The Effect of MyMedSchedule® Plus Smartphone Application on Antihypertensive Medication Adherence in Hypertensive Adults in the Outpatient Setting

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Abstract

One in three adults in the United States are diagnosed with hypertension, a leading risk factor for cardiovascular disease and stroke, which are two of the most common causes of death. Hypertension is often uncontrolled due to medication nonadherence related to forgetfulness. Technology, specifically the use of smart phones and their applications can aid in enhancing medication adherence through medication reminders and applications that track medication adherence. This quality improvement project evaluates the effectiveness of the smart phone application MyMedSchedule® Plus on enhancing medication adherence in hypertensive adults being treated in the outpatient setting. Data collection includes self-reported medication adherence through the use of the Morisky Green Levine Medication Adherence Questionnaire and self-reported medication adherence within the MyMedSchedule® Plus smart phone application. Findings from this quality improvement project did not hold high statistical significance, but conclude that MyMedSchedule® Plus is an effective self-reporting medication reminder and adherence tracking smart phone application that also has capabilities for patient, provider and pharmacist interaction that go beyond the limits of this study but are areas for future research.

Keywords: hypertension, medication nonadherence, smart phone technology, self-reported medication adherence, MyMedSchedule® Plus, Morisky Green Levine Medication Adherence Questionnaire

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Background of Problem

According to the Centers for Disease Control and Prevention (CDC), hypertension occurs in 1 of 3 adults in the United States, or roughly 75 million people (CDC, 2018). Of those individuals diagnosed with hypertension, only 54% have their blood pressure under control. Hypertension is a leading risk factor for cardiovascular disease and stroke, which are two of the most common causes of death (CDC, 2018). Hypertension has been referred to by many as the "silent killer" because, frequently individuals do not feel any effects of their elevated blood pressure until it has advanced, leading to severe symptoms and end organ damage. In 2014, the CDC revealed that there were 884,707 ambulatory care visits with the primary diagnosis of essential hypertension, with the state of Florida contributing 66,769 visits to that total.

Forgetfulness has been identified as a leading cause of medication nonadherence in all populations (Holt et al., 2014). Factors that contribute to forgetfulness and nonadherence are disruption in routine, loss of memory with advanced age, and, most notably, a lack of side effects and consequences from missing a dose of antihypertensive medication (Holt et al., 2014). Najimi, Mostafavi, Sharifirad, and Golshiri (2018) noted that individuals who commonly forget to take antihypertensive medications are those who are early in the disease process while still asymptomatic and those whose prescribed medications include only antihypertensives. The use of smart phone applications has been identified by patients as providing a helpful reminder (Dayer et al.,2013). Such technology allows for individualized patient medication reminders,

tracking of adherence, and communication between patient and provider, all of which contribute to overcoming medication nonadherence.

Purpose of Project

The purpose of this project is to determine whether the use of medication reminders through the MyMedSchedule® Plus smart phone application enhances adherence to antihypertensive medication and is an effective self-reporting tool for use by hypertensive adults in the outpatient setting. The primary objectives will be evaluated through patient self-reported adherence within the MyMedSchedule® Plus application and comparison between the initial intervention and post-intervention Morisky Green Levine Medication Adherence Questionnaire MGL. In addition, self-reported adherence levels from the MyMedSchedule® Plus application will be compared to those reported in the post-intervention MGL. Secondary objectives include comparing levels of correlation in adherence between the MGL and the MyMedSchedule® Plus application. Patient demographics (Appendix A)—including age, sex, race, employment status, and number of daily medication doses—will provide further insight regarding which populations receive the most benefit from the smartphone application and whether MyMedSchedule® Plus reminders have an effect on antihypertensive medication adherence across various populations.

Significance of Project

The significance of this project lies in its assumption that optimization of antihypertensive medication adherence and accurate self-reporting through smartphone applications can have a positive effect on patients and providers who are collaboratively managing risk factors associated with chronic cardiovascular disease, ultimately reducing morbidity and mortality as well as decreasing the financial impact that uncontrolled hypertension and cardiovascular disease have on the health care system. Determining whether a free, easily

accessible medication reminder tool such as MyMedSchedule® Plus is effective for medication reminders and for tracking self-reported adherence can change the way that patients and providers manage their medications not only for hypertension but for all acute and chronic diseases.

Problem Statement

Hypertension management in the primary care setting emphasizes reducing the risk for cardiovascular disease and the end organ damage that results from uncontrolled hypertension. However, many adults still have decreased adherence to antihypertensive medication medications for a variety of reasons, including cost, lack of understanding, and forgetfulness. The reported financial impact of hypertension in the United States in 2011 was $46 billion for care, medication coverage, and the cost of missed days of work (CDC, 2018). The current literature supports the utilization of technology and smartphone applications, such as MyMedSchedule® Plus, to aid in decreasing medication forgetfulness, improving medication adherence, and accurately documenting individual adherence.

