binary variable (1 = Hospital is academically-affiliated, 0 = not academically-affiliated); (3) Location was coded as a binary variable, based on VA administrative data derived from US Census definitions in 2010 (1 = Urban, 0 = Rural); (4) Geographic region, likewise, was defined through 2010 US Census designations and coded as a categorical variable representing North, South, Midwest, and West; and (5) The timing of CART implementation for a hospital with respect to the issuance of the senior leadership statement of support was coded as a binary variable (i.e., hospitals which initiated implementation after the

senior leadership statement of support were coded as "1" and those who initiated prior to the statement were coded as "0").

Statistical analysis: Differences in the outcome variable, time to full implementation in months, were assessed through univariate analyses based on each of the five predictor variables. For binary predictor variables, the differences in mean times to full implementation were assessed using independent samples *t*-Tests. For categorical predictor variables, differences in the mean times to full implementation for the categorical groups were assessed using one-way analysis of variance (ANOVA). All observations are independent. Outliers were assessed to ensure they did not represent data entry or measurement errors. Normality of the outcome variable was assessed to ensure the distribution was at least approximately normal and tolerable to assumptions via the Central Limit Theorem. Homogeneity of variances was tested with Levene's test for equality of variances. The significance level for all analyses in this thesis was evaluated at $\alpha = 0.05$, using two-tailed significance.

Secondary specific aim one

To evaluate if any hospital characteristics were associated with faster or slower full implementation times in multivariate analysis.

Outcome variable: The duration of time from t_0 through t_4, noted in Figure 7, was used to calculate the number of months required for full implementation (i.e., an

endpoint of full adoption) per hospital. A dichotomous variable was created to represent whether a hospital achieved the outcome (i.e., full implementation).

Predictor variables: Same as primary specific aim one. Any predictors in primary specific aim one which lacked significant variation (e.g., a binary predictor in which nearly all hospitals fell into only one of the two categories) were omitted from the multivariable analysis.

Statistical analysis: The association of hospital characteristics with the instantaneous "risk" of a hospital completing implementation was assessed using a Cox proportional hazards model. The Cox proportional hazards model has historically been used as a time-to-event model in analyses of survival times with respect to disease risk factors. For example, the survival time for a patient at risk of death from heart disease risk factors might be assessed using Cox proportional hazards. In that type of application of the Cox model, patients are evaluated based on whether they have specific risk factors for heart disease (e.g., age, smoking history, uncontrolled diabetes or other comorbidities) and perhaps whether they received a specific treatment or intervention. Patients are assessed over a period of time to determine if they reached an "event" being measured, such as death. The "survival time," or time to the event, is evaluated as the outcome variable in the Cox model, and assessed with respect to the presence of predictor risk factors or treatment. Therefore, in the Cox model, the outcome variable includes two parts: whether the patient reached the event (e.g., death) or not, and a measure of time from the start of measurement to the event. In

general, the Cox proportional hazards model can help the researcher understand if

specific predictors are associated with the times to events.

More recently, the Cox proportional hazards model has also been applied as an

event history model to evaluate times to events for diffusions of innovations

research.[92,93] The outcome assessed in these cases is the time required for a group to

achieve a level of diffusion. Predictor variables are defined related to characteristics of

the groups. For example, the time required for diffusion of smartphones in the United

States might be measured using a Cox proportional hazards model. The time required

for all members of a group, e.g., residents in a state, to adopt smartphones might be

assessed with respect to predictors such as availability of data networks, number of

smartphone operating systems, number of residents using smartphones, or cost of

smartphones. Many residents will achieve the event, or adoption of smartphones, and

some many not. Using the Cox proportional hazards model, it may be possible to

evaluate which predictors are associated with time to adopt.

More specifically, the Cox proportional hazards model measures the "risk" of an

event during a specific time interval. This "risk" is also known as the hazard function.

The general formula for the Cox proportional hazards model is as follows:[98]

$$h(t, X) = h_0(t)e^{\sum_{i=1}^{p} \beta_i X_i}$$

The left part of the equation, $h(t, X)$, is the hazard function, or the instantaneous risk of

the event at time t with respect to one or more predictor variables, denoted as X. The

right part of the equation is the product of the baseline hazard, h_0, for the event at time

t, and an exponential expression which incorporates the contributions of all of the predictors.   Importantly, the baseline hazard represents the baseline risk of the event at a specific time for any person or group, irrespective of the predictors.

There are several characteristics of the Cox proportional hazards model which make it a good choice for analyses of implementations. First, the Cox proportional hazards model assumes that the relationship between the outcome and the predictors is proportional over time. For example, if the risk of death for a man is twice that of a woman at a given time, then the risk of death at a later time will remain proportionally higher for a man. Likewise, if the "risk" of fully adopting smartphones at a specific time is two times greater for residents of a state with 4G data networks versus 3G networks at a specific time, the risk will remain two times greater at a later time. Second, the measure of the effect of a predictor on the hazard rate in a Cox proportional hazards model can be assessed without knowing the form of baseline hazard. Because of this, the Cox model is considered semiparametric.   This is particularly useful in implementation or diffusion analyses because there may not be reliable information available to specify the baseline hazard distribution. Finally, the Cox proportional hazards model accommodates people or groups which may not have reached the event, or have been censored.

In this aim, full time to implementation in months, was used as the outcome and all appropriate covariates from primary specific aim one were included as predictor variables. A dichotomous data element to represent whether a hospital achieved the

outcome (i.e., full implementation) was created. All Cox models in this thesis were evaluated for accuracy and fit through several steps. First, significance of the overall models are assessed through model likelihood ratios. Also, multicollinearity and pair-wise correlations amongst predictor variables are evaluated. Last, model accuracy was assessed by plotting deviance residuals.

The outputs for the Cox model in this aim and other later aims produce several components which require some interpretation. For each predictor the output is summarized with a regression, or β, coefficient, a value for the hazard ratio, the 95% confidence interval surrounding the hazard ratio, and a measure of statistical significance. In general for all models in this thesis, the directionality of the β-coefficient indicates whether a predictor is associated with faster (i.e., positive β-coefficients) or slower (i.e., negative β-coefficients) times.[1]

The hazard ratio provides a measure of the effect of the predictor on the outcome. For binary predictors in this thesis, for example Yes (1) and No (0), the hazard ratio is the ratio of the estimated hazards of the two groups; a hazard ratio of 1.25 would therefore indicate the hazard rate of the Yes group is 125% of that of the No group. If the predictor is significant as well, and the β-coefficient positive, this might be

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[1]This is analogous to the clinical study examining survival times in patients with heart disease. A positive coefficient indicates the risk of the event (e.g., death) is higher and therefore the prognosis poorer; a clinical risk factor predictor with a positive coefficient, therefore, might be associated with faster time to death or less survival. In the study in this thesis, however, faster times to the event (e.g., completion of implementation) are desirable.

interpreted as a predictor which is associated with 25% increased rate of implementation.

Tertiary specific aim one

To describe the relationship between the Activation Period, the duration of time between first contact with a hospital and completion of technical installation, and the Use Period, the duration of time between completion of the technical installation and full adoption.

Outcomes: The duration of time required to complete the Activation Period, t_0 through t_2, and the Use Period, t_2 through t_4, were calculated for each hospital.

Statistical analysis: Non-parametric Spearman correlation was used to explore a potential correlation between these two periods.

Primary specific aim two

The purpose of this aim was to describe facilitators and barriers identified in a survey of CART clinical champions from the CART hospitals. The survey is described more in the section on data sources. In brief, the survey was administered to clinical champions after full implementation in a hospital was achieved. Clinical champions were asked to first rank their top facilitators and barriers in CART implementation and then indicate their overall agreement with specific statements regarding key factors in implementation.

Outcomes: The CART clinical champions survey, section one, was used to assess primary specific aim two. In this section, respondents were asked to rank their top five facilitators and top five barriers from a larger list of each.

Descriptive analysis: The raw response counts are provided. In addition, weighted scores for facilitators and barriers were summarized by multiplying the number of selections of each by the weight of the response option. For example, a facilitator or barrier which received a rank of "1" is valued as a five; if that particular facilitator or barrier received ten "1" votes, this would equate to a score of 50 for "1" votes and would be added to the weights of the other ranks to create a summary score for the item. Importantly, the summary score is provided for visual convenience, since it is impossible to know that the ranking of top choices is uniformly distributed for each respondent; that is, the distance between what one respondent chooses as #1 and #2 may be different from other respondents' perceptions.

Secondary specific aim two

To determine key factors which clinical champions felt were important to overall implementation.

Outcomes: The CART clinical champions survey, section two, was used to assess primary specific aim two. In this section, respondents were asked to assess how strongly they felt key factors impacted the implementation of CART. Likert-scaled responses of "Strongly Agree," "Agree", "Neither Agree Nor Disagree," "Disagree", and

"Strongly Disagree" were coded as "1" if the response was affirmative (i.e., agreement or indication that an item was important) and "0" if the response was not affirmative.

Descriptive analysis: The percentages of affirmative responses are provided for each item.

Primary specific aim three

To understand if the top five facilitators and the top five barriers indicated in the Clinical Champions Survey were associated with the times for overall implementation.

Outcome variable: The duration of time from t_0 through t_4, was used to calculate the number of months required for full implementation (i.e., an endpoint of full adoption) per hospital. A dichotomous variable was created to represent whether a hospital achieved the outcome (i.e., full implementation).

Predictor variables: The top five facilitators and barriers in primary specific aim two were used as dependent variables, or predictors. Each facilitator and barrier was coded as a binary variable; if a hospital selected that item as a top five facilitator or barrier, it was given the value "1." Otherwise, it was denoted as "0."

Statistical analysis: The association of facilitators and barriers with the instantaneous "risk" of a hospital completing implementation was assessed using a Cox proportional hazards model.   Please refer to "Statistical analysis" plan for secondary specific aim one for the description of the Cox proportional hazards model, assessment of model accuracy and fit, and general interpretation.

Secondary specific aim three

To understand if the top five facilitators and the top five barriers or significant hospital characteristics from Aim One were associated with times to complete the Activation and Use Periods.

Outcome variables: The time required for the Activation Period (i.e., t_0 through t_2) and the time required for the Use Period (i.e., t_2 through t_4) were used. A dichotomous variable was created to represent whether a hospital achieved the outcome (i.e., completion of the Activation Period or completion of the Use Period).

Predictor variables: The predictor variable in the first two models (i.e., model of association with Activation Period and model of association with Use Period) was the binary variable representing whether a hospital initiated implementation after the senior leadership statement of support, coded as "1." The predictors in the final two models (i.e., again, one model related to the Activation Period and one related to the Use Period) were the top facilitators and barriers found in specific aim two.

Statistical analysis: The associations of the instantaneous "risk" of a hospital completing the Activation Period and the Use Period, respectively were assessed using a Cox proportional hazards model. Again, please refer to "Statistical analysis" plan for secondary specific aim one for the description of the Cox proportional hazards model, assessment of model accuracy and fit, and general interpretation.

CHAPTER IV

RESULTS OF ANALYSIS

Characteristics of CART hospitals

75 VA hospitals with cardiac catheterization labs implemented CART from March 2004 through January 2011. Hospitals were distributed across the United States, as shown in Figure 3 on page 32 and repeated below as Figure 8, for convenience. 40% (N=30) of the CART hospitals were located in the South. The 75 hospitals operated a median of 145 ± 80 beds (IQR 108, 204) in fiscal year 2011. The smallest CART hospital maintained 39 beds, while the largest maintained over 400 beds. 96% (N=72) of CART hospitals were located in urban settings and 100% (N=75) were academically affiliated. Table 3, on the next page, provides summary information for the hospitals in the CART implementation.

San Juan, Puerto Rico ⬤
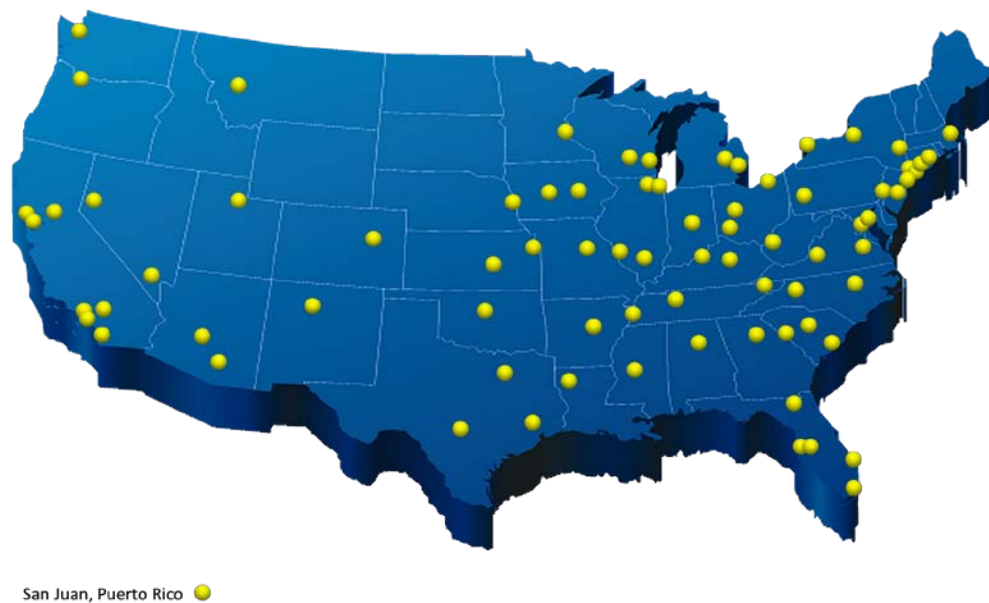
Figure 8. VA cardiac catheterization lab locations and CART hospitals, 2004-2011.

