ABSTRACT

Title of Dissertation: **CONTRADICTIONS AND OPPORTUNITIES IN MOBILE CARE MANAGEMENT ("mCare"): AN OBSERVATIONAL ANALYTIC COHORT STUDY**

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Chronic diseases such as diabetes are among the most widespread, expensive, and preventable of all health problems, accounting for approximately 86 percent of the United States' $2.7 trillion annual health care expenditures. In the face of such staggering numbers, it is surprising that our current approach to chronic disease care management has remained largely unchanged for decades, where the care team evaluates the patient and related data infrequently and episodically. However, mobile care management (mCare) information system use is growing, whereby individuals with chronic medical conditions such as diabetes are taught to monitor and manage their disease through the use of a mobile application for tracking, education and feedback, along with monitoring of vital signs with "connected" medical devices, and the support of a remote health coach. These mCare systems offer promise, but many

unanswered questions exist surrounding their effects on the health and healthcare of the users, and how user individual differences may influence these effects.

Informed primarily by the mobile health systems and health behavior literatures, this study provided a deeper understanding of the effects of an mCare platform on health outcomes and health services utilization of chronic disease patients, principally those with diabetes mellitus, and the effects of a user's social support on these outcomes. This study analyzed administrative claims, device readings, app usage, demographic and social determinant data of 163 diabetic mCare users from a 21-week observation period from mCare initiation, along with a well-matched control group of diabetic non-users, and a supplemental cohort of 127 non-diabetic mCare users with other chronic medical conditions.

mCare had a significant positive effect on users' adherence to physician's office visits, suggesting greater continuity of care, chronic care management, and a possible reduction in inpatient use (1.2 fewer encounters over 5 months, on average).

The findings show that mCare had a significant beneficial effect, on average, towards the cardiovascular health of the users as measured by the change in their diastolic blood pressure (- 2.8 mmHg, - 3.3%) and systolic blood pressure (- 6.7 mmHg, - 4.9%) in the five-month observational period, which is a primary therapeutic target for diabetes care and clinically important. Furthermore, linear mixed models of cardiovascular outcomes uncovered how those mCare users with a moderate degree of social support are likely to achieve greater benefit in from mCare on average relative to those with very high or very low social support in their lives.

This additional impact equated to on average a 2.4 mmHg drop (2.9%) in diastolic blood pressure and a 3.9 mmHg (3.1%) drop in systolic blood pressure over the five-month observational period, which is clinically significant. These results provide evidence to support a more precisely tailored future healthcare paradigm beyond the current one-size-fits-all archetype.

A primary goal of mCare is triaging emergency department use where appropriate; however, this study found that this did not happen in a significant manner in the treatment group compared to the control group. Furthermore, the study identified specific medical problems where improved mCare design is needed, including processes to prevent hyperglycemia, hypoglycemia and exacerbations of hypertension and pulmonary issues (such as asthma and chronic obstructive pulmonary disease), and a need to assess pain more effectively to foster more appropriate healthcare utilization.

Additional training for health coaches, as well as training and development of machine intelligence algorithms to better triage patient problems to appropriate sites of care, are productive directions for future research. mCare designers should seek to better gauge the severity of pain, and develop new sensor technologies to assess emergent issues, especially abdominal pain. mCare vendors should also seek to refine their processes to better manage glucose and respiratory issues to avoid exacerbations, and predict exacerbations earlier to intervene.

CONTRADICTIONS AND OPPORTUNITIES IN MOBILE CARE MANAGEMENT ("mCare"): AN OBSERVATIONAL ANALYTIC COHORT STUDY

by

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Dedication

Dedicated to my loving wife, Celine, and son, Hugo, who supported me throughout this journey, and in memory of my father, whose decades long struggle with chronic disease in part motivated my interest in health information systems research, and to Mac Greene, who passed away too soon from a preventable cancer, which further motivated my desire to discover ways to engage people more fully in their health and wellbeing.

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List of Abbreviations

BP – blood pressure
BPM – blood pressure monitor
CHF – congestive heart failure
CMS – Centers for Medicaid and Medicare Services
COPD – Chronic obstructive pulmonary disease
DALY - disability-adjusted life years
ED – emergency department
EDA - New York University Emergency Department Algorithm
ES – effect size
GM – glucose monitor
CCI – Charlson Comorbidity Index
CGM - continuous glucose monitoring
CHF – congestive heart failure
ICD10 - International Statistical Classification of Diseases and Related Health Problems version 10
IS – information systems
IT – information technology
JITAI – just-in-time adaptive intervention
lbs. - pounds
LMM – linear mixed model
mCare – mobile care management information system
mg/dL - milligrams per deciliter (used to measure blood glucose)
mHealth – mobile health information system
mmHg - millimeters of Mercury (used to measure blood pressure)
QALY - quality-adjusted life years
RCT – randomized controlled trial
SBS – social barrier score
SCT – social cognitive theory
T2D – Type 2 diabetes mellitus

Chapter 1: Introduction

1a. Background of the Problem

Chronic diseases are among the most widespread, expensive, and preventable of all health problems, accounting for about 86 percent of the United States' $2.7 trillion annual health care expenditures (Gerteis et al., 2014). The largest contributing factor to death and disability in the United States and across most of the world is behavioral choices (Institute for Metrics and Health Evaluation, 2015), as visualized in Figure 1 (next page). More than genetics and more than infectious disease, it is humans' everyday choices about activities like what to eat, how much physical activity to do, smoking, sleeping well, managing stress and adhering to medication regimens that determine our fate (McGinnis, Williams-Russo, & Knickman, 2002). Figure 1 shows the % of disability-adjusted life years (DALYs) associated with our behaviors and where these behaviors manifest as medical conditions (IHMS, 2017); the number of DALYs associated with a behavior (e.g. smoking), is the estimated number of years lost due to ill-health, disability or early death due to that behavior (Rushby, 2001). Billions of dollars of preventable costs and millions of preventable disability years are wrapped up in our behavioral choices (Center for Disease Control and Prevention, 2016).

In response to the monumental societal, personal and economic costs of chronic disease, a digital health revolution has been slowly emerging (Duggal,

Brindle, & Bagenal, 2018) . Digital health includes categories such as mobile health (mHealth), health information technology (IT), wearable devices, telehealth and telemedicine, and personalized medicine (FDA, 2019). The use of technologies such as smart phones, social networks and internet applications is changing the ways in which we engage with our health and care teams (Fiordelli, Diviani, & Schulz, 2013; Mileski, Kruse, Catalani, & Haderer, 2017).

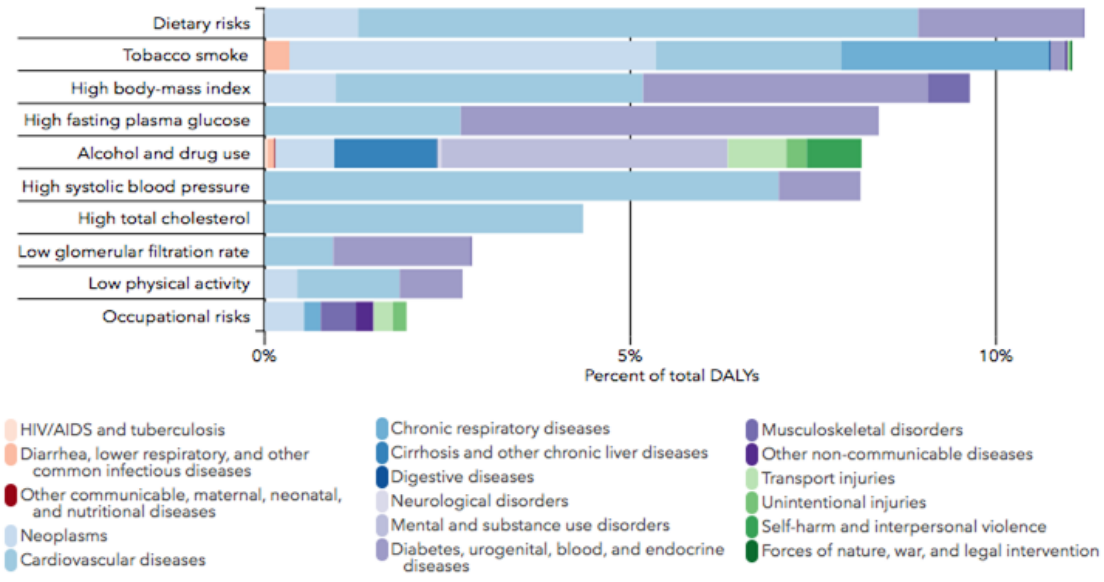


Figure 1. Risk factors contributing to death and disability (IHME, 2017)

Novel approaches to monitor our health and well-being offer improved access to information and support (Serbanati, Ricci, Mercurio, & Vasilateanu, 2011). In particular, mHealth, which is the use of mobile and wireless applications for healthcare purposes (HIMSS, 2019), is leveraging that ever constant companion, our smartphone, to change how healthcare traditionally has operated.

The adoption and use of these tools may offer promise, but to-date efficacy is mixed and there are many unanswered questions about the effects of these tools (De Geest et al., 2017; Hamine, Gerth-Guyette, Faulx, Green, & Ginsburg, 2015; Kitsiou, Paré, Jaana, & Gerber, 2017), some of which may be unintended (Maar et al., 2017) and potentially detrimental (Harrison, Koppel, & Bar-Lev, 2007). Critical issues exist about how the unique demographic, social determinant, medical and behavioral factors may impact the success or failure of digital therapies for those at-risk-of or living with chronic diseases (Hamine, Gerth-Guyette, Faulx, Green, & Ginsburg, 2015).

The current opportunity is particularly striking because the detrimental effects of diabetes and other so-called lifestyle diseases can be mitigated and even in some cases, reversed, through better disease management and self-care practices (R. Taylor, 2013) . This dissertation examines the effects of a particular mobile health intervention, mobile care management ("mCare"). In a typical mCare program, a care manager connects remotely with patients in need of medical condition improvement, provides disease management support and adjusts care using data streams generated via a patient's use of a smartphone or tablet application that includes features for delivering targeted education, tracking biometrics through connected devices (e.g. Bluetooth-enabled blood pressure cuff), and supporting communication between the patient and care provider (typically a live or avatar health coach) (Domengue & Sattelmair, 2017).

1b. Research Agenda

This dissertation seeks to contribute to the mobile health information systems literature regarding chronic care management strategies and tools. The findings will provide a deeper understanding of the outcomes of Medicaid mCare users' outcomes following mCare use. Theoretical underpinning is provided by the health information systems, health behavior and healthcare utilization literatures.

The study is important for several reasons. For one, there can be stark differences in how individuals respond to medical therapies. It is critical to understand how mCare may be impacting healthcare and economic outcomes for chronic disease patients when used as part of therapeutic regimen for diabetes, one of the most costly and prevalent chronic diseases. This study will quantify this through comparing a treatment and control group matched sample, a pre-post mCare use examination of outcomes, and a linear mixed effects models (to be described in detail in the Methods chapter).

Second, there is increasing credence regarding the role that an individual's social determinants of health play in predicting the health outcomes of individuals and populations (Marmot & Allen, 2014), yet the linking of one's social situation (a prominent social determinant) to the impact of mCare in chronic disease populations is not well-quantified (Marmot, Friel, Bell, Houweling, & Taylor, 2008). This dissertation helps to fill this void by measuring the interaction of social barriers (e.g. not having friends or family to provide support, experiencing social isolation) on the health outcomes from using an mCare system.

Third, by developing a greater understanding of the role of individual differences in moderating the effectiveness of mCare, policymakers can enact more efficient population health planning, in which resources and intervention choices can be directed towards those that are at risk, with the intervention choice that is likely to succeed for a target audience member, given choices of health intervention strategies.

Fourth, adapting digital health therapies for chronic disease is showing emerging signs of being a feasible strategy to improve chronic disease management (Kitsiou et al., 2017); however, more understanding is needed to understand the differences that may facilitate appropriate adaptation in diverse populations (Stowell et al., 2018). This dissertation will integrate and apply social determinants risk data, healthcare utilization data, medical condition data, medical device data, and mobile application data longitudinally to shed light on the use of mCare for diabetes. These data provide real-world evidence. Furthermore, this dissertation's analysis and insights from high-volume, high-frequency ecological observations may help generate future testable theories and facilitate comparisons of information systems in the care management domain. *The specific research questions this research aims to address include the following:*

RQ1: What types of health benefits does mCare provide to insurance plan members with type 2 diabetes?

RQ2: What types of utilization and cost implications does mCare have for insurance plans and their members with diabetes?

RQ3: How is the response to mCare of insurance plan members with chronic disease related to their demographics and social support?

A thorough set of methods and data have been used to answer these questions. The existing literature providing a foundation for this dissertation study are discussed next, followed by a description of the methods and data used to answer the research questions. The results are then reported, followed by a discussion of the findings in the context of the current healthcare system, along with the conclusions of the study including the implications for mCare practice, theory and design. Finally, limitations to the generalizability of the results are discussed and future research directions are proposed.

Chapter 2. Review of the Literature

Prior work relating to mobile health interventions, healthcare behavior theory, and utilization of healthcare, inform the conceptual territory and provide a theoretical grounding for this study.

2a. Mobile Health Interventions

mHealth (a common abbreviation for mobile health) is defined as mobile-based or mobile-enhanced solutions that deliver health (HIMSS, 2019). The ubiquity of mobile devices across all corners of the world presents the opportunity to improve health outcomes though innovative applications of data, devices and interactions. mHealth may include a wide array of sensors, connected devices like Bluetooth-enabled scales and glucose meters, and SMS-messaging and software applications that work on one's mobile smartphone. These tools, when designed well, may help patients manage chronic conditions outside of traditional healthcare settings (Garabedian, Ross-Degnan, & Wharam, 2015; Mileski et al., 2017). They can also provide value to healthcare providers and payers by facilitating disease prevention, diagnosis, and treatment (Hamine, Gerth-Guyette, Faulx, Green, & Ginsburg, 2015).