This national problem is also present in many local practices. Medication adherence in hypertensive patients being managed in the outpatient setting has raised concern for the providers who are stakeholders in this project. The proposed project is aimed at improving medication adherence in a local primary care practice that manages numerous uncontrolled hypertensive patients at their four locations in the Jacksonville area. The exact percentage of patient nonadherence throughout the practices is unknown, although providers report concerns with patients maintaining adherence to the prescribed treatment regimen. This warrants evaluation and intervention with a medication adherence target set for this project, of 80%

adherence, which is based on best practice standards for medication adherence in chronic disease (Hugtenberg et al., 2014)

Definition of Terms

Hypertension

The most recent guidelines define stage one hypertension as being a systolic blood pressure greater than 130-139 mmHg over a diastolic blood pressure of greater than 80-89, with stage two hypertension being a systolic blood pressure greater than or equal to 140 mm Hg and diastolic blood pressure greater than or equal to 90 mm Hg (American College of Cardiology, 2017). For patients included in this study, a previous diagnosis of hypertension is required.

Medication Adherence

Hugtenburg et al. (2013) defined medication adherence as "the extent to which patients are able to follow the recommendations for prescribed treatments" (p. 675). Adherence also addresses the extent to which the medication taking behavior corresponds with provider recommendations, suggesting collaboration between patient and provider. The definition of adherence for the four-item MGL utilized within this quality improvement project will be a score of 3 or higher out of a possible 4 points on the "yes or no" four-item questionnaire. Within the MyMedSchedule® Plus application, adherence will be reflected by the taking of 80% or more of prescribed doses, as adherence rates of 80% or higher are needed for optimal therapeutic efficacy (Kim, Combs, Downs, & Tillman III, 2018).

Medication Nonadherence

Medication nonadherence is either intentional or unintentional. Intentional nonadherence is defined as "a process in which the patient actively decides not to use treatment or follow treatment recommendations. This usually reflects a rational decision-making process in which

the patient weighs the pros and the cons of treatment" (Hugtenburg et al., 2014, p. 677). Hugtenburg et al. (2014) describe unintentional adherence as an unplanned behavior that is commonly the result of forgetfulness and lack of understanding of medication use and is less strongly associated with beliefs and cognition that play a role in intentional nonadherence. For the purpose of this project, nonadherence will be defined as taking less than 80% of prescribed doses as scheduled within MyMedSchedule® Plus, and a score of less than or equal to 2 on the 4-item MGL.

Variables

The independent variable in this study is the MyMedSchedule® Plus application. The dependent variable is self-reported antihypertensive medication adherence through the MyMedSchedule® Plus application and the MGL. Alternative variables include patient demographic information, specifically age and employment status, as well as prescription information, including medication, dose, timing, and frequency of administration. Evaluation of these variables will provide further insight into the exploratory objectives and enhance the generalizability of the findings beyond the patient population involved in this project.

Review of Literature

Search Process

Full text articles since 2013 from various databases are the primary source of information, with original research and data dating back to 2005 being used as a supplement to support the current research. PubMed, Ovid, and ProQuest produced the most abundant sources of relevant literature. GoogleScholar also yielded relevant research. All databases were searched with the same search terms: *medication adherence, medication nonadherence, medication adherence AND hypertension, hypertension, effects of uncontrolled hypertension, improving*

medication adherence WITH technology, *technology AND hypertension medication adherence*, *MyMedSchedule® Plus, medication reminders AND antihypertensive adherence*, *Morisky Green Levine questionnaire AND hypertensive adults,* and *Morisky Green Levine questionnaire*. Information on the origin of MyMedSchedule® Plus and MedActionPlan® was obtained through a Google search for MedActionPlan® that led directly to the site. The QI model was found through searching *Donabedian: Evaluating the quality of medical care* in Google, which yielded the original article as well as articles citing the original. The conceptual framework and information on the Health Belief Model were obtained through searches in ProQuest, Ovid, and EBSCOHOST with the search terms *health belief model* and *health belief model AND hypertension*. The self-report Morisky Green Levine questionnaire was cited in numerous articles obtained throughout the review of literature, and direct contact with its author, Dr. Donald Morisky, was made.

Hypertension

Hypertension is one of the most common diagnoses managed in the primary care setting.

Etiology. Hypertension is a leading risk factor for cardiovascular disease. Roughly 85 million people—or one in every three adults over the age of 20 in the United States—is currently diagnosed with hypertension (MacGill, 2017). Hypertension is defined as "consistent elevation of systemic arterial blood pressure" (McCance & Heuther, 2014, p. 1123). Hypertension, if untreated or poorly managed, can lead to myocardial infarction, stroke, and renal failure (American Family Physician, 2016).

The two most common types of hypertension are primary and secondary hypertension. Primary, or essential, hypertension makes up 95% of cases and its causes are multifactorial, whereas secondary hypertension is due to an alternate disease process in the body that may be

cardiac, renal, or endocrinologic in origin (Dunphy et al., 2016). Regardless of the type of hypertension, the pathophysiology behind the disease process is the same. The causes of hypertension are both modifiable and non-modifiable. Non-modifiable factors include age, sex, ethnicity, and family history of hypertension. Modifiable risk factors include obesity, pre-existing health conditions, including diabetes mellitus, chronic kidney disease, atherosclerosis, and lifestyle choices, such as high sodium diets, excessive alcohol intake, and smoking (MacGill, 2017). All of these factors lead to increased systemic vascular resistance due to vasoconstriction and increased cardiac output. These changes, over time, lead to left ventricular hypertrophy and, eventually, a decreased and inadequate cardiac output that affects all of the vessels and organs throughout the body.