Table 3. Characteristics of hospitals in CART implementation

Hospital Characteristics (N=75)	N (%)
Region	
Northeast	11 (14.7%)
South	30 (40.0%)
Midwest	19 (25.3%)
West	15 (20.0%)
Hospital Operating Bed Size	Md 145 ± 80 (IQR 108, 204)
Large (≥ 180 beds)	24 (32.0%)
Medium (121 - 179 beds)	26 (34.7%)
Small (≤120 beds)	25 (33.3%)
Urban Location (Yes)	72 (96.0%)
Academic Affiliation (Yes)	75 (100%)

Hallmarks of CART implementation

Figure 9, on the next page, illustrates the cumulative implementation of CART by hospitals over time. Hospitals are plotted relative to the time at which they achieved full use of CART (i.e., full implementation).   The first hospital achieved full use in August 2004 and the last of the 75 hospitals achieved full use in January 2011. The pattern of cumulative implementation of CART over time followed the "S-curve" shape typical for many diffusions of innovations, as described by Rogers (please see Figure 4 on page 33). Rogers's definitions relate to the percentage of implementers (i.e., adopters) over time

in a diffusion process. For example, the first 2.5% of adopters are called "Innovators,"

the next 13.5% are "Early Adopters," followed by "Early Majority" and "Late Majority"

which are each 34%, and finally, "Laggards," the last 16% to adopt. Per Rogers's

definitions, three CART hospitals were "Innovators" and achieved full use by December

2004. Nine hospitals were part of the next group, the "Early Adopters," achieving full

use by January 2006. There were 25 hospitals in each of the next two groups; "Early

Majority" hospitals completed implementation by July 2007 and "Late Majority"

hospitals completed by May 2009. Finally, 13 hospitals were part of the "Laggards"

group, finishing by January 2011.
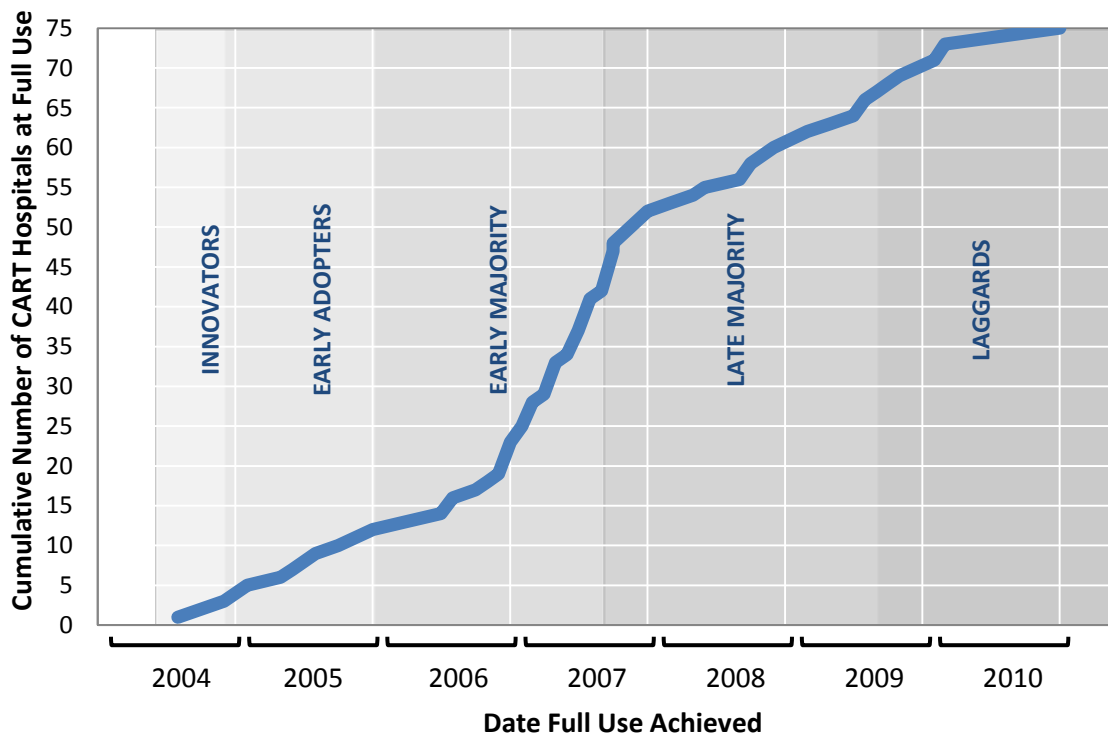
Figure 9. Cumulative implementation of CART over time.

The median durations for all components of implementation are summarized in Figure 10, below. Full implementation required a median of 13.98 ± 17.04 months (IQR 7.03, 32.93). The amount of time required for full implementation varied considerably among the 75 hospitals. The fastest hospital to implement completed all stages of the process in three months (0.25 year), while the slowest hospital required 75 months (6.25 years).   The Activation Period, a composite of the Initiation and Installation stages, was slightly shorter than the Use Period, a composite of Training and Clinical Use stages (Md 5.03 ± 11.89 months vs 6.02 ± 12.34 months). Among the four stages, Initiation and Training required the least amount of time (Md 2.02 ± 8.77 and 2.02 ± 6.15 months, respectively). The Clinical Use stage was the longest stage, at 5.00 ± 10.87 months. The individual durations per stage for each CART hospital over time are presented in Figure 11, on the next page.
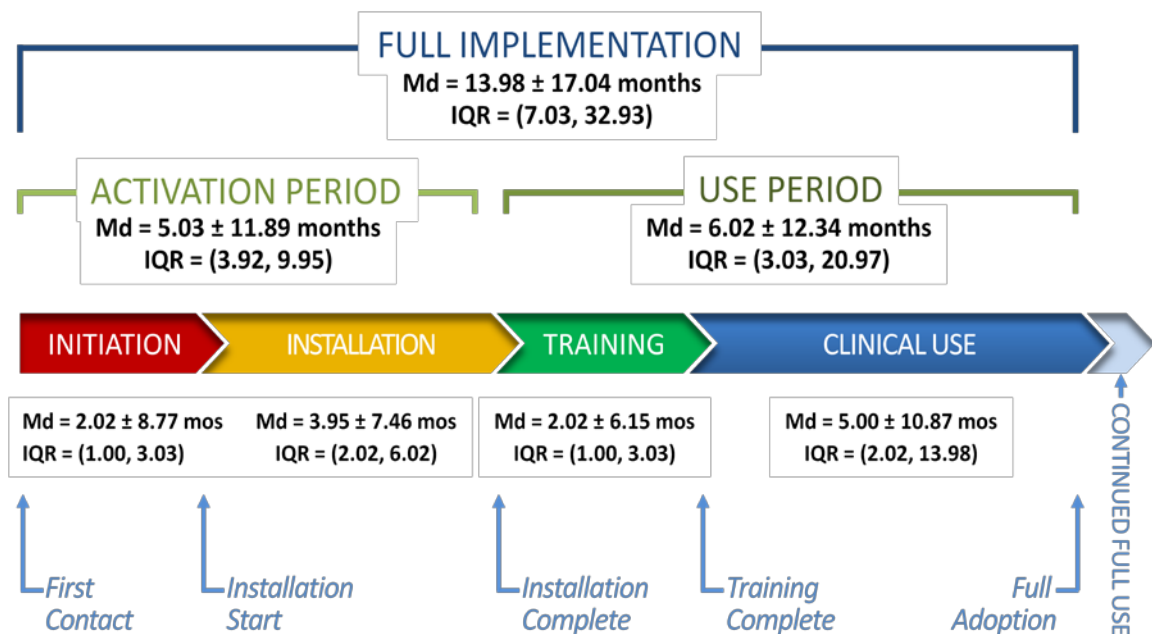
Figure 10. Implementation durations.
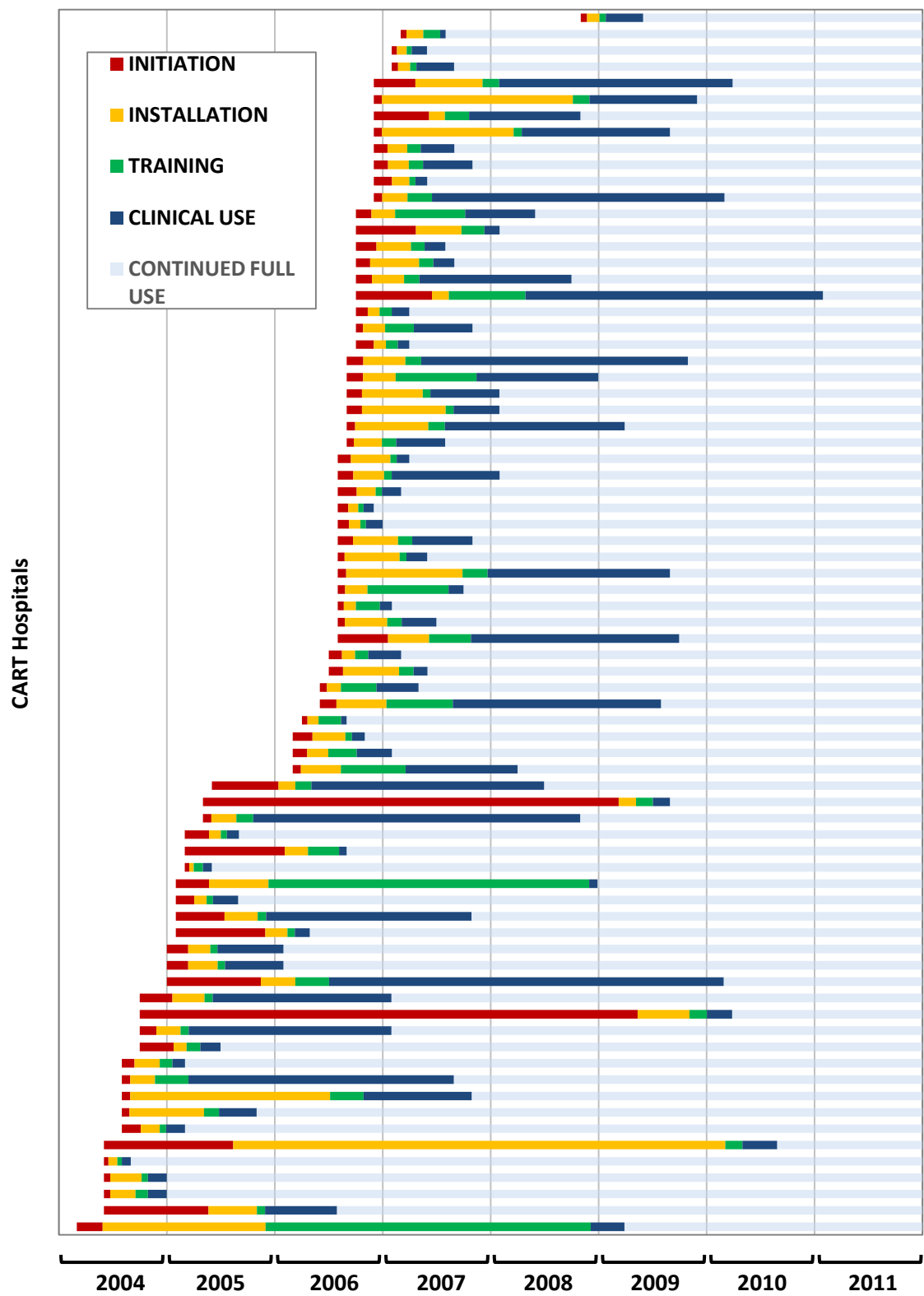
Figure 11. CART hospital implementation stages over time.

Plots of the individual stages are provided in Figure 12, below, and further demonstrate the level of variability in each stage. Each plot shows the time required per hospital to complete a stage, plotted against the time of first contact. There is little variability in the first three stages, but there is marked variability in the Clinical Use stage.

TIME OF FIRST CONTACT WITH HOSPITAL
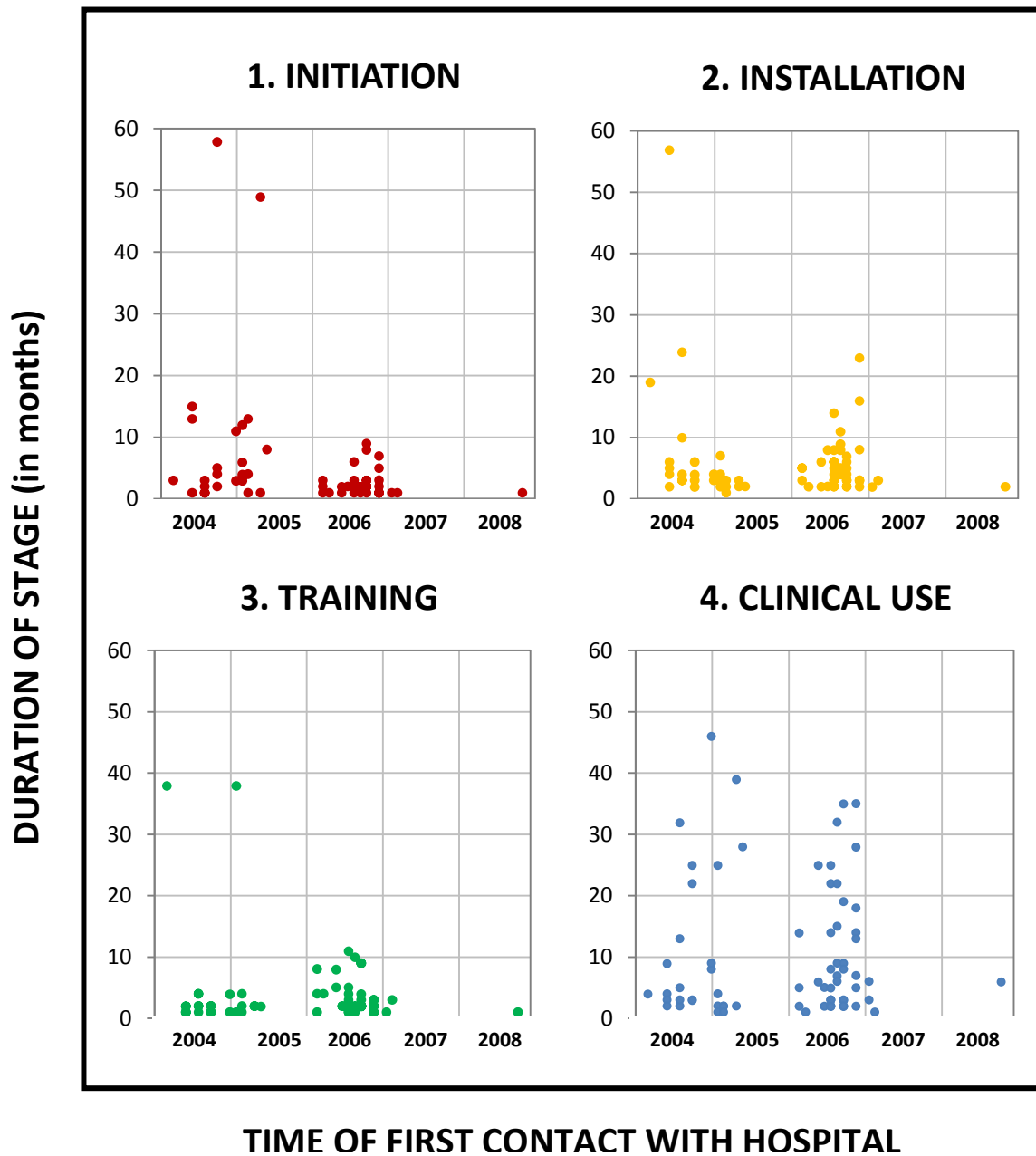
Figure 12. Durations of implementation stages over time.

Association with senior leadership endorsement

Approximately twenty months after the first hospital began implementing CART, a statement was issued by VA leadership supporting implementation of CART in all VA cardiac catheterization laboratory hospitals. By the time the statement of support was issued, over a third of the 75 hospitals had already initiated implementation (N=27; 37.3%). The remaining 47 hospitals (62.7%) initiated implementation after the senior leadership statement of support. The median time to fully implement for those who initiated before leadership endorsement was longer than the time to implement for hospitals beginning after the endorsement (Md 21.95 ± 21.48 vs 10.98 ± 12.57 months). The time required for full implementation by those hospitals which initiated implementation before the statement was issued and the time required for those which initiated after the statement was issued differed statistically significantly (95% CI 0.98 - 19.0, t(38.21) = 2.24, p = 0.031). (Figure 13, next page)

For the final three individual stages of implementation (i.e., Installation, Training, and Clinical Use), the durations required to complete each stage did not substantially change after the senior leadership statement of support was issued. However, the Initiation stage demonstrated a statistically significant reduction in duration after the endorsement (Md 3.00 ± 13.52 vs 2.02 ± 1.83; 95% CI 0.63 - 11.6, t(27.59) = 2.30, p = 0.029). This difference remained significant even if the two lengthiest hospital durations for the Initiation stage were omitted.
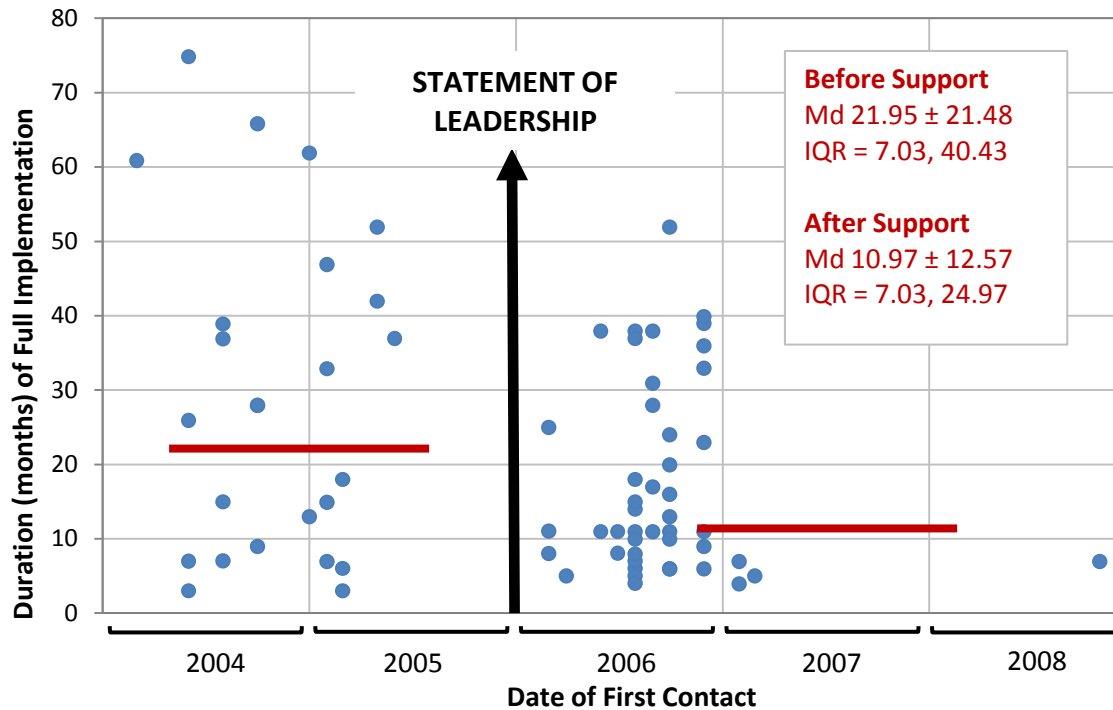
Figure 13. Leadership support and CART hospital implementation duration over time.