Much of the early work (de Jongh, Gurol-Urganci, Vodopivec-Jamsek, Car, & Atun, 2012; Fiordelli et al., 2013; Källander et al., 2013) in mHealth focused on providing health education and services in low-resource global environments. Recent work (Fu, McMahon, Gross, Adam, & Wyman, 2017; Inbal Nahum-Shani et al. 2016; Iribarren, Cato, Falzon, & Stone, 2017; Mileski et al., 2017; Peng, Kanthawala, Yuan,

& Hussain, 2016) is increasingly focused on using more sophisticated interventions that integrate mobile apps, cloud computing and connected sensors. mHealth consumer applications like fitness and nutrition tracking are expanding rapidly, both in terms of the number of users and the number of apps (Bardus, van Beurden, Smith, & Abraham, 2016). In contrast, the uptake of mHealth apps into healthcare management practices has been sluggish (Baniasadi, Niakan Kalhori, Ayyoubzadeh, Zakerabasali, & Pourmohamadkhan, 2018; Glick, Druss, Pina, Lally, & Conde, 2016; Peng et al., 2016).

Some of the core benefits of mHealth are assisting patients in understanding their health condition(s) (De Geest et al., 2017), promoting beneficial behaviors (Baron, McBain, & Newman, 2012), and fostering communication with trusted resources (De Geest et al., 2017). Table 1 reports several barriers patients face in managing a chronic disease and the mHealth benefits that can help to lower those barriers.

Table 1. Benefits of mHealth for chronic care
(Hamine et al., 2015; Hou et al., 2018; Quinn et al., 2011)

Patient Barriers to Good Diabetes Outcomes	Benefits of mHealth Features
Limited feedback and positive reinforcement of healthy behaviors	Automated feedback and positive reinforcing messages encourage beneficial behaviors.
Poor insight into health condition and lots of information to process	Increased relevant education delivery and micro-learning modules prevent overwhelming amounts of information.
Limited communication with the treatment team between office visits and lack of evaluation of self-collected diabetes data (e.g. capillary glucose, food intake, activity, medication adherence)	Tailored feedback for diabetes data and communicating actions to manage glucose may decrease risk of adverse events.
Transportation barriers, traffic congestion, limited parking for attending physical clinic visits	Reduced need for frequent visits and travel allows more patients to get the information they require.
Limited financial or healthcare resources to cover office visit copays, medications, and self-testing supplies	Reduced need for office visits may reduce costs for patients (e.g. copays).
Lack of self-motivation to improve health	Motivational messaging tailored to individual differences increases content alignment with patient needs.
Competing demands on patient time (e.g. work, school, family)	Therapeutic support at convenient times and places can yield more likely adherence and foster a usable system.

There is a growing body of scientific evidence that suggests mHealth can facilitate lifestyle behavior change and slow the progression of preventable chronic disease (Hou et al., 2018). Mobile messaging in particular has been demonstrated to be effective for use cases including reducing cardiometabolic risk factors (Chow et al., 2015), increasing appointment attendance (Gurol-Urganci, 2013), improving diabetes self-care (Ferrer-Roca, Cárdenas, Diaz-Cardama, & Pulido, 2004), improving medication adherence (De Geest et al., 2017), motivating physical activity (Hall, Cole-Lewis, & Bernhardt, 2015), and encouraging users to quit smoking in the short-term (Ybarra, Bosi, Korchmaros, & Emri, 2012). Randomized controlled trials

(RCTs) of mHealth interventions targeting diabetes have revealed benefits in quality, cost, and patient-centered outcomes (Marcolino et al., 2018; Quinn et al., 2011). However, while promising evidence exists about the benefits of mHealth for diabetes and other chronic conditions, the outcomes of mHealth interventions can be highly varied (Cajita, Gleason, & Han, 2015; Hamine et al., 2015; Marcolino et al., 2018). Experts have called for more pragmatic assessments of mHealth interventions (Collins & Riley, 2016).

A recent systematic review (Marcolino et al., 2018) concluded mHealth systems show benefits for chronic disease management, reducing deaths and hospitalization, and improving quality of life, *but more research is needed to unpack the drives and differences across subgroups*. An example of the types of individual factors that may affect the degree to which users benefit from mHealth include their psychological traits (Dugas, Crowley, et al., 2018), amount of social influence (Hoque & Sorwar, 2017), disease severity (Georgsson & Staggers, 2016), goal types (Adams et al., 2017), and health literacy status (De Geest et al., 2017).

Chronic disease mobile applications ("apps") are not new. Across the App Store and Google Play, there are hundreds of apps related to diabetes, for example. However, chronic disease apps have a mixed record for effectiveness (Marcolino et al., 2018). Programs with components such as goal-setting and self-monitoring that use multiple modes of communication with tailored messages were found to be more effective in additional reviews (Afshin et al., 2016, McKay et al., 2016).

Messages that are simple, brief and personalized have been reported to be the most effective for engaging users (Schmid, Rivers, Latimer, & Salovey, 2008). Even though personalization has been shown to increase engagement (Schmid et al., 2008), most existing mHealth communication strategies use a "one-size-fits-all" approach (Bardus et al., 2016). Personalization can meet the patient attributes that vary such as information needs, goals, challenges, and symptoms, etc. (Anderson, Burford, & Emmerton, 2016). Therefore not adapting to the significant heterogeneity across patients is a missed opportunity to increase efficacy through more relevant, salient and useful user interactions (Nahum-Shani, Hekler, & Spruijt-Metz, 2015).

Evidence suggests there is a considerable opportunity to improve outcomes and lower costs for many at-risk patients, such as those with diabetes who struggle with the complexities of blood sugar regulation (Cui, Wu, Mao, Wang, & Nie, 2016), or congestive heart failure patients who require motivation and reinforcement of behavior and medication management (Chen et al., 2016).

Jimison et al.'s (2008) seminal review of the barriers and drivers to the use of interactive consumer health information technology (IT) found that health IT systems tended to have a positive effect when the systems provided a complete feedback loop that included: (a) monitoring of current patient status, (b) interpretation of this data in light of established, often individualized, treatment goals, (c) adjustment of the management plan as needed, (d) communication back to the patient with tailored recommendations or advice, and (e) repetition of this cycle at appropriate intervals.

Systems that offered only one or a subset of these functions were less dependably effective.

A recent integrative review critiqued the interventions that support diabetes self-management (Carpenter, DiChiacchio, & Barker, 2019). The predominant interventions for diabetes include: technology-based interventions, patient education, motivational interviewing, problem solving therapy, lifestyle modification programs, mindfulness, and cognitive behavioral therapy. These interventions principally targeted reductions in glucose as measured by HbA1c, and recorded mixed results, that were typically at six months to one year in duration. The lifestyle modification interventions targeted diet, exercise, medication management, and behavior modification most often, and recorded changes in outcomes such as: diet; physical activity; self-efficacy; and stress. The most frequently used intervention was technology-based interventions, with telehealth the foremost mode of technology. Health coaches, both peer and professional, have been a frequent intervention strategy. Professional health coaches frequently employ motivational interviewing, which seeks to help patients change their ambivalence to changing behaviors (Hibbard, 2016). These interventions are frequently multi-modal, meaning they include multiple components (e.g. coaching plus telehealth plus problem solving therapy). The extensive review concluded that while the diabetes interventional research is vast, the translation to clinical utility remains mixed, and there is a need to further explore innovative care delivery models (Carpenter et al., 2019).

The health coaching used to help patients with diabetes better manage their disease traditionally encompasses five main roles, including: (1) providing self-management support, (2) bridging the gap between clinician and patient, (3) helping patients navigate the health care system, (4) offering emotional support, and (5) providing continuity of care (Bennett, Coleman, Parry, Bodenheimer, & Chen, 2010). While health coaches have always had to interpret information and decide engagement strategies, with the introduction of mHealth tools, an effective health coach must be able to interpret more frequent, voluminous and diverse data, in effect becoming a data analyst in addition to a behavior change agent. Health coaches must decide: who needs attention; the priority of outreaches; what mode of contact may work best; and what approach may be appropriate (Kivelä, Elo, Kyngäs, & Kääriäinen, 2014). Traditionally, these decisions and tasks were accomplished with judgments based on limited data. Prior work has shown that a primary benefit of health coaching for diabetes is helping patients reframe their perceptions of disease, including its manageability (Wolever et al., 2010). Virtual coaching eases access to support services, reduces patient travel time, and provides timely feedback (Ramchandani, 2019). Existing health coaching interventions for diabetes are represented by companies such as Omada Health, Virta, Vida, Vheda Health, Noom, and many insurance companies operate their own health coaching services.

The current state-of-the art in diabetes management is centered around building a more reliably predictive set of technologies that tailor not only to the unique education needs of a diabetes patient, but also adapt to their current state. The

focus of emerging diabetes health interventions on a more dynamic health behavior model leverages existing theory that health behavior is a function of physiological and psychosocial state (Glanz & Bishop, 2010), but advances our interpretation and practice of interventions by applying a dynamic adaptation (Nahum-Shani et al., 2015). In diabetes care, the use of continuous glucose monitoring (CGM) can now provide a near constant stream of blood sugar values. A new product, the Freestyle Libre, released by Abbott, now offers an option to scan one's blood sugar using a wearable sensor on the upper arm, rather than the traditional finger prick glucose monitoring method. This advance to reduce the level of effort and pain in ascertaining one's glucose level, should further enhance the ability of diabetes patients to self-manage. There is the Eversense sensor, which is an implant that will monitor blood sugar every 5 minutes for 90 days after being implanted. The consequences and impacts of these new interventions are unknown, but they will likely become more mainstream and integrated into managed care programs, mCare and traditional, in coming years.

Other gaps in understanding around the effectiveness of mHealth interventions comes from the lack of representation of people of low-socioeconomic status in mHealth studies (Stowell et al., 2018). More comprehensive information about the nuances of users and processes for achieving value from these systems is needed in order to yield better and more user-centered design of mHealth tools (Dennison, Morrison, Conway, & Yardley, 2013). A variety of strategies are being

used in mHealth, with mixed results. There is expansive room for future innovation. Future innovation should be driven by theory and empirical evidence.

Next health behavior theories are discussed and their relevance to this dissertation study.

2b. The Complex Landscape of Health Behavior

Various health behavior theories have been used to support mHealth interventions, although reviews have criticized the lack of theory in most mobile interventions (De Geest et al., 2017). Additionally, senior leaders at the National Institutes of Health (NIH) have asserted that current health behavior theories need updating for the mHealth age (Riley et al., 2011). The theoretical basis for mHealth interventions can be found in Ecological Momentary Interventions (Free et al., 2013; Moskowitz & Young, 2006), the Theory of Self-Efficacy (Albert Bandura, 1977), and the Transtheoretical Model of Change (Glanz, Rimer, & Viswanath, 2015).

Ecological Momentary Interventions are treatments that are delivered to people in their everyday lives and in natural settings (Moskowitz & Young, 2006). The theory of Ecological Momentary Interventions has strong rationale and a basis in psychotherapy, where clinicians have long encouraged patients to practice skills, do activities, and complete tasks between therapy appointments (Heron & Smyth, 2010). Activities between appointments act as a way to practice, generalize, and maintain therapeutic skills (Abraham & Michie, 2008). This approach is increasingly being

extended to include health behavior and psychosocial interventions (Heron & Smyth, 2010).

A timelier assessment of relevant patient information and responsiveness to it for patient care is believed to confer advantages over traditional interventions (Burner, Menchine, Kubicek, Robles, & Arora, 2014) . A more ideal mHealth system will nudge the user taking into account user state attributes (e.g. mood, vital signs) when needed, and conversely, the system can avoid prompting users to do a certain behavior when the behavior likelihood is low (Adams et al., 2017; Inbal Nahum-Shani et al., 2016). This interaction style facilitates more efficient allocation of a user's resources (Nahum-Shani et al., 2015). The design/architecture of more and more modern mHealth tools can facilitate more frequent, dynamic and customized feedback loops than have been traditionally applied in health behavior interventions (Nahum-Shani, et al., 2016). This enhanced customization using real-time data streams extends the capabilities of current interventions to more quickly respond and is hypothesized to increase relevance and perceived usefulness of the intervention (Nahum-Shani et al., 2015; Schmid et al., 2008). The process of dynamically communicating with patients and health coaches is being operationalized currently; for example, health coaches and patients may receive real-time alerts when any care gaps exist that need attention, such as a very high blood sugar reading or not conducting a device reading (De Geest et al., 2017).

Clinician participation is a frequent component to mHealth, and this social strategy is generally supported by the literature (Wolever et al., 2010). Engagement

with healthcare providers has been shown to significantly affect behavior and practices of individuals (van Dam et al., 2005). Researchers have found significantly improved adherence as a result of clinician engagement (Cutrona et al., 2010). Individual motivation arising from clinician engagement can be very useful to help patients overcome perceived barriers to healthy behaviors and treatment adherence. However, many studies using telemedicine technology find only moderate improvement in outcomes like glycemic control and little effect on costs (Free et al., 2013). Reviews (Hamine et al., 2015; Marcolino et al., 2018) have concluded that more holistic design is needed for interventions, which more fully takes into account the differences between users, such as their sociodemographics (Free et al., 2013), psychosocial factors (Dugas et al., 2018) and unique goals (Adams et al., 2017).

The term "health behavior" typically means any behavior that may affect an individual's health (physical or mental), or any behavior that an individual believes may affect their health (Sutton, 2004). Behavior is a complex set of processes involving interactions between temperament, personality, cognition, emotion and the environment (Horwath, 1999; Sheldon, Jose, Kashdan, & Jarden, 2015). Health behavior change models aim to identify and measure the factors that best predict health behaviors (Glanz et al., 2015). The science behind one's health decisions is a richly studied area, but sadly the field continues to inadequately explain the mysteries of human health behavior.

Changing behaviors is hard and maintaining a new behavior even harder (Pokhrel, Anokye, Reidpath, & Allotey, 2015). Health behavior research has led to

several prominent theories (Glanz et al., 2015) that help explain the structural and psychological determinants of behavior. Traditional health behavior models typically posit that individual differences, such as demographics, personality, education, beliefs, feelings and health status are predictive of behaviors (Glanz et al., 2015).

