A PRIMARY CARE INITIATIVE USING SMARTPHONE TECHNOLOGY TO IMPROVE ANTIHYPERTENSIVE MEDICATION ADHERENCE IN INDIGENT HISPANIC MEN

A Doctor of Nursing Practice Project Report

by

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This Doctor of Nursing Practice Project Report meets the standards for scope and quality of Texas A&M University-Corpus Christi College of Nursing and Health Sciences and is hereby approved.

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DEDICATION

First and foremost, I would like to dedicate this project to God. I pray for His continued mercy, grace and guidance in everything I do to help those in need. I dedicate this work to my children Kimberly, Oscar, Marlena and Amie for whom, I always strive to be a good example. I am extremely proud, blessed and humbled to be your mother. I would also like to dedicate this work to my grandchildren; Jaiden, Wesley and Walker (and those who are yet to be born) whom I hope will always face life with a thirst for knowledge and, a desire to leave your mark on this world to make it a better place for generations to come.

To my love, thank you for your patience and understanding. Your constant motivation and words of encouragement gave me the strength to keep going when I felt like giving up. Words cannot express how grateful I am for you.

To my momma, my biggest fan. Thank you for your unconditional love, guidance and for molding me into a strong, independent woman. I am, who I am, because of you! To my father, thank you for your unconditional love and for always believing in me. To my siblings Veronica, Joe and Lolli, aside from my children, you are my heart and soul. Because of you, I will always have a friend. I am truly blessed with the best siblings ever! I love you!

To my wonderful and loving grandmother (Elida), and aunts (Tia Betty and Tia Nea), who I know are looking down with pride from heaven. Thank you for always blessing me with your unconditional love, patience and kindness.

I would also like to dedicate this work to my family and friends who have provided unending support throughout this educational endeavor. Your continued love, support and encouragement were essential to the successful completion of this journey.

Finally, this work is dedicated to all who believed in me and to those who thought this once 15 year-old girl would be just another statistic, and told me that I would never amount to anything. This work is especially dedicated to all those who don't believe in themselves. Never surrender your hopes and dreams to the limitations others set on you. Never let naysayers and fear stop you! Be strong and courageous...for the Lord is with you wherever you go. Joshua 1:9.

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Lastly, for my children and grandchildren, may my persistence to succeed serve as an example for you to work hard and never settle for anything less than your dreams.

TABLE OF CONTENTS

CONTENTS PAGE

DEDICATION iv

ACKNOWLEDGEMENTS vi

TABLE OF CONTENTS vii

LIST OF FIGURES ix

ABSTRACT 1

INTRODUCTION 2

Background 3

Review of Literature 3

Problem Description in the Setting 6

Project Purpose and Aims 6

Guiding Frameworks 8

METHODS 9

Ethical Considerations 9

Project Design 10

Intervention 12

Data Collection 13

Measurement Tools 15

Data Analysis 16

RESULTS 18

DISCUSSION 23

Limitations 27

Interpretation 28

Conclusion 29

REFERENCES 31

LIST OF APPENDICES 36

LIST OF FIGURES

FIGURES PAGE

Figure 1: Medisafe Mean Monthly Adherence 20

Figure 2: Medisafe Monthly Adherence 20

Figure 3: Pre & Post Hill-Bone Scale Data 21

Figure 4: Hill-Bone Scale Medication Adherence Screening..... 22

LIST OF TABLES

TABLES PAGE

Table 1: Risk Assessment Table 11

Table 2: Timeline 15

Table 3: Demographics Table and Descriptive Statistics 17

Table 4: Mean Systolic (SBP) and Diastolic (DBP) Blood Pressures 23

Table 5: Descriptive Statistics and t-Test Results for Hill-Bone Scale and Blood Pressure 25

ABSTRACT

Background: Approximately 108 million adults in the United States (U.S.) have hypertension (HTN) of which only 24% have adequate control. Men have a higher incidence of HTN than women and only 25% of Hispanic males have adequate control compared to 32% of non-Hispanic white males. The purpose of this quality improvement initiative (QI) was to improve medication adherence screening by providers and adherence to antihypertensive medication in indigent, adult Hispanic males (25 – 64 years of age) with uncontrolled hypertension (HTN) at a large primary care clinic in South Texas, using a smartphone application (Medisafe) and the Hill-Bone Medication Adherence Scale (Hill-Bone Scale). **Method:** A before and after design was used to institute a hypertension protocol including the Hill-Bone Medication Adherence Scale in the clinic and the Medisafe medication reminder smartphone application by patients for a 3 month trial. **Results:** Utilization of the Medisafe application resulted in increased number of medication adherence days, improved self-reported medication adherence scores as well as improved overall mean systolic and diastolic blood pressure. **Discussion:** Self-reported medication adherence screening and utilization of the Medisafe medication reminder application has the potential to improve adherence and outcomes among patients with uncontrolled hypertension.

Key words: Medisafe, Hill-Bone Medication Adherence Scale, Hypertension, medication nonadherence

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A Primary Care Initiative Using Smartphone Technology to Improve Antihypertensive Medication Adherence in Indigent Hispanic Men

INTRODUCTION

Worldwide, hypertension (HTN) accounts for approximately 10 million deaths yearly, is the leading risk factor for stroke and heart disease and is the cause of 7% of global disability (Okello et al., 2016). Approximately 108 million adults in the United States (U.S.) have HTN however, only 24 percent have controlled HTN (CDC, 2020). Morbidity, mortality and disability is associated with uncontrolled HTN which can be attributed to nonadherence of antihypertensive medications (Abu-El-Noor et al., 2020). Lack of medication adherence leads to exacerbation of chronic illnesses and promotes disease progression, complications, a reduced quality of life and premature death (Moon et al., 2018). This quality initiative focused on identifying antihypertensive medication nonadherence and applying evidence-based interventions to improve adherence rates.

It is estimated that up to 65% of patients with hypertension have uncontrolled blood pressure due to medication nonadherence (Conn et al, 2015). Hypertension is classified as a systolic blood pressure equal to or greater than 140, diastolic equal to or greater than 90 (CDC, 2017). Non-adherence is described as taking less than 80% of prescribed medications (Kassahun et al., 2016). Approximately 50% of patients stop taking their medication within one year of initiating treatment, and 10% of patients are non-adherent to antihypertensive medication regimens soon after initiating medications (Conn et al., 2015). Among those taking antihypertensive medications, blood pressure control is higher in non-Hispanic white adults (32%) than in non-Hispanic black adults (25%), non-Hispanic Asian adults (19%), or Hispanic adults (25%) (CDC, 2020). Men (47%) have a higher incidence of HTN than women (43%)

(CDC, 2020). Men ages 18-39 have a higher prevalence of HTN than women (9.2% men, 5.6% women) as well as men ages 40-59 (37.2% men, 29.4 women) (CDC, 2017). The percentage of controlled HTN is lower in Hispanic men (43.5%) than Hispanic women (48.1%) (CDC, 2017).

Background

The economic burden of HTN in the United States including medication costs, healthcare services and productivity costs related to premature death is approximately $48.6 billion a year (CDC, 2018). Non-adherence to medications has been noted to be more prevalent in individuals of lower socioeconomic status (Kassahun et al., 2016). Approximately 17.3% of the population in Nueces County are uninsured and 42.4% of Hispanics live in poverty (DataUSA, 2020). The Nueces County Hospital District (NCHD) program provides funding collected by levying an ad valorem tax from county taxpayers, which provides funding for medical and hospital care to indigent residents (Nueces County Hospital District, 2017). Of the patients diagnosed with HTN covered under the NCHD program, 45.9% (1275) are males (NCHD Database Report generated October 2, 2020). Of the 1275 males with hypertension, 586 have uncontrolled HTN and 95.6% of those males are 25 – 64 years of age (NCHD Database Report generated October 2, 2020).

Review of Literature

Interventions that improve adherence rates can significantly reduce hospital admissions and decrease mortality and should be a part of every patient's self-care program (Ruppar et al., 2016).

As such, evidence-based interventions that address the most cited cause of medication non-adherence, forgetfulness, may assist patients with remembering to take their medications to avoid complications related to uncontrolled HTN (Marquez-Contreras et al., 2019). There is a need to explore the use of mobile phone medication reminder applications such as Medisafe for

improving medication adherence and HTN management (Gong et al., 2020). Thakkar et al. (2016) stated that finding interventions that improve medication adherence rates may have a far greater impact on overall public health than any other medical treatments. Mobile Health (mHealth), a smartphone application, is a feasible and convenient intervention to improve adherence rates however, utilization in healthcare is low and incorporating mHealth into routine clinical practice may be challenging (Thakkar et al., 2016).

