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2018

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Influences On The Effectiveness Of Information Technology Innovations In Primary Health Care

Ву

Jessica Leigh Watterson

A dissertation submitted in partial satisfaction of the requirements for the degree of

Doctor of Philosophy

in

Health Policy

in the

Graduate Division

of the

University of California, Berkeley

Committee in Charge:

Professor Hector P. Rodriguez, Chair Professor Stephen M. Shortell Professor Adrian Aguilera Professor Julia Walsh

Spring 2018

Abstract

Influences On The Effectiveness Of Information Technology Innovations In Primary Health Care

By

Jessica Leigh Watterson

Doctor of Philosophy in Health Policy

University of California, Berkeley

Professor Hector P. Rodriguez, Chair

Health information technology (HIT) represents one of the largest areas of innovation in health care in recent history. While earlier theoretical and empirical work has focused mostly on understanding the factors that lead health care providers or patients to use an HIT innovation, less is understood about whether and how this use leads to improved healthy behaviors or health outcomes. The first paper of this dissertation studies the relationship between the ease of use of electronic health records (EHR) and relational coordination among primary care team members. Support is found for the hypothesis that ease of use contributes to better team coordination through use of the EHR. The second paper is a mixed-methods study of a diabetes care management textmessaging intervention for low-income, Latino patients. We examine both the implementation and impact of the program, and find some evidence of improvements to blood glucose (HbA1c) among participants. The third paper studies the relationship between a text-messaging intervention for pregnant women in Samoa and antenatal care attendance. The findings suggest that the text-messaging intervention did not encourage, and might have even discouraged, antenatal care attendance. Together with findings on implementation barriers and facilitators, these findings are discussed in the context of other current literature on mHealth programs for maternal health. The three papers provide support for an overall conceptual model that draws upon earlier theoretical and empirical literature, and helps us to better understand the effectiveness of HIT innovations in a broad range of settings.

ACKNOWLEDGEMENTS

I would like to express my immense gratitude to my committee chair, Professor Hector Rodriguez, who provided me with unwavering support since my first day in the PhD program; his enthusiasm, work ethic and incredible generosity with his time kept me going. I am also deeply indebted to Professor Julia Walsh for her mentorship; she supported me from my first thoughts of getting a PhD, and her passion for improving health for marginalized communities has always been an inspiration. Next I would like to thank Professors Stephen Shortell and Adrian Aguilera for their support and guidance; they spent innumerable hours providing feedback on my work, greatly stimulating my learning and the quality of the research.

My gratitude also goes out to my mother and father, who taught me the incredible value of education and hard work, and without whom I would never have had the opportunity to study what I am most passionate about. My deepest thanks also go to my partner, Luke, whose patience and resolute belief in my abilities were just what I needed in challenging moments.

A very special thanks to the many other mentors and colleagues who supported and encouraged me along the way. Dr. Caricia Catalani introduced me to the field of mobile health and, along with Dr. Diego Castaneda, inspired me to try new things and not to be afraid to fail. Dr. Kamalini Lokuge was a welcoming mentor in a new university and an example of a researcher who demonstrates her belief in health equity every day. Lauren van der Walt motivated me to apply for the PhD program and was always there when I needed someone to talk over an idea or problem with. My PhD cohort, Drew Cameron, Leeann Comfort and Jessica Poon, provided essential encouragement and laughter along the way.

Finally, I would also like to thank some of the many partners who made this research possible: the Fulbright-Clinton Public Policy Fellowship, the Samoa Ministry of Health and National Health Service, the Center for Healthcare Organizational and Innovation Research, CareMessage, ChapCare, the Patient-Centered Outcomes Research Institute, DaVita HealthCare Partners and Advocate Health Care.

i

ABBREVIATIONS

ACO Accountable Care Organization

ANC Antenatal (also known as prenatal) care

BMI Body mass index Blood pressure

CFIR Consolidated Framework for Implementation Research

eHealth Electronic health

EHR Electronic health records
HbA1c Glycated hemoglobin

HIT Health information technology
HOT Human-organization-technology

ICC Intraclass correlation IT Information technology

MAMA Mobile Alliance for Maternal Action

MAR Missing-at-random mHealth Mobile health

MI Myocardial infarction

NHS National Health Service (Samoa)

PAID-5 Problem Areas in Diabetes questionnaire (short form with 5 questions)

PCP Primary care provider
RC Relational coordination
SD Standard deviation
SE Standard error

SMS Short message service

TAM Technology acceptance model WHO World Health Organization

TABLE OF CONTENTS

Acknowledgements	i
Abbreviations	ii
1. Introduction	1
2. Conceptual Model and Aims	3
3. Paper One: Ease of use of electronic health records and relational coordination among primary care team members	
3.B. Conceptual Model and Hypotheses	5 7
3.D. Results	
4. Paper Two: "Worrying about me": improved diabetes care management through a text-message intervention for low-income patients	15
4.A. Background4.B. Conceptual Model and Hypotheses	15
4.C. Data, Methods and Analyses4.D. Results	16
4.E. Discussion	29
5. Paper Three: Promoting antenatal care attendance through a text-message intervention in Samoa	
5.A. Background5.B. Conceptual Model and Hypotheses	
5.C. Data, Methods and Analyses5.D. Results	
5.E. Discussion	
6. Conclusions 7. References	
Appendix I: Paper Two Interview Guides	
Appendix II: Paper Two Additional Quotes	53

1. Introduction

In the face of rising rates of chronic disease and ongoing infectious disease risks around the world, health care providers and organizations must continue to innovate to find more effective and efficient methods to reduce suffering and premature death. The push for innovation in health has led to much theoretical and empirical work. Though definitions vary, innovations are generally defined as having three key components: (i) a **novel** idea, process, product or procedure (ii) the **application** to a role, group or organization, and (iii) being designed to be of **benefit** to individuals, groups or society more broadly [1,2]. Innovation is also the process of refining and improving a newly demonstrated, feasible concept (or an invention), for broader use [3]. In health care, innovations generally attempt to produce benefits in the form of improvements to quality, safety, outcomes, efficiency and/or costs [4].

Information technology (IT) innovations represent some of the greatest growth in novel human invention over the last four decades. Unsurprisingly, IT is one of the major areas of innovation in health care as well. Health information technology (HIT) innovations like electronic medical records, mobile phone applications, remote patient consultations via videoconferencing and many others have emerged and spread around the world. The most recent survey on the use of information and communication technologies in health found that 83% of World Health Organization member states have a mobile health (mHealth) initiative, telehealth is used in 77% of countries and 47% have a national electronic medical record [5].

Though HIT innovations have been studied since their emergence decades ago, no one overarching conceptual model has been developed and agreed upon, either for their use or for their effectiveness. Instead, many theoretical lenses and bodies of literature have been developed [6]. The paradigm that has dominated the study of HIT, until recently, is a focus on understanding the factors influencing adoption of IT innovations in health care [7]. Empirical research and theory in this area has identified important enabling conditions that must be present for users to engage regularly the IT innovation. This theory first grew out of Rogers' work on the Diffusion of Innovations, which identified five factors that influence the adoption of an innovation [8]. Rogers theorized that users must see that an innovation: has a relative advantage compared to what it replaces, is consistent with their needs and values (compatibility), is not difficult to use (complexity), can be tested before they commit to using it (trialability) and produces tangible results (observability), before they will adopt it. The Technology Acceptance Model (TAM) was subsequently developed in 1989, and identified two of these factors to be of particular importance for the adoption of an IT innovation: perceived usefulness (similar to Rogers' observability) and perceived ease of use (similar to Rogers' complexity) [9]. More recently, the Information System Success Model [10] and the Human-Organization-Technology (HOT) Fit framework [11] have emerged, sharing many similarities with the earlier models but also incorporating more features of the technology itself, such as system quality, and features of the implementing organization, such as its structure.

There has also been growing recognition that the study of HIT innovations must extend beyond only studying the factors that facilitate use of the innovation [7,12,13]. Once an innovation is adopted, what happens next? We must examine the performance impacts of HIT innovations, in an attempt to understand whether these innovations lead to their intended benefits and, if so, how they work. Electronic health records (EHR) are one of the most widely studied HIT innovations, and some studies have found that they have the potential to improve health outcomes and clinical efficiency [14-17]. Some studies have also found that mobile phone and telehealth interventions can improve patients' health behaviors and outcomes, though evidence is mixed [18,19]. Recent qualitative work has also suggested that HIT innovations might contribute to improved patient outcomes by facilitating communication, providing reminders and new information, as well as by influencing users' attitudes and beliefs, if designed and implemented properly [20,21]. However, this is the area of study that is least developed in the literature. Evidence for many HIT innovations remains mixed and many innovations that have evidence of effectiveness do not have well-understood mechanisms, limiting the ability of researchers and practitioners to replicate successful interventions in broader settings.

Despite the significant progress in understanding the enabling conditions and mechanisms of health IT innovations, several key questions remain unanswered. First, to what degree do HIT innovations need to be adapted to specific settings and users? Years of theoretical development in this area tells us that IT innovations must be tailored to their target users in order to be most effective. This stems from the concepts of "fit," "usefulness" and "ease of use" - an IT innovation must fit into a user's life, address their needs and be usable in order for them to actually engage with it. However, there has been relatively little empirical work examining the implementation of HIT innovations in users' lives, particularly among harder-to-reach populations. There is now growing recognition that a sociotechnical approach is needed, including both assessments of the technology itself and of the social/organizational context where it is implemented, to best understand whether and how an HIT innovation works [22]. Second, which IT innovations are effective at improving outcomes, such as treatment, diagnosis, prevention, education, research and outreach [4]? Though some evidence exists for older IT innovations, such as electronic medical records, newer innovations such as mobile phone tools, have limited evidence to support their effectiveness. Third, when IT innovations are effective, how do they produce better outcomes? As described above, relatively little attention has been devoted to examining the mechanisms through which IT innovations lead to improved clinical outcomes, both for patients and for health care teams and organizations. Yet this should be a pressing research question, as a deeper understanding of how HIT innovations contribute to health can facilitate their broader implementation and evolution into the future.

2. CONCEPTUAL MODEL AND AIMS

Drawing on the theoretical and empirical literature on health IT, outlined in the Introduction, the integrated conceptual model illustrated in Figure 1 was developed. The model integrates both the enabling conditions that facilitate routine use of an HIT innovation, as well as the mechanisms through which those innovations can then lead to improved team or individual outcomes.

The conceptual model also draws upon the Consolidated Framework for Implementation Research (CFIR), which combines overlapping theoretical constructs relating to the implementation of interventions, and allows for the systematic examination of "complex, interacting, multi-level and transient states" during implementation [23]. The CFIR consists of five domains, including: intervention characteristics, the outer setting, the inner setting, characteristics of individuals and the process. Within each of these domains, specific constructs are identified that influence implementation. For example, an intervention characteristic that influences implementation is the adaptability, or "degree to which an intervention can be adapted, tailored, refined, or reinvented to meet local needs" and in the outer setting, the degree to which the organization knows and prioritizes those needs is another important factor [23].

In addition, many enabling conditions for HIT implementation and adoption specifically have been identified through theoretical and empirical work. Factors such as system quality (e.g., technical infrastructure, interoperability), social factors (e.g., leadership support, peer's use of the innovation) and technical support (e.g., training, the ability to test the innovation) influence users from an organizational level [11,24,25]. At an individual level, factors such as ease of use of the innovation (which can also vary depending on the users' technological literacy), the fit of the innovation into their life or workflow, or the perceived usefulness of the innovation weigh into a users' decision to use it or not [8,9,24]. Once a user has decided to routinely use the IT innovation, they might begin to experience individual or organizational benefits from it. These benefits can in turn feed back into the perceived usefulness of the innovation, potentially causing them to use it more. Some potential individual and organizational benefits include: better information or improved knowledge, social support, cues to action/reminders, changes to attitudes or beliefs, or improved efficiency [20,21]. These types of changes in turn can lead to behavior changes, ultimately resulting in improved outcomes for the team or individual using the innovation.

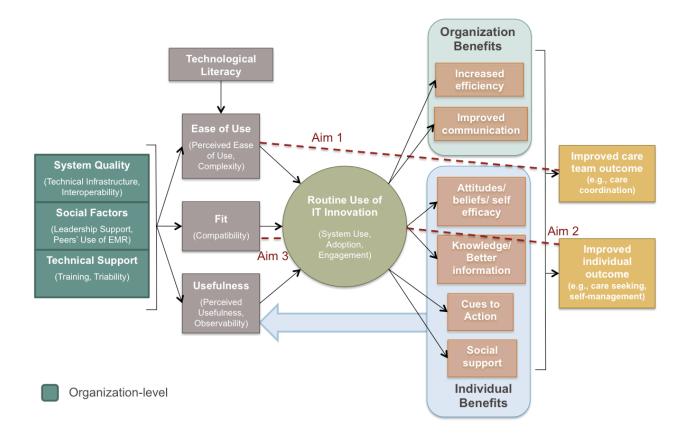
This dissertation will contribute to our understanding of the influences on the effectiveness of HIT innovations by examining three specific aims, addressing some of the gaps in the literature outlined previously. This dissertation aims to:

1. Examine the association between ease of use and improved care team outcomes.

- 2. Assess the relationship between routine use of an IT innovation and improved individual outcomes.
- 3. Assess the influence of fit on routine use of an IT innovation.