The Health Belief Model (one of the health behavior domain's oldest and most commonly used models), for example, conceptualizes an individual's likelihood of taking a health-related action (i.e., changing their diet), as resulting from four primary factors, including one's perceived susceptibility to disease, perceived severity of the disease, perceived benefits of the health promoting behavior, and their perceived barriers to successfully doing the behavior (Rosenstock, 2000). However, the Health Belief Model and most behavior change models generally fail to effectively explain how much the underlying factors influencing health predict health behavior outcomes, and these model factors are not very instructive for behavior change intervention designers (C. J. Carpenter, 2010; Glanz & Bishop, 2010). The majority of behavior change interventions based on the Health Belief Model have been shown to have modest predictive ability of actual health behaviors (Bilic, 2005; Wootton, 2012).

Stage-based health behavior change models have been popular frameworks, as well (Prochaska & Velicer, 1997; D. Taylor et al., 2006; Wilson, 1999). The most widely used stage model has been the Transtheoretical Model (TTM, also called Stages of Change), which posits (as virtually all stage-based models of behavior change) that individuals advance through a series of steps towards behavior change

(Glanz et al., 2015; Prochaska & DiClemente, 1982). The TTM indicates there are 5 to 6 stages, which may be repeated when regression or relapse occurs. These stages typically include: precontemplation, contemplation, preparation, action, maintenance, and termination. Some external factors have a stronger effect during specific stages. For example, social support is especially beneficial during the preparation, action, and maintenance stages (Horwath, 1999). Studies evaluating the TTM have shown that stages can be a useful approach to modeling human behavioral processes, albeit stage-based interventions have shown mixed efficacy (Johnson et al., 2008). The periodic and discrete nature of the stages is insufficient to fully capture human behavioral processes, as real-world behaviors are diverse and non-linear (Glanz & Bishop, 2010; Glanz et al., 2015).

More recent stage-based models have been proposed, such as Li and colleagues' stage model of personal informatics (Li, Dey, & Forlizzi, 2010), which was designed to model information behaviors among users of personal informatics systems, those systems that help individuals to track, monitor and understand their health information (Li et al., 2010). The five stages in Li's model include preparation (reasons for collecting data), collection (recording data), integration (how data are combined, augmented, and transformed), reflection (how a person makes sense of data), and action (whether a person acts on the data). Researchers have found that personal informatics systems can create problems at specific stages (Kim et al., 2016). For example, individuals who rely on activity tracking tools (e.g., FitBit) may encounter significant barriers in the data preparation and collection stages due to

limited access to raw data stored in proprietary systems. The use of mobile health systems, such as those which integrate expert help and decision-support for translating personal data into actionable disease guidance, has promise to overcome the limitations of individuals to understand and act on their personal health information. This type of mobile health system is being studied in this dissertation (to be discussed further in the Methodology chapter).

An individual's physical and mental states fluctuate regularly, in personally unique ways, moderated by one's attitudes, beliefs, and characteristics. Some individual states change near continuously (such a synapse firings), while others are more stable and constant (such as one's degree of neuroticism or age). An individual's state can influence his/her predicted likelihood of behavior change at any given point in time (Nahum-Shani et al., 2015). But unfortunately, current behavioral intervention designs do not generally incorporate functions to adjust to fluctuating states.

A key aspect predictive of one's behavioral outcome has been shown to be their level of motivation to achieve the given outcome (Ryan & Deci, 2000). Individuals are more motivated when they perceive themselves to be competent (Ryan & Deci, 2000). This concept is central to mCare platforms, which aim to enhance self-efficacy. Self-efficacy is concerned with people's beliefs in their ability to influence events that affect their lives (Bandura, 1986). Self-efficacy is the fundamental construct within Bandura's social cognitive theory (SCT), which describes how people initiate and sustain specific behavioral patterns (Bandura,

1986). The second core SCT construct is outcome expectations, which indicate one's judgments of the likely consequences of doing, or not doing, a particular behavior. Goals are the third construct, involving self-monitoring, specific goal-setting and self-reward. The use of mobile health systems, including mCare, may work because of their ability to increase perceptions of self-efficacy, goal setting and a better understanding of the potential outcomes from the use of these systems (Jimison et al., 2008).

Existing behavior change models suffer from two major limitations. Existing models do not adequately account for the near continuous changes in human's mental (e.g. depressed, motivated) and physical state (e.g. fatigue, rested) or context (e.g. with healthy or unhealthy peers). Rather, current models are general instruments, providing limited utility in guiding intervention strategies for behaviors moderated by frequent state changes, which are most behaviors. A second major limitation of behavior change models is related to translating models into interventions. The use of theory in intervention design and implementation fidelity to theory are generally poor (Abraham & Michie, 2008). For example, while existing models have identified the importance of tailoring interventions based on users' individual differences, the actual adaptation of interventions based on these differences is very limited (Marcolino et al., 2018).

Further, while many researchers have found evidence of the role of individual differences in moderating health behavior change efforts, historical applications of personalization have been generally blunt and weakly effective (Marcolino et al.,

2018). A more precisely tailored and temporally rich behavioral intervention design, such as well-designed mCare offers, may improve adoption and efficacious use.

A variety of factors influence one's ability to self-manage a chronic disease. One's social-economic context, i.e. "the conditions in which people are born, grow, live, work and age" (World Health Organization, 2011, p. 10) has received significant attention in recent years (Braveman & Gottlieb, 2014, pg 19) . These "social determinants" of health, include factors like socioeconomic status, education, neighborhood and physical environment, employment, and social support networks, as well as access to health care (Beddoe, 2012). At present in the United States healthcare market, healthcare provider and payer organizations are starting to test out the prescribing of social determinant solutions like healthy food and transportation (Weintraub, 2019). For diabetic patients, a systematic review identified that it was the patient's financial resources, co-morbidities, and social support that are the key influential factors impacting better diabetes self-management. (Nam, Chesla, Stotts, Kroon, & Janson, 2011).

Social relationships in particular have been shown to influence broad aspects of one's health and attitudes, and to be predictive of clinical outcomes (Christakis & Fowler, 2007). Chronically ill patients also frequently report barriers such as depression, weight problems, difficulty exercising, fatigue, poor physician communication, pain, and financial problems, but these problems vary in intensity across a patient population (Jerant, Von Friederichs-Fitzwater, & Moore, 2005). It is an important research and policy goal to better understand what are the most

influential barriers at the *individual* patient level and the health interventions that may be most effective for a particular patient at a specific point in time along their disease management journey.

While there is considerable prior health behavior theory (Glanz et al., 2015), the complexity of the human condition rarely fits neatly in health behavior change frameworks, and real-world evidence and trials of new digital health interventions are needed to achieve more consistent and greater beneficial impacts on chronic disease. A brief discourse on health services utilization is provided next.

2c. Health Services Utilization

The use of mCare has largely been advocated for based on the presumption that it can have a positive effect on the utilization of health care services. In particular, it is believed that its use may reduce unnecessary and expensive emergency department ("ED") use, and result in better use of office visits and primacy care (LaCalle & Rabin, 2010). ED use is of keen interest because of evidence of rising ED visit rates per capita, the expense of hospital-based emergency care relative to primary medical care, and ED use being considered a frequent proxy for inaccessible or low-quality outpatient care (Van den Heede & Van de Voorde, 2016).

Economic theory indicates that increasing access to health services, vis a vis insurance or other access mechanisms (e.g. mCare), could either reduce or increase ED use. The amount of money the patient pays "out-of-pocket" for going to the ED

is decreased significantly when they have health insurance (to their co-pay amount), which may lead to more frequent visits. However, if the ED has been used in place of outpatient care by the uninsured, then health insurance coverage may transfer care to office locations and reduce ED visits. The Oregon Health Insurance Experiment, a randomized trial of Medicaid coverage in Oregon conducted from 2008 to 2010, established that Medicaid coverage was linked to a 40% increase in ED use (Finkelstein, Taubman, Allen, Wright, & Baicker, 2016). However, other studies have shown that Medicaid coverage may reduce ED visits, such as when Tennessee removed nearly 170,000 adults from Medicaid and discovered that ED visit rates increased (Sommers, Blendon, Orav, & Epstein, 2016). These contradictory findings suggest there is more to the story.

Having access to healthcare through insurance is one factor in driving possible health services use. An additional possible influencer of health services use due to having insurance is that plan members receive information about their health and available healthcare services. This change to a health plan member's information environment may result in their greater consumption of this information. Health plan communications frequently promote wellness activities. Related to the consumption of health services is consumption of health information (Rosenstock, 2005). Several studies have shown that large numbers of healthcare consumers prefer to actively avoid information about their medical condition (Case, Andrews, Johnson, & Allard, 2005; Wong et al., 2000). Among diabetics in particular, these individuals were found to seek more diabetes-related information by witnessing or hearing about other

people developing diabetes-related problems (St. Jean, 2012) . In the context of mCare, a health coach is making the potential impacts of a disease more salient and understandable to patients and sharing the coach's experiences of working with other diabetics and what happened with those patients, so it may not be surprising if patients are more motivated to use health services and utilization increases. Making the disease proximate to individuals and thereby activating them is a well-known strategy of interventions and health behavior change theories (Abraham & Michie, 2008). Further, many diabetics are unsure where to turn for diabetes-related information on their own (Franek, 2013), so health coaching works to guide patients to the appropriate care (Hibbard, Mahoney, Stock, & Tusler, 2007), and therefore healthcare utilization may increase.

A recent review article covering the policy interventions aimed to reduce ED use (Van den Heede & Van de Voorde, 2016), concluded current evidence on the effectiveness of interventions to reduce ED use *remains inconclusive*. Very little is known on the impact of mCare in particular, on ED utilization. This dissertation helps to paint a more vibrant picture of how mCare influences health services utilization, which may inform future mCare programming, processes and policy.

Chapter 3: Methodology

The data used for this dissertation project was constructed from the real-world use of an mCare solution covering three health plan customers of an mCare services provider located in the eastern United States. This retrospective secondary dataset was approved for use in this study by the University of Maryland Institutional Review Board.

Technology and process being studied - mCare

This dissertation focuses on a particular type of mHealth intervention, which is a mobile care management system, also referred to as "mCare". mCare is an emerging tool to bring care management practices into the connected care and mobile age. The typical mCare platform includes multiple connected medical devices, a smartphone app, real-time assessment engine and a health coach operations dashboard.

Figure 2 below summarizes the mCare platform operations by its five primary steps: (1) Identify care plan through an app-based assessment protocol; (2) Perform live coaching through video conference and text via smartphone; (3) Provide feedback and monitor compliance with devices/sensors; (4) Identify and resolve care issues through real time analytics; and (5) Patient self-management with less frequent health coach support. Steps one through four are the "high touch" period, which is followed by a "low touch" period in which the patient is no longer meeting weekly with the health coach, but continues to monitor health and receive feedback from the

system about their disease self-management progress and possible issues. The approximate weeks of duration of these steps is provided in Figure 2.

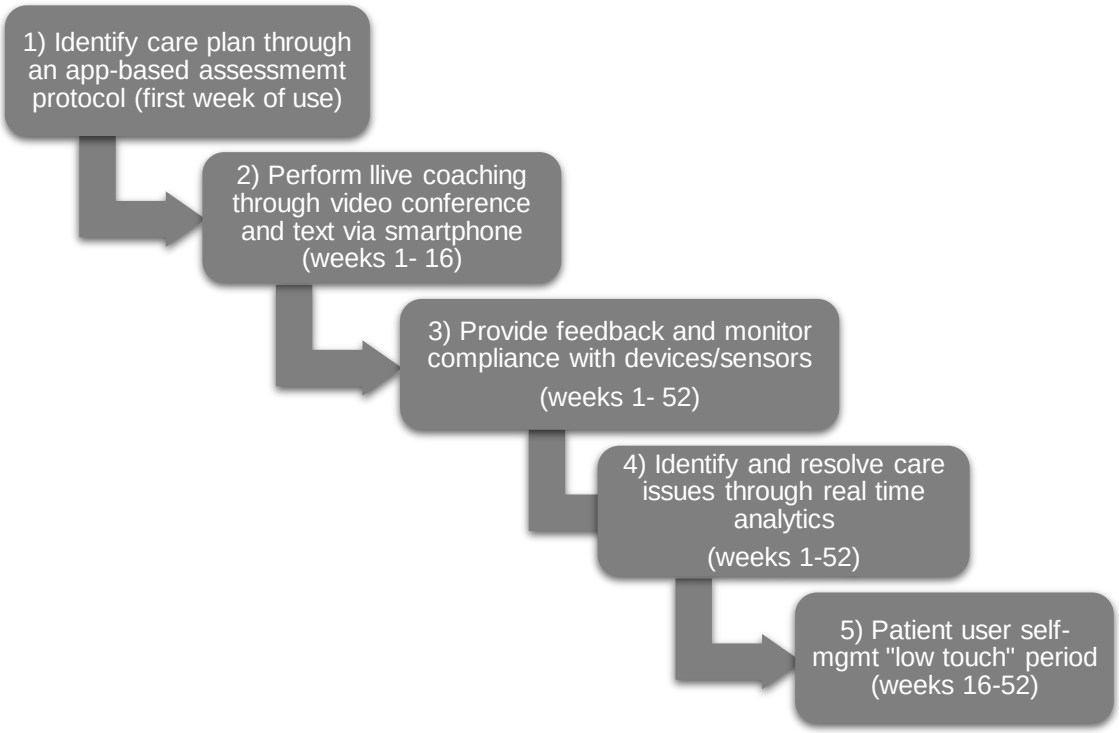


Figure 2. mCare process flow

The process of delivering mCare begins either with the health insurance plan or their designee identifying health plan members with problematic health and cost outcomes, usually via an analysis of medical claims data. Selection strategy typically entails an educated guess about the members for which the mCare provider can successfully improve outcomes. Member contact is made notifying the member of their eligibility, which may be with a letter (typical contact channel), phone call or email. Upon the member's verbal acceptance into the Company's program, an mCare

kit is shipped to the member. The kit typically includes a smartphone preloaded with the Company's mobile app, and a set of connected devices/ sensors such as a glucometer, weight scale, and blood pressure cuff. There are hundreds of possible connected devices that the platform could use.