The statement of senior leadership support at the end of 2005 also coincided with the cut-point for the final hospitals included in Rogers's "Early Adopters" group (please refer to Figure 9 on page 67.) "Innovators" and "Early Adopters" both initiated implementation of CART prior to the statement of senior leadership support. The timing of the endorsement is shown on Figure 14, page 733, in the context of the diffusion curves for completion of each stage. After the senior leadership statement of support, the slopes of all of the curves increased, noted through visual inspection. The sharpest increase over the 12-month period following the endorsement (i.e., through the end of 2006) was apparent in the diffusion curve for the Initiation stage.
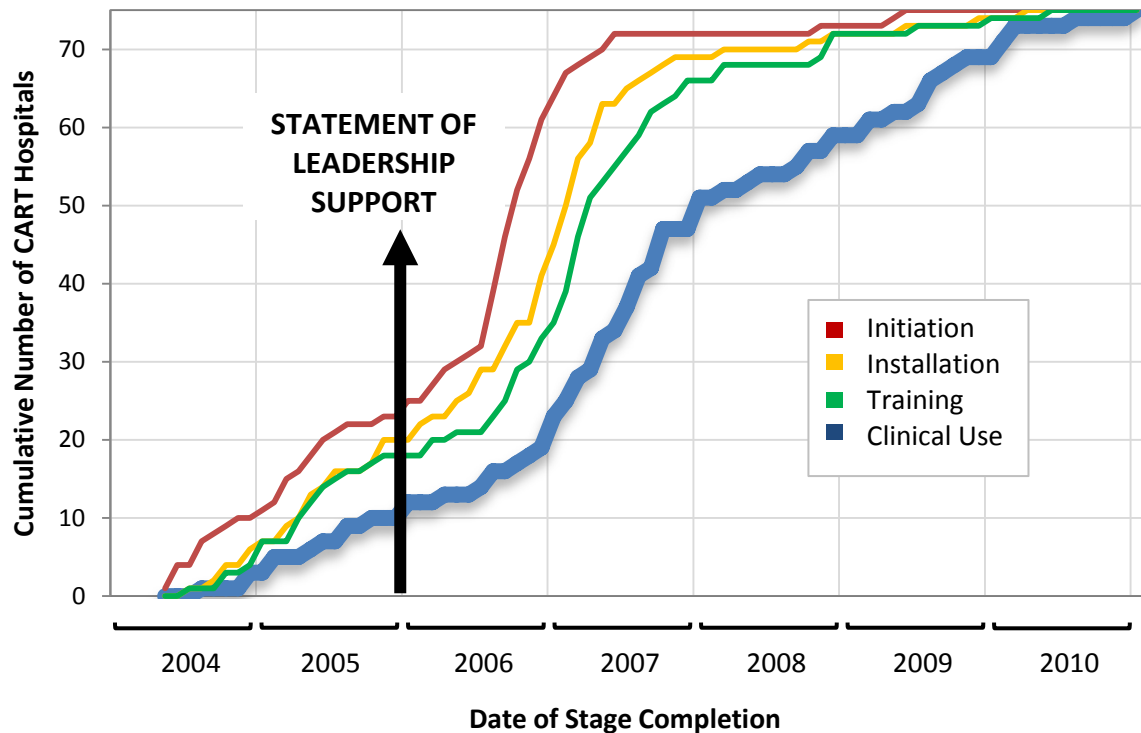
Figure 14. Cumulative number of hospitals for each implementation stage over time.

Primary specific aim one

Among the 75 hospitals that implemented CART, there were no statistically significant differences in overall time to implement between the four geographic regions, or with respect to hospital size, urban location, or academic affiliation. (Table 4, next page) Hospitals in the Northeast had the slowest median implementation times (32.93 ± 21.83 months), though there were no statistically significant differences between regions. There was no statistically difference in median times to implement based on hospital size. Medium-sized hospitals required a median of approximately 16 months to implement, which was slightly slower than large (10.97 ± 17.19 months) and small (12.97 ± 14.89 months) hospitals. Lastly, as reported in the previous section,

hospitals that initiated implementation after the senior leadership statement of support

had markedly, and statistically significant, faster overall implementation times (95% CI

0.98 - 19.0, $t(38.21) = 2.24$, $p = 0.031$).

Table 4. Comparison of hospital characteristics and time to full implementation

Hospital Characteristics (N=75)	N (%)	Time to Full Implementation in months (Md, IQR)	P-Value*
Region			0.075
Northeast	11 (14.7%)	32.93 ± 21.83 (10.97, 37.95)	
South	30 (40.0%)	12.00 ± 12.32 (7.03, 27.95)	
Midwest	19 (25.3%)	12.97 ± 16.18 (5.95, 24.97)	
West	15 (20.0%)	15.98 ± 20.04 (8.05, 46.87)	
Hospital Operating Bed Size			0.816
Large (≥ 180 beds)	24 (32.0%)	10.97 ± 17.19 (7.03, 34.93)	
Medium (121 - 179 beds)	26 (34.7%)	15.48 ± 19.23 (9.95, 27.95)	
Small (≤120 beds)	25 (33.3%)	12.97 ± 14.89 (6.93, 27.95)	
Urban Location (Yes)	72 (96.0%)	14.44 ± 16.83 (7.03, 32.90)	0.918
Non-urban Location	3 (4.0%)	9.95 ± 26.15 (3.92, 51.92)	
Academic Affiliation (Yes)	75 (100.0%)	13.98 ± 17.04 (7.03, 32.93)	n/a
Initiation After Leadership Statement of Support	47 (62.7%)	10.97 ± 12.57 (7.03, 24.97)	0.031
Initiation Before Leadership Statement of Support	28 (37.3%)	21.95 ± 21.48 (7.03, 40.43)	

*Independent samples *t*- tests for dichotomous independent variables and one-way ANOVA tests for categorical independent variables were performed with the Time to Full Implementation as the dependent variable. Significance was assessed at the 0.05 level.

Secondary specific aim one

In order to further evaluate if any of the hospital characteristics (i.e., geographic region, hospital size, urban location, academic affiliation, and timing of initiation of implementation with respect to leadership endorsement) were associated with faster or slower implementation times, a Cox Proportional hazards regression model was fitted with all hospital characteristic variables except urban location and academic affiliation, due to lack of variability in these data. The time to full implementation, in months, was used as the outcome variable in the model. Since all hospitals achieved full use, there was no censoring; an event variable was constructed to indicate full use (i.e., the event) was reached. The results of this multivariable analysis are presented in Table 5, on the next page.

In the model of hospital characteristics, region and hospital were not significantly associated with the time to full implementation. However, hospitals which initiated implementation after the senior leadership statement of support were significantly associated with faster implementation (*HR* 2.06, *95% CI* 1.21-3.51, *P*=0.008).   The hazard rate for those hospitals who initiated implementation after leadership endorsement was 49% of the rate for those who initiated prior to the endorsement. These results are supported by the median times for these groups represented in Figure 14 on page 73, and the corresponding univariate analysis.

Table 5. Hospital characteristics Cox proportional hazards model estimation for time to full implementation

Variable	β-Coefficient	Hazard Ratio	95.0% CI	P-Value
Hospital Operating Bed Size				0.784
Small (≤ 120 beds)	0.12	1.13	0.61 - 2.09	0.703
Medium (121-179 beds)	-0.09	0.91	0.51 - 1.65	0.763
Region				0.104
Northeast	-0.51	0.60	0.26 - 1.38	0.228
South	0.28	1.33	0.68 - 2.59	0.405
Midwest	0.41	1.50	0.73 - 3.09	0.269
Initiation After Leadership Statement of Support	0.72	2.06	1.21 – 3.51	0.008

Notes: Model likelihood ratio = 492.09; P = 0.037.

Several steps were taken to assess the accuracy of the Cox Proportional hazards model. First, pair-wise correlations were evaluated amongst the predictor variables. Also, multicollinearity amongst the predictor variables was assessed by evaluating variable inflation factors. Both of these steps were taken to ensure the parameter estimates had the best possible accuracy, as two or more correlated predictor variables may increase the variance of these estimates and thereby reduce the accuracy of the individual predictors. In the hospital characteristics model, no pair-wise correlations were high (i.e., greater than 0.7) and likewise, no variables had high variable inflation factors (i.e., >10), indicating there was not an issue with multicollinearity in this model.

Finally, overall model accuracy was tested by plotting the deviance residuals; in a fitted

model, the deviance residuals should be randomly distributed with approximately equal

numbers of positive and negative residuals and no substantial outliers (Figure 15,

below).

Deviance Residuals Plot
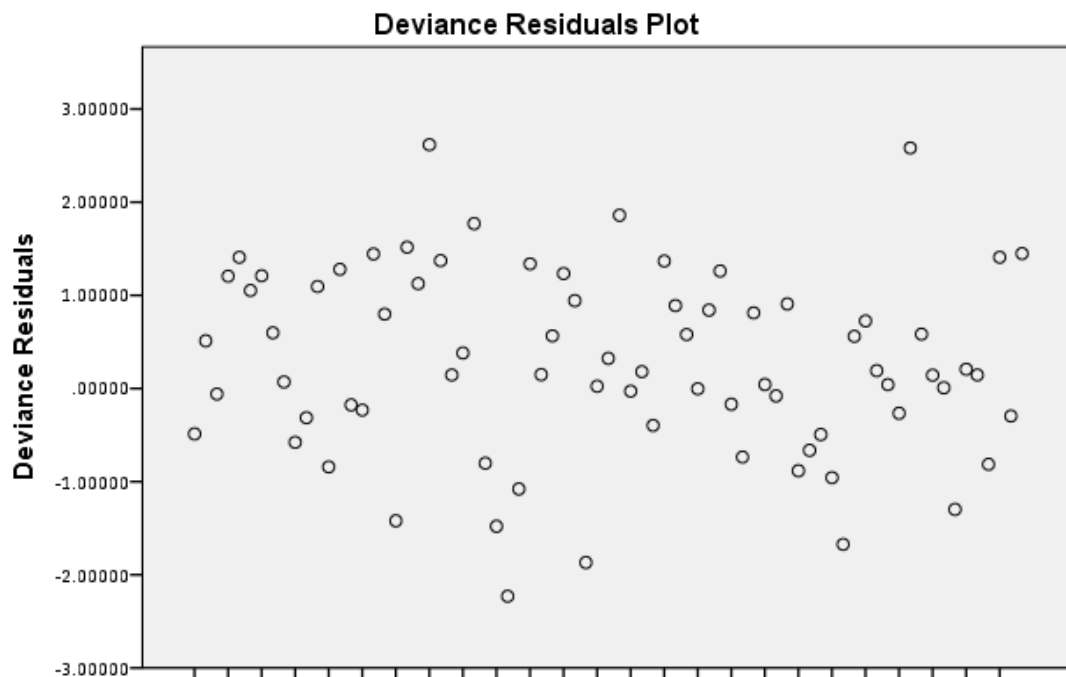
Figure 15. Deviance residuals, Cox Proportional hazards model for hospital characteristics and time to full implementation.

Tertiary specific aim one

The relationship between the Activation Period and Use Period was assessed

using correlation. The Activation Period is a composite of the Initiation and Installation

stages, beginning with first contact and concluding with completed installation. The Use

Period is a composite of the Training and Full Use stages, beginning with completion of

installation and concluding with demonstrated full use of the application. In this

implementation, there was a modest, positive correlation between the Activation and

Use Periods (r_s = 0.224; p = 0.054; 95% CI -0.0031-0.4291). A correlation plot, with

hospitals identified based on the timing of implementation with respect to the senior

leadership support statement, is presented below in Figure 16.
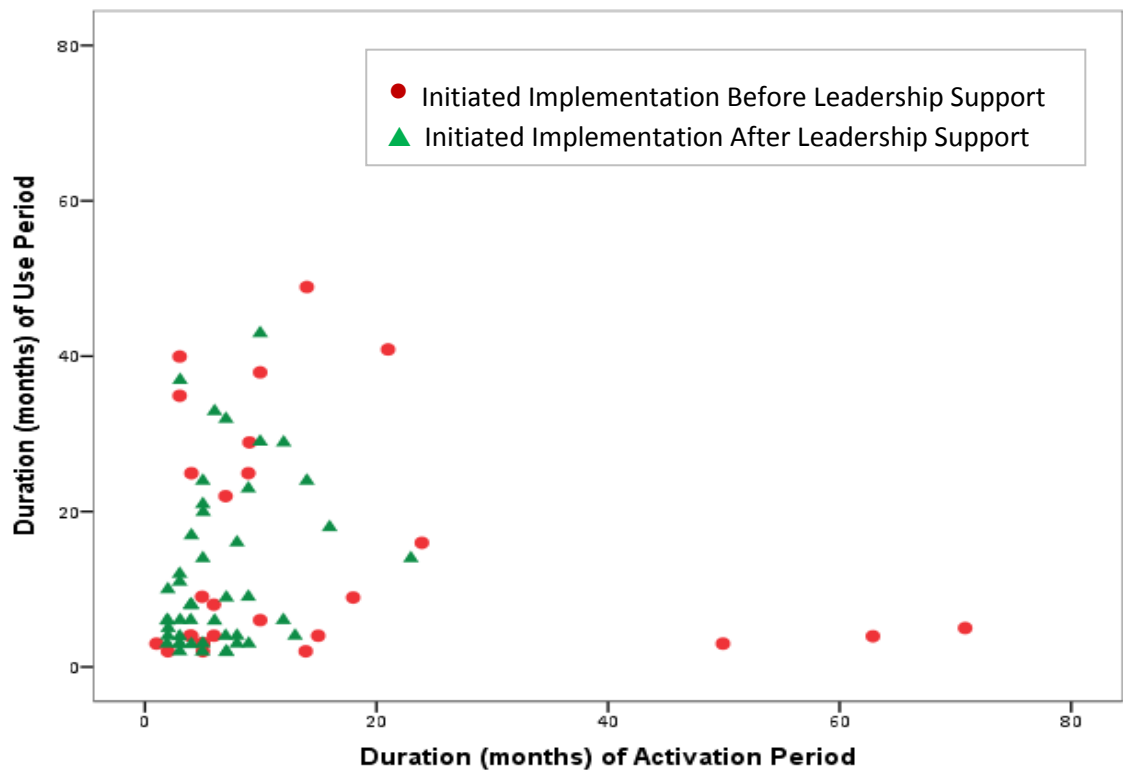
Figure 16. Correlation plot of Activation and Use Periods.