The review of literature supports the use of mHealth applications to improve medication adherence rates. Chandler et al., (2019) conducted a two-arm efficacy trial to assess the efficacy of smartphone in improving medication adherence in 54 Hispanic adults with uncontrolled HTN. Study findings indicated average adherence rates improved from 89.1% to 95.2% during the 9-month study period (Chandler et al., 2019). In addition, significant improvement was noted in the percentage of participants with improved systolic blood pressure in the study groups (all *p*-values ≤ 0.01). Overall study findings indicated smartphone programs may effectively promote medication adherence rates and health outcomes in Hispanic adults with uncontrolled HTN (Chandler et al., 2019). Hamine et al., (2015) conducted a systematic review of 107 studies that focused on the effectiveness of mHealth in supporting adherence for chronic disease management. Of the studies reviewed, 27 were RCT's which demonstrated significant improvement in adherence in 56% of the studies (difference between groups $P<.05$ to $P< .001$) which indicates that the mAdherence tool has the potential to significantly improve health outcomes for chronic diseases (Hamine et al., 2015). McGuiness et al., (2019), conducted a study assessing improvements of medication possession ratio (MPR) among participants in three treatment categories (HTN, diabetes mellitus (DM) and depression (MDD)) to assess the effectiveness of the Medisafe mobile phone application. They and found that all treatment groups

had significant improvements in MPR after utilizing the application (McGuiness et al., 2019). Post intervention, mean (SD) pre versus post MPR for HTN was pre 0.54 (0.20) versus post 0.86 (0.17) with the other two groups demonstrating similar improvements in MPR (all groups: $p<.0001$). They concluded that the use of mobile phone applications may benefit patients with a history of non-adherence (McGuiness et al., 2019).

Santo et al., (2019) conducted a parallel-design, single-center, single –blind randomized clinical trial (RCT) with 163 participants to assess the effectiveness of medication reminder applications to improve medication adherence. Study results found that after three months, participants using the medication reminder application demonstrated higher adherence compared to the control group (without any interventions) with a mean difference of 0.47 between groups (95% CI 0.12 to 0.82, p=0.008) (Santo et al., 2019). Morawski et al., (2018) conducted a RCT including 411 participants with poorly controlled HTN to assess the association of using the Medisafe smartphone application and improved medication adherence. After 12 weeks, there was significant improvement in medication adherence among the intervention group as compared to the control group (difference in groups: 0.4; 95% CI, 0.1-0.7; $P = .01$) (Morawski et al., 2018). Improvements in the systolic blood pressure was noted among both, the intervention group (decrease of 10.6 mmHg) and the control group (decrease of 10.1) (group difference: -0.5; 95% CI, -3.7 to 2.7; $P = .78$) (Morawski et al., 2018). Thakkar et al., (2016) conducted a meta-analysis including 16 RCT's with 2742 participants to assess the effect of mobile phone messaging and medication adherence rates among those with chronic conditions. The study found the use of mobile phone medication reminders significantly improved medication adherence demonstrating a 67.8% improvement in adherence among participants (odds ratio, 2.11; 95% CI, 1.52-2.93; $P < .001$) (Thakkar et al., 2016).

Problem Description in the Setting

This project was conducted in a family health clinic in a large metropolitan area that provided healthcare to the indigent population, covered under an indigent care program. The clinic was located in a low socioeconomic area with six associated clinics and two associated hospitals. It served approximately 200 patients per week, utilizing an interdisciplinary approach comprised of a physician, three nurse practitioners, four licensed vocational nurses, two medical assistants. Many patients seeking care at the primary care clinic were noted to have uncontrolled blood pressures. With permission from the clinic administrator and facilitated by quality improvement staff, a 12-month retrospective review of blood pressure (BP) data from the electronic medical record (EMR) was conducted to assess the percentage of patients with uncontrolled HTN. A report was generated for blood pressures over 139/89 for individuals prescribed blood pressure medications meeting the inclusion criteria including all Hispanic men covered under the NCHD program. Over 95% of males ages 25-64 insured under the NCHD program were found to have uncontrolled HTN (NCHD Database Report generated October 2, 2020). Given these findings and because there was not a protocol in place to screen for medication nonadherence, the facility administrators agreed an initiative was needed to screen for medication adherence and to implement an intervention that would help to empower patients to get their BP under control. Helping patients to improve BP control would reduce patient costs by preventing BP related complications and hospitalizations, as well as improve patients' quality of life.

Project Purpose and Aims

The purpose of this quality improvement (QI) initiative was to improve medication adherence screening by providers and adherence to antihypertensive medication in adult males

(25 – 64 years of age) with uncontrolled HTN at a large primary care clinic, utilizing a smartphone application (Medisafe) and the Hill-Bone Scale. The clinical question guiding this project was, **"**In hypertensive Hispanic males, ages 25-64, covered under the Nueces County Hospital District (NCHD) indigent healthcare program at the Family Health Clinic, does utilizing the Hill Bone Scale and smartphone technology compared to usual care, contribute to improved self-reported medication adherence rates and decreased BP within 90 days after initiating the protocol?". The American Association and Colleges of Nursing (AACN) Doctor of Nurse Practitioner (DNP) Essential exemplified by this QI project was DNP Essential VII: Clinical Prevention and Population Health for Improving the Nation's Health. DNP Essential VII aligns with this project's health promotion and risk reduction goal to improve HTN and medication nonadherence (AACN, 2020).

Project Aims

The specific aims of this project were:

1. To increase adherence to antihypertensive medications in the clinic's Hispanic male population by increasing the number of days participants take their medications using the Medisafe smartphone application (Medisafe, 2021). The Medisafe smartphone App provides medication administration reminders with a snooze option every 15 minutes up to one hour until the medication is taken and it also provides the patient with medication refill reminders. The App tracks doses taken or missed and provides a detailed report that can be emailed to the provider. The specific goal of this aim was to increase the percentage of adherence days in patients utilizing the Medisafe App for an increase of 10% in adherence from month one to month three. The 10% target improvement was selected after looking at similar research by Thakkar et al., (2016)

who noted pre to post study percentage of adherence increase from month one to month three by 17.8% for all participants after utilization of smartphone to improve medication adherence (Thakkar et al., 2016).

2. To improve self-reported medication adherence scores on the Hill-Bone Assessment tool. The specific goal was to improve mean Hill-Bone Scale scores by 10% from pre to post intervention. The 10% improvement target was selected after reviewing research by Maslakpak & Safaie (2016) who were able to accomplish improved mean Hill-Bone Scale compliance scores of 12% in their three-month study period.
3. To improve screening and assessment of risk of non-adherence to antihypertensive medications through implementation of the Hill-Bone Scale. The specific goal was that by end of three-month project period, 100% of individuals meeting criteria had medical record documentation that they were screened with the Hill-Bone Scale.

Guiding Frameworks

The theoretical framework that drove the implementation of this evidence-based project was Glasgow's Re-Aim Framework (1999). Glasgow's Re-Aim framework examines five dimensions that include reaching the target population, the effectiveness of intervention, adoption by setting, institution and staff, as well as implementation and maintenance of intervention over time (Glasgow et al., 1999). The RE-AIM (reach, effectiveness, adoption, implementation, maintenance) framework by Dr. Russ Glasgow was developed to enhance the impact of health promotion interventions by evaluating the dimensions considered most relevant to real-world implementation, such as the capacity to reach underserved populations and to be adopted within diverse settings (Glasgow et al., 1999). This model aided in systematically identifying facilitators, challenges, opportunities and lessons learned to be used in future

program planning and care delivery for patients (RE-AIM.org, 2020). The application of the theory helped identify challenges, and opportunities to implement interventions for a healthier lifestyle (King et al., 2015).

The Plan-Do-Study-Act (PDSA) framework is a four-step framework which was utilized to drive change in cyclical small-scale changes to determine the social, value and negative effects of the planned interventions (Coury et al., 2017). PDSA is an acronym for plan, do, study, act. The first cycle is the "planning phase" in which data collection and medical records reviews were conducted to identify non-adherent males with HTN who met the age criteria. The second "Do" phase was to carry out small scale testing by administering the adherence screenings, and educational meetings with staff and teammates. In the third "study" phase, data was collected from the EMR and analyzed. The BP data was evaluated for individuals meeting criteria including age, race, and sex to assist in identifying nonadherence to antihypertensive medications. The "act" phase included adapting, adopting or abandoning changes based on learning from testing during plan, do study cycles (Coury et al., 2017). The PDSA framework helped drive change and integrate evidence-based practices to the project clinic setting (Coury et al., 2017).

METHODS

Ethical Considerations

This project plan was reviewed by the Texas A&M University-Corpus Christi Research Compliance Office and received a determination of "Not Human Subjects Research" and permission to proceed as a Quality Improvement project. Refer to the Letter of Determination in Appendix A. Personal health information (PHI) was collected for project purposes only following execution of a HIPAA Confidentiality Agreement from the facility (Appendix B). A

letter of support was provided by the Director of Clinic Operations agreeing to fully support the project and acknowledging collection of PHI for project purposes only (Appendix C).