Clinical presentation. Hypertensive individuals often do not present with any acute complaints or symptoms. Individuals who have an extremely elevated blood pressure over an extended period of time might present with headache, cognitive or vision changes, stroke, aneurysm, or end organ damage, such as heart failure or chronic kidney disease (Monnet & Marik, 2015). These are considered to be complications of hypertension and the result of undiagnosed or poorly managed hypertension. It is rare that individuals present with these symptoms of hypertension without being previously diagnosed.

A thorough physical exam of an individual with hypertension should always be performed, but it likely will not show any abnormalities unless the disease has been poorly managed and has become progressive. Physical examination is often unremarkable, but with advanced disease it may show signs of end organ damage. Such findings may include abnormalities on fundoscopic exam, an abdominal or carotid bruit, extraneous heart sounds,

edema in the extremities, distension of the neck veins, thyroid nodules, or crackles throughout the lungs (Dunphy et al., 2015).

Screening. According to American Family Physician (2014), the United States Preventive Services Task Force (USPSTF) provides Grade A recommendations for screening all adults 18 years or older for high blood pressure. An average of two blood pressures, taken five minutes apart, using the appropriately sized cuff and with the patient in the sitting position, show the most favorable results. The USPSTF encourages the consideration of an ambulatory blood pressure measurement before the diagnosis of hypertension is made if the results in the clinical setting are variable. According to the USPSTF, every adult should be screened at 18 years old. A risk assessment should then be performed to determine frequency of future blood pressure screening. If the patient is found to be normotensive with no risk factors, screening is then recommended every 3 to 5 years. If risk factors such as obesity or being African American are present, then screening should be performed annually (American Family Physician, 2014).

Diagnosis. When diagnosing hypertension, it is important to consider and evaluate the various causes. The diagnosis of primary or essential hypertension arises due to risk factors that include diet, exercise, tobacco abuse, alcohol consumption, age, gender, ethnicity, and family history. These risk factors can be pertinent in the diagnosis of secondary hypertension as well, with secondary hypertension being caused by another disease process occurring simultaneously in the body, such as kidney disease, diabetes, or hormone irregularities (MacGill, 2017).

Blood pressure readings are the primary tool used for the diagnosis of hypertension. An average of multiple readings in various settings are required to ensure accurate and appropriate diagnosis. Research and current clinical guidelines suggest that an average of between two and six blood pressure readings be taken on separate occasions when formulating the diagnosis of

hypertension. The use of ambulatory and electronic monitors also affect blood pressure readings and need to be taken into consideration. Mueller (2011) evaluated a meta-analysis that focused on the accuracy of home- and clinic-based blood pressure readings for diagnosis and concluded that a mean clinic blood pressure of greater than 140/90 mmHg had both a sensitivity and specificity of 75%. That same meta-analysis showed that a mean home blood pressure of greater than 135/85 mmHg had a sensitivity of 86% and a specificity of 62%, indicating that ambulatory measurement was the gold standard for diagnosis (Mueller, 2011). The National Institute for Clinical Excellence also support the diagnosis of hypertension in the ambulatory setting, noting that in-office blood pressure measurement is simply a screening tool for hypertension (Kieldsen et al., 2014).

The most updated clinical guidelines redefine normal blood pressure being below 120/80, and stage I hypertension being present when blood pressure is 130/90 (American Heart Association, 2019). Research supports the change from the previous JNC 8 recommendations, noting that a lower blood pressure is better in all populations, regardless of age and comorbidities.

Medication Nonadherence

Medication nonadherence is a complex and multidimensional healthcare problem especially in the management of chronic disease including hypertension. The Global Burden of Disease study estimated that hypertension is now the leading risk factor of disability-adjusted life years worldwide and note that antihypertensive medication adherence is the cornerstone for achieving hypertension control (Abegaz et al., 2017). Nonadherence can be primary, where the prescription is never filled, or secondary, where the medication is available to the patient but is not taken as prescribed for any reason. The literature identifies many factors that influence

nonadherence, including age, education level, side effects of medications, number of medications prescribed, frequency of doses, and, most commonly, forgetfulness. It is also important to consider other factors that affect medication nonadherence such as patients' beliefs, their socioeconomic status, health literacy, race or ethnicity and gender (Abegaz et al., 2017). The systematic review and meta-analysis performed by Abegaz et al. (2017) identified 25 studies that utilized the MMAS-8 to measure medication adherence. In hypertensive patients alone, the overall medication nonadherence rate was 45.2% whereas hypertensive individuals with comorbidities had lower rates of medication nonadherence at 31.6% (Abegaz et al., 2017). The data also showed that nonadherence in uncontrolled hypertensive patients was as high as 83.7%. Although men are at 1.3 times greater risk for being nonadherent, they actually have greater rates of adherence than females. Interventions aimed at overcoming medication nonadherence are most effective when individualized and focused on overcoming barriers related to intentional, unintentional, primary, and secondary medication nonadherence. Early identification of patients' barriers to medication adherence is imperative in order to reduce cost, optimize drug therapy and achieve blood pressure control (Abegaz et al., 2017). A crucial step of the process to overcome medication nonadherence is collaboration among patients and their providers.