These aims will be addressed through three individual studies, all examining the factors that influence HIT innovations' effectiveness in relation to this conceptual model. The background, hypotheses, methods and preliminary results of these papers will be outlined individually in subsequent sections.

Figure 1. Conceptual model of influences on the effectiveness of health IT innovations



3. Paper One: Ease of use of electronic health records and relational coordination among primary care team members

3.A. BACKGROUND

Research demonstrates that electronic health records (EHR) have the potential to improve quality of care, health outcomes and efficiency [14–17]. However, these potential benefits can only be realized after successful implementation, and clinicians and staff members often fail to engage with the EHR if it is not adequately designed with their needs and workflow in mind [26–28]. One key factor that influences whether a staff member will engage with the EHR is how easy they find it to use [24]. If staff members encounter difficulty using functions or entering information, they are unlikely to continue to use parts of the EHR, or they will minimize their interactions with the EHR altogether.

Another factor that influences use of EHR is the benefit, or usefulness, that staff members feel they receive from using the system [24]. One hypothesized benefit that staff might receive from the EHR is improved communication with the rest of their care team, who are working with the same patients. There is some evidence that the need for collaboration and communication across multidisciplinary teams facilitates use [20,28]. Therefore, it is plausible to think that ease of EHR use could be related to improved communication among team members and that a potential mechanism for EHR's contribution to improved health outcomes could be through improved team communication.

In particular, this study examines team communication and relationships through the concept of relational coordination. The term relational coordination was developed to describe the "mutually reinforcing process of communicating and relating for the purpose of task integration" [29]. It is composed of the dimensions of shared goals, shared knowledge and mutual respect, as well as four dimensions of communication (frequent, timely, accurate, problem-solving). Relational coordination has been shown to predict important outcomes such as quality of care, improved efficiency and higher patient and staff satisfaction [29,30].

Though studies have shown the benefits of EHR, less is understood about the mechanisms that drive those improvements in patient outcomes, efficiency and costs. This study aims to fill a gap in the literature by clarifying the extent to which improved team coordination is one of the mechanisms through which EHRs can produce better patient outcomes.

3.B. Conceptual Model and Hypotheses

This study contributes to Aim 1 of the dissertation by examining the relationship between ease of use of an IT innovation (electronic health records) and an improved

care team outcome (relational coordination). Figure 2 illustrates the conceptual model examined in this paper.

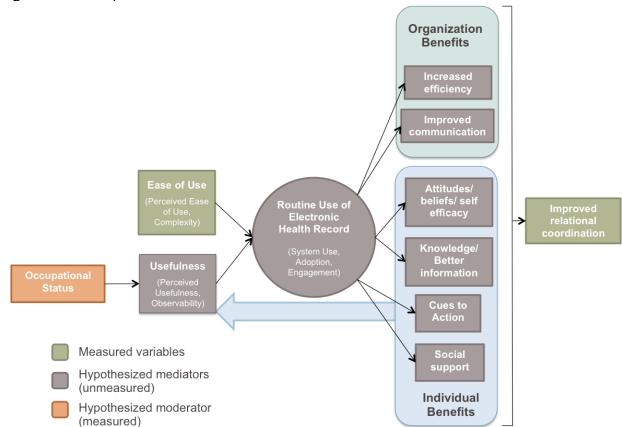


Figure 2. Conceptual Model: EHR Ease of Use and Relational Coordination

Ease of use has been shown to be an important factor in whether an individual decides to adopt an innovation. Rogers' work on the adoption and diffusion of innovations first identified the importance of the "complexity" of an innovation in a users' decision to adopt [8]. Later, the Technology Acceptance Model (TAM), developed by Davis in 1989, identified the importance of the user's perceived ease of use for acceptance of a technology [9]. More recent studies have continued to find empirical support for the importance of ease of EHR use in the decision to use an EHR [24,31].

Once a user decides to engage with the EHR, they might begin to experience more efficient access to patient information, better communication with other care team members as a result of improved information transfer, and therefore, improved relational coordination. These experiences could feed back into users' perceptions of how useful the EHR is, another factor that can influence a user's decision to adopt a technology or innovation [8,9]. Therefore, if they are receiving these benefits from the EHR, it could reinforce their regular, repeated use of the EHR.

Based on this model, we hypothesize that higher ease of EHR use could contribute to better relational coordination through greater engagement with the EHR. If staff and clinicians find the EHR easier to use, they are more likely to engage with it routinely, to experience benefits from that engagement and to continue its use. In addition, previous studies on care coordination and EHR have found some evidence that communication between providers can be improved through the use of EHR, providing preliminary support for this hypothesis [20].

 $H_{1.A}$: Greater ease of EHR use is associated with better relational coordination among clinicians and staff members, controlling for individual and practice characteristics.

There is additional evidence that occupational status may affect the degree of engagement with EHR, with more powerful actors (e.g., physicians) tending to avoid the use of technology [28]. Therefore, we hypothesize that the occupational status of the team member could affect both their decision to engage with the EHR and the relational coordination among team members. Evidence suggests that lower-status team members might have fewer opportunities to participate in the exchange of information than others [32]. As a result, non-primary care providers (PCPs) might be more likely to use the EHR, and to find they have better access to information through the EHR, leading them to use it more frequently and resulting in better communication. Therefore, we hypothesize that lower status team members (non-PCPs) will experience greater relational coordination benefits from ease of use of an EHR compared to PCPs.

 $H_{1.B}$: The positive relationship between ease of EHR use and relational coordination is stronger for non-PCPs compared to PCPs, controlling for individual and practice characteristics.

3.C. DATA, METHODS AND ANALYSES

DATA COLLECTION

The data used for the analyses were collected using a clinician and staff survey that assessed teamwork, relational coordination, and EHR use among adult primary care clinicians and staff members (n=304) caring for adult patients with diabetes and/or cardiovascular disease. The web-based survey was administered from January to April 2016. It was sent to 416 adult primary care staff members at 16 practice sites within two Accountable Care Organizations (ACOs) in Chicago and Los Angeles. All 16 sites across the two ACOs used the same EHR (Allscripts Enterprise TM). In 2011, Allscripts held roughly 16% of the market share of US ambulatory care EHR products [33] and it ranked third in Healthcare IT News' 2015 EHR Satisfaction Survey [34].

The survey had an overall response rate of 84.9 percent. From the initial 353 responses, 30 were excluded because the respondent does not use the EHR as part of their work and another 19 were excluded because they were missing responses to the RC measures. A total of 304 responses were included in this analysis, including: primary care providers (n=73, 24%), nurses (n=66, 22%), medical assistants (n=101,

33%), receptionists (n=40, 13%) and other staff (n=24, 8%, e.g., diabetes educators, social workers). Ethical approval for this study was obtained from the University of California Berkeley Center for the Protection of Human Subjects (Protocol ID 2014-08-6613).

EHR ease of use was measured using an eight item scale that assessed how easy or difficult the EHR is to use for tasks relating to accessing basic data, integrating data, communicating with other staff members and communicating with patients. These questions were developed drawing on earlier research that explored qualitatively how information systems can facilitate team coordination [35]. The survey also measured relational coordination (RC), using seven previously-validated items [36,37]. Each of the seven items asks staff to rate their communication and relationships with seven other team roles (e.g., nurses, primary care providers, receptionists, etc.) on a Likert-type 5item scale. The seven items include: frequency of communication, timely communication, accurate communication, problem-solving communication, shared goals, shared knowledge, and mutual respect. A single RC composite, continuous score was generated for each staff member by taking the mean of their responses to the seven items. In addition, "within" and "between" RC scores were calculated to see how staff and clinicians rate their coordination with others of the same role, as compared to those from a different role. The survey also collected background data on staff members' age, gender, race/ethnicity, average hours worked per week and years of membership in their care team.

MISSING DATA

In the main regression analyses, six observations were excluded due to missing data (age, gender, race, full-time status or years in team). As a sensitivity analysis, multiple imputation by chained equations was used, under a missing-at-random (MAR) assumption, to generate ten complete datasets. The multiply imputed datasets were combined for analysis using Rubin's combination rules [38]. The analysis results using the multiply imputed data were very similar to the main results, indicating that listwise deletion of the six incomplete observations did not likely introduce bias that would have affected our results.

DATA ANALYSIS

First, descriptive statistics were calculated across team role categories by unadjusted regression, logistic regression, or multinomial logistic regression (depending on type of data), and accounting for clustering by clinic site. The internal consistency reliability (Cronbach's alpha) of survey composite measures was estimated. Next, a variance components model of relational coordination was conducted. The intraclass correlation (ICC) for the RC composite measure was very low (ICC<0.01), indicating that the majority of the variance is explained within practice sites (e.g., between individual staff), rather than between practice sites. A likelihood ratio test comparing the variance components model to a model without a random intercept indicated that multilevel modeling is not necessary for this outcome measure (p=1.00). Therefore, the main analysis used linear regression with cluster-robust standard errors to examine the

unadjusted association between ease of EHR use and RC. Next, covariates were added to the regression to control for occupation, tenure, hours-per-week, age, race/ethnicity, ACO and practice size (Model 1). These covariates were included as they are potential confounders that could affect participants' perceptions of EHR or RC and are commonly used in other studies assessing these outcomes [22,23]. An additional linear regression model was estimated with an interaction term to determine whether the relationship between ease of EHR use and RC was stronger for non-PCPs compared to PCPs (Model 2). Data were analyzed using StataSE 13.0.

3.D. RESULTS

There was a wide distribution of age, years of membership on the team and race/ethnicity among primary care clinicians and staff (Table 1). Most of the respondents work full-time (78.8%) and most are female (83.1%). Ease of EHR use (α =0.90) was relatively high among respondents (mean= 3.5, SD=0.6) and differed by occupation, with nurses reporting the highest ease of EHR use (mean=3.7, SD=0.5) and PCPs reporting the lowest ease of EHR use (mean=3.3, SD=0.6) (Figure 3). RC (a =0.88) was high, but varied (mean=4.0, SD=0.7), particularly between individual respondents within sites. Figure 4 illustrates the variation between individual staff and clinician ratings of RC within clinic sites. RC was reported as lower between different roles than within the same role (Table 1).