A health coach is assigned, who will initiate virtual visits with the member. The member completes a series of questions in the mobile app to specify their sociodemographic characteristics and disease self-management potential barriers, including their social support situation. The program is typically planned for 12 months with a 4-month "high-touch" period consisting of education, health measure monitoring and weekly health coach visits, followed by an 8-month "low-touch" period. The expectation is that the member will have learned how to monitor and manage their medical condition during the initial four months. After four months, low touch monitoring continues for eight months, with ad-hoc health coach support as needed, such as if measures trend negatively or if the health plan member needs help triaging an issue like chest pain.

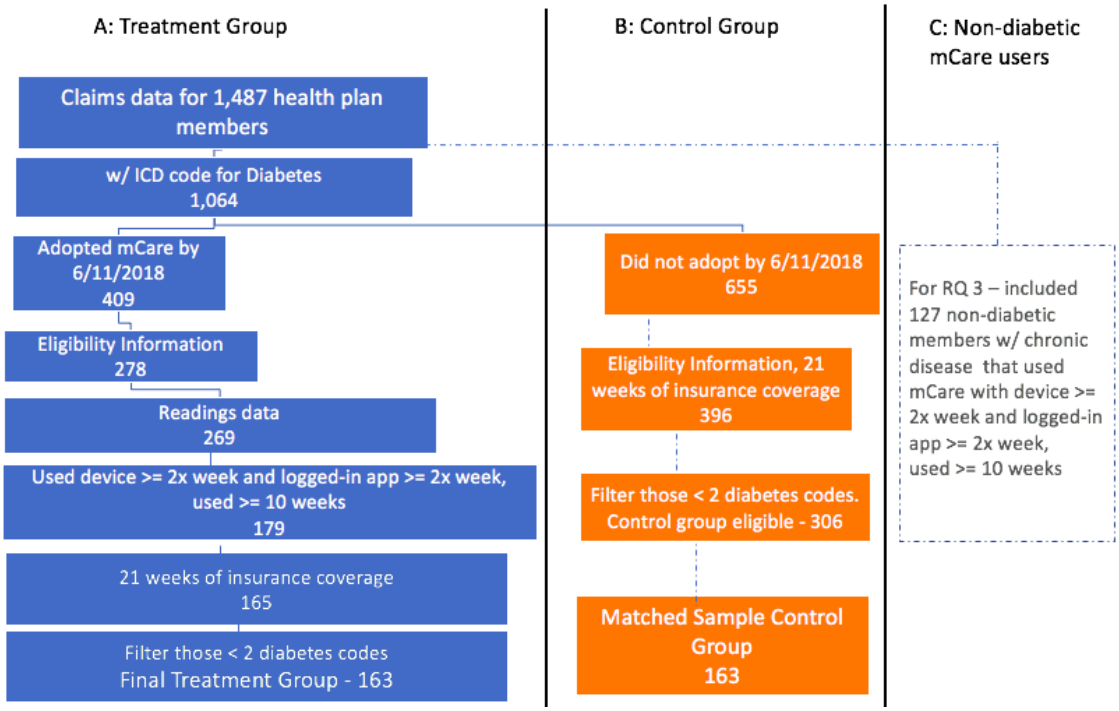
The observational period for this study is five months, covering the entire high touch period through the first month of the low touch period. The study participants and treatment and control group assignments are described next.

Study Cohort

Figure 3 lists the study population and the decision process for the assignment of the treatment and control groups. There were 1,487 members in the medical claims data provided by the 3 health insurance companies. After filtering for

members with diabetes using the R package Comorbidity (Gasparini, 2019) that resulted in 1,064 members with diabetes. Of those 1,064, 409 had begun using mCare by June 11, 2018, which was the mCare enrollment cutoff date for this study.

Figure 3. Treatment and control group selection



Of those 409 members, insurance eligibility information was available for 278 of them, which included their demographic data. Of these 278 members, 269 (96.8%) had medical device reading data. The comparison cohort members had to have a minimal level of usage to be representative of an mCare user. The 269 members were further filtered to include only those that had used a connected device at least two times per week on average, logged into the mobile app at least two times per week on average, and used the mCare system for at least 10 weeks of the 21-week

observational period. This filtering reduced the treatment cohort to 179 members. Next, only those members which had insurance coverage during the full 21-week observational period were included, which reduced the treatment cohort size to 165 members. Finally, a further screening of diabetic members was performed to remove any members that only had one instance of a diabetes ICD code in their claims records, as sometimes a single diabetes ICD code may be indicative of just a suspected diabetes diagnosis or screening. Using the diabetes codes identified by Qwan et al. (2015), this final screening procedure filtered out 2 of the 165 members, resulting in a final treatment cohort of 163 members.

For the creation of a control group (see column B in Figure 3), a similar selection approach was used. Of the 1,064 health plan members identified as having diabetes through the R Comorbidity package, there were 655 individuals that were not part of the mCare program. Of these 655, there were 396 plan members that had eligibility information including demographics and 21 weeks of continuous insurance coverage. These control group eligible members were screened to only include members with at least two diabetes ICD codes, which reduced the control-eligible sample to 306 members. A matched sample of 163 members from those eligible was generated using the matchit R package for propensity score matching (Ho, Imai, King, Stuart, & Whitworth, 2018), which is discussed further under the matching procedures section.

A further 127 non-diabetic mCare users (see column C in Figure 3) are included in the analysis for research question 3. The reason for the addition of this non-diabetic

cohort was for experimentation when no significant effects were found among the 326-member cohort (163 treatment group, 163 control group) of plan members with diabetes mellitus. By adding 127 other chronic disease patients using mCare at the same thresholds of use, the analysis sought additional power to detect the influence of social determinant factors on the effectiveness of mCare on chronic conditions in general. These 127 members had congestive heart failure (CHF) and/or chronic obstructive pulmonary disorder (COPD) and were using a similar mCare treatment regimen with health coach support, the app, and connected devices including a blood pressure monitor and weight scale.

Matching procedures for the treatment and control group

The 163-member treatment group was matched with a similarly structured 163-member control group. Balanced matching aims to ensure the distribution of the matching factors to be the same or nearly the same across groups of individuals (Mansournia, Hernán, & Greenland, 2013). Matching was performed using the available disease severity and demographic factors that are predictive of chronic disease health outcomes and healthcare use (De Boer, Wijker, & De Haes, 1997). These variables included: age, gender, whether the member has diabetes with complications, congestive heart failure (CHF), and the weighted Charlson Index score (a comorbidity severity measure). Following the recommendations of Ho et al. (2011), propensity score matching was used. In a perfect experiment, there would be exact matching by health insurance plan, however, given the composition of the member population and data availability of the three plans, this was not possible. A

perfect match on plan scenario was found to yield significant variation in clinical severity of the matched treatment and control groups; therefore exact matching by plan was not favored. Given the inability to exactly match on plan, additional robustness checks were conducted that analyzed the variation in results when excluding a plan from the sample versus inclusion of all three health plans.

Table 2 reports the absolute value or mean value of the attributes of the treatment and control groups, with the percentage variation. The table shows that for age, gender, and presence of diabetes with complications, the treatment group and control group are well-matched. The average weighted Charlson score, which is a measure of comorbidity typically ranging from 0 – least severe to 20 - high severity (described further in the proceeding section), in the control group is a 0.5 absolute difference higher, meaning the control group was slightly sicker than the treatment group, on average.

Table 2: Summary of balance for matched cohort

Attribute	Treatment Group	Control Group	Absolute Difference	% Difference
Cohort size	163	163	0	0.0%
Age	54.1	54.3	- 0.2	< 1%
Gender				
Male	56	59	- 3	- 5.0%
Female	107	104	3	2.8 %
Diabetes w/ complications	99	98	1	1.0 %
Charlson comorbidity score	5.24	5.75	- 0.5	- 9.7 %
Has CHF	54	57	- 3	- 5.6 %

Measures

A combination of clinical, administrative, sociodemographic and mCare system use measures were analyzed to develop the findings. *Table 3 Measures and Sources* reports the measures and data sources used for the analysis, followed by additional description of these variables.

Table 3. Measures and sources

Measure Construct	Variable(s)	Data Source
Cardiovascular health, diabetes management	Diastolic blood pressure (mmHg)	Device reading repository
Cardiovascular health, diabetes management	Systolic blood pressure (mmHg)	Device reading repository
Blood sugar regulation, diabetes management	Glucose (mg/dL)	Device reading repository
Body composition, diabetes management	Weight (lbs.)	Device reading repository
Demographics	Age, gender	Insurance eligibility file
Comorbidity	Charlson Comorbidity Index, presence of medical conditions	Claims records full patient pre-intervention history
Social support	Score of self-reported barriers (0-100 scale)	Patient-reported in app
Device readings	Frequency of device usage	App's device log data
App use	Frequency of logins	App's login log data
Place of service use	Number and costs of ED, physician's office, Inpatient visits. Type of ED visit.	Claims records (21 week observation period)
Place of service cost	Amount spent at sites of care (ED, physician's office, Inpatient)	Claims records (21 week observation period)

Comorbidity Measurement

To estimate the comorbidity of plan members, the Charlson Comorbidity Index (”CCI”) was applied (Charlson, Pompei, Ales, 1987). CCI is a method of predicting mortality by classifying a patient’s comorbid conditions (Charlson ME, Pompei P, Ales KL, 1987); this scoring system has been broadly applied by health researchers seeking to measure the burden of disease in individuals and populations (Quan et al., 2011, 2005), and has been validated for its ability to predict mortality in various disease subgroups (Quan et al., 2011). Each of 17 comorbidity categories (cancer, diabetes, congestive heart failure, AIDS …) used in the CCI has an associated weight (from 1 least severe to 6 most severe), based on the adjusted risk of mortality (i.e. the risk of dying associated with each condition), and the sum of all the weights results in a single comorbidity score for a patient (Johnson et al., 2015). The members included in this dissertation study ranged from a score of 1 to 22, with a mean and median of 5.5 and 5.0, respectively. To compute a score, for example, if one has a metastatic solid tumor (weight = 6) and diabetes with end organ damage (weight = 2), and no other conditions, this person’s score would be 8.

The following section further discusses the methods and data used to answer each research question.

RQ1: What types of health benefits does mCare provide to insurance plan members with type 2 diabetes?

For research question one, a Pre-Post Analytical Design is utilized to compare the 163 diabetic mCare users’ baseline readings of clinical indicators (blood pressure,

weight, glucose) with their device readings at the end of the 21-week observational period. For the baseline measure, the average of their week one readings are computed. For the post-mCare use reading measures, the average of their readings in month 5 (weeks 17-21) were used. The difference between these two measurements is their change. Mean values at each measurement period (baseline – week 1, month 1, month 2, month 3, month 4, month 5), along with 95% confidence intervals, were computed and then graphed using ggplot for R (Chang, 2013).

The primary dependent variable used for the RQ1 analysis was blood pressure (both systolic and diastolic), which is a primary indicator of cardiovascular health (D'Agostino et al., 2008). The reason for using blood pressure as the outcome variable, rather than hemoglobin A1c (which is a common outcome measure of diabetic outcomes), is threefold. First, patients with diabetes are at high risk of developing a major cardiovascular event, such as myocardial infarction or stroke (Angermayr, Melchart, & Linde, 2010). By better managing blood pressure, diabetes patients can reduce their risk of medical complications (Angermayr, Melchart, & Linde, 2010). Therefore, a key therapeutic target for physicians caring for diabetes patients and for care managers is well-managed blood pressure (Angermayr, Melchart, & Linde, 2010). The National Institutes of Health recommends the optimal treatment for a patient with diabetes is to manage the multiple modifiable risk factors including blood pressure (NIDDK Health Information Center, 2018). The second primary reason for selecting blood pressure is that the use of blood pressure in diabetes-focused research studies is less studied, which is a gap in understanding,

given the importance of blood pressure to diabetic patient health outcomes. Finally, given the data collection parameters of this real-world study, hemoglobin A1c was not an available measure.

In addition to blood pressure, the baseline, monthly average and ending measures of health plan members' weight and glucose are estimated. As previously discussed, members are provided with a weight scale that is connected to the cloud via a cellular signal. Members are also provided with a glucometer that connects to the mCare vendor-provided smartphone via Bluetooth, which then synchs with the cloud to upload the glucose data.

In order to minimize the potential effect of outliers, Winsorization (Ruppert, 2014) of reading values greater than three standard deviations from the mean reading value were trimmed. This Winsorization process was used with the blood pressure, weight and glucose reading values. The trimmed values represented less than 2% of device readings.

RQ2: What types of utilization and cost implications does mCare have for insurance plans and their members with diabetes?

Analysis was performed to quantify the use and cost of emergency department visits, office visits and inpatient stays in the treatment group and control group.

The administrative claims data used for this study includes the amount charged and paid for each member, place of service utilized (e.g. emergency department, hospital, physician's office.), each visit's ICD10 codes, short textual descriptions of the patient's chief complaint, and the dates of service. ICD10 is the

10th revision of the International Statistical Classification of Diseases and Related Health Problems, a medical classification list by the World Health Organization (World Health Organization, 2016).