Project Design

This DNP quality improvement initiative used a before and after design to implement a new HTN protocol using the Hill-Bone Medication Adherence Scale and Medisafe smartphone technology to improve patient medication adherence to antihypertensive medications in a South Texas primary care clinic. The population of interest was Hispanics males who made up over 70% of the patient population with uncontrolled HTN covered under the NCHD program of which, over 95% were males 25-64 years of age. As forgetfulness is the most cited cause of medication non-adherence, implementing an intervention that assessed self-reported medication adherence rates (Hill-Bone Scale) and improved medication adherence (Medisafe) would result in improved HTN management and reduce the incidence of complications related to uncontrolled HTN (Gong et al., 2020).

Risk Assessment. Potential barriers that could have affected the success of this QI project included staff being unwilling to participate in the project and lack of project buy-in from the clinic administrators. Another possible risk was that patients might have their phone service disconnected or changed interrupting the smartphone data collection. See Table 1 for a listing of facilitators and countermeasures taken to mitigate these risks such as educating staff on project goals and educating administrators to use the Medisafe App so they could serve as support for staff. The RE-AIM Framework helped to systematically identify facilitators, challenges, opportunities and lessons learned to be used in program planning and care delivery for patients (RE-AIM.org, 2020). The application of this theory helped identify challenges, and opportunities to implement interventions for a healthier lifestyle (King et al., 2015).

Table 1: Risk Assessment Table

Risk	Impact	Countermeasure	Resources	Barriers
1. Staff unwilling to participate in project	Had potential to hinder patient education, participation and recruitment	1. Educated staff on project goals 2. Educated staff on use of tools and rational for use	Administrative staff supported project and related participation to staff	Uncooperative administrative staff
2. No buy-in from clinic administrator	Had potential to hinder staff participation	1. Educated administrator to encourage buy in and assistance in helping with staff participation 2. Trained administrator on use of tool and Medisafe app so they may serve as a support person for staff	Director of Operations supported project and encouraged clinic administrator to support project as well	Administrators
3. Phone service disconnected	Potential for phone application to be unavailable	1. Educated patient to continue using application which was found to still provide alarms despite	Staff helped educate back up plans to patients	Patient refusing to document paper form

		having no service 2. Educated patient to document on paper days of adherence with no service if they should lose their phone		

Intervention

The project began with a recruitment process where participants were recruited from all interested patients that met the inclusion criteria. Of the 563 patients on the program with uncontrolled blood pressure, we were able to reach 63 patients within the project start time period who met criteria. Of the 63 eligible participants, 20 agreed to participate in the project but 10 dropped out (due to loss of phone service, loss of NCHD coverage, change of PCP), leaving 10 remaining participants. Inclusion criteria included: adult male aged 25 – 64 years; covered under the NCHD program; diagnosed with HTN and prescribed antihypertensive medication; owned a smart phone (Android or iPhone); and had an email. Individuals with cognitive impairment, imprisoned or diagnosed with psychological issues were excluded.

Project team members included the Family Nurse Practitioner employed by facility who served as the project director (PD). The PD educated all team members to administer the Hill-Bone Scale and interpret scoring and how to use the Medisafe app. Four licensed vocational nurses, as well as the three medical assistants who rotated shifts, administered the Hill-Bone Scale screenings and took blood pressure readings that were documented at each visit. The information technology personnel helped run reports that included criteria data.

Health records were reviewed for the 12 months prior to the start of the program to search for patients with uncontrolled hypertension and who met the inclusion criteria. Staff (nurses and medical assistants) phoned each patient meeting criteria and scheduled them for a visit if they were interested in participating in the project. In addition, patients who met criteria that presented to clinic as walk-in's or who were not previously recruited, were informed of the project at the time of visit and invited to participate.

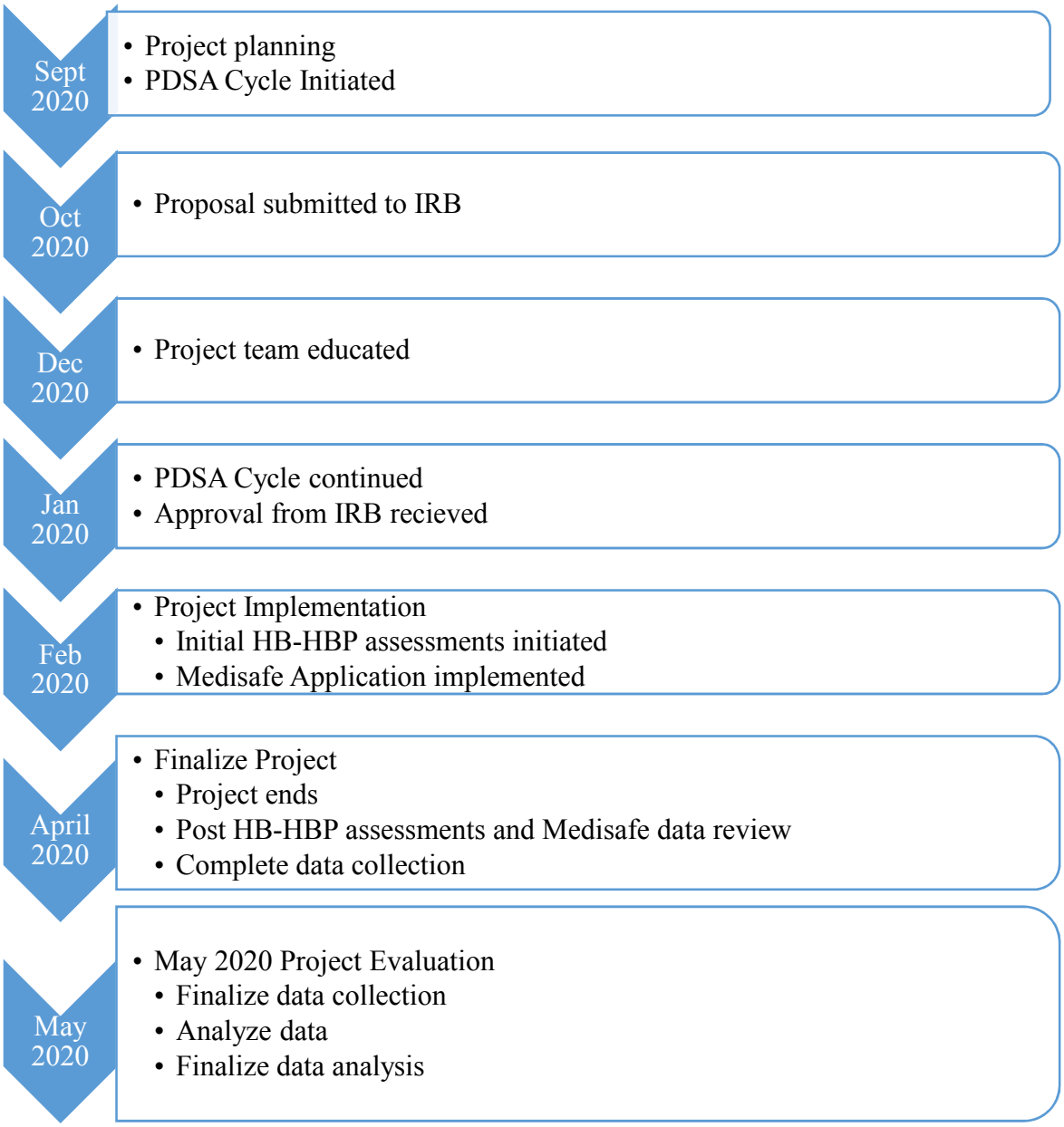
Once the patient agreed to participate in the project, they were asked to sign a participation agreement form (Appendix D), after which they received focused Medisafe patient education consisting of verbal and printed instructions, and a YouTube video demonstration that was provided by staff members. See Appendix E for the printed instructions and video link. The staff then assisted patients to download and use the smartphone application as well as entering their medications and reminders in the smartphone application. Once this process was completed, patients were ready to use the application. Patients were subsequently screened with the Hill-Bone Scale at the end of recruitment visit to establish baseline data that was also reassessed at the end of the project period.

Participants were assigned a number that was kept on a roster (with their names and assigned number) in a locked desk at the nurse's station to which only the project director had access and all of the documents were coded with the assigned number (no name). Patient blood pressure readings and Hill-Bone Scale scores were tracked on an Excel spreadsheet for tracking purposes that was saved on the project directors computer drive of which only the project director had access.