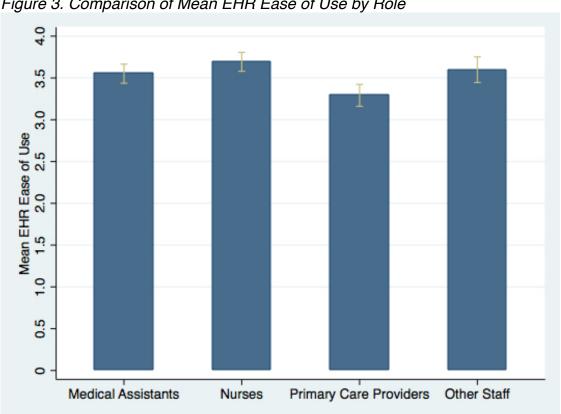


Figure 3. Comparison of Mean EHR Ease of Use by Role

Table 1. Descriptive statistics of individual variables by team role

tistics of individ	lual variables	by team role		
Primary Care	Nurses	Medical	Other	
				р
n (%)	n (%)	n (%)		
n=73	n=64	n=101	n=64	
6 (8.2%)	6 (9.4%)	18 (17.8%)	1 (1.6%)	0.14
7 (9.6%)	6 (9.4%)	17 (16.8%)	7 (10.9%)	
22 (30.1%)	16 (25.0%)	24 (23.8%)	20 (31.3%)	
17 (23.3%)	8 (12.5%)	14 (13.9%)	17 (26.6%)	
7 (9.6%)	18 (28.1%)	21 (20.8%)	14 (21.9%)	
14 (19.2%)	10 (15.6%)	7 (6.9%)	5 (7.8%)	
n=73	n=65	n=101	n=63	
46 (63.0%)	52 (80.0%)	89 (88.1%)	51 (81.0%)	0.08
27 (37.0%)	13 (20.0%)	12 (11.9%)	12 (19.0%)	
n=73	n=64	n=101	n=63	
16 (21.9%)	11 (17.2%)	47 (46.5%)	12 (19.0%)	0.02
17 (23.3%)	14 (21.9%)	27 (26.7%)	21 (33.3%)	
13 (17.8%)	21 (32.8%)	10 (9.9%)	12 (19.0%)	
27 (37.0%)	18 (28.1%)	17 (16.8%)	18 (28.6%)	
n=73	n=64	n=101	n=64	
30 (41.1%)	4 (6.3%)	6 (5.9%)	11 (17.2%)	<0.00
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n=73	n=64		n=64	
35 (47.9%)	19 (29.7%)		28 (43.8%)	<0.00
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23 (31.5%)	9 (14.1%)	6 (6.0%)	4 (6.3%)	
12 (16.4%)	4 (6.3%)	9 (9.0%)	4 (6.3%)	
Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	
4.0 (0.7)	4.03 (0.6)	4.07 (0.8)	4.0 (0.8)	0.67
3.9 (0.7)	3.9 (0.7)	4.0 (0.9)	4.0 (0.8)	0.86
4.2 (0.6)	4.3 (0.5)	4.2 (0.8)	4.1 (1.0)	0.37
3.3 (0.6)	3.7 (0.5)	3.6 (0.6)	3.6 (0.6)	0.04
	Primary Care Providers (n=73) n (%) n=73 6 (8.2%) 7 (9.6%) 22 (30.1%) 17 (23.3%) 7 (9.6%) 14 (19.2%) n=73 46 (63.0%) 27 (37.0%) 13 (17.8%) 27 (37.0%) 13 (17.8%) 27 (37.0%) n=73 30 (41.1%) 43 (58.9%) n=73 35 (47.9%) 2 (2.7%) 1 (1.4%) 23 (31.5%) 12 (16.4%) Mean (SD) 4.0 (0.7)	Primary Care Providers (n=73) n (%) n=73 n=64 6 (8.2%) 6 (9.4%) 7 (9.6%) 6 (9.4%) 17 (23.3%) 18 (28.1%) 14 (19.2%) 10 (15.6%) n=73 n=65 46 (63.0%) 52 (80.0%) 27 (37.0%) 13 (20.0%) 14 (21.9%) 13 (17.8%) 21 (32.8%) 27 (37.0%) 18 (28.1%) 14 (21.9%) 13 (17.8%) 21 (32.8%) 27 (37.0%) 18 (28.1%) 19 (29.7%) 10 (15.6%) 11 (17.2%) 12 (33.3%) 14 (21.9%) 13 (17.8%) 21 (32.8%) 22 (37.0%) 13 (20.0%) 14 (21.9%) 15 (23.4%) 17 (26.6%) 17 (26.6%) 4.0 (0.7) 4.03 (0.6) 4.2 (0.6) 4.3 (0.5)	Providers (n=73) Nurses (n=66) Assistants (n=101) n (%) n (%) n (%) n=73 n=64 n=101 6 (8.2%) 6 (9.4%) 18 (17.8%) 7 (9.6%) 6 (9.4%) 17 (16.8%) 22 (30.1%) 16 (25.0%) 24 (23.8%) 17 (23.3%) 8 (12.5%) 14 (13.9%) 7 (9.6%) 18 (28.1%) 21 (20.8%) 14 (19.2%) 10 (15.6%) 7 (6.9%) n=73 n=65 n=101 46 (63.0%) 52 (80.0%) 89 (88.1%) 27 (37.0%) 13 (20.0%) 12 (11.9%) n=73 n=64 n=101 16 (21.9%) 11 (17.2%) 47 (46.5%) 17 (23.3%) 14 (21.9%) 27 (26.7%) 13 (17.8%) 21 (32.8%) 10 (9.9%) 27 (37.0%) 18 (28.1%) 17 (16.8%) n=73 n=64 n=101 30 (41.1%) 4 (6.3%) 6 (5.9%) 43 (58.9%) 60 (93.8%) 95 (94.1%) n=73 n=64 n=1	Primary Care Providers (n=73) Nurses (n=66) Medical Assistants (n=101) Other Staff (n=64) n (%) n (%) n (%) n (%) n (%) n=73 n=64 n=101 n=64 (n=101) n=64 6 (8.2%) 6 (9.4%) 18 (17.8%) 1 (1.6%) 7 (10.9%) 22 (30.1%) 16 (25.0%) 24 (23.8%) 20 (31.3%) 17 (23.3%) 8 (12.5%) 14 (13.9%) 17 (26.6%) 7 (9.6%) 18 (28.1%) 21 (20.8%) 14 (21.9%) 14 (19.2%) 10 (15.6%) 7 (6.9%) 5 (7.8%) n=73 n=65 n=101 n=63 46 (63.0%) 52 (80.0%) 89 (88.1%) 51 (81.0%) 27 (37.0%) 13 (20.0%) 12 (11.9%) 12 (19.0%) n=73 n=64 n=101 n=63 16 (21.9%) 11 (17.2%) 47 (46.5%) 12 (19.0%) 17 (23.3%) 14 (21.9%) 27 (26.7%) 21 (33.3%) 13 (17.8%) 21 (32.8%) 10 (9.9%) 12 (19.0%) 27 (37.0%)

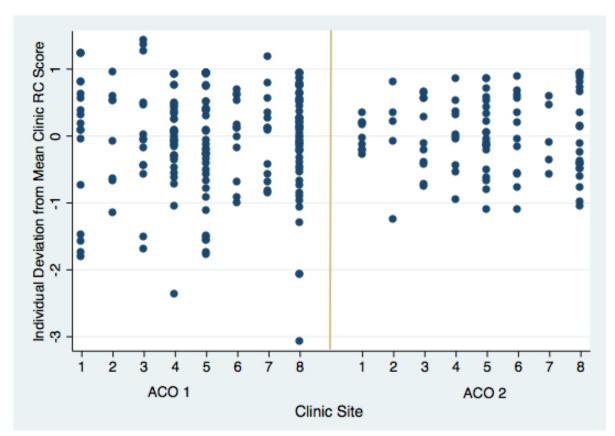


Figure 4. Variation of Relational Coordination within Clinic Sites

In unadjusted regression analyses, RC was 0.36 points higher for every one point increase in ease of EHR use (p=0.001) (data not shown). The effect was consistent when covariates were included in the model (Table 2, Model 1). As a sensitivity analysis, eight outliers with very low values of ease of EHR use and RC scores were removed, Model 1 was re-estimated, and the results did not change. Similarly, the sensitivity analysis using multiple imputation to address missing values for six observations (described in detail in the Data, Methods and Analyses section) produced very similar results.

In Model 2 (Table 2), the interaction term between EHR ease of use and non-PCPs was statistically significant (p=0.02), with non-PCPs experiencing a 0.40 point greater effect of EHR ease of use on RC, relative to PCPs and controlling for all covariates.

Table 2. Multivariate Regression Analyses of the Association of EHR Ease of Use and Relational Coordination among Primary Care Team Members

Relational Coordination among	Model 1 Model 2				
Variable	Estimate		Estimate		
	(SE) ^a	р	(SE) ^a	р	
EHR Ease of Use	0.36 (0.10)	0.002	0.06 (0.12)	0.63	
Role					
Nurse	ref		ref		
Medical assistant (MA)	0.20 (0.11)	0.10	0.23 (0.11)	0.06	
Primary care provider (PCP)	0.06 (0.12)	0.61	1.40 (0.55)	0.02	
Auxiliary clinical staff	-0.04 (0.18)	0.80	-0.04 (0.19)	0.85	
Receptionist	0.08 (0.10)	0.46	0.09 (0.10)	0.39	
Gender	, ,		,		
Female	ref		ref		
Male	0.17 (0.13)	0.19	0.24 (0.12)	0.06	
Hours	, ,		, ,		
Part time	ref		ref		
Full time	-0.16 (0.06)	0.01	-0.17 (0.06)	0.02	
Race/ethnicity	,				
White	ref		ref		
Hispanic/Latino	-0.08 (0.12)	0.50	-0.07 (0.12)	0.55	
Asian/Pacific Islander	0.02 (0.12)	0.89	0.03 (0.11)	0.77	
Black	0.12 (0.10)	0.25	0.12 (0.10)	0.22	
Other	-0.19 (0.18)	0.89	-0.14 (0.19)	0.46	
Age					
18-34 years old	ref		ref		
35-44 years old	0.01 (0.12)	0.91	0.03 (0.11)	0.78	
45-54 years old	0.19 (0.11)	0.12	0.22 (0.11)	0.06	
55+ years old	0.05 (0.10)	0.63	0.08 (0.09)	0.38	
Years in Team					
< 1 year	ref		ref		
1 year	0.06 (0.26)	0.83	0.02 (0.26)	0.93	
2-4 years	0.08 (0.21)	0.70	0.08 (0.21)	0.71	
5-9 years	0.02 (0.34)	0.96	0.01 (0.33)	0.99	
10-20 years	-0.02 (0.26)	0.93	-0.04 (0.26)	0.89	
>20 years	0.17 (0.27)	0.54	0.18 (0.06)	0.51	
ACO					
ACO 1	ref		ref		
ACO 2	-0.22 (0.11)	0.08	-0.21 (0.11)	0.07	
Practice Size (standardized)	0.05 (0.03)	0.15	0.05 (0.03)	0.12	
EHR Ease of Use x Non-PCP			0.40 (0.15)	0.02	
Constant	2.82 (0.35) < 0.000		2.44 (0.47)	<0.000	
R^2	0.13		0.14		

^a Cluster-robust standard errors, taking clustering within practices into account

3.E. Discussion

Our hypothesis that ease of EHR use facilitates improved relational coordination among primary care team members was supported ($H_{1.A}$). The results demonstrate that a one point increase in ease of EHR use is associated with a 0.36 point increase in RC. To put the size of this effect size into context, we can draw on earlier findings from a study that examined how RC is linked to outcomes of care. This study (using the same measure of RC) found that a 0.36 point increase in RC would be associated with a roughly 20% decrease in length of hospital stay after surgery [39], suggesting that the findings from our study have potentially meaningful clinical impact.

We also found evidence to support our second hypothesis $(H_{1.B})$, that the relationship between ease of EHR use and RC would be stronger for non-PCPs. These findings, coupled with earlier research, suggest that PCPs might avoid the use of technology [28], with less consideration for how easy the EHR is to use and therefore experience less RC benefits. In contrast, non-PCPs are of lower occupational status and their engagement with clinical information may enable them to more effectively cultivate RC with PCPs and other team members.

Further study is needed to understand whether ease of EHR use can be improved through interventions, such as better software or training, and whether different roles are more or less open to these interventions, given the different adoption barriers and facilitators that they experience [40,41]. Another interesting area for further exploration would be to understand the degree to which frequency of interactions with the EHR affects the relationship between ease of use and RC, as some roles interact more frequently with the EHR than others. We also found wide variation in reports of RC within practice sites (visible in Figure 4), highlighting the reality that not all members necessarily agree about how well their care team coordinates and communicates. This finding may indicate that relational coordination is difficult to improve through practice-level interventions because team members' baseline experiences of team coordination and communication vary widely. Future longitudinal studies could examine the degree to which RC can be improved over time through improved EHR functionality and EHR training.

The positive association between ease of EHR use and RC identifies a potential mechanism for how EHRs might improve outcomes of care. In spite of previous research that indicates that EHR implementation and use can improve health status, quality and patient outcomes [14–17], the mechanisms that contribute to these improvements have been unclear. Our results provide support for the hypothesis that EHRs contribute to better team communication and coordination, which in turn could lead to the observed improvements to care. Further research in this area is needed, both to further investigate this potential mechanism, as well as to determine whether care outcomes can be influenced through improvements to the EHR.

LIMITATIONS

The findings should be considered within the context of several limitations. First, given the cross-sectional nature of the study, we are unable to make any causal claims about the directionality of the relationship between ease of EHR use and relational coordination. However, we have developed a conceptual model connecting these factors that was informed by previous research. Longitudinal research could elucidate the directionality of the ease of use and RC relationship and assess alignment with our conceptual model. Second, the data are from providers and staff within two ACOs using one particular EHR system in the United States, who volunteered to participate in the study. The findings, therefore, may not be generalized to other ACOs in the United States or globally or to other health care organizations such as hospitals or post-acute facilities. Third, we were unable to collect information on the frequency with which the health care team members interacted with the EHR. Frequency of use could interact with ease of use in regard to promoting or inhibiting relational coordination. This is also an area for further research. Despite these limitations the findings add important knowledge of how ease of use of EHRs may promote better relational coordination among primary care team members, which, in turn, has been found to be associated with better outcomes of care.

CONCLUSION

Greater ease of EHR use is associated with better RC among primary care team members and the association is stronger for non-PCPs than for PCPs. Given the previous evidence linking RC to improved patient outcomes, better team coordination could be a potential mechanism through which EHRs can improve outcomes of care. Ensuring that clinicians and staff experience EHRs as easy to use for accessing and integrating data and for communicating with colleagues and patients could produce gains in efficiency and outcomes. Examining the degree to which improving EHR functionality and expanding EHR training can lead to improved team communication and subsequent improvements in patient outcomes, as well as testing approaches for doing so, is an important research priority.

4. Paper Two: "Worrying about me": IMPROVED DIABETES CARE MANAGEMENT THROUGH A TEXT-MESSAGE INTERVENTION FOR LOW-INCOME PATIENTS

4.A. BACKGROUND

An estimated 29.1 million people have diabetes in the United States [42] and over 2.3 million adults in California report being diagnosed [43]. As one of the most common chronic illnesses, diabetes leads to an estimated \$245 billion in economic costs annually and doubles the risk of death for those affected [42]. Further, the prevalence of diabetes among Latinos is almost double that of non-Latino whites, and rates of diabetes are also much higher among people with lower incomes and education [44]. In addition to higher rates of disease, evidence suggests that low-income patients also experience worse complications resulting from diabetes [45].

Text-messaging interventions for diabetic patients hold promise for improving patient satisfaction and intermediate health outcomes through better knowledge and self-management. In particular, there is evidence that text-messaging programs can improve glycated hemoglobin (HbA1c) levels in diabetic patients [46–48]. Following participation in these types of programs, patients have reported high levels of satisfaction and changes to their diet and other behaviors, which should lead to improved management of their diabetes [49–51].