Primary specific aim two

Characteristics of survey respondents and non-respondents

Clinical champions from 58 (77.3%) of the 75 CART hospitals responded to the

CART survey (Appendix E).   Champions were sent the survey after the hospital had

achieved full use of CART. Characteristics of the hospitals from which a clinical

champion responded are compared with those of non-responders in Table 6, on the next page. There were no significant differences between responders and non-responders for any of the hospital characteristics, which included geographic region, hospital size, urban location, academic affiliation, and time of implementation related to the senior leadership statement of support. Similarly, durations for the components of implementation are compared between respondents and non-respondents in Table 7, on page 81. No significant differences existed between respondents and non-respondents for durations of implementation.

Top facilitators identified by clinical champions in CART implementation survey

Respondents to the CART implementation survey were asked, in the first section of the survey, to rank their top five facilitators for CART implementation. A facilitator was described as "anything which might have contributed to the successful installation and adoption." A rank of "#1" indicated the respondent felt that facilitator was the most important one in facilitating implementation of CART. The facilitators are presented in Table 8, on page 822. A summary score column was added to simplify ranking and assessment; although the measurement between rankings for each respondent is not necessarily uniform, the summary score nevertheless represents a sum of the scores for that item, with a #1 rank receiving five points, #2 receiving four points, and likewise for the other ranks.

Table 6. Characteristics of hospitals, survey respondents versus non-respondents

Hospital Characteristics	Survey Respondents (N=58, 77.3%)		Survey Non-Respondents (N= 17, 22.7%)		P Value*
	N	%	N	%	
Region					0.526
Northeast	10	17.2%	1	5.9%	
South	24	41.4%	6	35.3%	
Midwest	13	22.4%	6	35.3%	
West	11	19.0%	4	23.5%	
Hospital Operating Bed Size					0.783
Large (≥ 180 beds)	19	32.8%	5	29.4%	
Medium (121 - 179 beds)	21	36.2%	5	29.4%	
Small (≤120 beds)	18	31.0%	7	41.2%	
Urban Location (Yes)	57	98.3%	15	88.2%	0.127
Academic Affiliation (Yes)	58	100%	17	100%	-
Initiation After Leadership Statement of Support	38	65.5%	9	52.9%	0.346

*Two-tailed chi-squares of categorical variables approximated by either Pearson chi-squares or Fisher's Exact Test, as appropriate.

The top five facilitators toward CART implementation, as ranked by clinical champion respondents to the survey, covered a wide range of topics important to health IT. The top facilitator was the integration of CART with the VA EHR. As described in the Methodology section of this thesis, CART was connected to the VA EHR to allow "single sign-on," or a single user authentication step from the EHR. Furthermore, when

launched from the EHR, CART maintained the active patient and automatically

transferred key information from the EHR into the CART interface. These steps reduced

duplicative keystrokes and data entry for cardiologists using CART.

Table 7. Implementation component durations, survey respondents versus non-respondents

Implementation Component	Survey Respondents (N=58, 77.3%)		Survey Non-Respondents (N= 17, 22.7%)		P Value *
	Md (months)	IQR	Md (months)	IQR	
Initiation	2.02 ± 9.86	1.00, 3.03	2.02 ± 2.37	1.00, 3.00	0.383
Installation	3.97 ± 8.28	2.93, 6.02	3.00 ± 3.34	1.98, 4.97	0.425
Training	2.02 ± 6.92	1.00, 3.95	1.98 ± 1.15	1.00, 2.02,	0.261
Clinical Use	5.00 ± 11.12	2.02, 13.98	5.95 ± 10.29	3.00, 9.03	0.947
Activation Period (Initiation + Installation)	5.52 ± 13.27	3.95, 9.95	5.00 ± 3.95	3.00, 5.52	0.252
Use Period (Training + Clinical Use)	7.02 ± 12.81	3.03, 20.97	6.02 ± 10.72	3.98, 9.98	0.537
Full Implementation	15.97 ± 18.00	7.03, 32.93	10.97 ± 12.62	7.03, 15.98	0.212

* Independent samples *t-* tests with equal variances assumed were performed on each implementation component.

Among the next four ranked facilitators, both organizational and IT-specific

factors emerged as top choices. First, the VA senior leadership statement of support

was the second highest ranked facilitator. The desire to improve quality and the

potential for research using CART were also selected as important facilitators.   Finally,

the CART technical support was also ranked as a top five facilitator. Of note, this

designation differs from VA-specific IT support, which was also an option in the list of

facilitators.

Table 8. Ranking of top facilitators for CART implementation by clinical champions

FACILITATORS	#1	#2	#3	#4	#5	Summary Score	RANK
CART integration with the VA EHR	18	11	8	1	4	164	1
Statement of strong support by VA senior leadership	13	1	8	3	5	104	2
Desire to improve quality	8	5	6	5	3	91	3
Future research possibilities with CART	3	8	2	7	12	79	4
CART technical support	4	6	7	4	1	74	5
Desire for standardized coding and reporting in the VA	2	4	4	6	5	55	6
Demonstrations and training for CART	1	4	3	6	3	45	7
Organizational support for CART	1	3	0	4	5	30	8
Technical support from IT department	0	1	6	2	2	28	9
Future interoperability or interfacing of CART	0	0	4	6	4	28	10
Appropriate staff resources	0	3	0	1	1	15	11
Clinical support in my department for CART installation	0	1	1	3	2	15	12
Impressions of CART from colleagues at other VAs	0	1	0	2	2	10	13
Other	0	2	0	0	0	8	14

Top barriers identified by clinical champions in CART implementation survey

In the second section of the CART implementation survey, clinical champions were asked to rank the top five barriers to CART implementation. A barrier was described as "anything which might have impeded or slowed successful installation and adoption." Like the facilitators section, a rank of #1 indicated the respondent felt that item was the most important barriers. The barriers are presented in Table 9, on the next page, and summary scores are again included.

Contentment with current processes was the top ranked barrier in CART implementation. Following contentment, clinical champions noted that technical support from their VA IT department was the second highest barrier. As described in the Methodology section, much of CART installation was performed by the CART development team, although a few technical parameters at each VA had to be established by the VA IT department at that facility.

Lack of interoperability or interfacing was identified as the third highest ranked barrier. In cardiac catheterization procedures, there are a number of computerized systems in use to monitor aspects of the procedure, including hemodynamic and fluoroscopy systems. Each of these systems has its own onboard electronic recording. A number of different vendors, each with proprietary interfacing requirements, are in use in VA cardiac catheterization labs around the country.   None of these systems currently interface with either the VA EHR or with CART.

Table 9. Ranking of top barriers to CART implementation by clinical champions

BARRIERS	#1	#2	#3	#4	#5	Summary Score	RANK
Contentment with current processes for cath lab reporting	15	4	1	7	6	114	1
Technical support from IT department	8	7	8	3	2	100	2
Lack of interoperability or interfacing with CART	4	10	5	8	3	94	3
Appropriate staff resources	7	6	5	7	5	93	4
Privacy and security regulations	9	4	4	3	2	81	5
CART technical support	0	5	7	3	3	50	6
Organizational support for CART	2	4	3	4	7	50	7
Clinical support in my department for CART installation	1	2	6	3	3	40	8
Organizational policies or mandates in order to install CART not met	0	3	2	6	8	38	9
Opinions of internally-developed software	1	4	2	2	5	36	10
Impressions of CART from colleagues at other VAs	0	1	3	2	1	18	11
Other	2	0	1	0	5	18	12
Statement of strong support by VA senior leadership	1	0	2	1	0	13	13

The remaining top five ranked barriers to CART implementation ranged from organizational and staffing issues to additional technical barriers. First, staffing resources was the fourth ranked barrier. VA cardiac catheterization labs have a variable number of staff, depending on the volume of procedures performed by that lab, and also depending on seasonal turnaround of training staff (e.g., residents and fellows). Lastly, privacy and security concerns were mentioned as a top barrier. Although the VA is a networked system, each VA hospital and IT department are separate entities. At the time CART was being implemented, there were no national policies to facilitate system-wide privacy and security approvals; installation of CART required local privacy and security paperwork and review by each of the 75 hospitals.

Secondary specific aim two

The final section of the CART implementation survey asked respondents to evaluate statements related to key factors in the implementation process using Likert-type scaled response options. These key factors were derived, as described in the Methodology section, from both literature review and VA- and CART-specific factors. The results of this section are presented in Tables 10 (page 866) and 11 (page 8888). For each item, a summary percentage is provided which is the number of affirmative responses for that item. For example, if half the respondents either strongly agreed or somewhat agreed, the item would indicated a 50% affirmative response. Likewise, if half the respondents felt an item was important, whether extremely, very, or fairly, that item would also indicate a 50% affirmative response.

Table 10. Importance of key implementation factors to clinical champions in the CART implementation survey

FACTORS	IMPORTANT
CART's integration with the VA EHR	96.2%
Future research possibilities using CART	92.3%
Statement of strong support by VA senior leadership	82.7%
Training and inservices for clinical staff to use CART	80.8%
Identifying the appropriate staff (clinical and technical) in your VA to champion this endeavor	76.9%
Need to standardized coding and reporting in VA cath labs	75.0%
The overall support of your organization for CART	75.0%
Lack of VA-wide standard cath lab report	69.2%
Desire to have CART conform to local reports or templates in your cath lab	63.5%
The impression held by colleagues at other VAs regarding CART	40.4%

When clinical champions were asked to gauge the importance of key factors related to CART implementation (Table 10), their assessments aligned well with the top five identified facilitators.   Although not all of the items in the facilitators list were repeated in the questions in this section, the item with the highest affirmative (i.e., "important") percentage was, in fact, the same as the top facilitator: CART's integration

with the VA EHR (96.2%). The senior leadership statement of support and research possibilities with CART, both top five facilitators, were also among the top items based on affirmative percentages (82.7% and 92.3%, respectively). The training provided to clinicians to use CART and the ability to identify appropriate staff, both technical and clinical, to champion CART were the fourth and fifth most important factors, based on percentages (80.8% and 76.9%, respectively). The desire to standardize coding and reporting was also deemed important (75.0%).

In the second listing of key implementation factors, clinical champions were asked to assess their level of agreement with a variety of statements. All of the "positive" statements elicited greater than majority agreement. Clinical champions had the highest level of agreement with the statement that they were able to identify the appropriate clinical person to champion CART (88.5%); since the survey was administered to clinical champions at each hospital, this high level of agreement is expected. Clinical champions also agreed that CART would improve on current processes (86.5%) and is user-friendly (82.7%).

Much less than the majority of respondents agreed with "negative" statements. For example, only 28.8% felt the time required for the CART team to acquire local technical access delayed the implementation. 23.1% agreed that the size of their department or proportion of full-time staff made it challenging to implement CART.

Table 11. Agreement by clinical champions in the CART implementation survey with statements regarding key implementation factors

FACTORS	AGREE
We were able to identify the appropriate clinical person to champion installing and implementing CART.	88.5%
CART will improve upon our current processes.	86.5%
CART is user-friendly.	82.7%
CART will improve quality.	78.8%
CART fulfills our reporting and data collection needs better than our previous methods.	78.8%
I have a desire to participate in testing and improvement of CART.	78.8%
Our department believed CART was strategically important to quality improvement in the VA system.	78.8%
I believe CART met all of the required policies or mandates.	78.8%
CART provides sufficient and appropriate data collection and reporting for our cath lab.	76.9%
We were able to identify staff within IT to help us get CART installed.	76.9%
The clinical in-service training we had for CART was appropriate.	73.1%
I have a positive opinion of internally-developed software.	67.3%
My colleagues at other VAs have a favorable opinion of CART.	61.5%
The time required for technical access for the CART team to install the software delayed the installation.	28.8%
The environment where I work was comfortable with their existing process and did not want to install or implement CART.	23.1%
The size of our department or proportion of full-time staff made it challenging to implement CART.	23.1%
Frequent personnel changes in my department made it difficult to implement CART.	13.5%

Primary specific aim three

Potential associations between facilitators and barriers identified in Primary Specific Aim Two, above, and the total time to full implementation were assessed using a Cox Proportional hazards regression model. The top five facilitators and barriers, based on summary scores, were included as predictors in the model. The outcome variable was time to full implementation, expressed in months. Because all hospitals achieved full use of CART, there was no censoring of data.

In the multivariable analysis of top five facilitators and barriers, several items were significantly associated with overall implementation time (Table 12, next page). Clinical champions who selected the potential of future research using CART data as a top facilitator were from hospitals associated with significantly faster implementation times (*HR* 3.10*, 95% CI* 1.43 – 6.70; *P* = 0.004). As a reminder, the directionality of the effect is indicated by the positive β-coefficient, indicating this facilitator was associated with a reduction in time to implementation. Likewise, those who rated CART technical support as a key facilitator were also from hospitals with significantly faster implementation times (*HR* 2.39, *95% CI* 1.01 – 5.62, *P* = 0.047). Among the top five barriers included in the model, contentment with current reporting processes was significantly associated with hospitals with slower implementation times (*HR* 0.42, *95% CI* 0.20 – 0.88, *P* = 0.022). Hospitals which regarded privacy and security regulations as a top five barrier also were associated with significantly slower implementation times (*HR* 0.27, 95% *CI* 0.13 – 0.56, *P* < 0.005).

Table 12. Top five facilitators and barriers Cox proportional hazards model estimation for time to full implementation

Item	β-Coefficient	Hazard Ratio	95.0% CI	P-Value
FACILITATORS				
CART integration with the VA EHR	0.49	1.64	0.59 – 4.57	0.347
Statement of strong support by VA senior leadership	0.63	1.87	0.88 – 3.98	0.105
Desire to improve quality	-0.39	0.68	0.35 – 1.32	0.251
Future research possibilities with CART	1.13	3.10	1.43 – 6.70	0.004
CART technical support	0.87	2.39	1.01 – 5.62	0.047
BARRIERS				
Contentment with current processes for cath lab reporting	-0.87	0.42	0.20 – 0.88	0.022
Technical support from IT department	0.23	1.26	0.66 – 2.39	0.480
Lack of interoperability or interfacing with CART	-0.13	0.87	0.42 – 1.82	0.719
Appropriate staff resources	-0.46	0.63	0.30 – 1.33	0.227
Privacy and security regulations	-1.33	0.27	0.13 – 0.56	<0.005

Notes: Model likelihood ratio = 282.81; P = 0.015.

In this model, there were no high pair-wise correlations and no high variable

inflation factors which could impact accuracy of the estimates. The deviance residuals

were randomly distributed with no significant outliers. While several facilitators and

barriers were significantly associated with overall time to implementation in this

regression analysis, all predictors included in the model were already identified as top

facilitators and barriers through Primary Specific Aim Two.

Secondary specific aim three

To further evaluate factors which may be important to specific time points, or

periods, in the implementation process, four final analyses were conducted.   The

associations between hospitals that initiated implementation after the leadership

endorsement and the times required to complete the Activation and Use periods,

respectively, were evaluated. In addition, the associations between top facilitators and

barriers and the times required for Activation and Use periods, respectively, were also

evaluated.

First, the times to complete the Activation Period, a composite of the Initiation

and Installation stages, and the Use Period, a composite of the Training and Clinical Use

stages, were used as outcomes in models evaluating the associations of hospitals that

initiated implementation after the leadership endorsement with these two times.

Second, these same times, Activation and Use periods, were again used as outcomes in

models evaluating the associations of top facilitators and barriers with these two times.