Data Collection

The Hill-Bone Scale was performed at the initial visit by the nursing staff or medical assistant to establish baseline data and again at final visit to assess for improved adherence. Hill-Bone Scale screening results were collected and scanned into each patient's file and logged on an Excel spreadsheet for tracking purposes. Blood pressure measurements were assessed by nursing staff or medical assistant at first visit, week four, week eight and twelve. Medication adherence data was collected by nursing staff or a medical assistant at the initial visit and at the end of the project period. At week 12, summary data from the Hill-Bone Scale, blood pressure measurements and Medisafe data was collected by the nursing staff and the medical assistant and analyzed by the PD. See timeline (Table 2) for a visual diagram of the timeline of this project from organizational assessment data to dissemination of results.

Table 2: Timeline



Measurement Tools

The Hill-Bone Medication Adherence Scale (Hill-Bone Scale) was used to measure self-reported medication adherence in adult male participants who met the criteria(Kim et al., 2000). The Hill-Bone Scale is a widely accepted medication adherence screening tool specific to

hypertension used by clinicians with good reliability and predictive validity (Mutneja et al., 2020). There are two Hill-Bone Scales available, one has nine questions and the other has 14 questions and each response choice could range from one to four on a Likert scale (1= all the time, 2= most of the time, 3= some of the time, 4= none of the time) (Mutneja et al., 2020). The nine question Hill-Bone Scale was used for this project and responses were summed for a final score of 9 (minimum) and 36 (maximum) with a higher score indicative of better compliance (Mutneja et al., 2020). The Hill-Bone Scale included questions regarding how often patients forget to take their medications, forget to get timely refills or run out of medications etc. (Mutneja et al., 2020). Uchmanowicz et al. (2016) found this scale had good psychometric qualities with a high internal consistency (Cronbach's alpha = .851) and validity to measure self-reported adherence levels. Permission to use the Hill-Bone Scale was obtained from the John's Hopkins School of Nursing Hill-Bone Scales Team (Appendix F) (Kim et al., 2000). The Medisafe mobile phone application provides medication reminders and has been shown to improve medication adherence rates among non-adherent patients (McGuiness et al., 2019). In a study by McGuiness et al., (2019), approximately 70% of non-adherent patients became adherent after using the Medisafe application. This application was utilized to track daily antihypertensive medication adherence among participants.

Data Analysis

JASP 0.14.1 statistical software was used to analyze the data. Demographic information, including, age, gender, ethnicity, and insurance is displayed in Table 3. The demographics (age) and outcomes data (pre and post systolic and diastolic blood pressure, pre and post Hill-Bone Scores) was checked for normality. Frequencies were conducted and characteristics were determined. Data was further analyzed using paired t-test which compared pre and post self-

reported medication adherence survey scores as well as pre and post systolic and diastolic blood pressure. Significance and Cohen's *d* was calculated to determine the effect size.

Table 3: Demographics Table and Descriptive Statistics

Participant Characteristics	*n*	%	Mean	SD	Min	Max
Age			47.8	5.45	41	58
24 – 34	0	0				
34 – 44	3	30				
44 – 54	5	50				
54 – 64	2	20				
Employment						
Unemployed	8	80				
Employed	2	20				
Gender						
Male	10	100				
Marital status						
Single	3	30				
Married/partnered	4	40				
Divorced/widowed	3	30				
Health Coverage						
NCHD	10	100				
Ethnicity						
Hispanic	10	100				

Note. Median age from all age categories is 48.

To determine whether Aim #1 was met, the mean number of adherence days was calculated from compliance reports received by the project director from the Medisafe application from each patient. The improved overall adherence percentage was calculated from

mean adherence percentage data from month one and month three. Monthly mean percentages were provided on a run chart to show improvements. To determine whether Aim #2 was met, the mean number of patient self-reported medication adherence days (assessed with the Hill-Bone Scale) were measured using monthly mean percentage of days medication taken (adherence rate) overtime and results were displayed on a bar chart to show adherence rates. To determine whether Aim #3 was met, the number of Hill-Bone screenings data kept on a log (See Appendix G) that is provided on a monthly basis and were measured providing percentages of people who received the Hill-Bone screenings compared to the percentage of people who did not. Percentage results were displayed on a run chart. Data was further analyzed using paired t-test which compare pre and post self-reported medication adherence survey scores. The significance level chosen for this study is $p = /< .05$ and a Cohen's *d* was calculated to determine the effect size.

RESULTS

Implementation

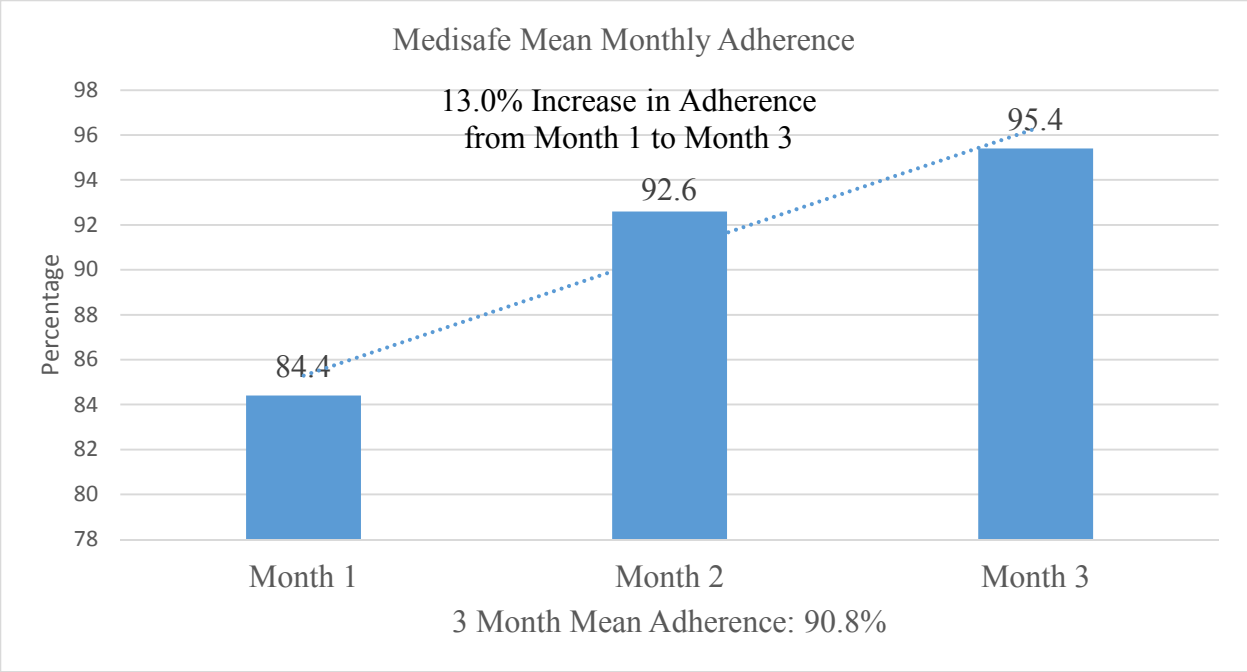
This QI initiative was conducted at a large primary care clinic in a large metropolitan area. The project began with a recruitment process where participants were recruited from all interested patients that met the inclusion criteria. Of the 63 eligible participants, 20 agreed to participate in the project, 10 dropped out, leaving 10 remaining participants. The implementation period was initiated February 1, 2021 and concluded May 31, 2021. The study period was dictated by the project director's ability to recruit participants amid the Coronavirus pandemic, which resulted in reduced scheduling for clinicians. In addition to the pandemic, a polar vortex swept through the area during the project period causing a power crisis and historic freezing temperatures for several days causing further delays in the recruitment process. In addition to these unforeseen circumstances, the facility was in the process of implementing a new electronic

medical record (EMR) system which provided additional obstacles in recruitment efforts. These delays led to fewer participants than anticipated. However, once recruited, the study continued as planned and participants were provided with a focused patient education intervention consisting of verbal and printed instruction, and a YouTube video demonstration on how to use the Medisafe smartphone application was provided by staff members. The staff then assisted patients to download and use the smartphone application entering their medications and reminders in the smartphone application; once this process was completed, patients were ready to use the application. Patients were subsequently screened with the Hill-Bone tool at the end of the recruitment visit to establish baseline data, which was reassessed at the end of the 90-day project period. Medisafe adherence data was then reviewed and analyzed at the end of the study period.

Outcomes

The mean age of participants in this study was 47.8 (SD = 5.45) years; all identified as Hispanic males; 80% were unemployed; and all received health coverage from NCHD. Refer to Table 3 for further details. Monthly Medisafe adherence data was collected to measure if Aim #1 was met by demonstrating at least a 10% improved medication adherence rate from month one to month three. Medisafe mean monthly adherence percentages: Month one 84.4%; month two 92.6%; month three 95.4%. An overall mean adherence rate of 90.8% was noted after three months which translates to an overall adherence increase of 13.0% from month one (84.4%) to month three (95.4%). See Figure 1 for details.