However, studies have also found that patient engagement and the resulting health effects from these programs can be worse for non-white, lower literacy and older patient populations [21,52,53]. This fact, coupled with the higher prevalence of diabetes among Latino and low-income populations, highlights the importance of tailoring the interventions to Latino populations, and examining their impact on care.

4.B. CONCEPTUAL MODEL AND HYPOTHESES.

This study contributes to Aim 2 of the dissertation, by examining the impact of an HIT innovation (a diabetes text-messaging intervention) on patient outcomes. It also contributes to Aim 3, by examining how an innovation's fit into users' lives influences the use of the innovation (please see the Conceptual Model in Figure 1).

Earlier studies have found that diabetes text-messaging programs can provide patients with cues to action and information [21,51], and can improve some clinical indicators for diabetic patients [46–48]. We hypothesize that this intervention, tailored for mostly low-income, Latino patients, can also make an impact on these indicators:

H_{2.A}: Patients receiving text messages experience greater improvements to HbA1c, body mass index (BMI) and blood pressure (BP) than patients not receiving them.

We also hypothesize that more engaged patients will have better results in the program, given earlier findings that various forms of patient activation and engagement can lead to better outcomes [54]:

 $H_{2.B}$: Higher engagement with the text-messaging program is associated with greater improvements to HbA1c.

4.C. Data, Methods and Analyses

This study employed a mixed-methods quasi-experimental design to examine the impact of a pilot three-month short message service (SMS) intervention for adult patients with diabetes, which sent automated, interactive text messages focused on diabetes self-management. Quantitative data included program and clinical indicators and qualitative data included semi-structured interviews of patient participants and clinic staff.

SETTING

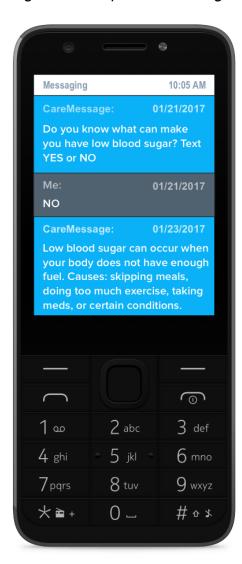
Participants (n=50) were Spanish (n=33) or English (n=17) speaking adult patients with diabetes attending two sites of an FQHC in Los Angeles, from September 2015 to February 2016. From October through December 2015, enrollment in the pilot intervention was offered to all adult patients with Type II diabetes with an HbA1c value above 8.5% that presented for an appointment at either of the two participating ChapCare clinics. The HbA1c cutoff was suggested by clinical staff, as they felt these patients might benefit most from the intervention. However, in January and February 2016, due to limited enrollment, patient eligibility was expanded to include all adult patients with Type II diabetes who presented for an appointment, until intervention group enrollment reached 50 participants. Front desk staff identified eligible patients with diabetes from a pre-printed list when they checked in for their appointment. The patient was then referred to an AmeriCorps volunteer, who explained the textmessaging program and offered to help them enroll. In order to enroll, patients had to have their own mobile phone with text messaging capabilities. Out of 65 patients who were approached, 50 (77%) enrolled in the text-messaging program. For the 15 patients who declined to enroll in the intervention, the following reasons were given: no mobile phone (27%), not comfortable with text messaging (20%), not interested in receiving health information via text (40%), and already comfortable with managing their diabetes (13%). No compensation was given to participants for participating in the textmessaging program. The sample size of 50 intervention participants and the follow-up period was selected based on earlier studies of text-messaging programs for patients with diabetes that examined HbA1c, BMI and BP as outcomes [46], as well as to limit disruption to the pilot clinics.

A comparison group (n=160) of adult patients with Type II diabetes was constructed through chart review. All patients with Type II diabetes that attended the clinics during the study period, but who were unexposed to the intervention, and who attended a follow-up visit before August 2017 were eligible for inclusion in the comparison group.

INTERVENTION

The text-messaging intervention was designed for adults with diabetes using a proprietary platform from CareMessage, a non-profit organization that designs mobile health tools. The 12-week intervention consisted of 3-4 educational text messages per

Figure 5. Sample text message



week in either Spanish or English, depending on the participant's preference. Most of the messages were bidirectional: 31% were multiple choice and 24% asked yes/no or true/false questions, similar to the example message in Figure 1. If a participant answered incorrectly, they would receive a gentle response with the correct answer. If the participant answered correctly, they received a response affirming that their answer was correct. The remaining 45% of messages were unidirectional (e.g., a health tip or reminder).

The program was tailored for low-income patients, and the Spanish-language version was further tailored to Latino patients. The Spanish program was not a direct translation of the English program, but instead was developed from the beginning of the program's conceptual design stages in Spanish. The development of both programs was informed by observing patients in one-on-one and education sessions in community clinics. In addition, focus groups were held with patients with diabetes after they received the messages as part of a 3month feasibility study in San Francisco in 2014. Following this formative research, the messages were tailored to address participants' concerns and culture. For example, Spanish-speaking patients more often discussed how family and traditional foods sometimes made it difficult to change their behavior, so the Spanish messages were adapted to address this topic and to include foods that may be prevalent in Latino populations. Some messages were also

adapted to incorporate income level into recommendations for exercise and disease management. For example, patients expressed concerns about being able to afford test strips and so, with guidance from a physician, the message was adapted to state they could potentially skip a day so they did not run out of test strips as quickly.

The messages address ten overall themes: Understanding Diabetes, Medication Adherence, Nutrition, Exercise, Mental Health, Resources, Managing Blood Sugar Levels, ABCs (A1C, Blood Pressure, Cholesterol), Foot Care and Annual Exams (Eye,

Kidney, Dental). The messages were developed using the American Diabetes Association guidelines for disease self-management, along with input from the health care providers at implementing clinics and oversight of the staff physician at CareMessage. The average grade reading level of the unique messages in the program is 6.2, according to the Flesch-Kincaid Grade Level Test [55].

QUANTITATIVE PROGRAM DATA

COLLECTION

At baseline, intervention participants answered five questions about diabetes-related emotional distress (PAID-5) in-person, right after registering for the text-messaging program [16]. Throughout the 12-week program, the text-messaging platform recorded patient response rates (calculated by dividing the number of valid responses from the patient by the total number of questions requiring a response, multiplied by 100%). At the end of the program, the follow-up PAID-5 questions and a user satisfaction survey were administered via text message. Demographic and clinical data were extracted by chart review from Chapcare's electronic health record at the conclusion of the study. These data included pre- and post-intervention measures of HbA1c, body mass index (BMI) and blood pressure (BP). Post measurements were taken from intervention group participants' follow-up visits within one year from the study start date. These data from charts were merged with the program data for the intervention group and de-identified before being shared with the research team. A de-identified dataset with the same demographic and clinical measures for the comparison group was also provided to the research team, and the two datasets were integrated for analyses.

ANALYSIS

First, descriptive statistics were examined for all study variables. This included mean, median and standard deviation for all continuous variables and frequencies, proportions and confidence intervals for all categorical variables. Baseline characteristics were compared between the intervention and comparison groups and between patients with missing and complete datasets, using chi-squared tests for categorical variables and two-sample t-tests with unequal variances for continuous variables. The analysis was then restricted to patients with complete baseline and follow-up measures of the dependent variables (HbA1c, BP and BMI). This resulted in listwise deletion of 25 observations (12 from intervention group and 13 from comparison group). Next, propensity score weights were calculated using gender, age, race/ethnicity and baseline HbA1c. A further 8 observations (all from the comparison group) were dropped because of missing data on race/ethnicity, which is needed to calculate the propensity score. Changes in clinical outcomes were compared between groups using individual fixed effects linear regression models with an ordinary least squares estimator. A sensitivity analysis was run with multiple imputation to handle missing data on the independent variable of race/ethnicity for 8 observations (all from the comparison group). The chained equations method was used, under the missing-at-random (MAR) assumption, to generate ten imputed datasets. Propensity score weighting was then conducted for each of the ten imputed datasets and the results were combined in the subsequent analysis using Rubin's combination rules [38]. Next, the individual fixed effects linear regression models were run and results were compared to the main analysis.

The final set of analyses were conducted on the data from the intervention group only. To examine associations between clinical indicators by time-invariant characteristics among intervention participants, population-averaged linear models were estimated with generalized estimating equations. These models facilitated the examination of differential effects of patient engagement on improvements in clinical outcomes among the intervention participants.

An additional post-hoc regression model was run to examine any associations between satisfaction with the program and personal characteristics, including patient engagement, among the intervention participants.

All models were run with cluster robust standard errors to correct for heteroscedasticity, and were clustered by patient identifier (to account for the fact that pre/post observations were clustered under each patient).

QUALITATIVE PROGRAM DATA

COLLECTION

All intervention participants were invited to complete a phone interview to provide feedback on the program and a total of 11 (22%) of the participants agreed to be interviewed in their primary language, either Spanish (n=6) or English (n=5). In addition, all 8 staff members participating in the implementation of the program were invited to participate in a phone interview to provide feedback on the program implementation, and all agreed to participate.

Verbal consent was obtained from all interview participants and they all received a gift card as a token of appreciation for their time. Structured interviews lasted up to 45 minutes and were recorded with the participants' permission. Interviews were conducted via phone by a researcher in either English or Spanish, depending on the participants' preference. The structured question guide, with probes, was used to facilitate discussion. The interview guide for participants asked questions aimed at understanding their experience with the program, such as, "Describe your first encounter with the text messages. What did you think?" The staff interview guide focused on implementation of the program and asked questions such as, "How easy or difficult has it been to incorporate CareMessage into your workflow?" The full interview guides in English are available in Appendix I. Ethical approval for this study was obtained from the University of California, Berkeley Office for the Protection of Human Subjects (Protocol ID 2015-11-8120).

ANALYSIS

Interview recordings were professionally transcribed and, when applicable, were translated from Spanish to English by a bilingual member of the research team. A preliminary codebook was developed by one researcher, drawing upon the existing literature on text messages for health, as well as the Health Belief Model [56] and

related theory. Coding of all patient interviews was then performed by two researchers, using ATLAS.ti software. The coding process was iterative and the codebook grew throughout the analysis as additional codes were added, based on the data. If a quote emerged that did not fit the preliminary codebook, a new relevant code was generated and discussed with the other researcher. For example, one patient explained that they thought the messages were automatically generated, but sounded like they came from a person. Preliminary codes only included "automatically generated" or "from a person," so this data point generated a new code to accommodate this finding. Coding of staff interviews was performed by one researcher. After coding was complete, common themes were identified. New concepts and themes were discussed among the research team until the codebook was finalized and all themes had been identified.

4.D. RESULTS

QUANTITATIVE RESULTS

Though demographic (Table 3) characteristics of patients in both the intervention and comparison groups were mostly comparable at baseline, there were some non-statistically significant differences between groups. There was a higher proportion of English speakers and females in the comparison group than the intervention group, however the differences were not statistically significant. Among both groups, an average of 56% of patients were primarily Spanish-speaking. In addition, an average of 69% of participants were of Hispanic or Latino ethnicity. Participants ranged widely in age and there were more female participants (62%) than males (38%) in both groups. Propensity score weighting resolves imbalances of un-weighted analyses and helped to further reduce overall mean bias on these observable characteristics by 5.2% and overall median bias by 7.9%.

Most participants (n=43, 86%) in the intervention group responded to at least one question with a valid answer (i.e., one of the multiple choice options provided). Participants received an average of 31.8 (interquartile range 28 to 35) questions requiring an answer over the course of the program. The average number of days that participants were enrolled in the program was 79.5 (SD=11.4), with only three participants leaving the program before 80 days. No reason was given when participants withdrew – they only had to text the word "STOP" or to tell the clinic staff member who enrolled them that they wished to stop receiving messages. The overall mean response rate was 57.1% (calculated by dividing the number of valid responses from the patient by the total number of questions requiring a response, multiplied by 100%), but it varied widely (SD=33.2%).