Again, all hospitals reached the events (i.e., completion of both periods), and no

censoring was required. Similar to previous analyses, pair-wise correlations,

multicollinearity, and deviance residuals were all checked to ensure the best possible

model accuracy. The results of the models related to of leadership endorsement as a predictor are included in Table 13, below. The results of the models for facilitators and barriers as predictors are presented in Tables 14 (page 94) and 15 (page 9595).

Table 13. Initiation of implementation after senior leadership endorsement of CART Cox proportional hazards model estimation with time to complete Activation and Use Periods

Item	β-Coefficient	Hazard Ratio	95.0% CI	P-Value
ACTIVATION PERIOD*				
Initiation After Leadership Statement of Support	0.66	1.93	1.16 – 3.22	0.011
USE PERIOD†				
Initiation After Leadership Statement of Support	0.23	1.25	0.77 – 2.04	0.362

* Model likelihood ratio = 501.578, *P* = 0.010
† Model likelihood ratio = 506.187, *P* = 0.361

In Secondary specific aim one, multivariable analyses demonstrated an association between hospitals that initiated implementation after the senior leadership support statement and their overall time required to fully implement; those hospitals which began implementation after the senior leadership statement of support were associated with significantly faster implementation times than those which initiated implementation prior to the statement. In further analyses in this aim, hospitals that initiated implementation after the leadership endorsement were significantly associated with faster Activation Period times (*HR* 1.93, *95% CI* 1.16 – 3.22, *P* = 0.011), but there was no significant association with the time required to complete the Clinical Use

Period. No issues with model accuracy were observed from pair-wise correlations,

multicollinearity tests, or the deviance residual plots.

In Primary Specific Aim Three, several of the top five facilitators and barriers

were significantly associated with overall time to full implementation. In further

analyses of the top five facilitators and barriers with the time required to complete the

Activation Period (presented in Table 14, next page) and the Use Period (Table 15, on

page 95), neither overall model was statistically significant. However, despite this, some

results from these models are still noteworthy. First, with respect to time to complete

the Activation Period, the overall model showed a trend toward significance (P = 0.056).

Among top five barriers, concerns with privacy and security regulations was individually

associated with hospitals that completed Activation Period significantly slower (*HR* -

1.26, *95% CI* 0.14 – 0.58, *P* = 0.001). Pair-wise correlations, multicollinearity tests, and

deviance residuals were plotted and did not show any issues with model accuracy,

though the lack of model significance makes interpretation of specific terms (e.g., future

research potential, *P* =0.030, and the senior leadership statement, *P* =0.026) less

reliable.

In the model of top five facilitators and barriers with the time to complete the

Use Period (Table 15, page 95), the overall model was not statistically significant (*P* =

0.423). Pair-wise correlations, multicollinearity tests, and deviance residuals were

plotted and did not show any issues with model accuracy. Although a couple of

individual items were statistically significant, the non-significant *P* value of the overall

model most likely reveals the model was overfitted.

Table 14. Facilitators and barriers Cox proportional hazards model estimation with time to complete the Activation Period

ACTIVATION PERIOD	β-Coefficient	Hazard Ratio	95.0% CI	P-Value
FACILITATORS				
CART integration with the VA EHR	0.85	2.35	0.78 – 7.05	0.128
Statement of strong support by VA senior leadership	0.85	2.33	1.10 – 4.92	0.026
Desire to improve quality	-0.38	0.69	0.36 – 1.30	0.246
Future research possibilities with CART	0.85	2.34	1.09 – 5.03	0.030
CART technical support	0.47	1.60	0.72 – 3.54	0.250
BARRIERS				
Contentment with current processes for cath lab reporting	-0.64	0.53	0.26 – 1.06	0.073
Technical support from IT department	0.45	1.57	0.80 – 3.09	0.191
Lack of interoperability or interfacing with CART	-0.67	0.51	0.24 – 1.10	0.085
Appropriate staff resources	-0.006	0.99	0.48 – 2.08	0.987
Privacy and security regulations	-1.26	0.29	0.14 – 0.58	0.001

Notes: Model likelihood ratio = 287.980, *P* = 0.056

Table 15. Facilitators and barriers Cox proportional hazards model estimation with time to complete the Use Period

USE PERIOD	β-Coefficient	Hazard Ratio	95.0% CI	P-Value
FACILITATORS				
CART integration with the VA EHR	0.53	1.70	0.66 – 4.39	0.269
Statement of strong support by VA senior leadership	0.32	1.37	0.66 – 2.86	0.401
Desire to improve quality	-0.22	0.81	0.42 – 1.56	0.521
Future research possibilities with CART	0.69	1.99	0.93 – 4.27	0.076
CART technical support	0.23	1.26	0.52 – 3.01	0.610
BARRIERS				
Contentment with current processes for cath lab reporting	-0.23	0.80	0.39 – 1.62	0.530
Technical support from IT department	-0.02	0.98	0.52 – 1.87	0.961
Lack of interoperability or interfacing with CART	0.17	1.18	0.58 – 2.41	0.648
Appropriate staff resources	-0.30	0.74	0.36 – 1.52	0.411
Privacy and security regulations	-0.79	0.45	0.23 – 0.92	0.028

Notes: Model likelihood ratio = 297.031, *P* = 0.423

CHAPTER V

CONCLUSIONS

This retrospective, observational cohort study describes the successful

nationwide implementation of the VA Clinical Assessment, Reporting, and Tracking

(CART) Program in all 75 VA cardiac catheterization laboratory hospitals. CART is a

national health IT solution which provides standardized electronic health record

documentation for all cardiac procedures performed in catheterization labs and

supports routine quality reporting and real-time monitoring of procedural and device-

related events. Prior to the implementation of CART, cardiac procedures in the VA were

recorded primarily via paper-based logs or local, non-interoperable solutions (e.g.,

spreadsheets or local databases) and reported in the health record through non-

standardized, unstructured dictated or manual reports. Real-time, automated

monitoring of serious events was not possible and quality reporting was only achievable

through time-consuming and costly retrospective review.

The implementation of CART began in 2004, prior to the HITECH Act of 2009, and

at a time when best practices for health IT implementation and information regarding

facilitators and barriers were just beginning to be assessed and summarized.   Although

approximately one-quarter of all US physicians in ambulatory settings were using some

form of electronic documentation at that time, most health IT system implementations

were still considered failures.[10,34] The successful implementation of CART proceeded

largely as a natural experiment and encountered challenges which parallel those now

described in the health IT and EHR implementation literature.

While the evidence base for health IT implementation has matured, much of

what is known today still relies on reports of cross-sectional surveys, case studies, and

editorials. In addition, the terms *implementation*, *installation*, and *adoption* continue

to be used synonymously to suggest a system (e.g., EHR) was merely installed; none of

these terms specify, however, that the health IT is fully used for all eligible procedures.

Using these terms interchangeably limits the ability to compare research in this field,

and potentially obfuscates important factors at various time points in the overall

process which may drive or delay implementation. To date, no study has followed the

complete and successful diffusion of health IT across a large, nationwide health care

system, with the endpoint of full use of the system, and evaluated key factors at specific

times.

This thesis reports the successful nationwide implementation of CART in all 75

VA cardiac catheterization laboratory hospitals. CART implementation was

conceptualized as proceeding through four specific stages from first contact with each

hospital, through technical installation, training, and concluding with full, clinical use

(Figure 5, page 39). The first two stages, Initiation and Installation, comprise the

Activation Period. The final two stages, Training and Clinical Use, comprise the Use

Period.[2] By applying this staged implementation framework, this thesis sought to explore the general question: What are the key factors associated with the implementation and full use of a nationwide health IT system? More specifically, the aims of this study were to: (1) evaluate variation in the durations of the chronological stages of implementation and assess the hospital-specific characteristics associated with the time required to achieve full implementation; (2) identify the top facilitators and barriers associated with implementation; and (3) explore the association of key factors (i.e., hospital characteristics, facilitators, and barriers) with the time required to complete full implementation and also two time periods within the implementation process. (Table 16 on page Table 16. Summary of results of hypothesis tests for all aims110, at the conclusion of the following section, summarizes the results of descriptive analyses and inferential tests on the hypotheses in the aims of this thesis.)

Summary of important findings

Hallmarks of CART implementation

Studies which have surveyed hospitals regarding EHR adoption suggest that hospital size, academic affiliation, and urban location are all associated with earlier – though not by definition *faster* - adoption, though geographic region is not.[20,96,99] The work reported in this thesis may be among the first to evaluate these hospital

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[2] The reader is encouraged to review Figure 6 on page 39, to recall how the CART implementation framework aligns with other implementation descriptions in the current literature.

characteristics specifically with respect to the time required to fully implement. In the

work reported in this thesis, however, none of these hospital characteristics were found

to be significantly associated with times to full implementation. In the multivariable

analysis, neither geographic region nor hospital size was significantly associated with the

time required to fully implement.   This lack of association, compared to previous

research on adoption, is not surprising for several reasons. First, previous work has

suggested an association between hospital characteristics and chronological time of

adoption, not with respect to duration of time to adopt. Second, the semantic

differences in how "adoption" has been defined make comparison difficult; while this

study explored the time to full implementation, with a measure of full use as the

endpoint of implementation, previous work has focused on varying endpoints, most

commonly the completion of technical installation. Finally, the lack of heterogeneity in

the characteristics of the hospitals included in this sample may be due to the setting

within a large health care system. Overall, these results suggest that the variability in

individual hospital characteristics may be less important than certain organizational

factors, at least for large health care systems.

Organizational support for CART implementation, in the form of a statement of

senior leadership support, was issued at the end of 2005. Hospitals which initiated

implementation of CART after this statement was issued had significantly faster overall

implementation times. Indeed, the multivariable results of this study suggest that

hospitals which began implementation of CART after this statement of support was

issued implemented CART approximately 50% faster than hospitals which initiated

implementation prior to the leadership endorsement. Importantly, while overall times

for implementation were shorter after the leadership endorsement, the majority of this

effect was felt in the Initiation stage; the Initiation stage, which begins with first contact

with a hospital and concludes when technical installation begins, was the only

implementation stage which showed a statistically significant reduction in the duration

of time to initiate for hospitals which began after the leadership endorsement was

issued.

The impact of the organizational support statement may initially seem critical,

but it is important to also acknowledge the timing of this statement with respect to the

overall diffusion of CART through VA hospitals. The statement of support was not

issued at the very beginning of the diffusion process, but after a period of time in which

CART was fully implemented and in use at fifteen hospitals, and implementation

initiated at over a third of all potential hospitals.   This timing coincided nearly perfectly

with the end of Roger's "early adoption" period and the beginning of the steepest slope

of the "S-curve" for diffusions of innovations.   It is impossible, through this study, to

know whether organizational momentum or organizational support were more

responsible for driving the "tipping point" in CART diffusion; most likely, these

organizational characteristics worked in concert, along with other key factors.

Overall, the timing of the stages of CART implementation for each hospital

demonstrated little variability, with the exception of the Clinical Use stage. The Clinical

Use stage commenced once key staff members had received training for CART, and concluded when there was evidence that the hospital was using CART to document all eligible procedures. This evidence of high variability is perhaps echoed in recent reports of "physician resistance" in the EHR adoption and Meaningful Use literature. Marcotte and colleagues from the Office of the National Coordinator for Health Information Technology, for example, state "Even the strongest enthusiasts for EHRs recognize that their adoption involves significant changes for physicians, with attendant dislocations in workflows, investments, and habits of practice."[100] Although VA physicians are accustomed to electronic documentation, the introduction of CART to document cardiac catheterizations procedures was a replacement for paper-based and dictation-based documentation. And, in addition, CART reports include much more structured data and are significantly more detailed and robust than any previous methods.[101] As a completely new health IT solution, CART too had the potential to disrupt workflow and habits analogous to health IT implementations described in other settings. Although all hospitals successfully implemented CART, the high variability in the Clinical Use stage hints that overcoming the challenges of end-users, and specifically physicians, is one of the most critical aspects toward achieving the full implementation of health IT.

Finally, the high variability in the Clinical Use stage may have also played a role in lack of a strong correlation between the Activation and Use Periods in this study. In the CART implementation framework, the Activation Period is defined as the time from first contact with a hospital to the completion of installation. Likewise, the Use Period is

the time post-installation until full use of the system is demonstrated.   The Activation

Period for health IT, under the CART implementation framework, aligns most closely

with what, to date, the ONC has described as "adoption" (i.e., EHR adoption; Figure 6 on

page 40).[7,100] As organizations plan health IT implementations, it may be instructive to

know if the time required to reach full clinical use in the post-installation period is

related in any way to the time it took an organization to initiate and complete technical

installation of the health IT.

In the assessment of the correlation between the Activation and Use Periods in

this study, only a modest, positive correlation was demonstrated.   However, inspection

of the 95% confidence interval for this correlation (-0.0031, 0.4291) revealed that the

correlation was not truly significant since the confidence interval crossed 0. Also, the

wide confidence interval also indicates a lack of precision.   If the assessment had

demonstrated even a modest effect size which was statistically significant and more

precise, this could perhaps provide organizations some context for planning in the Use

Period; if organizations know the time required to complete technical installation (i.e.,

Activation Period) is correlated with the time required to achieve full clinical use (i.e.,

Use Period), it might help in accounting for staff, monetary, and time resources for the

latter. However, in this study of 75 hospitals, the lack of a correlation is perhaps the

most telling and lends support to the argument that using the terms *installation,*

adoption, and *implementation* synonymously may overlook important characteristics at

key time points in the entire process - such as high variability per hospital in the time

required to achieve full clinical use - which cannot necessarily be anticipated by the speed with which a hospital completes technical installation.

Facilitators and barriers in CART implementation

The results of the CART clinical champions survey on facilitators and barriers add additional support to many key factors already identified in the health IT adoption and implementation literature, as well. Some of the top facilitators and barriers in this study, however, may have resonated specifically with this VA cardiology audience. Because this study represents one of the first assessments of facilitators and barriers related to the entire implementation process - importantly, ending in full, clinical use - some of the top facilitators and barriers identified may be helpful toward understanding how the challenges related to clinician use of health IT may be overcome.

Integration of CART with the VA EHR was identified as the top facilitator for implementation. Many studies and recent commentaries have stressed the need for interoperability and interchangeable data in health IT.[29,46,53,58-61, 102] In general, "EHR integration" and "interoperability" are often taken to represent the same technical constructs. However, "lack of interoperability" was the third highest barrier selected in the CART survey, warranting explanation of the difference, related to CART. In the VA, there have been many health IT efforts over the last few decades. Many of these arose as the result of specific quality improvement inquiries or, for example, the desire to create standardized documentation templates. Most of the health IT efforts, however, are standalone solutions and do not "speak" with the EHR; that is, the applications have

no ability for either uni- or bidirectional communication with the EHR. Moreover,

accessing specific patient information requires logging into the second system and

performing additional patient queries. Finally, real-time quality assessment or decision

support with these applications, using additional data from the medical record, is

prohibitive.

The technical design of CART stands apart from most other health IT in the VA.

First, CART is accessible directly from the EHR via a menu selection. When a patient is

selected in the VA EHR, CART maintains this "active patient" as CART opens so that

additional time is not spent looking up the same patient again in the context of CART;

additional patient queries are not required. Second, and importantly, CART utilizes

technical tools to extract data in real-time from the VA EHR related to the active patient

and pertinent to the cardiovascular procedure being performed. In this way, some data

do not need to be re-entered by physicians. These data are used to pre-populate

portions of the procedural documentation, reducing the amount of time required to

complete documentation and reducing errors associated with duplication or

transcription. And finally, CART automatically and dynamically generates the procedural

note from the entered data. This dynamically-created note may then be reviewed and

edited by the clinician, if necessary. It is then sent back to the VA EHR and recorded

with other clinical documentation.   These technical aspects of CART integration with the

VA EHR were likely responsible for clinical champions selecting "Integration with the VA

EHR" as their highest facilitator in CART implementation. [3]

Conversely, "Lack of interfacing or interoperability" was identified as a top

barrier in CART implementation. As explained briefly in the Results chapter, this

particular barrier was not specifically related to interfacing or interoperability with the

VA EHR. Rather, in cardiac catheterization laboratories, other electronic systems are

involved in monitoring various aspects of the clinical procedure. These vendor systems

are all proprietary and none currently interface with the VA EHR or CART.   Because

some relevant procedural data are stored in these systems, interfacing with CART would

further reduce data entry and work for clinicians and is desirable.