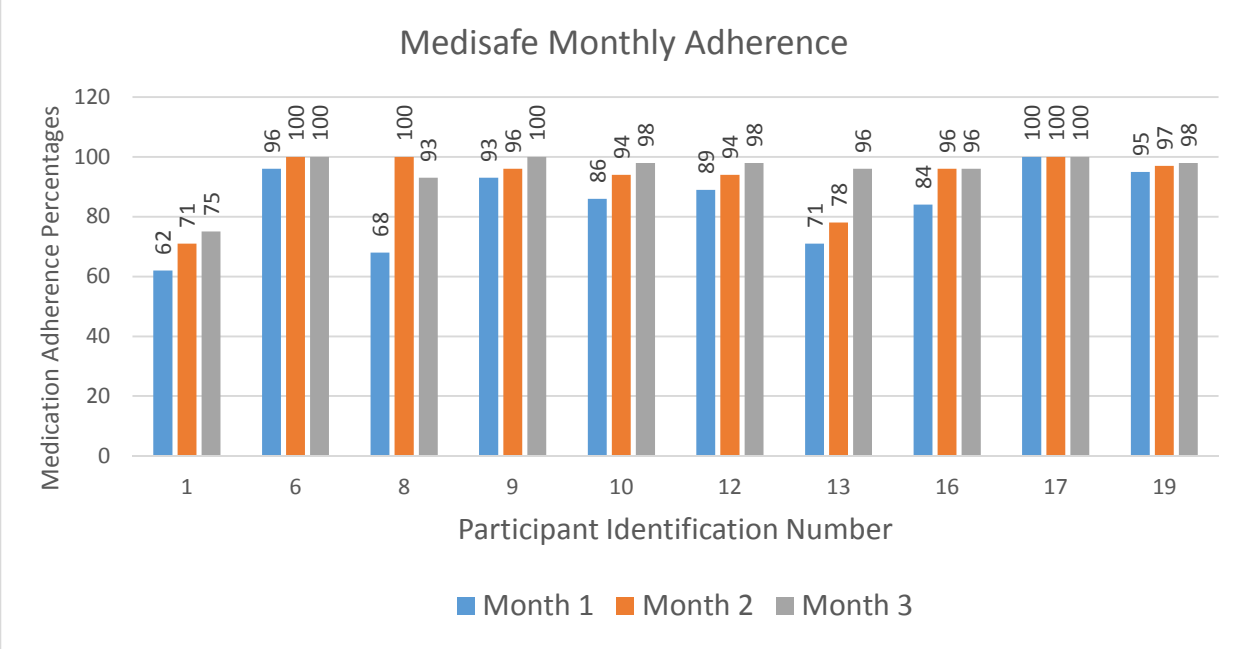
Figure 1: Medisafe Mean Monthly Adherence



Note. This figure represents the average monthly Medisafe adherence rates for all participants.

Individual monthly adherence percentages were tracked and displayed in Figure 2.

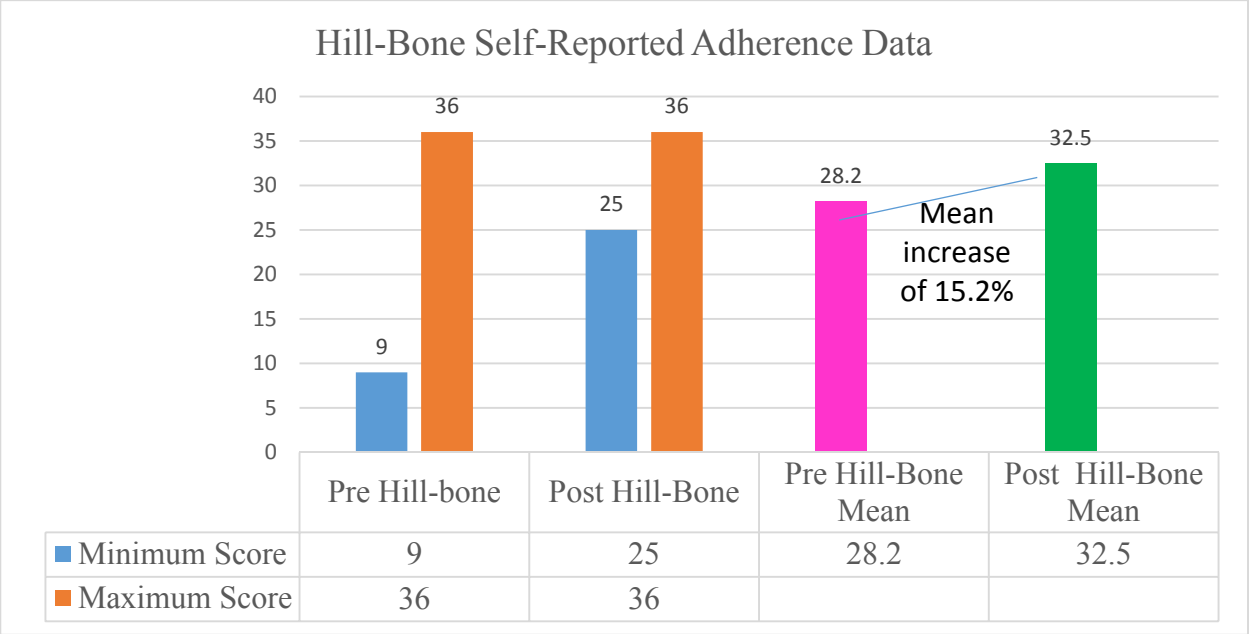
Figure 2: Medisafe Monthly Adherence



Note. This figure represents each participant's monthly compliance percentage.

Pre and post intervention Hill-Bone Scale scores were analyzed to determine if Aim #2 was met. Improved mean Hill-Bone Scale score was demonstrated after three months (pre Hill-Bone mean 28.2; Post Hill-Bone mean 32.5) with a collective improved mean self-reported adherence rate of 32.5% (See Figure 3). Pre and post Hill-Bone Scale scores with mean changes are displayed on Figure 3.

Figure 3: Pre & Post Hill-Bone Scale Data

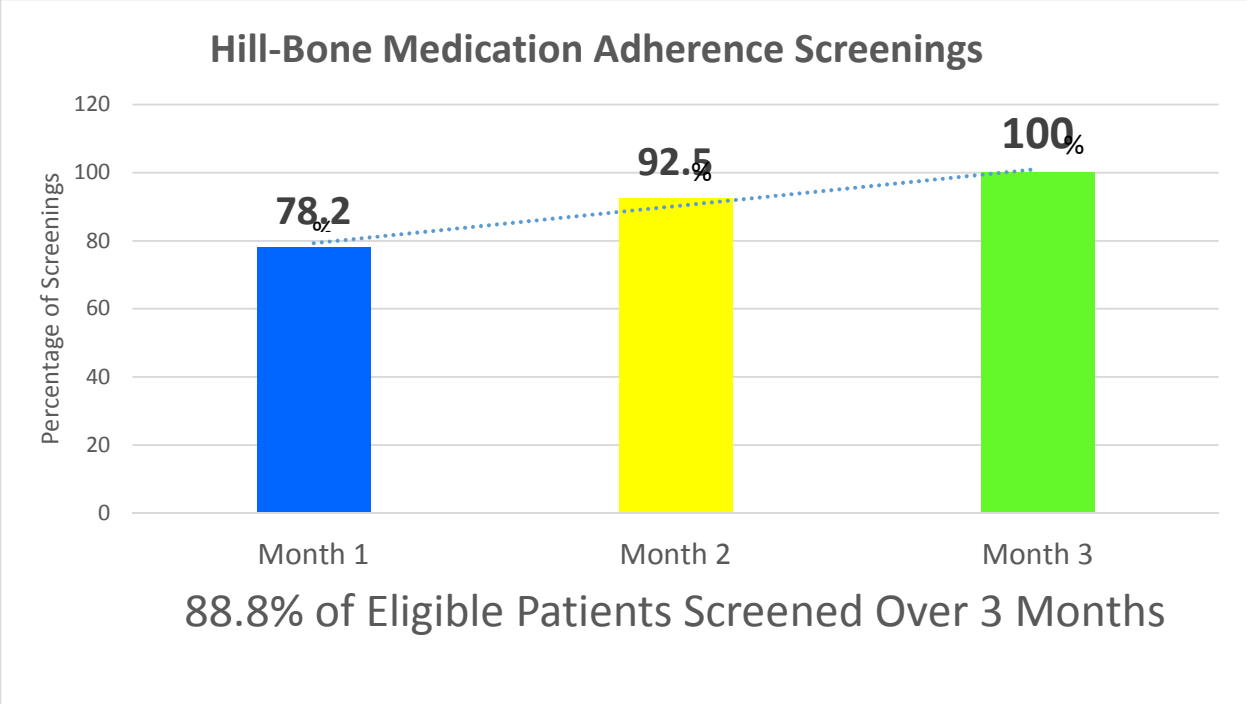


Note. This figure represents pre and post intervention Hill-Bone Scale scores including minimum and maximum scores for all participants as well as collective pre and post mean scores.