Vrijens et al. (2014) describe medication adherence as being a dynamic three-part process that changes over time. The three parts of the process include initiation, implementation, and persistence. Nonadherence occurs when the patient does not initiate treatment as prescribed, has suboptimal daily medication taking practices including missed doses, and fails to remain consistent with lifestyle changes and medication regimen. Vrijens et al. (2017) concluded that many patients are nonadherent with new therapy within the first 10 days of implementation, with 40% being nonadherent after the first year. The consequences from medication nonadherence are

evident in both the patient as well as the economics associated with increased demand for health care resources. Poor medication adherence leads to poor health outcomes, increased medical care utilization, increased health care costs, comorbidities, and an increased number of medications required by the patient (Vrijens et al.,2017).

Pantuzza et al. (2017) performed a systematic review to evaluate the effects of a complex medication regimen on levels of medication adherence. This review pointed out that there is no specific consensus about the definition or measurement of a complex medication regimen and that the complexity should be determined on an individual basis. This review considered 54 articles using cross-sectional and cohort designs, with most studies being performed among adults with chronic diseases and relying on self-report scales, such as those Dr. Donald Morisky designed for measuring adherence. Results from the systematic review show an inverse relationship between the complexity of a medication regimen and the rate of adherence. Increased frequency of doses and number of medications led to increased patient burden and, ultimately, decreased levels of medication adherence. Being aware of this information enhances providers' opportunities to eliminate barriers to adherence.

In 2015, Kumaraswamy et al. (2015) evaluated a prospective observational study that was performed on hypertensive adults in the outpatient setting in India focused on assessing the reasons for nonadherence to antihypertensive medication. The results of that study showed multifactorial reasons for nonadherence (see Figure 1). The study also identified various demographic characteristics associated with lower rates of adherence, including single, divorced, or widowed males age 35-60 with lower levels of education and lower socioeconomic status. The combination of neglect, no change in health status, and forgetfulness comprised 41% of the

reasons for nonadherence in the study, and they are well-documented reasons found throughout the literature for nonadherence among the hypertensive population.

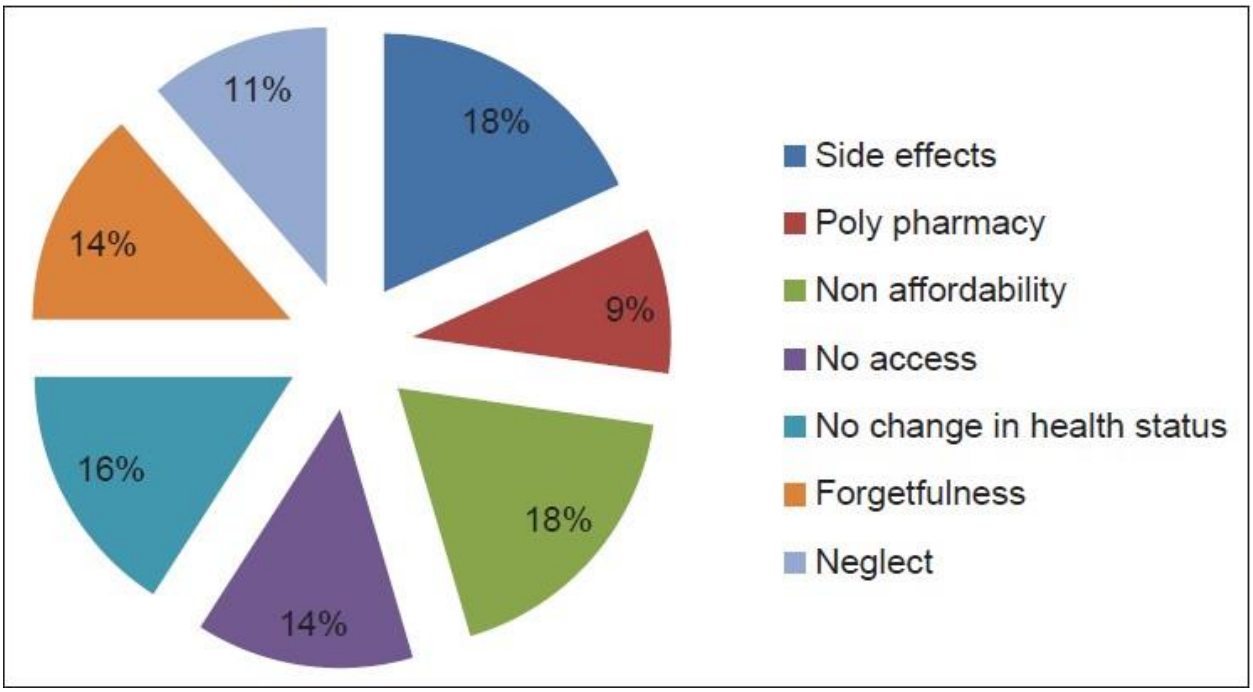

Figure 1. Determinants of nonadherence. *Source*: Kumaraswamy et al. (2015).