Table 3. Baseline characteristics of participants

Table 6. Dase		justed	Befor	e PSW	After PSW		
	Interventio	justou		Beloi	<u> </u>	Alterion	
Variable	n Frequency (n=50)	Comparison Frequency (n=160)	p ^a	Int Mean (n=38)	Comp Mean (n=140)	Comp Mean (n=140)	p ^b
Clinic							
Site 1	18 (36%)	21 (13%)	<0.00	0.37	0.12	0.12	0.00
Site 2	32 (64%)	139 (87%)		-	-	-	
Age Group							
18-44	12 (24%)	28 (18%)	0.53	0.29	0.17	0.19	0.19
45-54	16 (32%)	50 (31%)		0.32	0.31	0.32	1.00
55-64	22 (44%)	82 (51%)		0.39	0.52	0.49	0.29
Gender							
Male	23 (46%)	56 (35%)	0.16	0.42	0.35	0.38	0.67
Female	27 (54%)	104 (65%)		-	-	-	
Primary Lang	juage						
English	17 (34%)	76 (48%)	0.09	0.26	0.45	0.42	0.08
Spanish	33 (66%)	84 (53%)		-	-	-	
Race/Ethnicit	ty						
Hispanic or Latino	37 (74%)	108 (68%)	0.43	0.79	0.69	0.74	0.50
White	5 (10%)	18 (11%)		0.05	0.12	0.10	0.32
Other	8 (16%)	26 (16%)		0.16	0.16	0.16	1.00
Missing	0 (0%)	8 (5%)		-	-	-	
Smoking Stat	tus						
Current non- smoker	48 (96%)	147 (92%)	0.53	0.03	0.07	0.07	0.34
Current smoker	2 (4%)	13 (8%)		-	-	-	

a p-values are for chi-squared tests or Fisher's exact test where cell frequencies are less than 5

Table 4 outlines self-reported health indicators from participants in the intervention group, including the levels of diabetes-related distress (PAID-5) that participants were experiencing at baseline and follow-up (after the text-messaging program). Response rates to the follow-up PAID-5 text-message survey were relatively low, ranging from 12-54% (depending on the question), and therefore may not be representative of all participants' experiences. Most participants reported being in fair or poor health (78%) at baseline. In addition, most participants indicated some problems with feeling scared about living with diabetes (54%), feeling depressed about living with diabetes (52%), worrying about the future (74%) and other measures of diabetes-related distress at baseline.

b p-values are for t-tests

Table 4. Self-reported health indicators of intervention group

Table 4. Self-reported health indicators of intervention group								
Indicators	Baseline	Follow-Up						
	n (%)	n (%)						
Overall Health	(n=49)							
Poor	6 (12%)							
Fair	33 (67%)							
Good	8 (16%)							
Very Good	2 (4%)							
Excellent	0 (0%)							
Feeling scared when I think about living with diabetes.	(n=50)	(n=27)						
Not a problem/ minor problem	33 (46%)	12 (44%)						
Moderate/ somewhat serious/ serious problem	27 (54%)	15 (56%)						
Feeling depressed when I think about living with	(n=50)	(n=15)						
diabetes.								
Not a problem/ minor problem	24 (48%)	7 (47%)						
Moderate/ somewhat serious/ serious problem	26 (52%)	8 (53%)						
Worrying about the future and possible serious	(n=50)	(n=11)						
complications.								
Not a problem/ minor problem	13 (26%)	3 (27%)						
Moderate/ somewhat serious/ serious problem	37 (74%)	8 (73%)						
Diabetes takes up too much of my mental and physical	(n=50)	(n=11)						
energy.								
Not a problem/ minor problem	19 (38%)	4 (36%)						
Moderate/ somewhat serious/ serious problem	31 (62%)	7 (64%)						
Coping with complications of diabetes.	(n=50)	(n=15)						
Not a problem/ minor problem	19 (38%)	4 (27%)						
Moderate/ somewhat serious/ serious problem	31 (62%)	11 (73%)						
In the past week, how many times have you had a low	(n=50)	(n=14)						
blood sugar reaction (sweating, weakness, anxiety,								
trembling, hunger, or headache)?								
0	20 (40%)	4 (29%)						
1-3	26 (52%)	8 (57%)						
4 or more	4 (8%)	2 (14%)						

Following propensity score weighting, clinical indicators of patients (Table 5) in the intervention and comparison groups were similar at baseline. The intervention group had slightly higher HbA1c at baseline than the comparison group (8.7 vs. 8.0) but the difference was not statistically significant (p=0.07).

To check for systematic differences between patients who were excluded due to missing outcome data (n=25), their baseline demographics and clinical indicators were compared to the other patients in their respective group, using chi-squared tests for categorical data and t-tests for continuous data (results not shown in table). No statistically significant differences in age, gender, race/ethnicity, smoking status, baseline HbA1c, baseline diastolic BP or baseline BMI were detected. However, excluded patients were statistically significantly more likely to speak English than those

remaining in both the intervention (58% vs. 26%, p=0.04) and comparison groups (77% vs. 45%, p=0.03). In addition, patients excluded from the comparison group had statistically significantly higher baseline systolic blood pressure than those remaining in the comparison group (144.2 vs. 125.8, p=0.01).

Table 5. Propensity score weighted diabetes clinical indicators at baseline and follow-up

	Baseline			Follow-Up			Mean D	ifference
	Int	Comp		Int	Comp		Int	Comp
	(n=38)	(n=140)		(n=38)	(n=140)		(n=38)	(n=140)
Variable	Mean	Mean	p ^a	Mean	Mean	p ^a		
HbA1c	8.7	8.0	0.07	8.4	8.3	0.63	-0.3	0.3
Systolic BP	124.2	124.6	0.88	126.6	127.1	0.89	2.4	2.5
Diastolic BP	77.1	77.3	0.91	77.5	75.4	0.23	0.4	-1.9
BMI	32.7	33.5	0.59	32.4	33.3	0.53	-0.3	-0.2

a p-values are for two-tailed, two-sample t-tests

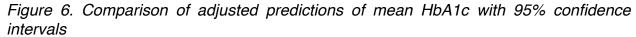
Individual fixed effects linear regression models (Table 6) on the propensity score weighted data indicate that the intervention group had an average estimated reduction in HbA1c of 0.40 points at follow-up, relative to the comparison group (p=0.06). This comparison is illustrated graphically in Figure 6. No significant differential reductions were found for BP or BMI. The sensitivity analysis, using multiple imputation for missing independent variables followed by propensity score weighting, produced similar results to the main analysis (results not shown in table). However, baseline balance between groups was not achieved and bias increased on some variables following propensity score weighting of the multiply imputed data.

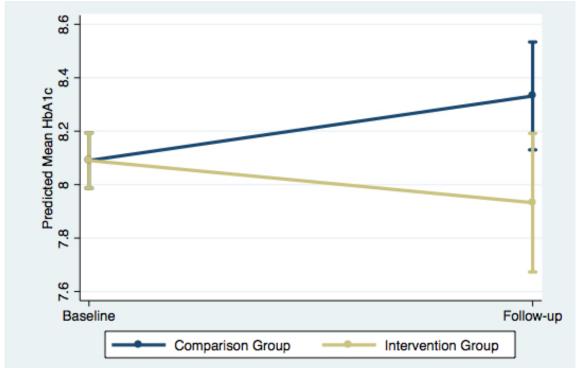
Table 6. Comparison of change in clinical indicators from baseline to follow-up between

intervention and comparison groups

	HbA1c		Systolic BP		Diastolic BP			ВМІ				
	(n=185)		(n=185)			(n=185)		(1	n=185)			
β	Est	SE a	р	Est	SE a	р	Est	SE a	р	Est	SE ^a	р
Constant	8.09	0.05	0.00	124.93	0.84	0.00	76.86	0.63	0.00	32.96	0.08	0.00
Time	0.24	0.13	0.06	2.43	1.29	0.06	-1.89	0.98	0.06	-0.13	0.15	0.39
Int Group x Time	-0.40	0.21	0.06	-1.02	3.38	0.76	3.17	2.53	0.21	-0.13	0.33	0.70
$\sqrt{\theta}$	0.95			3.37			2.86			1.08		

^a Cluster-robust standard errors





Population averaged linear models (Table 7) found that among the intervention participants, higher engagement (modeled through response rate to questions requiring a response) was associated with greater reductions in HbA1c, controlling for clinic site, age, gender, primary language and race. In particular, highly-engaged patients (defined as having a response rate ≥ the median of 64.5%), experienced a mean 2.23 point reduction in HbA1c relative to less-engaged patients (response rate < 64.5%). controlling for demographics (p<0.001) (Model A). To illustrate the relationship between patient engagement and HbA1c, Figure 7 shows the changes in unadjusted mean HbA1c values between highly-engaged and less-engaged patients. As a sensitivity test. a population averaged linear model was also run with a continuous, standardized response rate variable (Model B). This model found that an increase of one standard deviation in response rate over the mean was associated with a mean 0.93 point reduction in HbA1c, controlling for demographics (p=0.001), again supporting the finding higher engagement was associated with greater reductions in HbA1c. Subsequent sensitivity analyses were also run using the lower and upper quartiles of engagement as cutoff points. When defining highly-engaged patients as those with a response rate above 32% (the bottom quartile), no statistically significant change in HbA1c was found between highly-engaged and less-engaged patients (results not shown in table). However, when defining highly-engaged patients as those with a response rate above 86% (the top quartile), highly-engaged patients experienced a mean 2.0 point reduction in HbA1c relative to less-engaged patients (p=0.001, results not shown in table).

Table 7. Associations between patient characteristics and HbA1c

	ons between patient charact ariable	Estimate	SE a	р
	orical Response Rate Variable			
Clinic				
	ite 1	0.25	0.50	0.617
	ite 2	ref	ref	ref
Age		101	10.	101
	ge 18-44	ref	ref	ref
	ge 45-54	1.38	0.57	0.02
	ge 55-64	-0.45	0.49	0.36
Gender	<u></u>			
F	emale	ref	ref	ref
	1ale	-1.72	0.55	0.002
Primary language				
	panish	ref	ref	ref
	nglish	2.05	0.73	0.005
Race/ethnicity				
	/hite	ref	ref	ref
Н	lispanic/Latino	-1.14	1.79	0.52
	Other .	-2.43	1.65	0.14
Engagement with pr	ogram			
L	ow (response rate <64.5%)	ref	ref	ref
	ligh (response rate ≥ 64.5%)	-2.23	0.56	0.000
Constant	,	10.72	1.80	0.000
Model B with Contin	uous, Standardized Response	Rate Variable		
Clinic	·			
S	ite 1	0.22	0.51	0.66
S	ite 2	ref	ref	ref
Age				
A	ge 18-44	ref	ref	ref
A	ge 45-54	1.21	0.64	0.06
A	ge 55-64	-0.91	0.53	0.09
Gender				
F	emale	ref	ref	ref
N	lale	-1.27	0.47	0.007
Primary language				
S	panish	ref	ref	ref
E	nglish	1.72	0.62	0.006
Race/ethnicity				
V	/hite	ref	ref	ref
Н	ispanic/Latino	-1.64	1.74	0.35
C	other	-2.68	1.63	0.10
Engagement with pr	ogram			
S	tandardized response rate	-0.93	0.28	0.001
Constant		10.14	1.75	0.000

^a Cluster-robust standard errors

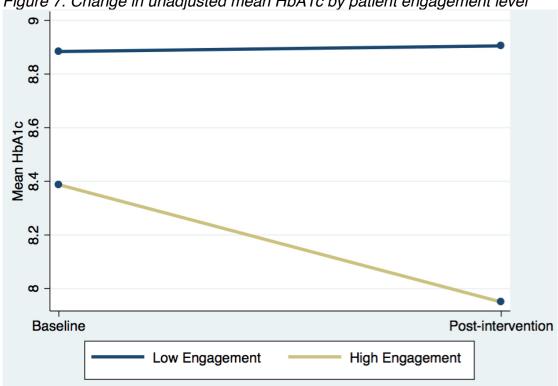


Figure 7. Change in unadjusted mean HbA1c by patient engagement level

Note: In Figure 4, "High Engagement" is defined as having a response rate above or equal to the median of 64.5%

Among intervention participants, being male was associated with a statistically significant decrease in HbA1c relative to female participants, controlling for other demographic characteristics and patient engagement rate. In addition, speaking English as a primary language was associated with a statistically significant increase in HbA1c relative to primarily Spanish-speaking participants, controlling for other demographics and response rate.

Table 8 presents findings on patient satisfaction with the text-messaging program. The overall response rate was 50%, due to substantial drop-off in responses as the textmessage survey progressed to question 5. Among those who responded, satisfaction with the program was high: 78% of respondents felt that they learned useful information from the text messages and 89% felt that the text messages helped them to better manage their diabetes. A post-hoc regression model with cluster-robust standard errors was run to examine any associations between satisfaction with the program and personal characteristics, including patient engagement, among the intervention participants, but no statistically significant associations were found.

Table 8. Intervention group satisfaction with text-messaging program

Statements and Responses	n (%)
I learn useful information from the text messages.	(n=36)
Strongly agree/ agree	28 (56%)
Not sure	1 (2%)
Disagree/ strongly disagree	7 (14%)
I find the text messages annoying.	(n=29)
Strongly agree/ agree	6 (12%)
Not sure	4 (8%)
Disagree/ strongly disagree	19 (38%)
The text messages help me better manage my diabetes.	(n=28)
Strongly agree/ agree	25 (50%)
Not sure	1 (2%)
Disagree/ strongly disagree	2 (4%)
The text messages are clear and easy to understand.	(n=27)
Strongly agree/ agree	25 (50%)
Not sure	2 (4%)
Disagree/ strongly disagree	0 (0%)
I would recommend the texting program to a friend with diabetes.	(n=25)
Strongly agree/ agree	23 (46%)
Not sure	2 (4%)
Disagree/ strongly disagree	0 (0%)

QUALITATIVE RESULTS

Most participants (9 of 11) in the text-messaging program felt that the messages were positive. One participant stated that the program was "positive, because it was telling us... what we have to do in our daily lives, and how a diabetic can't be hopeless because it is a disease that can be controlled." In addition, several participants explained that the program made them feel supported. This theme was especially common among Spanish-speaking participants (4 of 6). For example, one participant said, "The messages were helping me because these messages were as [if] a person was speaking to me, telling me what I should do, as if that message was from someone that was thinking of me and was telling me that I have to do this for my wellbeing." Another said, "It felt good... because I knew that someone was worrying about my health."