To determine if Aim #3 was met, the percentage of eligible patients visiting the clinic and screened using the Hill-Bone Scale was measured monthly. Results revealed a continuous

monthly increase from 78.2% the first month to 100% at the end of month three with a mean screening rate of 88.8% over the study period (See Figure 4).

Figure 4: Hill-Bone Scale Medication Adherence Screenings



Note. This chart represents monthly percentages of all eligible patients visiting the clinic with HTN screened with the Hill-Bone Scale screening tool over the three-month study period. The total percentage of patients screened during the three-month intervention period = 88.8%.

Blood pressure data was not originally intended to be collected however, improved blood pressure readings were noted on follow-up visits. The overall participant mean systolic blood pressure improved from 169.4 (pre-intervention) to 130.5 (post-intervention). The overall participant mean diastolic blood pressure improved from 102 (pre-intervention) to 84.7 (post-intervention). See Table 4 for further details. Overall, the impact on patient health and the ability to provide patients the tools to better manage their health is invaluable.

Table 4: Mean Systolic (SBP) and Diastolic (DBP) Blood Pressures

Characteristics	*N = 10*	Mean (SD) (mmHg)	
Pre SBP		169.4 (19.6)	
Post SBP		130.5 (12.8)	
Pre DBP		102 (12.7)	
Post DBP		84.7 (9.5)	
		Decrease (mmHg)	
Pre – Post SBP		38.9	22.4%
Pre – Post DBP		17.3	16.9%

Note. Abbreviations. Systolic blood pressure (SBP), Diastolic blood pressure (DBP). Results expressed represent the mean pre and post blood pressure for all participants (n=10). The decrease represents a decrease (mmHg) from pre and post blood pressure readings as well as the percentage of decrease from pre to post.

DISCUSSION

The purpose of this quality improvement initiative (QI) was to improve medication adherence screening by providers and adherence to antihypertensive medication in adult males (25 – 64 years of age) with uncontrolled HTN at a large primary care clinic utilizing a smartphone application (Medisafe) and the Hill-Bone Scale screening tool. Project results indicated that the purpose and aims of the project were accomplished. A positive change in practice at the facility was achieved by increasing screening for medication adherence in hypertensive patients using the Hill-Bone Scale. As aforementioned, blood pressure data was not

originally intended to be collected however, improved blood pressure control was noted, a positive outcome related to the evidence-based interventions implemented for this QI project. One of the major difficulties with this project was related to recruitment and retention of participants due to the various factors discussed in the limitations section of this paper.

Regarding Aim #1, monthly adherence rates improved each month beginning with 84.4% adherence at the end of month one, 92.6% at the end of month two and, 95.4% at the end of month three. After three months of usage of the Medisafe app, the overall mean adherence rate for participants was 90.8% which translates to adherence rates improving by 13% from month one (84.4%) to month three (95.4%). (See Figure 1).

This increase surpassed the 10% increase in adherence goal set for improvement from month one to month three. These results demonstrate that the Medisafe smartphone application greatly improved medication adherence rates in the sample of patients in this clinic. These findings are supported by existing literature. Márquez-Contreras et al. (2019) conducted a cluster-randomized trial to evaluate the effectiveness of a smartphone application on medication adherence in patients (n= 154) with hypertension. The study included men (47.9%) and women (52.02%) with a mean age of 57.9. Researchers found 77.02% global adherence, daily adherence rates of 74.32% and 28.3% of patients with uncontrolled HTN at the end of the study period. Similar to this QI project finding, their findings indicated the intervention resulted in improved adherence rates as well as improved blood pressure control (Márquez-Contreras et al., 2019). Xion et al. (2018) conducted a systematic review of 21 studies on the effectiveness of a smartphone application on medication adherence in patients with hypertension and found that mobile phone applications helped improve medication adherence as well as blood pressure control in patients with hypertension.

Regarding Aim #2, the Hill-Bone self-reported medication adherence scale scores were measured with mean changes displayed on Figure 3. After three months, the mean self-reported medication adherence score was 32.5. This represented an increased mean Hill-Bone compliance score of 15.2% from baseline to end of the project period surpassing the goal of 10% improved mean scores. See Figure 3 for details.

Descriptive statistics and a paired t-test were used to detect statistically significant differences between pre and post Hill-Bone self-reported mean monthly adherence scores. There was a statistically significant difference between pre Hill-Bone self-reported mean monthly adherences scores (M = 28.2, SD = 8.6) and post intervention Hill-Bone self-reported mean monthly adherences scores (M = 32.5, SD = 4.5), $t(9)$ = -2.45, and p = 0.036. The Cohen's d effect size was d = -0.08 which aligned with Cohen's (1988) convention of a small effect (d =.20) (Grove & Cipher, 2020). See descriptive statistics Table 5.

Table 5: Descriptive Statistics and T test Results for Hill-Bone Scale and Blood Pressure

Variable	Mean (SD)	$t(df)$	p	Cohen's d
Hill-Bone Scores				
Pre-Intervention Mean	28.2 (8.6)			
Post-Intervention Mean	32.5 (4.5)			
		$t(9) = -2.45$	.036	-0.08
Systolic Blood Pressure				
Pre-Intervention Mean	169.4 (19.6)			
Post-Intervention Mean	130.5 (12.8)			
		$t(9) = 4.89$	<.001	1.55
Diastolic Blood Pressure				
Pre-Intervention Mean	102 (12.7)			
Post-Intervention Mean	84.7 (9.5)			
		$t(9) = 4.06$	0.003	1.28

These findings are supported by existing literature that the use of the Hill-Bone Self-Reported Medication Adherence Scale tool can help assess adherence levels and improve self-reported medication adherence rates (Abu-El-Noor et al., 2020). Abu-El-Noor et al. (2020) conducted a randomized clinical trial study (n=191) utilizing the Hill-Bone Scale to assess self-reported medication adherence along with use of a mobile phone medication reminder application. This study included males (n=75) and females (n=116) with a mean age of 56.4. Study findings revealed improved Hill-Bone medication adherence scores after utilizing the mobile phone reminder application with post intervention statistical significance (p=0.000) (Abu-El-Noor et al., 2020).

To determine whether Aim #3 was met, the number of all eligible patients with HTN who visited the clinic each month was tracked, and of those eligible patients, the number of patients who were screened using the Hill-Bone Scale each month was documented to determine the percentage screened each month. Results revealed continuous monthly improvements in screenings from 78.2% month one, 92.5% month two, and 100% at the end of month three with a mean screening rate of 88.8% over the project period (See Figure 4). These findings met the specific goal of 100% screenings by the end of the month three.

To determine the impact of the interventions on blood pressure control, descriptive statistics along with a paired t-test were conducted to detect statistically significant differences between pre-intervention systolic and diastolic and post-intervention systolic and diastolic blood pressures. There was a statistically significant difference between pre-systolic blood pressure (M = 169.40, SD = 19.6) and post systolic blood pressure (M = 130.50, SD =12.8), $t(9) = 4.89$, and p = <.001. The effect size was calculated using Cohen's d (d = 1.55) which exceeded Cohen's

(1988) convention for a large effect (d = .80) (Grove & Cipher, 2020). There was a statistically significant difference between pre-diastolic blood pressure (M = 102.00, SD = 12.7) and post-diastolic blood pressure (M = 84.70, SD = 9.5), $t(9) = 4.06$, and p =0.003. The effect size was calculated using Cohen's d (d = 1.28) which exceeded Cohen's (1988) convention for a large effect (d = .80) (Grove & Cipher, 2020). See descriptive statistics Table 5.

Limitations

This QI project had limitations. One limitation was a small sample size. Of the 63 eligible participants, we were only able to contact 56, of which 20 consented to participate however, only 10 participants remained by the end of the protocol period. The 10 patients dropped out due to reluctance to be seen the clinic due to the Coronavirus pandemic. Future projects aimed at improving medication adherence may focus on methods to improve participation rates. Perhaps incentives or more time spent on education and provider encouragement will help increase participation. Another limitation of this project was the inability to obtain a complete three-month data set due to project deadlines, reduced scheduling resulting from the pandemic, a power crisis due to freeze, and an EMR implementation causing recruitment delays. To minimize these barriers going forward, recruitment over the phone, home blood pressure checks and telephone medication adherence surveys may help to facilitate conducting the study for a longer study period. Practice changes that may weaken over time include reduced practice of offering the Medisafe application to patients and utilization of medication adherence tool. It is expected that these practices may weaken due to heavy patient loads, short staffing or provider / staff forgetfulness. To minimize this problem going forward, Medisafe information will be posted in the clinic lobby and patient exam rooms, which may prompt patients to inquire about the application, in turn prompting staff to discuss the application with the patient. In addition,

incorporating the medication adherence questionnaire into triage or initial assessment documentation will help to minimize these barriers.