Strategies for overcoming nonadherence are directed towards changing patient behavior through the use of reminders, counseling, reinforcement, education, dose simplification, or a combination of these methods. These interventions are categorized into behavioral, educational, or organizational changes that address specific barriers to nonadherence, furthering the patient's and provider's insight into how to create an individualized medication regimen to which the patient will adhere.

In 2014 a qualitative study was performed on hypertensive adults in the outpatient setting over the age of 65 with the goal of gaining a deeper understanding of the barriers that this population faces with medication adherence, and also determining effective and feasible strategies for improving adherence. This study indicated that health behaviors and outcomes are influenced by patients, their social networks including family and friends, their relationships with

their healthcare providers, and health policy that affecting cost of medications (Holt et al., 2014). Patients repeatedly identified memory and forgetfulness as barriers to adherence, and noted that a medication taking routine, as well as reminder phone calls would be beneficial. Another important factor was the patients' beliefs about their condition, and that missing a dose lacked significant immediate consequence due to the asymptomatic nature of hypertension. Side effects and discomfort associated with the prescribed regimen were also noted to be significant barriers to antihypertensive medication adherence.

The influence of family, friends and community became important in this study population. Participants noted that support from family and friends were helpful with reminding them to take their medication, and also helped to normalize medication taking behavior and decreasing stigma (Holt et al., 2014). Participants identified a collaborative relationship with a provider as making them more inclined to take medication and ask questions (Holt et al., 2014). Finally, the cost and availability of medications were identified as a barrier. If medications were costly or not covered by insurance, participants stated that they split or skipped a dose in order to stretch their medications. This study supports the multifactorial nature surrounding medication adherence, and highlights the importance of a collaborative patient provider relationship, with open communication and an individualized approach to identifying and overcoming barriers to medication adherence.

Technology and Medication Adherence

Mobile phones, the most commonly used form of technology worldwide, provide the greatest chance to influence the largest number of people. The use of mobile phones allows for practical and inexpensive medication monitoring and eases contact between pharmacies, physicians, and patients regarding medication regimens. Given that the technology is familiar

and easy to use for many patients, it has the ability to incorporate medication regimens into daily routines, ultimately increasing medication adherence. The U.S. Department of Health and Human services, along with the World Health Organization, acknowledge the positive effects and outcomes that the use of technology has on medication adherence (as cited in Bhutada, 2014). Applications for mobile phones that use text messages, alarms, and personal reminders have been reviewed throughout the literature, and researchers have concluded that they have a positive effect on medication adherence among those with chronic disease.

The majority of current literature evaluates the use of text messages and their efficiency as medication reminders, as well as patient satisfaction with receiving such reminders. A systematic review performed by Park et al. (2014) reviewed the use of one-way and two-way text messages in patients ranging in age from 11-75 with a variety of chronic conditions including diabetes, HIV/AIDS, asthma and hypertension. The one-way messages do not allow for any response, whereas the two-way messaging allows for patient response that provides patient interaction and can also be used as self-reporting. The context of the messages varied from a simple medication reminder, to education and support, as well as personalized messages including the patients name, or a personalized message of their choosing. To summarize their overall findings, Park et al. (2014) concluded that text messages can be an effective medication reminder tool in all populations, including those with basic messaging functions, as well as those with smartphone technology. Longevity and continued use of text messages beyond the study window were observed in the populations, with two-way messaging adapting to feedback via the responses they were providing. Cost and feeling sensitive about health information were identified reasons for individuals to stop receiving text messages. Park et al. (2014) noted that

although text messages were a useful first step in implementing mobile phones into healthcare, the future will likely be based on smartphone applications instead.

In addition to text message reminders, Vervloet et al. (2012) support the use of electronic reminder devices that provide patients with an audio or visual reminder at a predetermined time. Such reminders are validated through the principles of the behavioral learning theory - stating that behaviors are driven by stimuli or cues generated internally through thoughts, or externally through environmental cues. A systematic review evaluating the effectiveness of both text messages and electronic reminder devices found that both were effective at enhancing medication adherence in participants with chronic diseases such as HIV/AIDS, asthma, glaucoma and hypertension. This systematic review also concluded that reminders are beneficial for improving adherence in patients of all ages with different reasons for nonadherence. Elderly patients tend to be at higher risk for forgetfulness related to memory problems and complexity of their medication regimen, whereas younger populations are at higher risk for nonadherence due to their busy social lives. Regardless of the cause, technology can be aimed at overcoming barriers to adherence.