Technical support was another factor in the CART survey of clinical champions

which shows up on both the top facilitators and top barriers lists, thereby warranting

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[3] Among the technical tools CART utilizes are real-time remote procedure calls (RPC).
RPCs permit a brokered exchange of data with the VA native data layer. The reader is
encouraged to review the Literature Review chapter to recall the history of the VA EHR.
With respect to data, however, the VA EHR is not based on modern architectural
standards and the data are stored in such a manner that relationship modeling is very
challenging for the uninitiated. Technically, the VA data stores were not designed a
priori to be *n*-tiered. While there are many modernization and standardization efforts
underway as of this writing, accessing data in the VA EHR in the manner CART uses
requires very extensive modeling and technical skill. At the time CART was developed,
other health IT applications had used similar RPC brokering strategies, but none as
extensively as that required to support a full, real-time, clinical health IT system such as
CART. In addition, though beyond the scope of this thesis, the strategies employed by
the CART Technical Director, both to extract VA EHR data and also to construct the user
interface, rely on meta-modeling techniques which enable most of the CART system to
be dynamically-driven with little hard coding. This design is an immeasurable key to the
technical success of CART, because the system is easily modified, has a small IT
footprint, and is extensible.

additional description. Many health care organizations have their own IT departments

and support, whether internal or contracted.   Typically, when new health IT is

implemented, additional technical resources are required. As noted in the Literature

Review chapter, technical support has been perceived as a barrier when the technical

installation is complex and there are insufficient personnel and resources to facilitate.[46,]

[52. 58, 64, 65] Technical support can also be a barrier when new health IT is introduced

without sufficient resources to support maintenance and sustainability.[64, 66]

From a technical standpoint, the installation of CART was streamlined and in

general, required little of local IT departments other than establishing some folder-

based access and permissions. In addition, during the diffusion process for CART, the VA

adopted new certification and accreditation standards for health IT to ensure that

health IT met appropriate standards for privacy, security, and technical fidelity. CART

fully complied and received full certification and accreditation after these standards

were established. Despite the ease of installation and the certification of CART, local

VA IT might have been reluctant to assist with CART installation out of concerns related

to the maintenance and sustainability of CART, not fully understanding that this was

health IT supported through means other than VA IT.

Several other top facilitators and barriers identified in the CART survey add

additional support to findings and statements already in the literature. The support of

senior leadership for health IT in an organization has been acknowledged in many

assessments as a key facilitator[15,47,48], and this study has demonstrated that the VA

106

senior leadership endorsement was associated with significantly improved overall

implementation times. Likewise, contentment with current processes[7,32,99,103,104] and

privacy and security concerns[46, 63] have both been documented as barriers to health IT

implementation, and were similarly indicated in the CART survey.

Interestingly, in this study, "the desire to improve quality" and "future research

potential using CART data" were among the top facilitators for implementation noted by

clinical champions. Quality improvement was, in fact, a critical focus of the IOM reports

which helped create an impetus for health IT.[1,18] Clinicians in the VA may be particularly

invested in quality improvement and clinical research due to the VA's tight academic

affiliations and existing data resources. But, quality improvement and research

potential using health IT may be strong motivators even beyond the VA. In particular,

these two facilitators could be viewed as key drivers for *clinician* adoption of health IT.

Several publications have recently recognized the importance of clinician resistance in

adopting EHRs as a barrier to realizing the full potential of health IT. [102,103,105]   Buntin

and colleagues from the ONC, in a systematic review of the literature on outcomes

related to adoption of health IT, find that "The association between assessment of

provider satisfaction and negative findings is a strong one." [105] Identifying clinician-

specific motivators, such as the ones revealed as top facilitators by VA clinical

champions, may help overcome clinician resistance to using health IT.

Key factors associated with implementation times

In the final aim of this thesis, the association of key factors with the time required to complete full implementation, or parts of the implementation process, was evaluated. Several time-to-event analyses were conducted to understand potential associations between (a) the overall time to fully implement and top facilitators and barriers, (b) top facilitators and barriers and the time required to complete the Activation and Use Periods, respectively, and (c) the timing of a hospital's implementation initiation with respect to the senior leadership statement of support and their time to complete the Activation and Use Periods, respectively. This study is perhaps the first to evaluate the time required to complete aspects of implementation , and implementation as a whole with the endpoint of full, clinical use.   It is also likely the first to explore the associations of key factors with these times.

In the multivariable analysis of top facilitators and barriers with respect to overall implementation times, future research potential using CART data and CART technical support were both associated with faster overall implementation times. Contentment and concerns regarding privacy and security were associated with slower times. In particular, the future research potential of health IT as a facilitator which has the potential to improve the time required for health IT achieve full, clinical use strengthens the supposition that clinician-specific motivators are critical toward achieving full use of health IT.

Likewise, contentment with current processes as a barrier which has the

potential to slow down overall implementation times might be taken as a key strategic

target for organizations implementing health IT.   Buntin et al. point out that "The

'human element' is critical to health IT implementation."[105] Humans are typically

resistant to change if existing processes appear sufficient, and as shown in this study,

such contentment can have powerful consequences in slowing health IT

implementation. Coplan and Masuda point to the importance of change management,

in addition to project management, for the successful implementation of health IT. [106]

To combat contentment as a barrier to timely implementation, organizations should

manage both the planning and technical aspects of the installation of health IT, but

balance this with management of the organizational expectations and education related

to the health IT.

The top facilitators and barriers were also assessed with respect to the durations

for the two periods of implementation, the Activation and Use Periods. These period-

specific analyses were conducted to understand if there were key facilitators or barriers

which might be associated with faster or slower times to complete the two main periods

iin implementation, that is, installation of health IT and full clinical use. The overall

models for each assessment were not statistically significant, though individual

facilitators and barriers were: clinical champions who indicated the senior leadership

statement of support and future research possibilities as top facilitators were from

hospitals which completed the Activation Period faster; and champions who stated

privacy and security regulations as a top barrier were associated with hospitals with

slower Activation Period times and slower Use Period times.   These results align with

and support other findings in this study.

Table 16. Summary of results of hypothesis tests for all aims

HYPOTHESIS	RESULT	NOTE
AIM ONE: **Hospital and system characteristics and the time required to achieve full implementation**		
1A. In univariate analyses, there will be no difference in the time required to reach full implementation based on any individual hospital characteristic.	REJECT	There was a statistically significant reduction in implementation times for hospitals initiating after the senior leadership support statement.
1B. In multivariate analyses, there will be no association between any hospital characteristics and the overall time to reach full implementation.	REJECT	Initiation after the senior leadership support statement was associated with faster implementation times.
1C. The Activation Period and Use Period will not be correlated.	FAIL TO REJECT	There was a modest, but underpowered, positive correlation.

Table 16 (Continued). Summary of results of hypothesis tests for all aims

HYPOTHESIS	RESULT	NOTE
AIM TWO: **Facilitators and barriers to the implementation of CART**		
2A(Facilitators). Integration with the VA EHR, the senior leadership support memo, and desire to improve quality will be the most important facilitators noted by CART clinical champions.	FAIL TO REJECT	These facilitators were among the top five facilitators.
2A(Barriers). Contentment with current processes and lack of interoperability with other cardiology-specific software (e.g., hemodynamic systems) will be the most important barriers noted by CART clinical champions.	FAIL TO REJECT	These barriers were among the top five barriers.
2B (Importance). CART Clinical Champions will indicate that integration with the VA EHR and desire for standardized reporting were factors influencing implementation.	FAIL TO REJECT	Both factors were supported by a majority of respondents.
2B(Agreement). CART clinical champions will most strongly agree that identifying an appropriate clinical champion and the belief that CART will improve quality were important to CART implementation	FAIL TO REJECT	Both factors were supported by a majority of respondents.

Table 16 (Continued). Summary of results of hypothesis tests for all aims

HYPOTHESIS	RESULT	NOTE
AIM THREE: **Key factors and the time required to achieve full implementation and to complete the Activation and Use Periods**		
3A. There will be no association between any facilitators or barriers and the overall time to reach full implementation.	REJECT	Research potential using CART and CART technical support were facilitators associated with faster implementation. Contentment and privacy and security concerns were barriers associated with slower implementation.
3B. There will be no association between any facilitators, barriers, or hospital characteristics and the times for the Activation and Use Periods.	REJECT	Individually, initiation of implementation after the senior leadership support statement, and the facilitators related to the senior leadership statement and future research potential were associated with faster Activation times. Privacy and security concerns as a barrier were associated with slower Activation and Use times.

Perhaps most illuminating, however, is that the perception by clinical champions of the senior leadership statement of support as a top facilitator was significantly associated with faster Activation Period times but not with faster Use Period times. This finding is further supported by the models which evaluated the association

between a hospital's initiation of implementation after the leadership endorsement and

their overall time to complete the two implementation periods. In these two

assessments, no association was found with the Use Period, but hospitals which

initiated implementation of CART after the senior leadership support statement were

significantly associated with faster Activation Period times. When taken in context with

other results in this study, this association with faster Activation times, and the lack of

association with Use times, suggests the faster overall implementation times for

hospitals which initiated after the leadership endorsement are mostly accounted for by

faster Activation Period times. Hospitals which initiated implementation after the

leadership endorsement were associated with Activation Period times, the period from

first contact to completion of installation, which were 50% faster than those who

initiated prior, and subsequently, were associated with 50% faster overall

implementation times.

Implications

The diffusions of innovations and stages of health IT implementation

Health IT implementation in this thesis, and specifically the implementation of

CART in the VA, is described as a staged process which begins with the first contact with

a hospital and proceeds sequentially through technical installation, training, and

concludes with evidence of full, clinical use of the health IT. Adopting this structured

framework helps to elucidate characteristics of the entire process in two critical ways.

First, the framework implicitly acknowledges the myriad steps and individuals involved

in implementing health IT; key factors and key individuals may play roles in aiding the

progress of each stage. Second, this framework clarifies the distinction between

technical installation of health IT and achieving full use of health IT; by clearly defining

and including both the Activation Period and the Use Period, the framework supports

better assessment and comparison of the components of implementation, and helps to

illuminate the gap currently assumed between "adoption" (i.e., installation) and

eventually realizing the full benefits of health IT. As Davidson et al pointed out:

> We believe that the full impact of health IT has not been realized because of the
> failure to recognize both that the availability of applications to anticipated
> benefits passes through a series of discrete steps and that progress can be
> stopped at any one of these steps.[81]

The staged implementation framework helps us to understand the process by

which each hospital achieves full implementation of health IT. In a hospital system,

moreover, this thesis found the cumulative implementation, or the *diffusion* of health IT

(i.e., CART), followed the distinctive "S-curve" shape characteristic of diffusions of

innovations.[91] In 2006, Ford et al., hypothesized that ubiquitous and full diffusion of

EHRs for physician practices in the United States will not occur until 2024[4]. He and his

colleagues constructed three possible models for EHR diffusion, utilizing the statistical

application of Rogers Diffusions of Innovations theory empirically modeled by Bass,

known as the Technical Diffusion Model. The mathematical assumptions required rely

on two key influences: (1) innovation factors, which embody the effect of external

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[4] Recall that the original goal when the ONC was established was to implement EHRs
within ten years, or 2014.[27]

influences; and (2) social contagions, which are internal influences that contribute to the probability that adoption will increase as more and more individuals or groups adopt. Diffusion might follow an "inverted J curve" if the influence of innovation factors is high, or a "S-curve" if the influence of social contagions is high.[5] All three predictive models constructed by Ford and colleagues followed the S-shaped pattern to model EHR diffusion. Their results, in combination with those also described in this thesis, suggest that understanding the typical patterns for cumulative implementation of health IT across a group or system may help us predict the overall trajectory of an implementation, which in turn, may aid planning and policy.

Drivers and faciliators of health IT implementation

As mentioned in the previous section, various factors may influence the implementation processes for a hospital. Understanding the key factors which may drive or delay implementation is particularly useful today as organizations struggle to implement EHRs and meet Meaningful Use requirements. While the HITECH Act established financial incentives for providers, groups, and organizations which meet the Meaningful Use requirements, there were also financial penalties established for those that do not. As soon as 2015, those who do not use an EHR will be penalized and recent data estimates that 74% of hospitals have not yet met the required criteria.[103]

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[5] An example of an inverted J-curve occurs, according to Ford, for innovations which involve less risk, such as new consumer products like washers or dryers. These innovations are quickly adopted and then diffusion tapers off.

In the diffusion of CART, it is possible that the endorsement of CART by senior leadership acted as a key driver of implementation. This was suggested by both univariate and multivariate analyses. However, the timing of the endorsement at the end of the "early adopters" phase, right before the sharpest part of the curve of CART diffusion, somewhat complicates this assessment. Diffusion theory suggests, instead, that the leadership endorsement was a strong facilitator; the distinction between *driver* and *facilitator* in this context is subtle but important. The S-curve pattern of CART diffusion indicates organizational momentum was probably already at work. Rogers, Kauffman, DeKimpe, and others have stated that when such momentum exists, it has the potential to further condition diffusion.[91-93] In the process, it "often results in the imposition of standards or special regulations." [92] In this sense, the organizational momentum behind CART helped drive a leadership endorsement which, in turn, facilitated the tipping point of CART diffusion. CART had already been implemented in many hospitals and grass-roots support was building as clinicians tested CART and shared their experiences with colleagues; it is inappropriate to acknowledge the importance of leadership endorsement without also weighing these additional factors.

In addition to time-specific influences on diffusion, such as the timing of the senior leadership endorsement, other more general factors also contributed to the complete diffusion of CART. CART was eventually implemented in all eligible VA hospitals, despite acknowledged barriers. The top facilitators for implementation identified by CART clinical champions have been discussed individually throughout

116

sections of this thesis. But, when taken as a whole, they provide a much more unified

portrait of the keys to a successful health IT system such as CART. CART had the

potential, like many applications of health IT, to disrupt workflow and create additional

documentation for busy cardiologists. However, CART integrated with the VA EHR and

provided rapid, automatic generation of procedural reports to improve documentation

efficiency. The interface of CART was designed to resemble the EHR so that use of CART

could be a logical extension of previously-adapted behaviors, making CART easy to

learn. And CART was designed to be used by the clinicians performing the procedures,

at the point of care, thus fitting into the workflow of the catheterization laboratory and

ensuring the most accurate data possible. All of these characteristics have been

identified as targets which might help clinicians to adopt health IT and enable health IT

to achieve its potential.[102]   Moreover, it is important to recall that CART was initially

conceived through a VA clinical quality improvement initiative, as part of an overall plan

to improve cardiovascular care and to facilitate performance measurement. As such,

CART was intentionally designed to incorporate the standardized data elements

necessary to enable immediate generation of quality data.[107] In short, the form of CART

truly followed the intended function.

Full, clinical use as the endpoint in health IT implementation

In this study, the lack of variability in the times required to complete the first

three stages of implementation, combined with the high variability in the time to

achieve full use of CART through the Clinical Use stage, confirm the supposition that it is

inaccurate to view health IT implementation as a single fluid process, described by interchanging the terms *installation*, *adoption*, and *implementation*. In heath IT implementation research to date, there has been a tendency to view health care systems, hospitals, and even practice groups as large, homogeneous entities in which all members are dedicated to a shared goal (i.e., EHR adoption), based on similar motivations.   The results of this study paint a more complex picture of a staged process with different actors and motivations at different times in the process.   This is particularly evident in the lack of even a conservative correlation between the Activation and Use Periods; those responsible for installing health IT are not the same as those responsible for using health IT and their motivations for implementation might be very different.