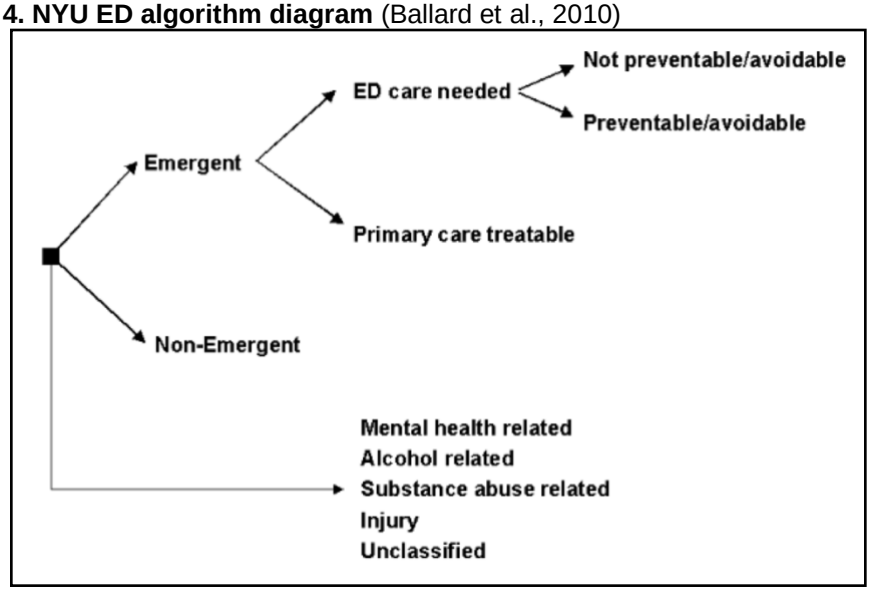
The analysis went a step further and reviewed the most frequent diagnoses found in the treatment and control groups in order to evaluate the reasons why they used the different treatment sites of interest. The analysis also conducted textual analysis of the diagnosis descriptions found in the claims records to help identify potential patterns or services within and across the treatment and control groups. To perform this text analysis, NVivo 12 was used to quantify the word frequencies.

A key area of concern for mCare companies and their insurer customers is appropriate ED use and triaging care to the most appropriate and cost-effective site of care. For this study's ED utilization analysis, multiple methods were applied. First, ED visits were identified using their place-of-service code (code = 23). Then, each health plan member's ED visit was classified into one of four severity categories using the New York University ED Algorithm (EDA) (Ballard et al., 2010; Gandhi & Sabik, 2014). The EDA was developed based on expert reviews of information from comprehensive medical charts of nearly 6,000 patients, from which each ED visit is classified into categories. The ICD9 and ICD10 codes of those reviewed visits were analyzed and translated into an algorithm for classifying ED visits. The potential visit categories, as defined by the NYU ED algorithm authors (Billings, Parikh, & Mijanovish, 2000), include:

- **Non-emergent:** The patient's initial complaint, presenting symptoms, vital signs, medical history, and age indicated that immediate medical care was not required within 12 hours;
- **Emergency care needed: Primary care physician treatable**: Based on information in the record, treatment was required within 12 hours, but care could have been provided effectively and safely in a primary care setting. The complaint did not require continuous observation, and no procedures were performed or resources used that are not available in a primary care setting (e.g., CAT scan or certain lab tests);
- **Emergency care needed - Preventable/Avoidable:** Emergency department care was required based on the complaint or procedures performed/resources used, but the emergent nature of the condition was potentially preventable/avoidable if timely and effective ambulatory care had been received during the episode of illness (e.g., the flare-ups of asthma, diabetes, congestive heart failure, etc.); and
- **Emergency care needed - Not Preventable/Avoidable:** Emergency department care was required and ambulatory care treatment could not have prevented the condition (e.g., trauma, appendicitis, myocardial infarction, etc.).

Figure 4 depicts the flow of classifying the ED visits, observing that mental health-related, alcohol-related, substance abuse-related, injury, and unclassifiable are classified into a separate category.

Figure 4. NYU ED algorithm diagram (Ballard et al., 2010)



Independent researchers have conducted analysis that supports the validity of this algorithm for differentiating ED visits based on need for hospitalization and/or mortality risk (Ballard et al., 2010). The ED algorithm is therefore a useful tool to support assessment of interventions and policies aimed at reducing the use of the ED for non-emergencies.

In order to minimize the potential effect of extreme outliers, Winsorization (Ruppert, 2014) of values greater than three standard deviations from the mean number of encounters by site was used. Winsorization was also applied to the cost of paid claims estimates by site, at the three standard deviation mark.

The treatment and control groups' utilization for the different visit types were compared. Descriptive statistics, t-tests, and effect size estimates were used to model the differences between the treatment and control group. The results were analyzed with all three insurance plans included in the analysis sample, and with the exclusion

of a health plan. Paired t-tests were used for comparison of matched samples, following the recommendations of Austin (2011).

RQ3: How is the response to mCare of insurance plan members with chronic disease related to their demographics and social support?

Research question 3 seeks to gauge how the social context and demographics of an individual with diabetes and/or another type of chronic disease may moderate the health outcomes associated with the use of mCare. To estimate the effects of mCare, descriptive statistics, t-tests, effect sizes and linear mixed models were used. Linear mixed modeling was applied using the R package lme4 (Bates, Mächler, Bolker, & Walker, 2015).

When an mCare user begins the mCare program, they are served an in-app questionnaire asking about their particular barriers. Of particular interest for this dissertation study was the degree of social support an individual perceives and their access to healthcare. The full questionnaire is considered proprietary to the mCare vendor, and therefore is not possible to share.

In order to assess the possible groupings of the member responses to the in-app questionnaire into themes related to this study's research question, the inter-relatedness of the social support-related questions were evaluated using Cronbach's alpha (α) (Bland & Altman, 1997). Cronbach's alpha is a measure of internal consistency; that is, how closely related a set of items are as a group. Cronbach's alpha is a commonly used measure of scale reliability (Santos, 1999). The social

support barriers' combined Cronbach's alpha is 0.74, which is considered an acceptable level for grouping (Taber, 2018).

Social support barrier questions:

- I spend most days at home alone: 0 (never) …. 100 (always)
- I have friends I can rely on and talk to: 0 (whenever I need them) … 100 (not reliable)
- My family gets along: 0 (a lot of the time) …. 100 (rarely)
- My family talks about everything; both good and bad: 0 (most of the time) …. 100 (rarely)

Table 4 reports the mean value of the treatment cohort's self-reported assessments of their social barriers.

Table 4. Social support barrier questions and descriptive statistics

Question	Mean (sd[1])
My family gets along	22.1 (31.7)
My family talks about everything; both good and bad	22.6 (33.5)
I spend most days at home alone	30.6 (33.9)
I have friends I can rely on and talk to	21.5 (32.6)
Composite Social barrier score	24.2 (24.1)

1. sd = standard deviation

Figure 5 shows the interface similar to the one used to input a response to the social support barrier questions. A user has a slider bar that represents the degree of social support the respondent perceives with a positive and negative anchor on each end of the scale, with a color transition corresponding to positive (green) and negative (red). The leftmost side of the scale equates to a zero barrier score and the rightmost side as a barrier score of 100; if the respondent marked their social support barrier in the middle, that equates to a score of 50, for example.

Figure 5. User mobile interface for questionnaire (0 = never, 100 = always)

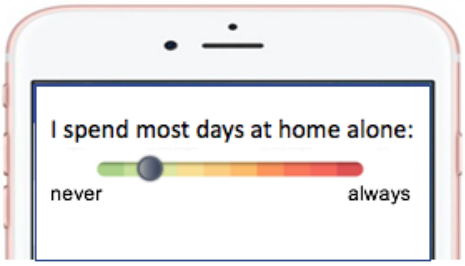


Table 5 summarizes the methods used to address each of the three primary research questions. Well-designed observational studies have been shown to provide results similar to randomized controlled trials (Song & Chung, 2010) , and this set of methods yielded a satisfactory set of research results, which are discussed in the next chapter.

Table 5. Summary of research methods used

Research Question	Primary Methods
RQ1: What types of health benefits does mCare provide to insurance plan members with type 2 diabetes?	Pre-post measurement of clinical condition indicators (blood pressure, glucose, weight) of treatment group. Indicators include diastolic blood pressure, systolic blood pressure, glucose level, and weight.
RQ2: What types of utilization and cost implications does mCare have for insurance plans and their members with diabetes?	Differences among treatment and control group utilization of health services, including number of visits and cost of inpatient stays, office visits, and ED use. Frequency of specific ICD codes.
RQ3: How is the response to mCare of insurance plan members with chronic disease related to their demographics and social support?	Linear mixed-effects models of clinical condition indicators (blood pressure, glucose, weight) changes with covariates including sociodemographic indicators.

Chapter 4: Research Results

The analysis of these health plan members' use of mCare yielded several interesting findings. These results are discussed in the proceeding section in the order of their corresponding research question.

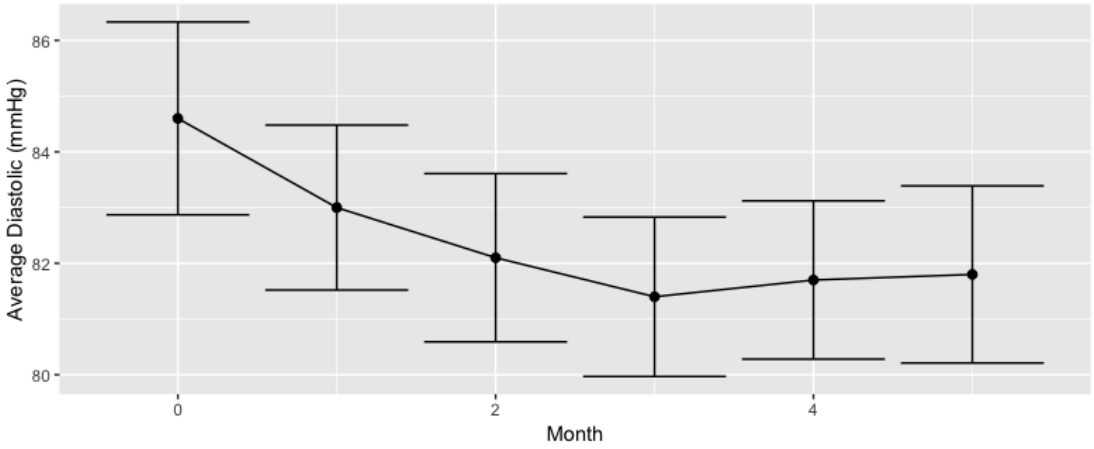
RQ1: What types of health benefits does mCare provide to insurance plan members with type 2 diabetes?

For research question one, a pre-post mCare use analysis of the treatment cohort was applied regarding changes in blood pressure, weight and glucose levels. (Device readings are not available for non-mCare users in the control group)

Diastolic blood pressure: Results revealed a significant decrease in mean diastolic blood pressure at observational period end (month 5) versus baseline. The mean diastolic blood pressure at baseline equaled 84.6 mmHg (standard deviation = 11.28, standard error = 1.73, 95% confidence interval), whereas the mean diastolic blood pressure at month 5 equaled 81.8 mmHg (standard deviation = 10.38, standard error = 1.59, 95% confidence interval). On average, members reduced their diastolic blood pressure by 2.8 mmHg, which is a 3.3% reduction. Approximately 85% of treatment group members monitored blood pressure during month 5. About 52% of the treatment group who initiated mCare had a ½ mmHg or greater drop in diastolic blood pressure over the 5-month observational period. A Welch's 2-sample t-test indicates that there was a significant decrease in diastolic blood pressure (mmHg) at a 95% confidence interval (t = 2.2392, df = 287.59, p-value = 0.02591). Figure 6

reports the mean value of diastolic blood pressure (mmHg) at monthly intervals, with the 95% confidence interval range as whiskers.

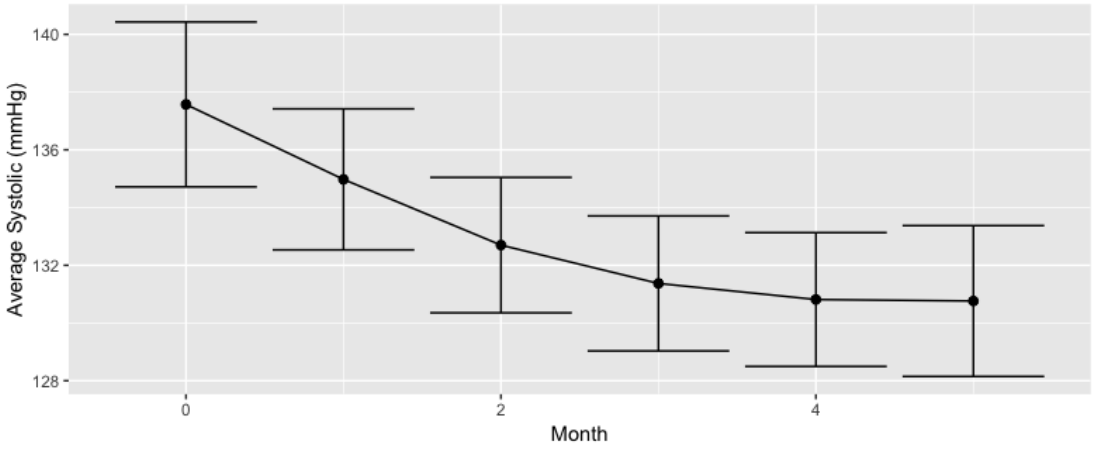
Figure 6. Monthly diastolic blood pressure average value (mmHg)



Systolic blood pressure: Analysis of systolic blood pressure results reported a significant decrease in mean systolic blood pressure at observational period end versus baseline. The mean systolic blood pressure at baseline equaled 137.5 mmHg (standard deviation = 18.7, standard error = 2.86, 95% confidence interval), whereas the mean systolic blood pressure at month 5 equaled 130.8 mmHg (standard deviation = 17.1, standard error = 2.63, 95% confidence interval). On average, members reduced their systolic blood pressure by 6.7 mmHg, which is a 4.9% reduction. Eighty-five percent of treatment group members monitored blood pressure during month 5. Fifty-eight percent of the treatment group who initiated mCare had a ½ mmHg or greater drop in systolic blood pressure. A Welch's 2-sample t-test indicates that there was a significant decrease in systolic blood pressure at a 95% confidence interval (t = 3.2155, df = 287.16, p-value = 0.001451).

Figure 7 reports the mean value of systolic blood pressure (mmHg) at monthly intervals, with the 95% confidence interval range as whiskers.

Figure 7. Monthly systolic blood pressure average value (mmHg)



The results reported suggest that the use of mCare can significantly influence cardiovascular health targets, as measured by diastolic and systolic blood pressure. Table 6 reports the mean absolute and percentage changes in diastolic and systolic blood pressure, and shows that on average, members using the mCare system dropped their blood pressure, with those members in the 1st quartile of degree of change reducing their diastolic blood pressure by 9.3% and systolic blood pressure by 9.6%.