Smartphone utilization. The use of applications downloaded to smartphones is increasing in popularity, and patients can easily access these applications at any time. Once installed, the applications allow patients to set reminders to take medications, order refills through the pharmacy, log when doses are taken for future reference and follow up visits, and access information that is specific to the drug. Updated technologies are also allowing direct access for pharmacists, physicians, and patients to view and make changes to medication regimens within the applications. Dayer et al. (2013) performed a study of the medication applications available for Android OS, iPhone®, and Blackberry® platforms to determine their

functionality and evaluate specific features within each application. Of the 160 applications available, the 10 mostly highly rated apps, based on their desirability and functionality, were downloaded to each platform and tested on subjects using a standardized medication regimen consisting for four medications dosed at various times and frequencies throughout the day. Reminders were most commonly provided as either a text message or a "push notification" with a generalized reminder stating that it was time to take a medication, with further medication and dose information made available once the alert was acknowledged and the application opened. Dayer et al. (2013) recommended MyMedSchedule® Plus along with two other applications with the highest ratings based on their wide range of features and high levels of functionality. Although many of these applications have not been involved in rigorous clinical studies, they have been identified as helpful tools to recommend to patients who can benefit from enhanced medication adherence.

In 2016, Mowarski et al. performed a randomized clinical trial titled MedISAFE-BP with the intent to determine the association of a smartphone application with medication adherence and blood pressure control. This study divided participants into a control group who received no intervention, and an intervention group instructed on the use of the smartphone application Medisafe. The Medisafe application allows for manual programming of the participants medication list and time to receive reminders; self-reporting of medication taking within the application; and storage of biometric information such as blood pressure measurements. It also allows for a "Medifriend" who is able to access the individual's information within the application. Pre- and post-intervention MMAS-8, as well as pre- and post-blood pressure readings were performed to evaluate adherence, and a statistically significant increase in self-reported adherence in the intervention group was noted as an increase in MMAS-8 scores from

baseline. Participants also noted a high satisfaction with Medisafe, and the literature supports its high usability scores (Mowarski et al., 2018). However, Medisafe does not allow for provider or pharmacist interaction and collaboration, leaving other applications potentially more desirable from the health care professional perspective.

With smartphone technology so readily available, it is important to consider the feelings of individuals towards such interventions. Morrissey et al. (2018) performed a qualitative study of hypertensive adults between the ages of 50-83 with the intent to explore their perspectives on the use of the smartphone application MiBP to enhance antihypertensive medication adherence. A number of themes were developed, beginning with "development of digital competence," meaning the pathway to becoming familiar and comfortable with using technology to manage hypertension (Morrisset et al., 2018). Some individuals were resistant to technology, as they felt they already had an established routine. Others preferred utilizing pen and paper for medication lists and reminders. Many participants were interested in using the application but intimidated by the technology and felt they would need instruction to feel comfortable. The second theme was rules of engagement, centered on participants' engagement and disengagement with the application, and motivations behind such behaviors (Morrissey et al., 2018). Again, some individuals were intimidated by the functions of the application and that prompted disengagement; others found the interaction, self-reporting, reminders, and enhanced ability to keep track of information to share with providers to be a motivator for engagement. The final theme was sustainability and participants' thoughts regarding continued use of the application for hypertension management. While some were concerned about privacy, others felt the application would be more beneficial with a wider range of features, such as the ability to contain a full medical history and medication list, as well as provider engagement and interaction. Awareness

of these themes and barriers to the acceptance of smartphone technology is imperative to the success of developing an individualized approach to enhance medication adherence.

MyMedSchedule® Plus. MyMedSchedule® Plus is one part of MedActionPlan®, which focuses on medication adherence through the use of smartphone applications and medication reminders. With the slogan "Educate. Empower. Adhere.," MedActionPlan®'s mission is "to help patients to become active partners in their healthcare by offering providers innovative tools and resources that combine the latest technology with proven health literacy principles" (MedActionPlan, 2018, p. 1). The health literacy team at Tim Peters and Company, one of the first medical education companies, originally developed MedActionPlan® with the intent to create a tool for healthcare providers to educate patients about their medication regimens (MedActionPlan, 2018). By 2004, MedActionPlan® was one of the first web-based software companies available to providers aimed at improving patient medication adherence and safety. In 2007, MyMedSchedule® was introduced as one of the first interactive patient portals, one aimed at involving patients in their health care, encouraging a proactive approach. The MyMedSchedule® mobile application, fully launched in 2008, has been refined over the years to enhance patient and provider interaction, accessibility, reminders, and medication regimen monitoring (MedActionPlan, 2018). In 2014, Elder et al. reported that with the use of MedActionPlan®, patients with various chronic diseases had a greater understanding of their medication regimens 98% of the time, increased adherence 69.2% of the time, and greater feelings of empowerment with regard to their own care 73% of the time.

MyMedSchedule® Plus is an updated smartphone application under the MedActionPlan® umbrella that allows provider and patient access to their medication schedules anywhere they go, with the ability to include multiple providers, update and change medications,

receive reminders when medications are due, and view their progress and medication adherence (MedActionPlan, 2018). Various clinical studies have been performed using MyMedSchedule® that provide evidence demonstrating decreases in inpatient length of stay, decreases in readmission rates among those with chronic heart failure, enhanced patient education about their medication regimen, and improved continuity of care. Dayer et al. (2013) also evaluated MyMedSchedule® and found that providers have the ability to access and edit patients' medication regimens, set reminders, then "push" those changes back to the patient. MyMedSchedule® also utilizes a HIPAA compliant cloud server to protect patient information while keeping it updated and easily accessible by both parties.