As organizations struggle to meet Meaningful Use requirements, the specter of clinician resistance even for those who have invested in and installed EHRs is all too real, particularly in light of the considerable investments made and the urgency of avoiding Meaningful Use penalties.   In 2002, Cedars-Sinai in Los Angeles abandoned a $34 Million EHR implementation for a variety of factors, all occurring post-installation.[108] In Phoenix recently, a large number of physicians' groups were reportedly 'de-installing' their EHRs.[109] And, a 2013 report by Black Book Rankings estimates that as many as 17% of the 17,000 EHR adopters may be removing their first choice EHR for a different vendor in the near future.[110] McClellan et al., state "Adoption of health IT by practices does not mean physicians will use the health IT."[111] For the value of health IT to be

realized, clinicians must use it, and the high variability in the Clinical Use stage shown in this study suggest that this is the most serious challenge for health IT implementation.

Recommendations

The research presented in this thesis provides new insights into several aspects of health IT implementation which warrant further investigation. First, additional research on key innovation factors and social contagions in the implementation of health IT may help support more accurate models for the diffusion of EHRs and additional clinical applications which may be necessary to accommodate Meaningful Use or quality assessments. Second, there are many studies in the literature related to facilitators and barriers in health IT implementation, though this is the perhaps the first to suggest an association between specific factors at different time points in implementation. Further research to elucidate factors impacting specific stages, which have the potential to improve the overall speed of health IT dissemination, would be highly beneficial. Last, much has been written about the challenges of clinician use, but this is one of the only empiric studies to document the high level of variation in times to achieve full use of health IT, particularly with respect to the Clinical Use stage. Although the HITECH Act and accompanying financial incentives appear to have been necessary factors in moving the diffusion of health IT forward in the United States, financial motivations are not sustainable in the long term. Understanding the key motivators for clinicians to adopt health IT is a timely and critical area for additional research.

From a practical standpoint, these results also indicate key focus areas for organizations implementing health IT. First, both organizational momentum and organizational support should play roles in implementation; the timing of leadership endorsement may be strategic, after the health IT is "proven" among early adopters, but early enough to facilitate diffusion. Second, too much health IT, and EHRs in particular, have not been designed a priori to provide value to clinician end-users, such as incorporating efficiency and usability into design or the ability to conduct real-time clinical quality assessments. And, many systems simply try to do too much at once, embedding reminders, alerts, decision support, billing and documentation into one "big bang" type roll-out. Working with vendors to customize and adjust systems such that the form follows the function is imperative, as well as consideration of staged functionality roll-outs so that end-users learn new capabilities after first mastering basic requirements. Finally, organizations should consider the balance of project management in the installation of health IT with change management to support the process and workflow redesign necessary to achieve full, clinical use.

Limitations

There are many important considerations in the interpretation of the research presented in this thesis. Most importantly, this study is an observational study and, as such, can only suggest potential associations between outcomes and predictors. Causal inference is not possible in this context. However, it would be costly and time-consuming to conduct a trial to detect causality in the factors assessed by this thesis.

When the study was conducted, no standardized survey instrument to evaluate

facilitators and barriers existed. To overcome this, key facilitators and barriers from the

health IT literature were used as well as VA-specific factors. In addition, the survey is

limited by both selection and recall biases. Only clinical champions were asked to

complete the survey. While this limits applicability of the findings to technical aspects

of implementation, it did permit insights into the perception of the clinicians, a very

important population in health IT implementation. Unfortunately, these clinical

champions were only surveyed after full, clinical use was demonstrated, impacting recall

of earlier stages.

There are important considerations, as well, in the analyses provided in this

thesis. As stated above, this observational study can only suggest associations. There is

no way, through this study, to state definitively whether specific facilitators drive or

specific barriers delay the duration required for implementation, or specific components

of that process. Facilitators and barriers in this study must only be considered as

markers of the process. In addition, because of the observational nature of this work, it

is also impossible to uncover mediators or confounders related to health IT

implementation.

Many of the analyses in this thesis utilized Cox proportional hazards as a time-to-

event model. However, many of the significant findings from these models exhibited

wide confidence intervals. These wide confidence intervals do not negate the existence

of an association, particularly considering none cross "1." While the sample size of 75

hospitals was robust and included all eligible hospitals, a larger sample might have aided

precision and provided more certainty regarding the results.

The use of the Cox proportional hazards models to relate the facilitators and

barriers with the time required to achieve certain outcomes also is at risk of ecological

fallacy. These analyses assess functions of groups (i.e., hospital implementation times)

against the opinions of individuals. Inclusion of more types of respondents could help

reduce this risk, but it will still remain salient. Despite this, there is still value in

understanding what the individuals ultimately responsible for the end-point of the

implementation process (i.e, full, clinical use) deemed important.

Lastly, there may be limits to the generalizability of this work due to the setting

in the VA. First, the VA has had an EHR for over a decade and thereby, a culture

accustomed to electronic documentation. Given that CART was designed to be

cognitively compatible with the VA EHR, this may have reduced the training time

required to use CART. However, CART was, like many health IT implementations, a

replacement for a formerly manual method of documentation and there was still

evidence of significant variability in achieving full use. Some may feel the electronic

culture of the VA limits generalizability of this work to EHR implementation in previously

paper-based organizations, but this work remains potentially useful to those

organizations which are implementing additional health IT technology to augment or

extend an EHR. Last, due to the setting, this study was also unable to address financial

factors as motivators in health IT implementation; the motivations of various individuals

in CART implementation may not fully represent motivations which are important in other settings.

Conclusion

This observational study of the successful implementation and full use of health IT is likely the first to follow complete diffusion across a large, nationwide health care system and evaluate key factors at specific times. This study observed a pattern of cumulative adoption typical of innovations, providing empiric evidence to support previous theoretical models. By clarifying and defining the terms surrounding the installation and full use of health IT, and applying this as a concise, staged framework to conceptualize implementation, this research extends knowledge by uncovering specific factors which may speed or delay the overall process at specific time points. Organizations should be mindful of motivational factors to move beyond installation of health IT to full, clinical use. Ultimately, the results of this study reinforce that successful health IT implementation does not end with technical installation and training, and must support clinical use as part of routine care delivery in order to realize the full benefits of health IT.

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APPENDIX A

PUBMED LITERATURE SEARCH CODE

The PubMed search code is adapted from the PubMed comprehensive query for

"Electronic Health Records" found at http://www.nlm.nih.gov/services/ehr.html.

Additionally, the results of the search were limited to United States and publications in

the past ten years (i.e., 2002-2012). The following abbreviations are employed in this

code and full definitions of these abbreviations may be found at

http://www.ncbi.nlm.nih.gov/bookshelf/br.fcgi?book=helpPubMed&part=PubMedhelp:

[tw] = Text Words

[majr] = MeSH Major Topic

[mh] = MeSH Terms

[ti] = Journal Title

PubMed Master Search Code:

> ((health information technology [tw] OR
> healthcare information technology [tw] OR
> health care information technology [tw] OR
> electronic health data [tw] OR
> personal health data [tw] OR
> personal health record [tw] OR
> personal health records [tw] OR
> Health Records, Personal [Majr] OR
> Health Record, Personal [Majr] OR
> ehealth [tw] OR
> e-health [tw] OR
> medical informatics application [mh] OR
> medical informatics applications [mh] OR
> medical records system, computerized [mh] OR
> medical records systems, computerized [mh] OR

computerized patient medical records [tw] OR
automated medical record system [tw] OR
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automated medical records systems [tw] OR
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ehrs [tw] OR
phr [tw] OR
phrs [tw] OR
emr [tw] OR
emrs [tw])
AND
(j ahima [ta] OR
j am med inform assoc [ta] OR

amia annu symp proc [ta] OR
health data manag [ta] OR
int j med inform [ta] OR
yearb med inform [ta] OR
telemed j e health [ta] OR
stud health technol inform [ta]))

The results from the master search were then combined with key topic areas as title

searches and "United States" as text words. In addition, each of these searches were

limited to English language and last ten years. For example:

[PubMed Master Search Results] AND
United States [tw] AND
Progress [ti]

APPENDIX B

GOOGLE SCHOLAR LITERATURE SEARCH CODE

Title-based search using "intitle:" in Google Scholar was not included in this code

because it created queries too lengthy to process.   Specifying "where my words occur:

anywhere in the article" in the advanced search criteria was sufficient. In addition,

Google Scholar is able to imply plurals and compound words, so the various iterations of

"health care" or "healthcare," for example, are not necessary.   However, the Google

Scholar search fields only accept 256 characters per search, including spaces, so the

overall search had to be more focused than the PubMed search.

Google Scholar Master Search Code:

> "health information technology" OR "electronic medical record" OR "medical
> informatics" OR "medical record system" OR "computerized medical record" OR
> "electronic health record" OR "electronic patient record"
> =210 characters

As with the PubMed searches, the Google Scholar master search code, above, was then

appended with the key topic area as part of the title, United States as a text word, and

limited to English language articles published in the last ten years. For example:

> [Google Scholar Master Search Results] AND "united states" AND intitle:Progress

VA RAPID RESEARCH PROPOSAL FOR FUNDING OF A PORTION OF THESIS RESEARCH

<u>BRIEF OVERVIEW AND AIMS</u>: AS STATED IN FORM 10-1313-2, THE GOALS OF THIS PROPOSED RRP ARE TO MEASURE THE VARIATION IN IMPLEMENTATION OF CART-CL ACROSS THE VA, AND TO EVALUATE THE FACILITATORS TO SUCCESSFUL IMPLEMENTATION AS WELL AS THE BARRIERS TO DELAYED AND/OR INCOMPLETE IMPLEMENTATION. THE **<u>SPECIFIC AIMS</u>** OF THE PROJECT ARE:

1. TO MEASURE THE RATE AND DEGREE OF IMPLEMENTATION OF CART-CL IN THE 75 VA CATH LABS.
2. Combining quantitative and qualitative techniques, determine the clinician, technical, and system facilitators associated with timely and complete adoption of CART-CL.
3. Combining quantitative and qualitative techniques, identify the key barriers to complete adoption and ongoing use of the system.

<u>Background</u>: CART-CL is a software application for standardized report generation, a national data repository, and a national quality improvement program for VA cath labs. It was developed collaboratively between IHD-QUERI, Patient Care Services, and the Office of Information. The application is integrated within CPRS, enabling providers to document care as part of routine clinical work, automatically incorporating data from CPRS (history, medications, vitals, labs). CART-CL tracks all cath lab procedures to accomplish workload capture (CPT/ICD-9 coding). Summary data (e.g. procedures, complications) are provided to each site, to support local quality improvement. CART-CL enables participation by all VA cath labs in the American College of Cardiology National Cardiovascular Data Registry for national benchmarking. Beta testing of CART-CL started at 6 sites in mid-2004, with subsequent national installation over the last 2 years. CART-CL is now installed or in the final stage of installation in all 75 VA Cath Labs. Yet, there has been significant observed variation in the speed of installation and degree of adoption of CART-CL, making it an ideal time to quantify and evaluate its' implementation.

<u>Significance</u>: The topic of this RRP was specifically requested by the Research and Methodology Committee as part of the IHD-QUERI annual review. It is intended that the results of this study will: a) identify specific targets to enhance ongoing adoption and sustained use of CART-CL, b) have direct import for other QUERI groups as well as other key entities within VHA (PCS, OQP, OI&T, etc.) with regard to conducting successful national implementation projects, and c) contribute to implementation science, including both the quality improvement and health information technology implementation literatures.

<u>Methods</u>
Aim 1: We will quantify the: 1) <u>speed of installation</u> (days), 2) <u>speed of adoption</u> (days), and 3) <u>degree of adoption</u> (proportion of staff cardiologists using CART-CL and proportion of cath lab procedure reports/month being generated using CART-CL), and 4) <u>persistence of adoption</u> (proportion of monthly cath lab procedure reports generated

using CART-CL over a 6+ month period) for each of the 75 sites. This will allow a typology of all sites (e.g. slow versus rapid installation, incomplete versus complete clinical adoption). Data sources will be: a) the CART-CL internal process tracking system that includes dates of first contact, initiation of installation, completion of installation, clinical in-service, and initiation of clinical use for each site, b) the CART-CL data repository for monthly procedure volume for each site; and c) review of local cath lab logs to assess the denominator for degree and persistence of adoption. To demonstrate feasibility of obtaining local log data, we obtained the logs from 2 sites and mapped CART-CL procedures to the local logs, demonstrating 98% and 90% concordance. This data was obtained from each site within 48 hours of request. Results will be descriptive (the metrics described above for each site as well as summary statistics including ranges, medians, and proportions for the VA cath lab system as a whole).
Aims 2 and 3: We will perform structured interviews of a sample of site contacts, and then survey all 75 sites to identify facilitators and barriers to the implementation of CART-CL. Recognizing that CART-CL implementation is contingent – that is, clinical adoption is contingent upon technical installation, and that actors and facilitators for these phases may differ, we will target (interviews and surveys) both technical and clinical site contacts.

   We will conduct the qualitative interviews with technical and clinical contacts at each of 8 to 12 facilities. Interviews will follow a structured, open-ended interview guide addressing CART-CL implementation history and facilitators and barriers.[1] Two researchers will conduct interviews via telephone, taking ~1 hour. Interviews will be recorded and transcribed verbatim. The researchers will independently code transcripts for specific implementation barriers and facilities. The researchers will share and update a common coding manual, and reach consensus on coding of transcripts. Coded transcript material will be extracted into narrative reports on barriers and facilitators which will be used to help develop the survey items.[2,3]
   Information from the interviews will be combined with potential facilitators and barriers derived from the literature and from key personnel involved in the development and implementation of CART-CL to inform survey content. The recently published 'Fit framework for IT Adoption' by Ammenwerth et al. (**Figure**) was used as a conceptual framework.[4] Space precludes listing possible facilitators and barriers based on the literature and experience of CART-CL personnel (to be augmented by the structured interview data). However, a listing of potential facilitators and barriers is in the **Appendix**, with references listed on the next page.[4-12]
   A web-based survey will be developed and administered to technical and clinical contacts at the 75 sites. To support anonymity and minimize response bias, a commercial web-based survey tool will be used (e.g. SurveyMonkey), which is external to the VA intranet. The survey will incorporate skip logic based on the respondent's role and responses to specific questions. Respondents will be asked to rate, using Likert scale methodology, the impact of potential barriers and facilitators to their facility's adoption of CART-CL. In addition, respondents will be asked to rank barriers and facilitators to evaluate their relative importance, and will be able to provide comments. The survey is anticipated to take <=20 minutes. Survey results (summary quantification of responses to individual items) will be presented as both national averages and also by typology of site as determined in Aim 1 (e.g. incomplete versus complete clinical adoption).

Timeline: 1) Obtain data from individual site logs (*Month 1*); 2) Analysis of CART-CL tracking/repository data and site data for Aim 1 (*Month 2*); 3) Conduct qualitative interviews (*Months 1-2*); 4) Develop web-based survey (content + technical development)(*Months 1-3*);   5) Conduct web-based survey (*Months 3-5*); 6) Analyze data and present results (*Months 5-6*).

Project Management

John Rumsfeld MD PhD (PI): Clinical Director, CART-CL; Clinical Coordinator, IHD-QUERI; **Christian Helfrich MPH PhD** (Co-PI): Implementation Research Coordinator, IHD-QUERI; **Tamara Box MPH** (Co-I): CART-CL Site Manager; CART-CL Web-based application developer/programmer; **Mary Plomondon PhD** (Co-I), CART-CL Project Manager/Analyst; **Stephan Fihn MD MPH** (Co-I), CART-CL Director; Research Coordinator, IHD-QUERI; **Robert Jesse MD PhD** (Co-I): National Program Director for Cardiology; **Hans Gethoffer, DrIng** (Consultant): Technical Director, CART-CL; **Anne E. Sales PhD RN** (Consultant): Former IRC, IHD-QUERI; Implementation Science Researcher.