Table 6. Blood pressure at observational period end (mo. 5) versus baseline

	Change in Diastolic BP (mmHg)		Change in Systolic BP (mmHg)	
	Absolute change	% change	Absolute change	% change
1st quartile	- 7.9	- 9.3%	- 13.2	- 9.6%
Median	- 2.9	- 3.4%	- 6.7	- 4.9%
Mean	- 2.8*	- 3.3%	-6.7**	- 4.9%
3rd quartile	1.9	2.2%	2.4	1.7%

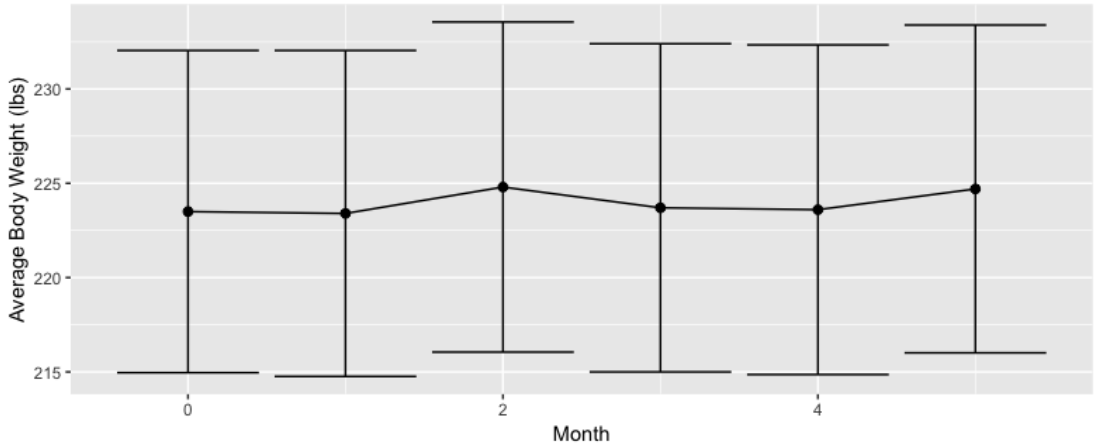
+Significant based on Welch's two sample t-test (*** p-value < 0.001, ** < 0.01, * <0.05)

The analysis also assessed the changes in bodyweight and glucose of the treatment cohort; these results follow.

Weight: The analysis included a comparison of bodyweight across the observation period. The bodyweight analysis revealed no significant changes in weight at the observational period end versus baseline. Mean body weight at baseline equaled 223.5 lbs. (standard deviation = 55.6, standard error = 8.54, 95% confidence interval), whereas the mean body weight at month 5 equaled 224.7 lbs. (standard deviation = 56.6, standard error = 8.69, 95% confidence interval). A Welch's 2-sample t-test indicates that there was not a significant change in weight at a 95% confidence interval (t = -0.17085, df = 266.36, p-value = 0.8645).

Figure 8 reports the mean value of body weight at monthly intervals, with the 95% confidence interval range as whiskers.

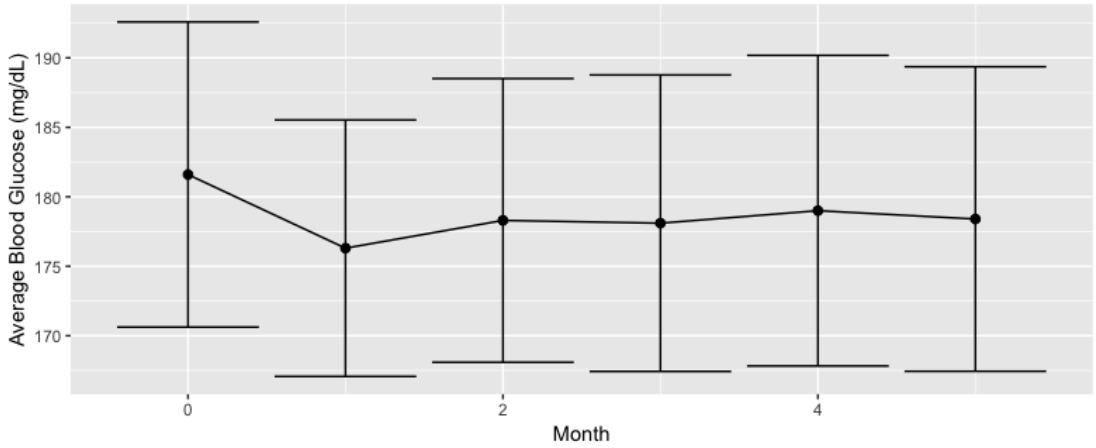
Figure 8. Monthly bodyweight average value (lbs.)



Results revealed no significant changes in blood glucose levels at observational period end versus baseline. Mean glucose level at baseline equaled 181.6 mg/Dl (standard deviation = 71.5, standard error = 10.98, 95% confidence interval), whereas mean blood glucose level at month 5 = 178.4 mg/Dl. (standard deviation = 71.4, standard error = 10.96, 95% confidence interval). A Welch's 2-sample t-test indicates that there was not a significant change in blood glucose levels (mg/Dl) at a 95% confidence interval (t = 0.23575, df = 103.45, p-value = 0.8141).

Figure 9 reports the mean blood glucose level at monthly intervals, with the 95% confidence interval range as whiskers.

Figure 9. Monthly blood glucose average value (mg/dL)



This dissertation study is also concerned with utilization and costs information associated with mCare use, which is discussed next.

RQ2: What types of utilization and cost implications does mCare have for insurance plans and their members with diabetes?

Research question 2 pertained to outcomes of keen interest to health insurance plans, which serve as one of the primary purchasers of mCare systems. As described in the Methodology chapter, two principal measures were evaluated through the comparison of the matched control group with the treatment group, including the use of care locations (e.g. ED and office visits), and cost of health services as evidenced by the amount paid by the insurer. The most frequent conditions presenting at certain sites of care was also evaluated.

Table 7 reports count of visits to the emergency department (ED) for the treatment and control group over the course of the five-month (21 weeks) observational period. The visits are further classified by ED visit type (Ballard et al.,

2010), as detailed in the Methods section. The absolute and percentage differences are provided, as well as an effect size estimate.

Table 7. Emergency department utilization during observational period (treatment vs. control group)

	Treatment	Control	Absolute difference	% difference	Significant +	Effect size
Emergent						
Visits+	141	119	22	15.6%		
Mean visits	0.86 (1.4)	0.73 (1.3)	0.13	15.6%	***	0.09
Emergency care need – Primary care physician treatable						
Visits+	54	42	12	22.2%		
Mean visits	0.33 (0.6)	0.26 (0.6)	0.07	22.2%	***	0.11
Emergency care needed - preventable						
Visits+	21	13	8	38.1%		
Mean visits	0.13 (0.4)	0.08 (0.3)	0.05	38.1%	**	0.12
Emergent care needed not preventable						
Visits+	57	52	5	8.8%		
Mean visits	0.35 (0.7)	0.32 (0.7)	0.03	8.8%	P = 0.07	0.03
Non-emergent						
Visits+	53	56	-3	-5.7%		
Mean visits	0.33 (0.7)	0.34 (0.6)	-0.02	-5.7%	p = 0.32	-0.06
Unclassifiable						
Visits+	64	66	-2	-3.1%		
Mean visits	0.39 (0.7)	0.40 (0.8)	-0.01	-3.1%	p = 0.53	-0.01
Injury						
Visits+	21	16	5	23.8%	*	
Mean visits	0.13 (0.3)	0.10 (0.3)	0.03	23.8%		0.10

+Based on paired t-test (*** p-value < 0.001, ** < 0.01, * <0.05). Visits greater than 3 standard deviations from mean visits have been Winsorized.

As reported in Table 7, a statistically significant difference between the treatment group and control group were found for four of the ED visit classes. A statistically significant difference between the treatment group and control group were found for: the mean number of Emergent visits (t = 4.0203, df = 162, p-value = < 0.001 percent confidence interval: 0.06773702, 0.19852064, sample estimates mean of the differences: 0.13); for the mean number of Emergency care need –

Primary care physician treatable visits (t = 3.142, df = 162, p-value = 0.002, 95 percent confidence interval: 0.02621152, 0.11489278, sample estimates mean of the differences 0.07); and the mean number of Emergency care needed – preventable visits (t = 2.95, df = 162, p-value = 0.004, 95 percent confidence interval: 0.01582371 0.07988181, sample estimates mean of the differences = 0.05). A statistically significant difference between the treatment group and control group was also found for ED visits for injuries (t = 2.2642, df = 162, p-value = 0.03, 95 percent confidence interval: 0.003921813, 0.057427880, sample estimates mean of the differences: 0.03).

While there were significant p-values reported for the treatment group relative to the control group for the above mentioned ED visit types, the effect sizes were low, all < 0.15, suggesting very little effect of the mCare on an increased number of ED visits. In addition to the data reported in Table 7, robustness checks were conducted regarding the frequency of visit types if one of the health plans was excluded from the analysis sample. This procedure, which results in a non-matched sample, found no significant differences between the frequency of visits using a Welch's t-test with a 95% confidence interval. This further supports the finding that mCare did not significantly reduce the incidence of ED visits.

Analysis of the primary medical complaints from the ED visits was conducted. Table 8 reports the diagnoses from the Emergent ED visits identified in the claims records. The description is the medical condition to which the ICD code

relates. Counts is the number of times this primary diagnosis was reported in the claims records for the Emergent ED visits during the 21-week observational period.

Table 8. Emergent ED visits primary diagnosis (top 10)

ICD	Description	Total Count	Treatment Count	Control Count
R079	Chest pain, unspecified	49	23	26
R0602	Shortness of breath	24	13	11
R0789	Other chest pain	23	12	11
R109	Unspecified abdominal pain	18	12	6
I509	Heart failure, unspecified	8	4	4
E1165	Type 2 diabetes mellitus with hyperglycemia	7	4	3
J069	Acute upper respiratory infection, unspecified	7	4	3
E11649	Type 2 diabetes mellitus with hypoglycemia without coma	6	4	2
R55	Syncope and collapse	6	4	2
R1013	Epigastric pain	5	5	0

Table 9 reports the diagnoses from the Emergency care needed - PCP treatable visits identified in the claims records from the ED visit. The description is the medical condition to which the ICD code relates. Counts is the number of times the diagnosis was reported. Table 9 shows that abdominal pain, chest pains and respiratory issues accounted for the majority of the PCP treatable ED visits.

Table 9. Emergency care needed – PCP treatable visits primary diagnosis (total codes> 1)

ICD	Description	Total Count	Treatment Count	Control Count
R109	Unspecified abdominal pain	18	12	6
J069	Acute upper respiratory infection, unspecified	7	4	3
R072	Precordial pain	6	3	3
R1031	Right lower quadrant pain	6	3	3
R1013	Epigastric pain	5	5	0
R1084	Generalized abdominal pain	5	3	2
R1032	Left lower quadrant pain	4	2	2
R1012	Left upper quadrant pain	3	3	0
R0781	Pleurodynia	3	2	1
L03311	Cellulitis of abdominal wall	2	2	0
R1030	Lower abdominal pain, unspecified	2	2	0

It is also instructive for mCare vendors to better understand the patterns of their users whose ED visits are considered preventable. Table10 reports the primary diagnoses from the preventable ED visits identified in the claims record. Table 10 shows that heart failure, hyperglycemia, hypoglycemia, exacerbation of asthma, and exacerbation of chronic obstructive pulmonary disease symptoms were the primary reasons for presentation at the ED for visits that are considered preventable.

Table 10. Emergency care needed – preventable visits primary diagnosis (total codes > 1)

ICD	Description	Total Count	Treatment Count	Control Count
I509	Heart failure, unspecified	8	4	4
E1165	Type 2 diabetes mellitus with hyperglycemia	7	4	3
E11649	Type 2 diabetes mellitus with hypoglycemia without coma	6	4	2
J45901	Unspecified asthma with (acute) exacerbation	6	3	3
J441	Chronic obstructive pulmonary disease with (acute) exacerbation	5	3	2
J189	Pneumonia, unspecified organism	3	2	1
R569	Unspecified convulsions	3	2	1

Non-emergent ED visits, which are classified as those ED visits where the presenting problem did not require immediate medical care within 12 hours, is another area to analyze in order to target improvements to ED triage processes. Table11 reports the primary diagnoses from the non-emergent ED visits identified in the claims record. Table 11 shows that headaches, hypertension, and dizziness were the primary reasons for presentation at the ED for visits that are considered unnecessary.

Table 11. Non-Emergent ED visits primary diagnosis (total codes > 1)

ICD	Description	Total Count	Treatment Count	Control Count
R51	Headache	11	6	5
I10	Essential (primary) hypertension	11	4	7
R42	Dizziness and giddiness	9	5	4
M7989	Other specified soft tissue disorders	7	5	2
R918	Other nonspecific abnormal finding of lung field	6	3	3
R112	Nausea with vomiting, unspecified	5	4	1
M25511	Pain in right shoulder	3	2	1
M25561	Pain in right knee	3	2	1
M542	Cervicalgia	3	2	1
M549	Dorsalgia (back pain), unspecified	3	2	1
M79602	Pain in left arm	3	2	1
M79671	Pain in right foot	2	2	0

The results of the primary diagnosis analysis help illuminate specific medical condition areas where mCare vendors may choose to focus their processes to reach ED utilization goals, which is deliberated further in the Discussion chapter.

The analysis also examined the frequency and costs of office visits and inpatient visits. These results are reported in Table 12.