Interpretation

The application of the RE-AIM (reach, effectiveness, adoption, implementation, maintenance) framework helped in identifying challenges, opportunities and lessons learned for future project planning. The reach portion of this framework, assisted in reaching and recruiting the target population for this project. The effectiveness portion of the RE-AIM framework assisted in assessing the effectiveness of the Medisafe application. Every patient who completed the study period was asked what they thought about the application and if it was helpful. All patients expressed they were excited about using the Medisafe application and commented that it helped them remember to take their medications. One positive unexpected outcome was that some patients stated that on occasion, prior to using the application, they could not remember if they had taken their medication and sometimes double dosed themselves. Using the Medisafe medication log helped them to realize that they had already taken their medication. The adoption portion of the RE-AIM framework helped to identify that all staff members were eager to participate and assist in initiating the program. The implementation portion of the RE-AIM framework helped to assess the staffs commitment to implementing the project and continue screening patients with the Hill-Bone Scale assessment tool as well as encouraging patients to utilize the Medisafe application. The number of screenings were tracked as well as new patients who agreed to utilize the application.

One unexpected outcome was the low sample size. As discussed in the limitations section, this was largely affected by the implementation of a new EMR, the Coronavirus pandemic, as well as the freeze that occurred causing power outages for several days. These

variables resulted in clinic closures and reduced patient volumes causing recruitment delays. Plans for improvements and sustainability include ongoing recruitment processes and education for staff members and patients to be conducted in the next PDSA cycle. To sustain the changes we have attained in improving medication adherence and improved blood pressure, we will continue to encourage staff to screen all hypertension patients for medication adherence and offer the Medisafe application to patients. The financial implications are promising as increased visits result when patients come in for monthly blood pressure checks until their blood pressure is regulated. Patients who have had their medications adjusted are asked to return for a blood pressure check in 10 days. These visits result in increased revenue in addition to contributing to improved blood pressure control, and improved patient outcomes.

Conclusion

Among participants in this QI project with uncontrolled hypertension, utilization of the Medisafe application resulted in increased number of medication adherence days, improved self-reported medication adherence scores, as well as improved overall mean systolic and diastolic blood pressure. This project also demonstrated that screenings for self-reported medication adherence as well as encouraging patients to use the Medisafe medication reminder application changed practice at this clinic and improved patient outcomes. This protocol has the potential to improve medication adherence among patients with uncontrolled hypertension. The Medisafe application is a very user-friendly application and in retrospect, instead of having each patient watch the Medisafe instructional video in clinic, having the patient watch the video as a reference on their own time could have allowed more time for patients to navigate the application and gain assistance from staff members. In addition, patients do not need to have an email to use the medication reminder application however, part of the inclusion criteria for this

project was that the patient had to have an email so they could send us the Medisafe progress reports for statistical purposes. Several patients who did not have an email who may have benefited from the medication reminder application were excluded. In hindsight, assisting those patients in creating emails would have allowed for them to be included.

Expanding the use of the Medisafe application and screenings with the Hill-Bone Scale could have similar results in other primary care clinics within the organization. Medisafe is a versatile application, which can help improve medication adherence in a variety of settings and patient conditions. With increasing numbers of individuals utilizing smartphones, providers in various settings can capitalize on this by encouraging patients to utilize medication reminder applications to improve medication adherence. Future projects including other patient populations and chronic diseases can determine if medication adherence screenings and utilization of smartphone applications can have the same success in improving medication adherence and outcomes. Improving medication adherence can result in improved health outcomes and reduced societal financial burdens related to reducing complications related to uncontrolled blood pressure. To maintain the changes brought about by this project, ongoing medication adherence screenings will need to continue and providers and staff should continue recommending the use of the Medisafe application.

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LIST OF APPENDICES

APPENDIX PAGE

APPENDIX A: IRB Determination Letter 37

APPENDIX B: HIPPA Permission..... 39

APPENDIX C: Facility Support Letter..... 40

APPENDIX D: Phone Consent and Participation Agreement Form 41

APPENDIX E: Medisafe Instructions 42

APPENDIX F: Hill-Bone Instrument Authorization for Use 43

APPENDIX G: Facility Intervention Log..... 44

APPENDIX A: IRB Determination Letter

From: irb@tamucc.edu <donotreply@redcap.tamucc.edu>
Sent: Friday, January 29, 2021 8:05:54 AM
To: Walker-Smith, Tammy <Tammy.Walker-Smith@tamucc.edu>
Cc: IRB <irb@tamucc.edu>
Subject: Not Human Subjects Determination: Not Research

Dear Dr. Tammy Walker-Smith,

Activities meeting the DHHS definition of research or the FDA definition of clinical investigation and involves human subjects are subject to IRB review and approval.

On 12-21-2020, the Office of Research Compliance reviewed the project below and determined that the proposed activity does not meet the FDA definition of a clinical investigation or DHHS definition of research:

Type of Review:	Not Human Subjects Determination
IRB ID:	TAMU-CC-IRB-2020-12-122
Project Lead:	Dr. Tammy Walker-Smith
Title:	Implementing Smartphone Applications at a Family Health Center to improve Self-Reported Medication Adherence and Blood Pressure Control in Indigent Hispanic Males
Rationale:	The project will not develop or contribute generalizable knowledge

Therefore, this project does not require IRB review. You may proceed with this project.

Limits to this determination:

1. This determination applies only to the activities described in the documents reviewed. Any planned changes require submission to the IRB to ensure that the research continues to meet criteria for a non-human subject research determination.
2. This project may NOT be referenced as "IRB approved".

The following statement can be included in the manuscript: "This Project was reviewed and determined to not meet the criteria for human subjects research by the Texas A&M University-Corpus Christi Institutional Review Board."

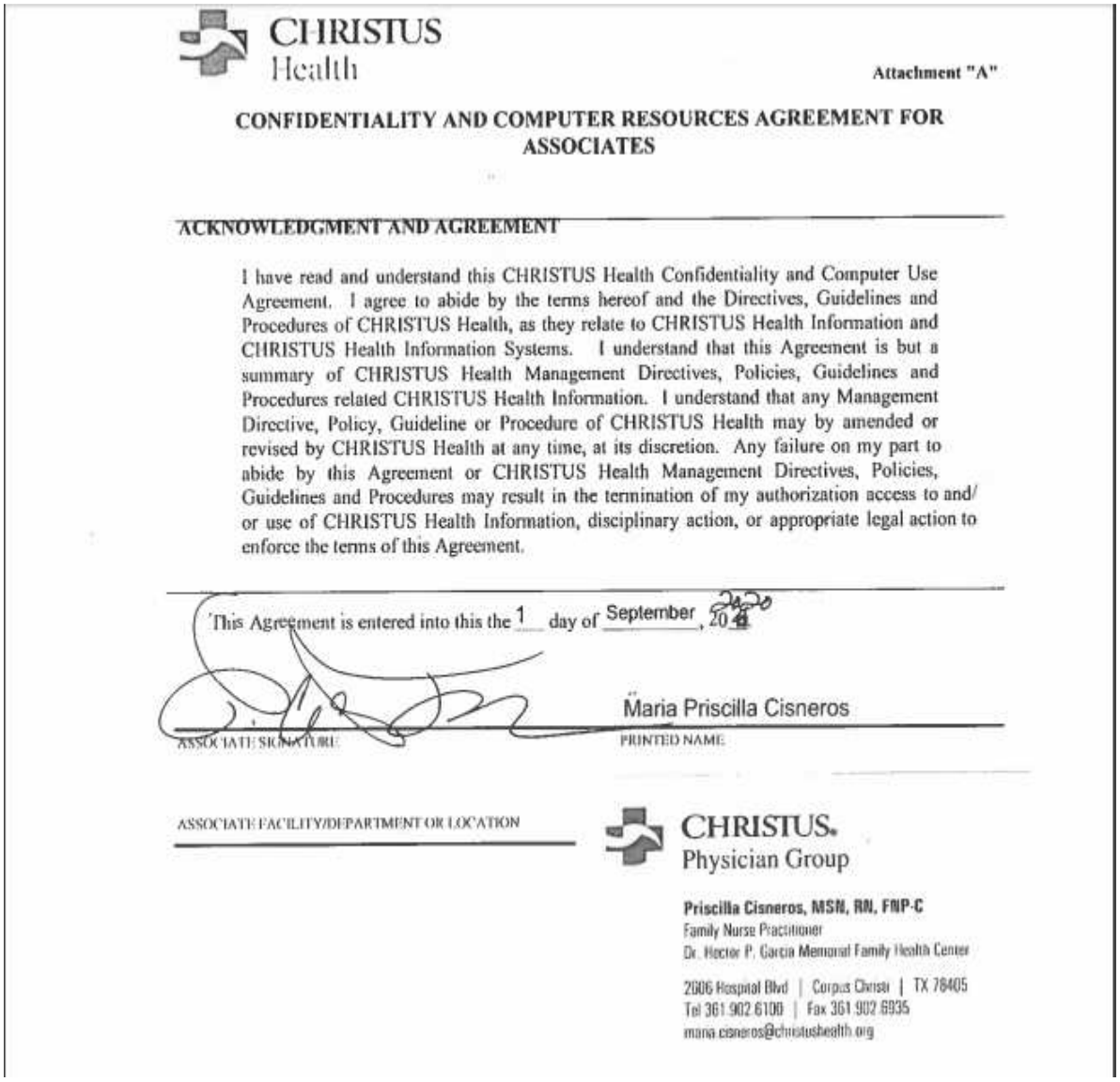
Please do not hesitate to contact the Office of Research Compliance with any questions.