   THE PROJECT TEAM HAS BEEN DIRECTLY RESPONSIBLE FOR THE OVERSIGHT, DEVELOPMENT, AND IMPLEMENTATION OF CART-CL, AND MAINTAINS THE CART-CL DATA REPOSITORY. THE INVESTIGATORS HAVE SIGNIFICANT EXPERIENCE IN THE DEVELOPMENT, CONDUCT, AND INTERPRETATION OF SURVEYS/SURVEY DATA (JR, SF, AS, MP), QUALITATIVE INTERVIEWS (CH, AS), TECHNICAL ASPECTS OF THE PROPOSED STUDY (TB, HG) AND DATA MANAGEMENT/ANALYSIS (JR, MP, AS) TO EXECUTE THE SPECIFIC AIMS AS OUTLINED.
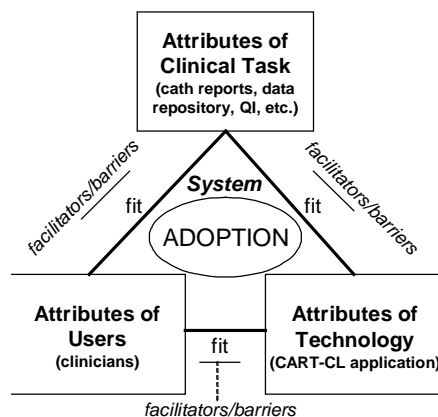

Figure: Conceptual framework[4]

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APPENDIX: SAMPLE POTENTIAL FACILITATORS & BARRIERS (derived from the literature and from personnel directly involved in the implementation of CART-CL)

Clinical		
FACILITATORS		**BARRIERS**
National Directive	⬌	National Directive
Engagement of local champion(s)	⬌	Failure to identify and/or engage local clinical champion(s)
Belief that CART-CL will improve current processes (cost/time)/benefit	⬌	Belief that CART-CL will not improve upon existing processes (cost/time)/benefit
Belief that CART-CL will improve quality	⬌	Belief that CART-CL will not necessarily improve quality
Positive opinion of internally-developed software	⬌	Distrust of internally-developed software; reliance on vendor systems
Desire to participate in development/testing/improvement of CART-CL	⬌	No desire to be involved in development/testing/improvement of CART-CL (e.g., lack of time, interest)
CART-CL provided sufficient and appropriate reporting and data collection for cath lab procedures	⬌	Request for additional reporting or data collection beyond core mission of CART-CL (e.g., conscious sedation)
Enthusiasm for more standardized coding and reporting processes in organization (e.g., VA-wide)	⬌	Lack of VA-wide standard cath lab report and desire to have CART-CL conform to local reports
CART-CL perceived as user-friendly / useful	⬌	CART-CL is perceived as not being user-friendly / useful
		Clinical inertia; reliance on prior methods of report generation (e.g. dictation)
Interest in future research using data from CART-CL		

Technical		
FACILITATORS		**BARRIERS**
National Directive	↔	National Directive
Engagement of appropriate IT contact	↔	Failure to identify and/or engage local IRMS staff
IRMS felt that installation process minimally affected resources (e.g., human and system)	↔	IRMS felt that installation process was resource-intensive (e.g., human and system)
Integration with CPRS	↔	Lack of specific/desired integration with CPRS (e.g., pasting and/or customization of reports
IT leader had positive opinion of internally-developed software	↔	IT leader had negative opinion of non-certified or internally-developed software
Desire to participate in development/testing/improvement of CART-CL	↔	No desire to be involved in development/testing/improvement of CART-CL (e.g., lack of time, interest)
Potential future interoperability	↔	Lack of interoperability with existing reporting systems or interfaces
CART-CL technical team had appropriate privacy and security credentials and training for required technical access level	↔	Paperwork and time delay in granting CART-CL technical team required technical access levels

System		
FACILITATORS		**BARRIERS**
Focus on quality improvement/strategic importance of CART-CL	⬌	Change resistance
Continuity of key IT and clinical leaders	⬌	Personnel changes affecting key IT and clinical leaders
CART-CL met all required policies or mandates (e.g., top-down mandate from National Director sufficient)	⬌	CART-CL requested to meet additional policies or mandates (e.g., C&A)
Knowledge diffusion appropriate (e.g., inservices for clinicians, demos for IT)	⬌	Lack of knowledge diffusion
Technical support from CART-CL team	⬌	Lack of technical support or response from CART-CL team
Overall support of local organization for CART-CL (including clinical and IT)	⬌	Overall lack of organizational support for CART-CL (including clinical and IT)
CART-CL penetrance at other VA's viewed favorably		
Structural features (size of cardiologist staff; proportion of cardiologist staff full time VA; academic affiliation/presence of fellows; etc)	⬌	Structural features (size of cardiologist staff; proportion of cardiologist staff full time VA; academic affiliation/presence of fellows; etc)

DEPARTMENT OF VETERANS AFFAIRS
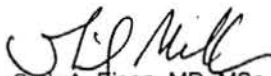**Veterans Health Administration**
Washington DC 20420

Director (00/151)
VA Medical Center
1055 Clermont Street
Denver, CO 80220

In Reply Refer To: 124Q

SUBJECT: Notification of Review Outcome/ Funding Decision, QUERI Program
Proposal Number: SDR 07-278
Title: Evaluating the Implementation of the VA Cardiovascular
Assessment Reporting Tracking System for Cath Labs (CART-CL)
Principal Investigator: John Rumsfeld, MD, PhD

1. **Funding Decision.** I am pleased to notify you that the Health Services Research and Development Service (HSR&D) Quality Enhancement Research Initiative (QUERI) Program has approved funding for the subject proposal. Acceptance of this funding acknowledges agreement to comply with VA policies regarding intellectual property disclosure obligations and ownership rights resulting from this work. Funding will begin on **8/20/2007**.

2. **Budget Information.** We will ask the Office of the Chief Financial Officer, Allocation Control Service, to transfer Program 870 funds to your facility for **FY 2007**, with plans for continued support through **2/28/2008** as detailed in the enclosed budget documents (**Enclosure 1**). Support beyond FY 2007 is contingent upon the availability of QUERI Program 870 funds and satisfactory progress of the project. The project budget will be transmitted electronically to the Veterans Administration Medical Center for distribution to the field.

3. **Reporting Requirements.** The QUERI program requires three types of regular reports for every project: annual progress report (abstract); copies of all publications based on the QUERI-funded work; and a final report. Approval of future QUERI funding is contingent on the investigator's adherence to these critical requirements. For additional information and details regarding investigator reporting requirements, please consult your local R&D office.

    a. Annual Report. A brief annual report (or abstract) is due every anniversary of the start of the project. This report must provide a clear, concise description of the project, including its current status and expected or actual impact, in a specified format.

    b. Publication Transmittal. Investigators are required to send HSR&D QUERI a copy of each article resulting from QUERI- funded research as soon as it is accepted for publication. Submit each article by e-mail to vhacohsrd@hq.mail.va.gov, also copy ORD Communications via research.publications@va.gov.

    c. Final Report. A Final Report, conforming to current HSR&D instructions, is required at the conclusion of the funding period.

4. **Modifications**. Any significant modification in the approved project plan or budget requires a written request, for review and approval by the HSR&D QUERI Program. Please contact your local Research Office for details.

5. **VA Acknowledgment**. All publications based on this project must acknowledge VA support, and the investigator's VA affiliation must appear, before any other, in the following form: "The project reported/outlined here was supported by the Department of Veterans Affairs, Veterans Health Administration, Health Services Research and Development Service Quality Enhancement Research Initiative (project no.). Dr._____ is the (position title) at (location)." In addition, all publications should include a disclaimer similar to this statement: "The views expressed in this article are those of the author(s) and do not necessarily represent the views of the Department of Veterans Affairs."

6. **Communications**. You may direct general questions regarding this project to Linda McIvor, MS, MHS, QUERI/Implementation SDP Program Manager (124-Q), at 202-254-0230 or Linda.McIvor@va.gov. For questions regarding the distribution of project funds, your administrative officer should contact Georgette Njemanze at 202-254-0215 or Georgette.Njemanze@va.gov . Please include the proposal number (above) in any communication concerning this project. Please be reminded that all communication regarding this proposal should go through the local research office. The principal investigator is responsible for relating all communications from VA Central Office to any co-principal investigator and/or other co-investigators, as necessary.

Seth A. Eisen, MD, MSc
Director, Health Services Research
    and Development Service

Enclosure: Budget sheet

cc: John Rumsfeld, MD, PhD (151)
    ACOS/R&D (151)
    Georgette Njemanze (12B)
    VACO Read
    Project File

COMIRB EXEMPTED RESEARCH APPROVAL

CMIRB	Colorado Multiple Institutional Review Board 13001 E. 17th Place Building 500, Room N3214 Aurora, Colorado 80010-7238	Mailing Address: Mail Stop F-490 P.O. Box 6508 Aurora, Colorado 80045-6508	(303) 724-1055 [Phone] (303) 724-0990 [Fax] www.uchsc.edu/comirb [Web] comirb@uchsc.edu [E-Mail] FWA#: FWA00005070

University of Colorado Hospital
Denver Health Medical Center
Veteran's Administration Medical Center
The Children's Hospital
University of Colorado Health Sciences Center
Colorado Prevention Center

Tamara (tami) Box
111B

07/24/2007

Certificate of Exemption

Investigator: John Rumsfeld

Sponsor(s):   Va Health Services Research & Development Queri

Subject: **COMIRB Protocol 07-0622**   Title:
      Initial Review (APP001)
      1st   EVALUATING THE IMPLEMENTATION OF THE VA CARDIOVASCULAR
      ASSESSMENT, REPORT, AND TRACKING FOR CATH LABS (CART-CL)

Effective Date: **19 July 2007**

Expiration Date: **Exempt**

Exempt Category: **2, 4**

Includes: **Protocol - Investigator - 3 Questionnaire(s)**

This protocol qualifies for exempt status. Periodic continuing review is not required. For the duration of your protocol, any change in the experimental design/content of this study must be approved by the COMIRB before implementation of the changes.

The anticipated completion date of this protocol is **12/31/2008**. COMIRB will terminate this project on this date unless otherwise instructed either by correspondence, telephone or e-mail to COMIRB@uchsc.edu.

Any questions regarding the COMIRB action of this study should be referred to the COMIRB staff at 303-724-1055 or UCHSC Box F-490.

Ken Easterday, R.Ph. Warren Capell, M.D.	Hans Neville, M.D. Chris Duclos, Ph.D.	Dave Lawellin, Ph.D. Douglas Ford, M.D	Steve Bartlett, R.Ph. Mary Geda, RN, MSN

Revised 03/05   **VA 07-0622 Panel: X/ Exempt**

APPENDIX E

CART CLINICAL CHAMPIONS SURVEY

[*NOTE: In this survey, CART is referred to as "CART-CL." The "CL" stands for Cath Labs. This was how CART was originally introduced to the VA. After implementation and becoming a routine part of clinical care the name was shortened to simply CART.]*

PURPOSE OF THIS SURVEY:

As a person involved with CART at a VA hospital, we are interested in your perspective regarding CART-CL. (CART-CL is the Clinical Assessment, Reporting, and Tracking system for Cath Labs.)

In particular, we would like to understand potential facilitators and barriers to the installation and subsequent use of CART-CL at your VA, and your opinions regarding CART-CL.

We anticipate this survey should take no more than five minutes of your time. Your responses will remain anonymous and results from this survey will be reported in groups (i.e., in aggregate).

FACILITATORS

Please rank the TOP 5 possible FACILITATORS to getting CART-CL installed and implemented in your VA. A facilitator is anything which might have contributed to the successful installation and adoption of CART-CL at your VA. If an important facilitator at your VA is not included in the list, please choose "Other" and use the comment box to describe it. Please rank the top five FACILITATORS with #1 being the most important facilitator:

Answer Options	#1	#2	#3	#4	#5
CART-CL integration with the VA EHR					
CART-CL technical support					
Demonstrations and training for CART-CL					
Organizational support for CART-CL					
Appropriate staff resources					
Desire for standardized coding and reporting in the VA					
Desire to improve quality					
Statement of strong support by VA senior leadership					
Clinical support in my department for CART-CL installation					
Technical support from IT department					
Future interoperability or interfacing of CART-CL					
Impressions of CART-CL from colleagues at other VAs					
Future research possibilities with CART-CL					
Other					

BARRIERS

Please rank the TOP 5 possible BARRIERS to getting CART-CL installed and implemented in your VA. A barrier is anything which might have impeded or slowed successful installation and adoption of CART-CL at your VA. If an important barrier at your VA is not included in the list, please choose "Other" and use the comment box to describe it. Please rank the top five BARRIERS with #1 being the most important barrier:

Answer Options	#1	#2	#3	#4	#5
Privacy and security regulations					
CART-CL technical support					
Contentment with current processes for cath lab reporting					
Organizational support for CART-CL					
Appropriate staff resources					
Opinions of internally-developed software					
Statement of strong support by VA senior leadership					
Clinical support in my department for CART-CL installation					
Technical support from IT department					
Lack of interoperability or interfacing with CART-CL.					
Organizational policies or mandates in order to install CART-CL not met					
Impressions of CART-CL from colleagues at other VAs					
Other					

KEY FACTORS - 1

During the process of getting CART-CL installed in your VA and implemented in your cath lab, how important were the following:

Answer Options	Extremely Important	Very Important	Fairly Important	Somewhat Important	Not At All Important
Lack of VA-wide standard cath lab report.					
Need to standardized coding and reporting in VA cath labs.					
Desire to have CART-CL conform to local reports or templates in your cath lab.					
The VA senior leadership statement supporting installation and implementation of CART-CL.					
Identifying the appropriate staff (clinical and technical) in your VA to champion this endeavor.					
CART-CL's integration with CPRS.					
Training and inservices for clinical staff to use CART-CL.					
The overall support of your organization for CART-CL.					
The impression held by colleagues at other VAs regarding CART-CL					
Future research possibilities using CART-CL					

KEY FACTORS - 2

Please tell us how much you agree or disagree with these questions based on your feelings at the time CART-CL was being installed and implemented in your cath lab:

Answer Options	Strongly Agree	Somewhat Agree	Neither Agree nor Disagree	Somewhat Disagree	Strongly Disagree
CART-CL will improve upon our current processes.					
CART-CL will improve quality.					
CART-CL provides sufficient and appropriate data collection and reporting for our cath lab.					
CART-CL is user-friendly.					
CART-CL fulfills our reporting and data collection needs better than our previous methods.					
We were able to identify the appropriate clinical person to champion installing and implementing CART-CL.					
We were able to identify IT staff to help us get CART-CL installed.					
I have a positive opinion of internally-developed software.					
I have a desire to participate in testing and improvement of CART-CL.					

KEY FACTORS - 3

Please tell us how much you agree or disagree with these questions based on your feelings at the time CART-CL was being installed and implemented in your cath lab:

Answer Options	Strongly Agree	Somewhat Agree	Neither Agree nor Disagree	Somewhat Disagree	Strongly Disagree
The time required for technical access for the CART-CL team to install the software delayed the installation.					
The environment where I work was comfortable with their existing process and did not want to install or implement CART-CL.					
Frequent personnel changes in my department made it difficult to implement CART-CL.					
Our department believed CART-CL was strategically important to quality improvement in the VA system.					
I believe CART-CL met all of the required policies or mandates.					
The clinical in-service training we had for CART-CL was appropriate.					
The size of our department or proportion of full-time staff made it challenging to implement CART-CL.					
My colleagues at other VAs have a favorable opinion of CART-CL.					