Table 12. Comparison of treatment and control group office visits and inpatient encounters during the observational period

	Treatment	Control	Absolute Difference	% Difference	Significant[2]	Effect size[3]
Office visits						
Mean costs (sd[1])	$660 ($591)	$558 ($774)	$102	15.5%	No	
Mean visits (sd)	8.2 (5.9)	5.7 (5.7)	2.5	29.4%	***	0.44
Inpatient encounters						
Mean costs (sd)	$437 ($1,045)	$666 (1,450)	-$229	-52.4%	No	
Mean visits (sd)	2.5 (5.3)	3.7 (7.5)	-1.2	-48%	***	-0.16

1 sd = standard deviation
2 Based on paired t-test (*** p-value < 0.001, ** < 0.01, * <0.05)
3 Effect size = (mean treatment group – mean control group) / control group standard deviation

As reported in Table 12, the mean number of office visits during the observational period is statistically significantly higher in the treatment group based on a paired t-test (t = 29.307, df = 162, p-value = < 000.1, 95 percent confidence interval: 2.322967, 2.658628, mean of the differences = 2.5). It is also shown in Table 12 that the mean number of inpatient encounters during the observational period is statistically significantly lower in the treatment group based on a paired t-test (t = -5.436, df = 162, p-value = < 000.1, 95 percent confidence interval: -1.6058081, -0.7500201, mean of the differences = -1.2). The implications of these findings will be further considered in the Discussion chapter.

Table 12 also reports the mean costs of office visits and inpatient encounters for the treatment and control groups during the observational period. While the mean values of the treatment group compared to the treatment group are different, the differences were not significant.

A robustness check of the findings reported in Table 12 without a plan included was performed. This robustness check found that there persisted a significant effect on office visit compliance when excluding the Charlie plan, or excluding the Papa plan. When excluding Bravo, the results are not significant, but the sample becomes much smaller. Given the strength of the results for 3 plans, and two combinations of 2 plans, the office visit adherence effect of mCare is robust, as is an effect size of 0.44.

RQ3: How is the response to mCare of insurance plan members with chronic disease related to their demographics and social support?

As explained in the Methods chapter, linear mixed models were used to estimate the possible interaction effect between mCare users' attributes, including their demographics (age, gender) and social support, on their diastolic and systolic blood pressure outcomes. The reasons for using blood pressure as a key outcome variable has been detailed in the Methods chapter; blood pressure regulation is a key cardiovascular therapeutic target and a key diabetes management therapeutic target, which is under-reported.

In the first analysis related to RQ3, the treatment group of 163 mCare users was assessed for changes in diastolic and systolic blood pressure over the five-month observation period in combination with their individual attributes. (Medical device reading data and questionnaire data is not available for the control group of non-users of mCare)

Table 13 reports the results of the linear mixed effect modeling, with an explanation of the technical details and results following.

Table 13. Linear mixed model output with diastolic BP as the dependent variable

Fixed Effects	*Estimates*	*Std. Error*	*p-value*
(Intercept)	81.70	1.19	**<0.001 *** **
Month	-0.30	0.10	**0.003**
Has diabetes	1.14	1.13	0.315
Male	2.26	1.04	**0.030 ***
Age	-0.22	0.07	**0.001 ** **
Social support barriers - medium	0.62	1.25	0.622
Social support barriers - high	-0.80	1.76	0.651
Month * Social support barriers medium	-0.48	0.16	**0.003 ** **
Month * Social support barriers high	0.02	0.23	0.913
Random Effects			
σ_2	24.78		
$T_{00\ UID}$	79.52		
ICC	0.76		
N_{UID}	289		

The interpretation of Table 13 is as follows. There are 1,652 observations included in this analysis from 289 different mCare users. The analysis has a Marginal R_2 of 0.05 and a Conditional R_2 of 0.77, meaning the fixed effects part of the model explained approximately 5 % of the total variation in the outcome. The random and fixed effects parts of the model explained approximately 77% of the total variation in the outcome. P-values are computed using lmerTest package default methods via ANOVA and use Satterthwaites's methods for degrees-of-freedom (Kuznetsova, Brockhoff, & Christensen, 2019). Each of the factors used in this analysis are defined below:

Month: The month of the observation period measured in 4-week intervals from baseline (week 1) through month 5.

Has Diabetes: Whether the patient has diabetes or not (0,1). This variable is included since RQ3 broadened the mCare user cohort of interest beyond the diabetic patients of primary interest (when there was not significant power to detect effects in the smaller sample of 163 users).

Male: Whether the user is male or female (0,1)

Age: The user's age in years

Social support barriers – low: Social support barriers low is the default scenario, and these users self-reported a social barrier score between 0 and 20 out of a possible score of 100.

Social support barriers – medium: Grouping variable representing the users who self-reported a social support barrier score between 21 and 50

Social support barriers – high: Grouping variable representing the users who self-reported a social support barrier score greater than 50

Month * Social support barriers – medium: This represents the interaction effect between time and the group (in this case the group of users with a medium social support barrier score)

Month * Social support barriers – high: This represents the interaction effect between time and the group (in this case the group of users with a high social support barrier score)

The model estimates at each level of social support barrier score grouping are provided below. At the baseline level of social support barriers (i.e. low social support barriers), the model equation ($\hat{y}$ = predicted diastolic blood pressure (mmHg) is: $\hat{y} \approx 126.7 + -0.82 \times \text{Time} + 6.52 \times \text{Diabetes} + 5.5 \times \text{Male} - 0.15 \times \text{Age}$

Therefore, if time increases by one month (specifically four weeks) the outcome will decrease by 0.30 unit on average and this difference is significant (p-value < 0.05). The average difference between Diabetic and non-diabetic patients is 1.14 units (mmHg of diastolic BP, and this difference is significant (p-value = 0.03), which health-wise is not very meaningful. If the average age increases by one unit (year) over then the outcome will decrease by -0.22 unit (mmHg) on average, and this effect is significant (p-value = 0.001), meaning the older individuals in the sample

benefitted slightly more in terms of their change in diastolic blood pressure. The mean age was 53.5 years.

The average difference between male patients and female patients is 2.26 units (mmHg) of diastolic BP, and this difference is significant (p-value = 0.03), meaning on average males had 2.26 mmHg higher diastolic blood pressure relative to females.

For the group with a medium level of social barriers, the estimate is:

$$\hat{y} \approx (81.7 + 0.62) + (-0.30 - 0.48)\times\text{Time} + 1.14\times\text{Diabetes} + 2.26\times\text{Male} - 0.22\times\text{Age}$$

Therefore, for the medium social barrier group when time increases by one month (specifically four weeks) the outcome (mmHg diastolic BP) will decrease by 0.78 units (mmHg) per month on average, or 3.9 units (mmHg) over a five-month period; and this effect is significant (p-value = 0.003).

For the group with a high level of social barriers, the estimate is:

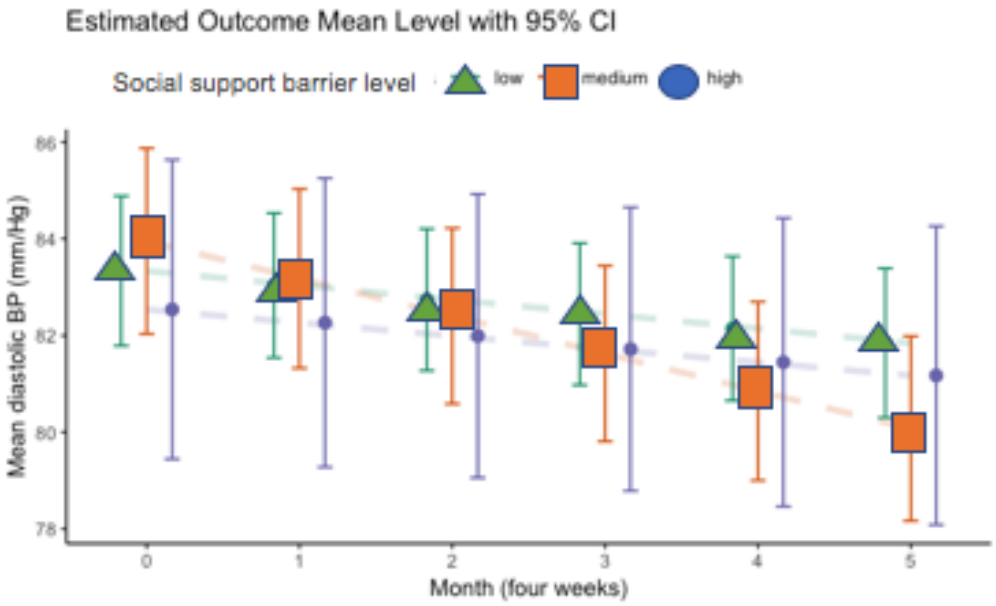
$$\hat{y} \approx (81.7 + 0.62) + (-0.30 + 0.02)\times\text{Time} + 1.14\times\text{Diabetes} + 2.26\times\text{Male} - 0.22\times\text{Age}$$

For the high social barrier group, when time increases by one month (specifically four weeks) the outcome (mmHg diastolic BP) will decrease by 0.28 units (mmHg) per month on average, or 3.9 units (mmHg) over a five-month period; however, this effect is not significant (p = 0.913).

Figure 10 visualizes the change in mean diastolic blood pressure at baseline, and at each 4-week period through month 5 for each of the three groups representing those members with low, medium and high social barriers. The graph shows the group with the medium level of social barriers, on average, has a greater decrease in the mean blood pressure. However, as the whiskers show, at a 95% confidence

interval, the significance is marginal. The p-value reported estimates that there is a significant drop in diastolic blood pressure in the social support medium barrier group relative to the social support low barrier group.

Figure 10. Linear mixed model: Diastolic BP mean outcomes by social support barrier level



The same linear mixed modeling method was applied with systolic blood pressure as the dependent variable. Table 14 reports these results, and is followed by a description of the information in the table.

Table 14. Linear mixed model output with systolic BP as the dependent variable

Fixed Effects	*Estimates*	*Std. Error*	*p-value*
(Intercept)	126.73	1.89	**<0.001*** **
Month	-0.82	0.16	**<0.001*** **
Has diabetes	6.52	1.80	**<0.001*** **
Male	5.50	1.66	**0.001** **
Age	0.15	0.10	0.156
Social support barriers - medium	3.27	2.00	0.103
Social support barriers - high	-1.66	2.80	0.554
Month * Social support barriers medium	-0.77	0.26	**0.003** **
Month * Social support barriers high	-0.07	0.37	0.854
Random Effects			
σ_2	65.89		
$T_{00\ UID}$	200.24		
ICC	0.75		
N_{UID}	289		

The interpretation of Table 14 is as follows. There are 1,652 observations included in this analysis from 289 different mCare users. The analysis has a Marginal R_2 of 0.07 and a Conditional R_2 of 0.77, meaning the fixed effects part of the model explained approximately 7% of the total variation in the outcome. The random and fixed effects parts of the model explained approximately 77% of the total variation in the outcome. P-values are computed using lmerTest package default methods via ANOVA and use Satterthwaites's methods for degrees-of-freedom (Kuznetsova et al., 2019).

The variables used in Table 14 are the same as those used (and described) in Table 13, with the exception of systolic blood pressure replacing diastolic blood pressure as the dependent variable.

The model estimates at each level of social support barrier score grouping are provided below. At the baseline level of social support barriers (i.e. low social support barriers), the model equation ($\hat{y}$ = predicted systolic blood pressure (mmHg)) is: $\hat{y} \approx 126.7 + -0.82 \times \text{Time} + 6.52 \times \text{Diabetes} + 5.5 \times \text{Male} + 0.15 \times \text{Age}$

Therefore, if time increases by one month (specifically four weeks) the outcome will decrease by 0.82 unit (mmHg) on average and this difference is significant ($p < 0.05$). The average difference between Diabetic and non-diabetic patients is 6.52 units (mmHg of systolic BP), and this difference is significant (p-value < 0.001). If the average age increases by one unit (year), then the outcome will increase by 0.15 unit (mmHg) on average, and this effect is not significant (p-value = 0.156).

The average difference between male patients and female patients is 5.5 units (mmHg of systolic BP), and this difference is significant (p-value = 0.001).

For the group with a medium level of social barriers, the estimate is:
$\hat{y} \approx (126.7+3.27) + (-0.82-0.77) \times \text{Time} + 6.52 \times \text{Diabetes} + 5.5 \times \text{Male} - 0.15 \times \text{Age}$
Therefore, for the medium social barrier group, when time increases by one month (specifically four weeks) the outcome (mmHg systolic BP) will decrease by 1.59 units (mmHg) per month on average, or 7.95 units (mmHg) over a five-month period, and this effect is significant ($p = 0.003$).

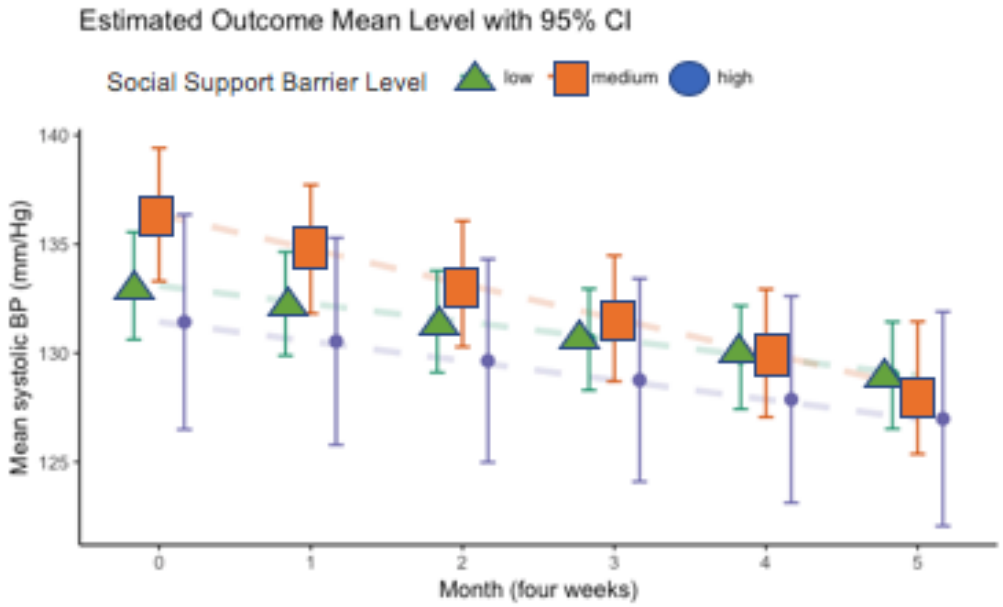
For the group with a high level of social support barriers, the estimate is:

$\hat{y} \approx (126.7\text{-}1.66) + (\text{-}0.82 - 0.07) \times \text{Time} + 6.52 \times \text{Diabetes} + 5.5 \times \text{Male} + 0.15 \times \text{Age}$

For the high social barrier group, when time increases by one month (specifically four weeks) the outcome (mmHg diastolic BP) will decrease by 0.89 units (mmHg) per month on average, or 4.45 units (mmHg) over a five-month period; however, this effect is not significant ($p = 0.854$).