The medication reminders within MyMedSchedule® Plus allow patients to input each medication on their medication lists, including such details as the dose, frequency, timing, purpose, a photo of the pill, a refill reminder, and even notes about the specific medication. At a patient-selected reminder time, a notification from the MyMedSchedule® Plus application will appear on the home screens of their smartphones stating that they have a dose of the medication due. At this time, the patient can snooze the alert (to be reminded again within a time frame of a few minutes) or they can mark doses individually as taken. MyMedSchedule® Plus allows doses to be marked as taken after the alert for an unlimited amount of time and, if no response is given, that dose is recorded within the application as a missed dose.

MyMedSchedule® was used as a self-directed technology platform in a study performed by Walker et al. (2014) with individuals being treated for heart failure in the outpatient setting. The aim of that study was to determine whether MyMedSchedule® improved medication adherence among heart failure patients, and also explore the feasibility and acceptance in using technology. The participants took a pre and post medication adherence questionnaire to

determine the effectiveness of the MyMedSchedule® intervention. The results showed a slight increase in medication adherence post intervention, but participants expressed great comfort, confidence, and satisfaction with the MyMedSchedule® program, noting the technology to be easy to use and customize to their medication regimen. Walker et al. (2014) encourage advanced practice providers to promote the use of such self-directed technologies to assist patients with improving adherence, promoting drug safety, and enhancing communication between patients and providers.

Morisky Green Levine Medication Adherence Questionnaire

The MGL was originally developed in 1986 and has been modified over the years to scales that are currently used in clinical practice: the Morisky Medication Adherence Scale-4 (MMAS-4) and the Morisky Medication Adherence Scale 8 (MMAS-8; Morisky, Green, Levine, 1986). A meta-analysis by Perez-Escamilla et al. (2015) used validated questionnaires to measure adherence to pharmacological antihypertensive treatments. The four-item MGL was included and its results for reliability and validity were compared to a number of other medication adherence questionnaires. The four items included in the questionnaire are as follows:

1. Do you ever forget to take your medicine?
2. Are you careless at times about taking your medicine?
3. When you feel better, do you sometimes stop taking your medicine?
4. Sometimes, if you feel worse when you take the medicine, do you stop taking it?

Perez-Escamilla et al. (2015) concluded in their meta-analysis that the MGL is quick and easy to use with good sensitivity, specificity, and both positive and negative predictive value. The

Cronbach's alpha in their study was 0.61, which considered fair for reliability in group-level measurement.

Other analyses of the MGL's reliability show that it varies with a wide range in the Cronbach's alpha, but the tool is still frequently utilized in clinical practice as a way for providers to assess for medication adherence. In 2008, this tool was further developed into the Morisky Medication Adherence Scale-8, which has an improved capacity to collect information while maintaining acceptable validity and reliability, as originally established in the original MGL (Perez-Escamilla et al., 2015). The MMAS-8 is not available for independent study use; hence, the MGL is used for this QI project. The MMAS-8 collects four additional items in the questionnaire that go beyond assessing the MGL data on forgetfulness and symptom severity and delve into situational and emotional reasons for nonadherence, such as feelings of pressure or reasons other than forgetfulness (Sison, 2018). These additional items enhance the tool's sensitivity, specificity, and positive and negative predictive values while maintaining acceptable validity and reliability (Perez-Escamilla et al., 2015).

Self-Report Measures of Medication Adherence

According to Stirratt et al. (2015), self-report is the most common method for assessing medication adherence behavior in research and clinical care, but its validity and precision is often questioned. In terms of patients not benefitting from a prescribed medication regimen, it is first important to determine adherence to that regimen, which is often evaluated through self-reported measures and validated questionnaires. Such measures have been noted to overestimate adherence, and they often have a high specificity with a low sensitivity, but providers still frequently use them due to their low cost and ease of implementation across numerous populations and medication regimens (Stirratt et al., 2015).

Other key factors of self-reporting include their minimal patient burden, ease of use, and adaptability to patient medication regimens and schedules. Information obtained from self-reporting can include doses taken, the patient's understanding of the medication regimen, the reasons for nonadherence, attitudes and beliefs towards medication, and other psychosocial factors (Stirratt et al., 2015). Self-reporting is often used in conjunction with other measures of adherence to gather objective data, such as electronic drug monitors, to establish convergent validity. Stirratt et al. (2015) performed a meta-analysis of many studies that evaluated medication adherence through convergent validity and found that 92% of studies estimated higher rates of medication adherence through self-reporting, while only 15% actually showed improved adherence when convergent validity was utilized.