In addition to emotional support, all participants (n=11) cited learning new information and setting new goals as a result of the program. Some participants felt the messages provided more detailed information than they get in medical appointments, and the text message format allowed them to refer back to the information. One participant said, "It's just that the messages explains things... better. Because when I go to an appointment and ask, then the doctors speak in English and if the girls that they provide interpret for you, [they] don't fully explain the conversation that you would have with a doctor." Most participants also stated that they already knew some of the information (10/11), but

many also struggled to recall specific content from the messages (7/11), suggesting that knowledge retention from the messages may be low.

Many felt that the messages provided helpful reminders (7/11) to check their blood sugar and/or to take their medication. All participants stated that the program led them to set new goals, to contemplate behavior change or to change their behavior relating to their diet, medication, and/or exercise. For example, one participant reported taking their medication more regularly after the messages: "[The messages] said that you're supposed to take [medication] twice a day at about the same time, and so we instituted a little thing where I have the little days of the week [on a]... holder that says, "Noon, Morning, Evening, Night," and we put the pills in there so I take them on the right times... I'm doing it after the messages."

Some participants offered feedback to improve the program. Two participants felt that the times the messages were sent were not always convenient for them. Most participants wanted more messages, and two felt it would be helpful to tailor the program to participants' baseline diabetes self-management knowledge levels. Additional quotes from the interviews with participants, organized by theme, are provided in Appendix II for interested readers.

Staff who implemented the program identified key facilitators and barriers to the program's success. The major facilitator cited by staff was that this text-messaging program allowed them to provide health education to patients using relatively few resources, making implementation more feasible for a resource-limited FQHC. However, they also identified some barriers to program success, particularly for scaleup beyond an initial pilot. Temporary staff (AmeriCorps volunteers) were used to enroll participants for this pilot, which minimized the program's disruption to the clinic workflow, but also limited integration into routine clinical practice. Interviewees suggested that no staff outside of those directly involved in management or enrollment (i.e., none of the clinical providers) knew about the program. In addition, there was no systematic monitoring of patient responses, in part because the text-messaging platform was not integrated with the electronic medical record system in the clinic. Similarly, identifying patients with diabetes eligible for the intervention was a challenge, requiring printing of lists of eligible patients, cross-checking with the clinic schedule, and identification of patients when they presented for appointments. Much of this was done by volunteers, but would likely be burdensome for existing staff if the program were to be scaled up to more patients with diabetes in the future.

Finally, staff also provided some feedback to improve the program in the future. Two staff members suggested that including more clinical staff could improve the program. One suggested that having clinicians mention the text-messages during visits could give the program more "standing" with patients. Staff also suggested hosting an in-person meeting at the start of the program to ensure all involved staff understand the project and their roles.

Overall, despite some of implementation barriers cited by staff, most felt the program worked well and had the potential to help patients with diabetes; some felt the program provided an easier-to-understand and more accessible form of health education than the brochures or written materials usually provided by FQHCs.

4.E. DISCUSSION

PRINCIPAL RESULTS AND COMPARISON WITH PRIOR FINDINGS

A diabetes text-messaging program provided instrumental and emotional support for participants and was associated with clinically meaningful improvements in HbA1c. These findings were similar to earlier studies of text messages for diabetes in broader populations, which also found evidence of reductions in HbA1c [46-48]. A recent randomized-controlled trial of a text-messaging program in a similar low-income, Latino, diabetic population also found evidence of improved glycemic control following participation, though the program also collected patient-reported glucose levels via text message, unlike the CareMessage program [57]. We also examined BMI and blood pressure, but no significant improvements were observed, in contrast to our first hypothesis. This could be due to the relatively short duration of the study and/or the intervention's emphasis on glycemic control for diabetes, rather than weight loss or blood pressure specifically. Our findings suggest that text-messaging interventions for diabetes management might be effective among patients who are low-income and Latino, if adapted appropriately. This finding is especially relevant given that earlier studies have found these groups can have lower engagement with text-messaging programs and smaller health effects than other patient groups. We also found evidence in support of our second hypothesis that patients who are more engaged with the program might experience greater improvements to HbA1c, suggesting encouraging patient participation could lead to greater health effects more broadly.

These findings indicate that diabetes-management text-messaging programs have potential for enabling goal setting and behavior change, ultimately producing a long-term, meaningful impact on health. A meta-analysis of five earlier randomized controlled trials reported that a mean 0.9 point reduction in HbA1c significantly reduced events of non-fatal myocardial infarction (MI) by 17% and events of coronary heart disease by 15% [58]. Therefore, applying these estimates to our findings, a mean improvement of 0.4 points (from the individual fixed effects models, Table 6) could result in up to an 8% reduction in non-fatal MI and a 7% reduction in coronary heart disease events. Among highly engaged participants, these effects could be even larger, where a mean reduction of 2.2 points in HbA1c (from population-averaged linear models, Table 7) could result in up to a 40.8% reduction in non-fatal MI and a 36% reduction in coronary heart disease events. The application of these earlier findings suggests that the text-messaging program has the potential to result in clinically meaningful effects for people with diabetes.

Qualitative analyses highlight the potential mechanisms that could lead to improved intermediate outcomes for people with diabetes participating in the program. Many

participants cited receiving both instrumental and emotional support from the program. First, participants described how the messages reminded them to take their medication or to check their blood sugar. These descriptions evoked "cues to action" as described by the Health Belief Model, and as found by other studies of similar interventions [21]. Though the constructs of this model were not assessed directly in this study, the CareMessage text-messaging platform was informed by the Health Belief Model and patient interviews explored these concepts. Participants also described feeling that someone was thinking or worrying about them, suggesting that they received emotional support from reading and responding to the messages, particularly among Spanish-speaking participants. These results aligned with earlier findings that text messages for diabetes management were able to produce greater positive and optimistic feelings in patients, as well as reducing denial of diabetes among patients participating in these types of programs [51]. Similar findings have also been observed among Spanish-speakers in a text-messaging intervention for depression [59].

The interviews of patients and staff identified some facilitators and barriers to the implementation of this program. First, the ease of reaching many patients at once with diabetes self-management information made this program significantly more feasible for a resource-limited FQHC. However, the clinic experienced challenges of integrating the program into their routine care processes. Recommendations to facilitate implementation and improve patient experiences include adapting the messages to baseline patient knowledge and linking in-person clinical care with the text-messaging program. These types of improvements could have positive effects on both patients' satisfaction with the program, as well as on patient engagement with the program, which could lead to improved self-management and outcomes of care, but they would also require changes in provider behavior and clinical workflow.

LIMITATIONS

This study has important limitations. First, because the text messages were implemented as a pilot program to assess feasibility and potential impact, the analytic sample is modest. In addition, operational constraints were not conducive to randomizing patients to the intervention and comparison groups, which could have improved causal inference. As a result of the lack of randomization and the potential for the Hawthorne effect to have influenced the intervention group, we cannot conclusively determine that the intervention caused any observed differences between the groups. However, we were able to use propensity score weighting to balance confounding factors between groups, reducing concerns about selection bias. A second limitation of this study is missing data. Despite the use of a long observation period following the intervention (1 year), about 22% of the intervention group did not attend a follow-up visit, leading to missing outcome data. However, when comparing the baseline HbA1c of patients who came for a follow-up visit to those who did not, we found no evidence of a statistically significant difference in HbA1c among non-returning patients, reducing concerns about bias. A third limitation to this study is that the qualitative interviews were only conducted with patients who volunteered to participate, and therefore might not be representative of all patients' experiences with the program. Interviewed patients,

however, provided critical feedback to improve the program. Another important limitation is that the follow-up patient satisfaction questions and diabetes-related distress (PAID-5) had low rates of response, likely due to the delivery via text message late in the program and the high number of questions delivered. In the future, response rates could potentially be improved by delivering this survey in-person at a visit to the clinic (as was done with the PAID-5 measure at baseline) or by incentivizing completion. Finally, we do not have data on the proportion of messages actually received and read by participants and there is potential that mobile phone plans or changes to phone numbers could have affected receipt of the messages. However, 100% of the messages were reported as delivered by the text-messaging platform and 86% of participants responded to at least one question with a valid answer, suggesting that if there were patients who did not receive the messages, it was not a widespread issue.

Conclusion

This study contributes to our understanding of the effectiveness of diabetes management text-messaging programs among patients who have low income and are mostly Latino. We found evidence that glycemic control of adult patients of FQHCs with diabetes might be improved through participating in a text-messaging program for diabetes self-management. The findings also suggest that patient engagement with the program could contribute to improved self-management and clinical outcomes. By supporting patients with education, reminders and positive messages during the course of their daily life, diabetes management text-messaging programs have potential to increase and sustain healthy behaviors and improve clinical outcomes among low-income patients with diabetes.

5. Paper Three: Promoting antenatal care attendance through a text-message intervention in Samoa

5.A. BACKGROUND

Samoa has some promising indicators relating to maternal health, including relatively high rates of deliveries in medical facilities (82%) and high rates of women receiving some antenatal care (93%) [60]. However, only 73% of women receive four or more antenatal visits, as recommended by the World Health Organization (WHO), and only 12% register for care in the first trimester [60]. In order to improve both maternal and infant health, rates of early, regular antenatal care (ANC) attendance should be improved. This could help to lower Samoa's maternal mortality ratio (an estimated 100 maternal deaths per 100,000 live births in 2010) and infant mortality rate (an estimated 16 deaths under age one per 1,000 live births in 2011) [61]. The Ministry of Health's Antenatal Care Survey in 2012 found that many mothers did not think they needed to attend ANC because they felt their baby was safe and in good health (23%) [62]. These results indicate that the importance of ANC must be emphasized to pregnant women to ensure they attend ANC, even if they feel healthy.

Text message reminder and education interventions for pregnant women have been implemented widely around the world, but relatively few have been systematically evaluated to determine their effects on maternal care-seeking behavior or health outcomes. Among the studies that have examined outcome measures, there is some evidence that text-messaging programs can improve health care utilization, knowledge and satisfaction with care. For example, Lund, et al. conducted a pragmatic randomized controlled trial in Zanzibar and found that women receiving unidirectional text messages and mobile phone vouchers to communicate with their health provider had double the odds of attending four or more antenatal visits, relative to the control group [63]. Similarly, a study in Malawi found increased antenatal care attendance among women who received an SMS intervention and access to a case management hotline [64]. Other studies have also found SMS interventions to increase mothers' knowledge, preparedness and satisfaction with antenatal care [65,66].

Samoa provides a promising context in which to study text messages for maternal health. An estimated 90% of the population of Samoa had access to a mobile phone in 2013 [67], and nearly 99% of the adult population is literate [61]. In addition, free antenatal care is provided at public health facilities across the country. Though a handful of studies have found evidence for the effectiveness of SMS programs at increasing antenatal care attendance, more evidence is needed to understand in what environments these programs can produce results for women's health [68]. Previous studies have examined outcomes of these programs in countries in Africa and Asia with different cultures, religions, literacy rates, incomes and health care systems – all factors that could contribute to or detract from the effectiveness of a pregnancy text-messaging intervention. Therefore, this study explores whether this intervention can be effective in

the Samoan context, contributing to a more nuanced understanding of how the setting and implementation factors might affect the outcomes of a pregnancy text-messaging program.

5.B. Conceptual Model and Hypotheses

This paper addresses Aim 2 of the dissertation by testing the effects of engagement with an HIT innovation (text-messaging program for pregnant women) on improved individual outcomes (antenatal care attendance). It also addresses Aim 3 by examining how the fit of the innovation in users' lives and workflow impacts their engagement with it.

Based on earlier findings that text-messaging interventions have been successful at improving antenatal care attendance in other developing countries, we hypothesize that:

H_{3.A}: Pregnant women receiving the text-messaging intervention will attend a higher number of follow-up antenatal visits than women not receiving them, controlling for other individual characteristics.

Studies have also found that around the world, younger people tend to have higher rates of mobile phone ownership and higher technological literacy [69,70], suggesting that the effect of a text-messaging intervention could be even greater for younger women. In addition, these women are more likely to be first-time mothers and to be interested in additional supportive information, like that provided by the SMS program.

*H*_{3.B}: The text-messaging intervention will have a greater effect on younger pregnant women's antenatal care attendance compared to older women, controlling for other individual characteristics.

5.C. Data, Methods and Analyses

The study was conducted from March to September 2014 in the Independent State of Samoa. The study took place on the island of Upolu, the most populated island and home to the capital city (Apia). The National Health Service (NHS) runs six health centers on the island (one urban and five rural), all offering free antenatal services to pregnant women. Ethics approval for this study was obtained from the national Health Research Committee of Samoa on 6 February 2014. Analysis of the de-identified dataset was deemed to be "not human subjects research" by the UC Berkeley Office for the Protection of Human Subjects on 7 September 2017.

This study employed a quasi-experimental study design, where half of the health centers (n=3) were randomly selected to offer the SMS intervention to pregnant women presenting for their first antenatal visit, and the other half of the clinics (n=3) were randomly selected to offer the usual care only. Figure 8 illustrates the locations of these clinics on Upolu island. Pregnant women registering at an intervention clinic were

offered the SMS intervention by the midwives staffing the clinic (n=728), and pregnant women registering at comparison clinics during the study period were automatically enrolled in the comparison group (n=251). Though randomization of individual women would have improved causal inference, the intervention was offered at the health center level because this approach did not require health workers to keep track of which individuals to offer the intervention to.