Figure 11 graphs the mean value of systolic blood pressure at baseline and each of the four-week intervals. The whiskers represent the 95% confidence intervals. The graph show that the slope of the medium group is slightly steeper than the other two groups, meaning on average, the systolic blood pressure rate of decrease was greater among the moderate social support barrier group.

Figure 11. Linear mixed model systolic BP mean outcomes by social support barrier level



Further interpretation and sensemaking regarding these results are discussed in the next chapter, including potential limitations to generalizability and directions for future research.

Chapter 5: Discussion, Conclusions and Future Directions

5a. Discussion

This dissertation study aimed to reveal patterns regarding the use and impact of an mCare system, especially as it relates to use by health plan members with diabetes. Specifically, the analysis reported in this dissertation sought to understand mCare's influences on health outcomes and healthcare utilization.

RQ1: What types of health benefits does mCare provide to insurance plan members with type 2 diabetes?

mCare aims to improve patient self-management of chronic disease by helping patients better sense, measure and understand their specific risk factors. In the case of reduction of cardiovascular risk factors through more well-regulated blood pressure, over the five-month observational period the use of mCare achieved this aim for the majority of it users, and on average across the mCare users.

On the other hand, decreases in weight and glucose were not reported at a significant level during the 5-month observational period.

The specific mechanisms for the improvements in blood pressure are less clear. It may be that medication adherence improved from the monitoring, the individuals adjusted their diets, or they reduced stress, or a combination thereof. The health coaches seek to identify the specific barriers patients face and educate and motivate them to be better stewards of their health.

RQ2: What types of utilization and cost implications does mCare have for insurance plans and their members with diabetes?

The analysis of ED utilization found that the use of mCare by the treatment group did not significantly reduce the use of the ED compared to the control group. The analysis reviewed the frequency of several classes of ED visits and the complaints (diagnoses) for those visits. The treatment group used the ED at a small, but significantly higher rate, than the control group for emergent ED visits, Emergency care need – Primary care physician treatable visits, and Emergency care needed – preventable ED visits, albeit with very small effect sizes (< 0.15).

This pattern of ED visits suggests that mCare processes regarding the triage of problems to non-ED sites of care could be better constructed. Many of the complaints the members using mCare presented with at the ED are classified as treatable in non-acute care settings. The practice of medicine in the United States has developed a very low tolerance for risk, which may help explain the use of the ED at the first sign of pain even if the pain or other problem is related to a problem that does not require ED use. On the one hand, the fact that the treatment group members were more activated to respond to particularly dangerous health conditions is positive; on the other hand, the member, coach and decision support should be better able to discern that the issue is able to be treated at the primary care physician's office or is non-emergent.

One of the primary goals of mCare is to reduce and appropriately triage possible ED visits to more appropriate and less costly sites of care. On average, this

was not observed in this study. Particularly noteworthy was that the ED visit type comparison between the treatment and control group of the Emergency care needed - primary care physician treatable visit type, and Emergency care needed - preventable/avoidable visit type, did not show marked improvements.

The Emergency care needed - preventable/avoidable visit type means that ED care was required based on the complaint or procedures performed/resources used, but the emergent nature of the condition was potentially preventable/avoidable if timely and effective ambulatory care had been received during the episode of illness (e.g., the flare-ups of asthma, diabetes, congestive heart failure, etc.). The Emergency care needed - preventable/avoidable visit type of the treatment and control groups in this study were frequently related to heart failure, hyperglycemia, hypoglycemia and pulmonary issues (such as asthma and COPD). The analysis revealed that the hyperglycemic events in the control group were more common than that of the treatment group, indicating that the avoidance of hyperglycemia in particular is an area in which mCare may be showing progress. The study results reinforce that mCare vendors should focus on hypertension management and hyperglycemia avoidance as key components of their therapeutic goals.

The Emergency care needed - primary care physician treatable visit type means that based on information in the record, treatment was required within 12 hours, but care could have been provided effectively and safely in a primary care setting. The vast majority of these visits witnessed during this study were related to abdominal pains, precordial pain, and respiratory infections. These results suggest

mCare could do a better job at gauging the causes of pains, assuaging pain and triaging users to sites of care more appropriately.

There were also a significant number of non-emergent ED visits reported by the treatment group at rates similar to the control group. These visits were frequently related to headaches, hypertension, dizziness, swelling (soft tissue disorders), and pulmonary issues. These results suggest mCare vendors can do a better job triaging cases that are not true emergencies. Among these results, there were fewer hypertension ED cases in the treatment group versus the control group, suggesting mCare may be helping with better hypertension management.

What may be driving the ED use of the treatment group? Prior work (Painter, Borba, Hynes, Mays, & Glanz, 2008) suggests that when individuals with chronic disease become more aware of the severity of their condition, the possible consequences, and their ability to do something about it, then they, on average, become more activated healthcare consumers. Prior work in the health information behavior domain has also shown that there is a sizable population of individuals that actively avoid health information and services, and that the tendency to engage in avoidance is greater in individuals with lower health literacy and greater socioeconomic disadvantage (Case et al., 2005). This describes the population of interest in this study, which are members of Medicaid managed care plans.

This study also examined the differences in usage of other sites of care. The results suggest an increased activation of patients within the treatment group. mCare users were more likely to adhere to physician office visits, and less likely to have an

inpatient hospital encounter. These results indicate mCare can be useful in helping individuals maintain their continuity of care and visit their doctors.

The findings regarding health effects revealed a small, but clinically and statistically significant, impact on cardiovascular health. While an average 3-point diastolic drop may not seem substantial, a meta-analysis that comprised over 460,000 people reported that for a BP reduction of 10 mmHg systolic or 5 mmHg diastolic, there was a 22% decrease in coronary heart disease events and a 41% decline in stroke (Mensah et al., 2017).

An interesting finding was that there were differences in the degree of benefit received in terms of blood pressure management from the mCare users based on their social barriers These results provide supporting evidence of the role of social barriers in moderating the potential effectiveness of mCare interventions. One reason that this finding may be expected, is that those individuals with existing social support through family, friends or other personal relationships and networks may have less need for the social support that a health coach provides as part of an mCare system. Interestingly, it was the group with a moderate amount of social support that had a significant benefit, suggesting that those individuals with the most challenging social situations may need extra supports. Furthermore, given the complex landscape of health behavior theory, quantifying factors such as social support that influence the impact of mobile health systems can lead to more complete health behavior models better suited to the mobile age.

As the healthcare industry seeks to unlock the secret to precision tailoring of behavioral interventions, this study's findings indicate that focusing particularly on those individuals who report a moderate gap in social support, the return on investment may potentially increase. This finding does not advocate that population health managers ignore those individuals with very low or very high social support barriers, but rather, when designing program components, one must consider the individual nuances and find targeted ways to better engage particular patient subgroups.

The empirical evidence of the importance of creating social support and conducive environments for disease self-management are evident. How can the health system possibly expect someone to regularly check their blood sugar, adjust their diet, purchase new medication, stand on an internet-connected scale, and communicate back to their care providers through an app if they don't have a stable and supportive life situation? The addition of social supports such as mCare offers may help, and this study's results suggest that the health coach can positively impact those chronic disease plan members moderately low in social support, but not too low.

5b. Conclusions

This dissertation sought to answer how an mCare system may impact health outcomes and healthcare utilization for mCare users and to uncover potential variation in the effects of mCare in relation to the individual differences of the mCare end users.

This study's conclusions include the following. mCare has a significant effect on the cardiovascular health of the users as measured by their diastolic and systolic blood pressure, whereas the effect on weight and average glucose was less significant. mCare has a significant effect on the use of office visits by its users, resulting in greater continuity of care, and perhaps contributing to fewer inpatient visits, on average. mCare did not reduce emergency department visits or triage emergent problems that are considered treatable at the primary care office, or non-emergent problems relative to non-users in the first five months of use. mCare did not reduce preventable ED visits in the first five months of use, relative to the control group, suggesting there may be a longer time horizon needed to change health trajectories, on average. mCare users had significantly less frequent inpatient encounters, 1.2 fewer encounters on average, during the five-month observational period. Those mCare users who had a moderate degree of social support in their lives on average benefitted from the intervention in terms of improved cardiovascular health outcomes more so than users with a lot or no social support. This benefit equated, on average, to a 2.4 mmHg drop (2.9%) in diastolic blood pressure and a 3.9 mmHg (3.1%) drop in systolic blood pressure, both of which are clinically significant. On average, females

realized significantly greater benefit from the mCare intervention than men in terms of a reduction of blood pressure.

Implications for practice, design and theory

For designers, this study identified specific targets of mCare use where mCare is showing success (e.g. office visits), and other areas (e.g. emergency department triage) where improved information system and process design is needed. mCare designers and vendors can focus their attention accordingly. For example, by designing better pain triage mechanisms and diagnostics, presumably an improvement in the rate of unnecessary and primary care treatable ED visits can be achieved.

Additional training for health coaches, as well as training and development of machine intelligence algorithms to better triage patient problems to appropriate sites of care, are needed. mCare designers should seek to better gauge the severity of pain, and develop new sensor technologies to better assess emergent issues, especially abdominal pain, based on biomarkers or other physiological signals. mCare vendors should focus on refining their processes to enable better glucose management that avoids exacerbations, and to predict exacerbations earlier so that they can be avoided. For medical conditions in which getting patients to regular office visits is a challenge, but these visits offer significant therapeutic and/or cost-effective benefit, mCare may be a successful strategy for achieving visit adherence goals.

Most health behavior theories were constructed at a time when mobile applications and connected sensors were not readily available; therefore the mental model of behavior change that supported these theories was different from how the

world works today. The theoretical constructs purported to influence health behavior and intervention design such as an individual's health literacy, beliefs, and capabilities likely still influence health behavior; however the mechanisms of how these constructs can be influenced in a mobile-digital age are evolving. In the current environment, healthcare professionals have an expanded arsenal of tools to equip patients; it is important to understand how the individual factors of each patient may translate into successful outcomes from the use of these tools. This dissertation helped contribute to a more nuanced understanding of the effects of mCare.

This study illuminated differences in the effects of mCare based on one's social support environment. It may not be surprising that simply providing a person with chronic disease an mCare solution will not be equally successful across a population. This dissertation uncovered, interestingly, that those with a moderate degree of social support were more likely to achieve benefit, on average, relative to those with high or low social support in their lives. This dissertation corroborates that an application that uses a one-size-fits-all approach that doesn't account for the unique social support situations of individual, may not be optimally engaging its users.

5c. Limitations

This research yielded insights regarding the impacts of mCare usage on health plan members with chronic disease. As with all scientific inquiry, there are

limitations to the generalizability and interpretation of the results that should be considered.

The strength of evidence in the study of a health intervention using an observational cohort is less than that of a randomized controlled trial. However, observational, well-controlled studies can have good validity and a matched sample is a feasible approach (Thiese, 2014). A limitation is that the treatment and control group were not exactly matched by health plan. Rather, members were matched on the attributes that are most relevant to similarity in disease burden and demographics, as an exact matching by plan would yield a poorly matched control group.

The duration of the study is 21 weeks, a relatively short period in the context of the life of an individual who has a chronic disease. Yet, the results provide real-world evidence of what happens in the five months after the start of an mCare regimen, and the data is able to provide statistically significant and interpretable results. While the effect sizes may be small, in the context of the vast network of factors that may drive health outcomes and use, it is nonetheless instructive. This study design has the strength of multiple data types, covering the timeframe before, during, and at the completion of five months of mCare use. While changes in blood pressure and healthcare utilization over the course of the study period cannot be *fully* attributed to the specific mechanisms of intervention (the coach, drug adherence, etc.), there is reasonable evidence to defend the conclusions of this study.

5d. Future Directions

Future work should examine the long-term outcomes of mCare. These longer term views may integrate additional economic measures such as Quality of Life-Adjusted Years (QALY's), which is a measure of disease burden, incorporating both the quality and the quantity of life lived (Ryen & Svensson, 2015).

Another limitation of this study is that we do not know the exact mCare features and functions that the health plan members used, given the dataset of this study. Future work may explore the specific features used and their relationship to the mCare outcomes observed. In addition to evaluating feature use, given the heterogeneity of users, testing of specific messaging and adaptation strategies for system interaction would be useful. There are emerging methods and systems (e.g. JITAI's) that support the real-time adaptability of interventions based on a variety of user data (e.g. psychology, mood, health trajectory, etc.), which is an exciting area for future study.

Future work may include a prospective randomized controlled trial whereby individuals with social barriers can be appropriately randomized to allow for further validation of the findings. mCare vendors/researchers should experiment with adjusting the level of social support based on the target user's unique situation.

In preparation for such a trial, further validation of the social support scales is recommended. The scales used in the mCare questionnaire for this study have not been validated. However, they have simplicity in structure and design, which allows for confidence in their use and interpretation. As future scales are developed, in

particular for social support, tailoring them to the mCare context may benefit future practical use and related health services research.

The study results suggest there is not a highly accurate method to triage pain and decide whether the pain requires emergency intervention. Biomedical sensor designers should seek to provide sensors and decision-support that can more accurately identify when situations are truly an emergency.

Future work may also explore incentives and other mechanisms that may be used to triage chronic disease patients to the most fitting healthcare delivery locations. Finally, research into the specific coaching strategies being employed in relation to the chronic disease member's attributes and how it may differentially impact mCare user outcomes could yield fruitful future intervention designs that are more precisely tailored.

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