Respectfully,

Germaine Hughes-Waters

Office of Research Compliance

APPENDIX B: HIPAA Permission



CHRISTUS Health

Attachment "A"

CONFIDENTIALITY AND COMPUTER RESOURCES AGREEMENT FOR ASSOCIATES

ACKNOWLEDGMENT AND AGREEMENT

I have read and understand this CHRISTUS Health Confidentiality and Computer Use Agreement. I agree to abide by the terms hereof and the Directives, Guidelines and Procedures of CHRISTUS Health, as they relate to CHRISTUS Health Information and CHRISTUS Health Information Systems. I understand that this Agreement is but a summary of CHRISTUS Health Management Directives, Policies, Guidelines and Procedures related CHRISTUS Health Information. I understand that any Management Directive, Policy, Guideline or Procedure of CHRISTUS Health may by amended or revised by CHRISTUS Health at any time, at its discretion. Any failure on my part to abide by this Agreement or CHRISTUS Health Management Directives, Policies, Guidelines and Procedures may result in the termination of my authorization access to and/ or use of CHRISTUS Health Information, disciplinary action, or appropriate legal action to enforce the terms of this Agreement.

This Agreement is entered into this the 1 day of September, 2020

ASSOCIATE SIGNATURE

Maria Priscilla Cisneros

PRINTED NAME

ASSOCIATE FACILITY/DEPARTMENT OR LOCATION

CHRISTUS Physician Group

Priscilla Cisneros, MSN, RN, FNP-C
Family Nurse Practitioner
Dr. Hector P. Garcia Memorial Family Health Center

2606 Hospital Blvd | Corpus Christi | TX 78405
Tel 361 902 6100 | Fax 361 902 6935
maria.cisneros@christushealth.org

APPENDIX C: Facility Support Letter

OUR MISSION "To Extend the Healing Ministry of Jesus Christ"

CHRISTUS SPOHN
Dr. Hector P. Garcia Memorial Family Health Center

Dr. Sara Baldwin
Associate Dean for Academic Programs
College of Nursing and Health Sciences
Texas A&M University – Corpus Christi
6300 Ocean Drive
Corpus Christi, TX 78412

August 27, 2020

Dear Dr. Baldwin,

The purpose of this letter is to provide Maria Priscilla Cisneros, a Doctor of Nursing Practice student at Texas A&M University College of Nursing and Health Sciences, support in conducting a quality improvement project at Hector P. Garcia Memorial Family Health Center. The project, assessing nonadherence to antihypertensive medications to decrease cardiovascular risks among the indigent, entails uncontrolled blood pressure and nonadherence to antihypertensive medications.

The purpose of this project is to help identify medication nonadherence and contributing factors which can be utilized to develop evidence-based interventions that can contribute to improved adherence rates among adults (25 – 64 years of age) diagnosed with HTN as compared to current clinic protocol. The Hector P. Garcia Memorial Family Health Center was selected for this project because we have a large population with uncontrolled blood pressure. Maria Priscilla Cisneros is employed at this institution, and does have an interest in improving care at this facility.

I, Bert Ramos, Director of Clinic Operations as Hector P. Garcia Memorial Family Health Center, do hereby fully support Maria Priscilla Cisneros in the conduct of this quality improvement project, assessing nonadherence to antihypertensive medications to decrease cardiovascular risks among the indigent at Hector P. Garcia Memorial Family Health Center.

I also approve Maria Priscilla Cisneros to access protected health information (PHI) for purposes of conducting this quality improvement project. She has signed a HIPAA release form.

Sincerely,

Bert Ramos, MPH
Director of Clinic Operations
CHRISTUS Spohn Hospital Corpus Christi
Dr. Hector P. Garcia Memorial Family Health Center
2606 Hospital Blvd.
Corpus Christi, TX 78405
Office 361-902-4780, Cell 361-726-7374
humberto.ramos@christushealth.org

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Tel 361.902.0900 | Fax 361.902.0905

APPENDIX D: Phone Consent and Participation Agreement Form

Name: _____ **DOB**:_____

Phone: _____

Best time to call (circle): morning afternoon anytime

Email: _____

Please initial below:

_____ I give permission to contact me to follow-up regarding my blood pressure and medication adherence.

_____ I agree to participate in this project and understand that this is voluntary, I may withdraw at any time, refusal to participate will involve no penalty, I will not lose any personal legal rights and my personal health information (HIPPA) will be protected.

_____ I have received education and installed the Medisafe App on my mobile phone device.

_____ I have completed the pre-intervention Hill-Bone Scale adherence screening.

_____ _____

Signature **Date**

APPENDIX E: Medisafe Instructions

What is Medisafe?

Medisafe is a smartphone medication reminder application that helps to remind you to take your medications and also provides refill reminders.

Benefits:

- This application is easy to use on your smartphone device
- It provides daily medication reminders
- Provides refill reminders
- Provides medication education and interaction warnings
- Medifriend feature allows family, friend or caregiver notification if you forget your medication so they can help remind you to take it
- Provides medication coupons
- Easy way to communicate with your provider

How to Get the Medisafe Application:

1. Go to your app store and download Medisafe
2. Go to Medisafe website at: https://www.Medisafe app.com/ to download Medisafe

How to Get Started:

1. Once Medisafe application is downloaded on your phone. Find icon on your phone and tap to open.
2. Click "Start Now" to enter your medication
3. Enter Medication name, select dosage, appearance then click "next" to set reminders
4. Reminder: select many times a week, how often per day, and what time you take medication then click "save" then click "next". This will take you to the refill screen.
5. Refills: type in prescription number and how many pills you have left. Then turn refill reminder "on" and select the number of days ahead you'd like to be reminded before you run out. You can also set a reminder alarm to a time you select if you desire.
6. Click "OK" to : allow Medisafe to send you notifications
7. You can follow the same process to add another medication.
8. Watch YouTube links below for further Medisafe education

Source: Medisafe Help Center https://www.Medisafe app.com/help/

YouTube Education Links:

iPhone Medisafe App Education Video: https://www.youtube.com/watch?v=eSAPn4TjS50

Android Medisafe App Video: https://www.youtube.com/watch?v=FS3z4Adnf-E

APPENDIX F: Hill-Bone Instrument – Authorization for use

Please consider this message as permission to use the Hill-Bone Scale(s).*

Click the link below to access articles regarding scoring, validation and the original scales. We request that you cite the scale using the references provided in the link. We appreciate you sharing the findings of your project with us.
Link: https://nursing.jhu.edu/faculty_research/research/projects/hill-bone/hill-bone-scales-confirmation.html

Please don't hesitate to reach out to us at SON-HillBone@jhu.edu if you have any follow-up questions.

Best,

The Hill-Bone Scales team

* Note: Please do not share these documents with anyone else outside your project. We ask that anyone who wishes to use the scale should submit a formal request using the link provided for proper authorization.

Reference

Kim, M. T., Hill, M. N., Bone, L. R., & Levine, D. M. (2000). Development and testing of the Hill-Bone compliance to high blood pressure therapy scale. *Progress in Cardiovascular Nursing, 15*(3), 90-96.

APPENDIX G: Facility Intervention Log

Instructions: At each visit, list each patient that meets criteria (Hispanic Males ages 25-64 with HTN) and document whether or not they agreed to perform the intervention.

Date	**Patient Code**	**Completed Hill-Bone Assessment (Yes or No)**	**Dowloaded Medisafe App (Yes or No)**