The study included a total of 979 women, all of whom registered at one of the six public antenatal clinics in the study period. The only pregnant women not eligible for inclusion in the study during this time period were those who did not attend antenatal care in a clinic (e.g., those visiting a traditional birth attendant, estimated at about 3% of pregnant women [60]), or those that visited a private healthcare provider. This should be a relatively small percentage of the population, based on the significantly higher cost and limited reach of most private facilities (most are located in the capital city, Apia).

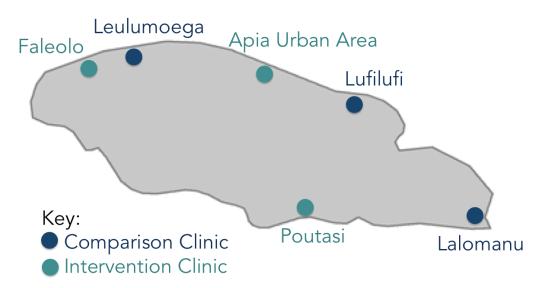


Figure 8. Map of National Health Service (NHS) clinics on Upolu, Samoa

Women in the intervention group received two educational messages per week, with content adapted to their gestation. The text messages were adapted for the local context and translated to Samoan from the free library developed by the Mobile Alliance for Maternal Action (MAMA), based on the Lancet Maternal and Neonatal Survival Series. Women in the intervention group also received a text message appointment reminder the day before their scheduled appointment. Finally, a reminder message was sent to women who were more than four weeks overdue for an appointment.

This study examined the effect of text message education and reminders on antenatal care attendance, measured by the number of follow-up ANC visits attended. Though women were of different gestations at registration, and therefore had different recommended antenatal schedules, gestational age is controlled for in the multivariate

analyses. Demographic information was also collected for each woman, including her age, marital status, parity, whether she or her partner were employed outside the home (inferred from listed employment categories in the medical record) and her home village. A survey for implementation feedback was also conducted about one month after beginning the program with the implementing midwives (n=7) and detailed implementation notes and records were kept by the researcher.

MISSING DATA

Problems with locating complete paper medical records led to one or more demographic variables missing for 214 participants. The distribution of this missing data is outlined in Table 9 in the Results section. The missing data was relatively evenly distributed across both intervention and comparison groups, reducing concerns about bias. The main analyses used listwise deletion of these observations with missing values (106 from the per-protocol intervention group and 108 from the per-protocol comparison group). As a sensitivity analysis, multiple imputation by chained equations was used to generate 20 datasets with 975 complete observations each, which were then combined for analysis using Rubin's combination rules [38]. Data was imputed for the variables: age at registration, parity, marital status and employment status. Data was not imputed for the four observations missing the distance from their home village to registration clinic, due to the high correlation of this variable with other variables (the model did not achieve convergence). The number of imputed datasets was determined using the proportion of missing data and the acceptable power falloff [71]. The sensitivity analysis then proceeded with the same models as the main analysis (described below in the Data Analysis section) and results were compared.

DATA ANALYSIS

Statistical analysis was conducted using StataSE 13.0 software. Basic descriptive statistics were calculated for all variables and separately for the intervention and comparison groups. This included means, medians and standard deviations for all continuous variables and frequencies, proportions and 95% confidence intervals for all categorical variables. Descriptive statistics for both groups were compared using t-tests for continuous variables and chi-squared tests for categorical variables.

The intervention and comparison groups were categorized using both the intention-to-treat and per-protocol principles. In intention-to-treat, all women registering for antenatal care at an intervention clinic were treated as receiving the intervention, regardless of whether they signed up to receive the text messages or not. In the per-protocol analysis, the women who did not actually receive any text messages were considered part of the comparison group, regardless of which clinic they registered at.

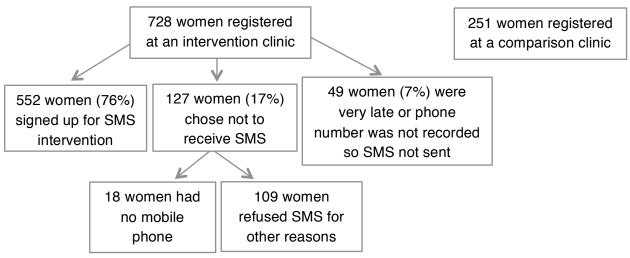
To study the significance of differences in the number of antenatal visits that were attended between the two groups, multivariate linear regressions were estimated, controlling for patient demographics and accounting for clustering within clinics. Next, the same model was run with an interaction term for young women (defined as under age 25) and being in the intervention group.

Implementation survey data was analyzed by calculating basic descriptive statistics for quantitative questions. Open-ended responses to survey questions and implementation notes were carefully reviewed to identify common themes.

5.D. RESULTS

Figure 9 outlines the results of the study registration. A total of 728 women registered for antenatal care at one of the three intervention clinics during the study period. Of these women who were offered the SMS intervention, 552 signed up. The majority of women who registered at an intervention clinic but did not receive the SMS registered very late in pregnancy (i.e., within 2 weeks of their due date), or their phone number was not recorded so messages could not be sent (n=49). A total of 127 women elected not to receive the SMS, and 18 of those women did not have a mobile phone. A total of 251 women registered at a comparison clinic during the study period.

Figure 9. Antenatal care and text message registration results (N=979)



Challenges locating complete paper records led to one or more demographic variables missing for 214 participants. The distribution of this missing data is outlined in Table 9. These observations with missing values were excluded from subsequent analyses.

The basic descriptive statistics for both intervention and comparison groups with complete data, according to both intention-to-treat and per-protocol categorization, are outlined in Table 10. The size of the intervention group was larger than the comparison group, due to the inclusion of the antenatal clinic in the main hospital as an intervention site (Tupua Tamasese Meaole hospital). This clinic saw the highest numbers of women registering for antenatal care, which resulted in a larger intervention group.

Table 9. Distribution of missing observations across groups

	Intenti	on-to-Treat	Per-Protocol		
Variable	Intervention (n=728)	Comparison (n=251)	Intervention (n=552)	Comparison (n=427)	
Age	128 (17.6%)	45 (17.9%)	95 (17.2%)	78 (18.3%)	
Parity (including current pregnancy)	127 (17.4%)	47 (18.7%)	97 (17.6%)	77 (18.0%)	
Distance from home village to registration clinic (km)	4 (0.5%)	0 (0.0%)	1 (0.2%)	3 (0.7%)	
Married/in partnership	94 (12.9%)	42 (16.7%)	66 (12.0%)	70 (16.4%)	
Employed and/or partner employed	147 (20.2%)	61 (24.3%)	104 (18.8%)	104 (24.4%)	
Missing any of the above variables	151 (20.7%)	63 (25.1%)	106 (19.2%)	108 (25.3%)	

Table 10. Baseline characteristics of intervention and comparison groups

Intention-to-Treat Per-Protoc						
Variable	Intervention (n=577)	Comparison (n=188)	р	Intervention (n=446)	Comparison (n=319)	р
	Continuous variables: Mean (SD)					
Age	26.7 (6.4)	27.1 (6.5)	0.53	26.6 (6.3)	27.2 (6.5)	0.18
Parity (including current pregnancy)	3.2 (2.0)	3.3 (2.0)	0.62	3.1 (1.9)	3.3 (2.1)	0.25
Distance from home village to registration clinic (km)	11.9 (13.1)	6.6 (7.2)	<0.00	12.3 (13.9)	8.3 (8.6)	<0.00
Gestation at registration (weeks)	27.2 (6.7)	26.5 (6.0)	0.13	27.4 (6.5)	26.6 (6.6)	0.10
Number of follow-up antenatal visits attended	2.2 (1.9)	2.6 (1.7)	0.01	2.1 (1.7)	2.5 (1.9)	<0.00
Categorical variables: n (%), excluding missing						
Married/in partnership	519 (89.9%)	171 (91.0%)	0.69	401 (89.9%)	289 (90.6%)	0.75
Employed and/or partner employed	405 (70.2%)	89 (47.1%)	<0.00	327 (73.3%)	167 (51.9%)	<0.00

The demographic characteristics of women in the intervention and comparison groups were similar at baseline, with two exceptions. The proportion of women and/or their partners who were employed outside the home was statistically-significantly higher in

both intervention groups, regardless of whether they were categorized according to perprotocol or intention-to-treat. Similarly, the mean distance traveled by women from their home village to the clinic they registered at was higher among the intervention groups than comparison groups, though these distances varied widely (from 0 to 117 km), and thus have high standard deviations. This was also likely due to the inclusion of the main hospital as an intervention site, as women are more likely to have traveled from a rural area to the capital city to attend their appointment there.

Using the intention-to-treat principle, women registering at intervention clinics attended on average only 2.2 follow-up visits, as compared to 2.6 in the comparison group (p=0.01). Similarly, in the per-protocol analysis, women receiving the intervention attended only 2.1 follow-up visits on average, compared to 2.5 visits in the comparison group (p<0.00). These unadjusted comparisons are presented in Table 10.

Contrary to hypothesis 3.A, the multivariate regression analyses (Table 11) showed that women in the intervention group attended a mean 0.32 (Intention-to-Treat) to 0.37 (Per-Protocol) fewer follow-up ANC visits than women in the comparison group, controlling for all covariates. The interaction term between younger women (defined as under 25 years old) and receiving the intervention in the subsequent regression model was not statistically significant (p=0.33), suggesting the effect of the intervention on ANC attendance was similar across age groups (results not shown in table). Therefore, support was not found for hypothesis 3.B.

As a sensitivity analysis, the multivariate regressions were run again with the 20 multiply imputed datasets (n=975). The estimated effect of receiving the intervention on the mean number of follow-up ANC visits attended was closer to zero and no longer statistically significant in these regression results (β =-0.26, p=0.17, per-protocol).

Table 11. Comparison of visits attended between intervention and comparison groups,

controlling for demographic characteristics

.	Intention-to-Treat		Per-Protocol			
Variable	Estimate	SE	р	Estimate	SE	р
Intervention Group	-0.32	0.19	0.15	-0.37	0.15	0.05
Age at Registration	0.01	0.02	0.56	0.01	0.02	0.59
Married/in partnership	-0.12	0.27	0.68	-0.12	0.29	0.70
Parity	-0.04	0.05	0.45	-0.04	0.05	0.44
Employed and/or partner employed	-0.22	0.15	0.21	-0.19	0.18	0.33
Distance from home village to registration clinic (km)	0.00	0.00	0.39	-0.00	0.00	0.34
Gestation at registration (weeks)	-0.02	0.01	0.01	-0.02	0.01	0.03
Constant	3.17	0.45	<0.00	3.14	0.41	<0.00

The results of the survey with implementing midwives (Table 12) suggest that they found the program to be useful (mean score of 4.0 out of 5). The average rating of how interested they thought their patients were in receiving the messaging was lower (mean score of 3.1 out of 5). In addition, the midwives felt that registering pregnant women for the messages (which involved recording the woman's name, phone number and gestation on a form) was fairly difficult (mean score of 4.29 out of 5, where 5 is difficult).

Table 12. Quantitative results of survey of implementing midwives

Question	Mean score (n=7)	SD
Please rate how easy or difficult it is to register pregnant women for the text messages on a scale of 1-5 (1=Easy, 5=Difficult)	4.29	0.76
2) Please rate how interested you think your patients are in receiving text messages during their pregnancy on a scale of 1-5 (1=Not interested, 5=Very interested)	3.14	1.86
3) Please rate how useful you think this text message program is for your patients on a scale of 1-5 (1=Not useful, 5=Very useful)	4.00	1.83

The analysis of the qualitative data from implementing midwives and implementation notes identified some facilitators and barriers to successful implementation of the textmessaging program. A key barrier was difficulty with consistently offering and explaining the intervention to women at intervention clinics. Despite the implementing midwives participating in training at the program's start and regular visits from the researcher to discuss the program and collect data, evidence suggests that some pregnant women might not have received a clear explanation of the program, or might not have been offered the program even if they registered for ANC at an intervention clinic. One midwife wrote, "[I] sometimes forget to fill in forms but will improve as it becomes part of daily routine." This quote highlights that implementation of the intervention did not fit into the midwives' existing workflow, which might have contributed to inconsistent registration, and could explain why the midwives rated registering pregnant women for the program as fairly difficult. In addition, the researcher received responses to some of the text messages asking who the message was from. This could suggest potential issues such as a) someone else was using the mobile phone, as phone sharing is a common practice among friends and families in Samoa or b) the women had not understood or had forgotten that she signed up for the messages at the clinic.

One of the key facilitators that was identified was offering the option for women to enroll in the message by paper during their ANC visit, rather than requiring them to send a text message to enroll. Many mobile messaging applications enroll participants by having them send a short-code to a phone number. However, this can cost the participant mobile phone credit to send a message. All but one of the participants in this study chose to enroll by paper, suggesting that it was the preferable enrollment option in this population.

Implementing midwives also suggested ways to improve the program if it were to be continued. Two midwives suggested adding messages telling pregnant women to avoid abdominal massage during their pregnancy, as massage is a common practice by traditional healers in Samoa. One midwife also suggested trying to get husbands or partners to participate in the text-messaging program as well.

5.E. Discussion

These findings suggest that, despite some previous evidence for the effectiveness of text-messaging interventions for pregnant women, they are not necessarily effective at improving health-seeking behavior when implemented alone. In fact, this study found some evidence that women receiving the messages attended fewer follow-up ANC visits than the women not receiving the messages, controlling for individual characteristics and clustering within clinics. One potential explanation for this finding could be that the messages led participants to feel more connected to the clinic, or that they had sufficient information, reducing their motivation to attend an in-person check-up. Further study is needed to understand the components of text-messaging programs that encourage ANC attendance and whether adjustments to the implementation (e.g., content, scheduling, etc.) could impact the effectiveness of the intervention. To date, only a handful of studies have looked at outcome measures for SMS interventions for maternal health and found positive results, and each of these studies has included some features beyond what our intervention offered [68]. For example, a study in Sierra Leone found an increase of 11.3% in attendance to the fourth antenatal visit after implementation of two-way SMS intervention that allowed pregnant women to communicate with healthcare workers [72]. Similarly, a study in Malawi found an increase in antenatal attendance after implementing a case management hotline and unidirectional SMS text and voice messaging [64]. Coupled with our findings, these studies suggest that interventions might need to incorporate more interaction with pregnant women, beyond unidirectional reminders and health tips, to have an impact on their care-seeking behavior. A similar conclusion was also drawn by a recent literature review of studies using text-messaging for maternal and infant health, which found evidence that two-way messaging might be more effective [73]. Based on our implementation findings, another idea to explore in future research is whether the participation of women's partners, family members or friends could improve the program's outcomes. Other members of women's social networks, if included in text-message education and appointment reminders, might encourage and support the women to attend antenatal visits.

LIMITATIONS

This study has important limitations. First, we were unable to collect any data on the presence of pregnancy complications to include as a control variable in our analysis. Pregnancy complications could have influenced the number of antenatal care appointments attended (e.g., if a woman is experiencing complications, her midwife will encourage her to come for more frequent check-ups). However, based on the even distribution of most demographic characteristics across the intervention and comparison

groups, we believe it is likely that women with complications were similarly distributed over both groups, but we have no way to test this with our current dataset. A second limitation of our data is that one intervention clinic was based at the main hospital in the capital city, and thus was significantly larger than any of the other clinics. We know that women traveled from many rural parts of the island to receive their antenatal care at this clinic, but we do not know if there are other systematic ways in which the women registering at this clinic are different from women registering elsewhere. We account for the potential of longer distances traveled and the clustering of women within clinics in the multivariate regression models in an attempt to address this issue. Third, due to difficulties locating paper medical records in many of the clinics, there was a significant amount of missing demographic data. The results of the sensitivity analysis with multiply imputed data found that the intervention and comparison groups attended a similar number of follow-up ANC visits, which could suggest that the lower attendance found in the intervention group in the main analysis could have been due to bias introduced by the missing data. Fourth, the surveys were completed by a relatively small number (n=7) of midwives who were directly involved in the program, and therefore may not be representative of the views of all clinic staff involved in antenatal care. Future research should also collect feedback directly from the pregnant women participating in the intervention to identify other areas for improvement.

CONCLUSION

Despite these limitations, this study contributes to our understanding of the effectiveness of SMS interventions for antenatal care attendance. When combined with the other limited findings available on these interventions, it appears that the level of interaction women have with the program could matter. In addition, these results provide important reminders that we cannot assume more information will increase care-seeking behavior – it could in fact deter women from attending antenatal visits. This intervention was relatively low-intensity and likely was not sufficient to overcome larger barriers to women seeking antenatal care, such as transportation, inconvenience, competing priorities and cultural factors. Further study of the specific features of text-messaging programs for pregnant women that contribute to their effectiveness should be a high research priority.

6. CONCLUSIONS

The findings from these three studies provide valuable insights into the factors that influence the effectiveness of HIT innovations, including electronic health records and mHealth interventions. Aim 1 was addressed by Paper 1, which examined the relationship between ease of use of EHR and improvements to team outcomes (care coordination). Some evidence was found to address Aim 2, where routine use of a diabetes text-messaging intervention (Paper One) was associated with improved clinical indicators (HbA1c), and the potential mechanisms of this improvement were explored through our qualitative results. Paper 3 (text messages for pregnant women) also addressed Aim 2 but, interestingly, found that the HIT innovation was not effective at producing improved individual outcomes (antenatal care attendance), likely due to characteristics of the intervention and implementation barriers. Finally, Aim 3 was explored in Papers 2 and 3, which examined implementation of the HIT innovations and the role that fit played in use of the innovation.

These findings also contribute to addressing gaps in the HIT innovation literature. In the Introduction of this dissertation, three key remaining questions were identified, including: the degree to which HIT innovations must be tailored to target populations, how effective HIT innovations are at improving care and outcomes, as well as what mechanisms HIT innovations produce these results through. Paper One helped us to begin to understand the mechanism through which EHR might produce better outcomes, by first improving care coordination. Paper Two, on a diabetes text-messaging program for low-income, Latino patients, provided evidence for the effectiveness of an HIT innovation that was tailored for a traditionally hard-to-reach population. Finally, Paper Three, examining a text-messaging intervention for pregnant women in Samoa, provided some information on characteristics of HIT innovations that might limit their effectiveness at improving care-seeking behavior, as well as potential facilitators and barriers to successful implementation of HIT innovations.

The papers also provide further support for earlier findings. For example, the findings from Paper One are consistent with earlier evidence that the need for collaboration and communication across multidisciplinary teams facilitates use of EHR [20,28]. Paper Two's results were in line with earlier evidence that text-messaging interventions can provide patients with social/emotional support, as well as information and cues to action [21,51,59]. Findings from Paper Three are consistent with some findings from a recent literature review of text-messaging programs for maternal and infant health, which found that two-way messaging might be more effective than unidirectional messages [73].

The results of this dissertation provide policymakers and practitioners with valuable evidence for which HIT innovations are effective, as well as insights into facilitators and barriers for successful implementation. By better understanding the mechanisms through which HIT innovations improve care or outcomes, we can improve their design and effectiveness. For example, evidence from Paper One suggests that by improving

EHR ease of use, there is potential to also improve care coordination. We also found evidence that higher engagement with a diabetes text-messaging program is associated with better outcomes. Therefore, future implementations could examine ways to better engage patients in the program. These findings have important implications for both research and public health practice, and ultimately for reducing morbidity and mortality with ongoing HIT innovation.

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APPENDIX I: PAPER TWO INTERVIEW GUIDES

Patient Participant Interview Questions

- 1. Who enrolled you in the program? Did you find that getting signed up was easy?
- 2. Describe your first encounter with the text messages. What did you think?
- 3. Who did you think the messages were coming from?
- 4. Do you think the number of messages (e.g., should the frequency of messages be customizable by patient) was too few, about right, or too many? Why?
- 5. Were the education messages about diabetes helpful? Please tell me a couple of key things you remember from the messages.
- 6. Were the messages positive, neutral or serious? How would you describe the tone of the program?
- 7. After using CareMessage and thinking more about your diabetes, did you set any new goals for improving your diabetes control? What were your goals and did you feel that you made progress?
- 8. To what extent did the messages impact your exercise, smoking, medication taking, and/or diet?
- 9. Was the system an effective way to get answers to your questions?
- 10. Did you discuss the messages with any of your family or friends?

Implementing Staff Interview Questions

- 1. Can you describe how your clinic is going about <u>planning and implementing</u> the CareMessage program? What is your role?
- 2. [RELEVANT STAFF ONLY] Are you comfortable explaining what CareMessage is to patients? Do you feel like the patients understand the concept of the text-messaging program?

- 3. How easy or difficult has it been to incorporate CareMessage into your workflow? How much did the program change your interaction with patients? Describe your new routine. On a scale from 1 to 10, how disruptive was the addition of CareMessage into your existing workflow (1 being not disruptive and 10 being very disruptive)? What was disruptive about the implementation?
- 4. How many people in the clinic have been affected by the implementation of CareMessage?
- 5. Have you had any training or resources (protected time, etc.) for implementing the CareMessage program? If so, probe: What are these resources? What other resources or supports do you think might help with implementing the change?
- 6. Do other clinicians and staff not directly involved in the implementation of the program know about the changes? If so, probe: How are they reacting to these changes?
- 7. What is working well in this program?
- 8. What challenges have you experienced so far with this program?
- 9. Do you monitor patient responses in the program? If no, why not? If so, what do you monitor and how does it impact the care the patient receives?
- 10. Is there anything else that you can think of that may <u>help</u> you and other staff as you implement this change? Anything else that is hindering or creating <u>barriers</u> for implementing this change?

APPENDIX II: PAPER TWO ADDITIONAL QUOTES

Table 13. Example Quotes from Qualitative Interviews with Intervention Participants (n=11)

Theme	Quote
Felt supported (5/11)	"The messages were helping me because these messages were as a person was speaking to me, telling me what I should do, as if that message was from someone that was thinking of me and was telling me that I have to do this for my wellbeing."
	"It was really encouraging, I thought, because if you, for example, asked how I felt about diabetes after I was diagnosed, is it helping me to manage it better, I mean that was some of the multiple choices. And let's say if I answered that, you know, I was depressed, whatever, then it would send me like a really encouraging message that, you know, hey diabetes can, you know, because of diabetes you'll learn to live a more healthy life, you know, something positive that I thought."
	"It felt good also because I knew that someone was worrying about my health."
	"I thought that there was people that think about your life more than anything else. That's what I liked. That they are trying to help you so that you don't like with the mindsight of "Oh, I am going to die or this is going to happen to me." You understand? To know what you need to do in order to look for a solution, not to be stuck on something that you know you already will have. And to not think negatively."
Learned new information (11/11)	"It's just that the messages explains things more Better. Because when I go to an appointment and ask, then the doctors speak in English and if the girls that they provide interpret for you don't fully explain the conversation that you would have with a doctor."
	"Ah, yes. Because the medical staff only prescribe me things, they don't advise. They should advise the patient more and I did feel that the message that I received was more helpful in terms of informing more about diabetes."
	"Oh wow did you know that, hey I didn't know this," it's something new, new things that are in there."
	"I had no idea, you know, how bad carbs are for you. Now I read the labels."
Set new goals, contemplated behavior change, or changed behavior (11/11)	"First off, I am more calm. In another aspect, because I am checking my sugar levels and it is lower and I am doing things that I did not do before, such as doing exercise, having tranquility, be more positive for myself, taking myself into account, appreciating myself as a person and taking my

medication how they are supposed to because I wouldn't take them how I was supposed to before."

"So I have had my daughter in law make me up a sheet of papers to print out where it has that I took it in the morning and I pinned it on the wall... going in and out of my room I see this... I took this insulin and then I just mark it and I put the time. So that helped me, I'm not gonna say it helped me to do that but I would say it kind of inspired me to pay more attention to my diabetes."

"Before I didn't take it into consideration and would continue as if I didn't have diabetes. It never impacted me, and I never took into consideration to keep taking care of myself. That is why it helped me change the way I would live and eat."

"Because you know, I was reminded by the text, so I get out walking again. You know, not that far, because I got tired. But then I began walking more. So now I walk about an hour a day."

"Sometimes I do the chores later in the day and in the radio they put on cumbias and I will be sweeping and mopping and then I finish after an hour because that's how long they put the songs on for. At times there are resting periods and I dance one cumbia and then the other, like two or three songs I continuously dance to... Because I have the broom and it seems like it is a partner and you dance and at the same time you are exercising right? Even though it's a little bit, but it works, everything counts."

"It said that you're supposed to take it twice a day at about the same time, and so we instituted a little thing where I have the little days of the week and I have a little... holder that says, you know, "Noon, Morning, Evening, Night," and that, we put the pills in there so I take them on the right times... I'm doing it after the messages."

"Well look, I ate a lot of bread. I ate a lot of bread and tortillas. That were some of my excessives. That was the reason why I couldn't lose weight because honestly I would say. "No it is a little bit, two in the morning, three in the afternoon." It was five tortillas at times... So when the messages would say that everything that was carbohydrates would turn into sugar, I would say, well then imagine, five tortillas that at times I eat... My body doesn't want to eliminate it, and if it can't eliminate it, well I shouldn't be putting into the body what it can't eliminate right? And well I did do some changes. Right now what is bread and tortillas I don't eat anymore. Not even one tortilla, it's been like three months that I don't even eat one tortilla. I only use the fork. Before I wouldn't do that and I am feeling better. I am losing weight."

Helpful reminders (7/11)	"I felt that these little messages that I got daily kind of reminded me to take my insulin and take my medication. Because I may have been left the house and then all of a sudden I get this ding! And I'm like oh man and then I look and then it's like, "Oh I forgot to take my pills."
	"Yeah, I think the way they did it was fine because it'd kinda catch me off guard and then it would remind me to do these things. 'Cause sometimes I get in a rush and then I'll forget about checking my blood or I'll proper stuff to be eaten and to it was a constantly reminder of things that I needed to do and things I should be aware of. So I thought that was pretty cool 'cause then because I get caught up and I forget I even have diabetes and stuff."