When determining which self-reporting method will provide the most valid and reliable results, it is important to use a well-validated scale and define specific adherence constructs of interest, such as extent of nonadherence versus reasons for nonadherence, utilizing optimized recall periods such as the last 30 days, and avoiding interview-based assessments, as they may lead to bias and over reporting (Stirratt et al., 2015). Again, convergent validity is recommended when evaluating clinical outcomes to evaluate critically the intervention and its effect on the outcome. For the proposed study, two measures of self-reporting will be utilized in combination to determine the accuracy and correlation between the two measures.

As previously noted, there are various ways to measure self-reported adherence, with self-report measures varying in accuracy. Non-invasive methods are less accurate but more accessible and widely accepted; whereas invasive methods are the most accurate but require more resources. Vrijens et al. (2017) suggest the use of non-invasive methods for tracking adherence such as patient interview, patient diary, adherence questionnaires, pill count,

prescription record review, and electronic monitoring. Although these are less accurate, they are the most commonly used practices in health care today. Invasive methods such as drug measurement in body fluids and biomarker measurement in body fluids are more accurate, but also require blood draws, waiting for results, and are more of a burden on patients and providers. Invasive methods of measurement are not suitable for this QI project, therefore are not being implemented.

Theoretical Framework

QI Model

The QI model utilized in this QI project will be that of Avedis Donabedian, which is a model comprising three components that are designed to evaluate the quality of care and determine whether a QI project has had the desired effect. The three required Donabedian components for a QI project are structures or inputs, processes, and outcomes. For the purpose of this QI project, the structures include consideration of individual patient demographics, such as their age, sex, race, and employment status as well as their health beliefs (which will be further discussed below). The process focuses on the care that is delivered to patients. In this project, there will be consultation with the QI project lead to discuss the structural inputs and also the utilization of the MyMedSchedule® Plus application. The outcome will be measured by the MGL post intervention as well as the total percent of adherence within the MyMedSchedule® Plus application.

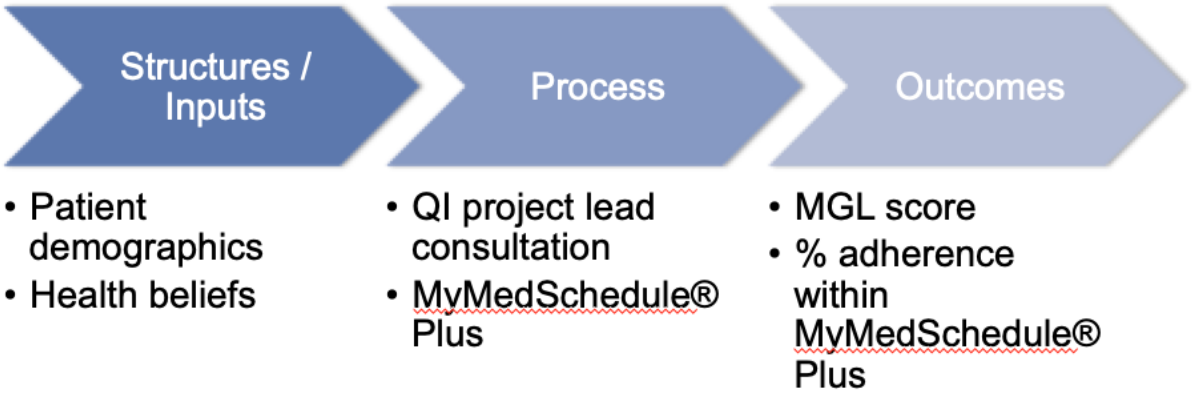

Figure 2. Donabedian QI Model. *Source*: Kelly (2019).

The Health Belief Model

The U.S. Public Health Service developed the Health Belief Model in the 1950s to explain reasons for low participation of individuals in disease detection and prevention programs. This model is the most commonly used for addressing health promotion and health education among populations. Jones and Bartlett (2015) stated that the underlying concept is based on the fact that "health behavior is determined by personal beliefs or perceptions about a disease and the strategies available to decrease its occurrence." According to this model, there are four predominant existing beliefs: perceived seriousness, perceived susceptibility, perceived benefits, and perceived barriers. All of these elements play a role in determining the behavior of an individual as well as the individual's likelihood of adhering to lifestyle modifications (Jones & Bartlett, 2015).

The ways in which individuals perceive the seriousness of a disease are variable, primarily dependent on how individuals see the disease affecting their daily lives. Another important factor is an individual's level of knowledge regarding the disease process and its complications, which derives from personal experiences they may have had with others who have suffered through the same disease process. Next, the individual's perceived susceptibility is

addressed. Individuals who believe that they are truly susceptible to a disease will be encouraged to change unhealthy behaviors and decrease the risk of disease development. Conversely, when people believe that they are at a much lower risk for developing a disease, they can easily adapt unhealthy behaviors that put them at greater risk for disease development and other adverse events. In combination with an individual's perception of seriousness of the disease, their susceptibility is likely to promote a change in behavior.

Perceived benefit is also related to the individual's opinion of the value and usefulness of changing a behavior to decrease the risk of disease. Often, if individuals do not see positive outcomes or benefits from the changes that they are making in their lives, the changes are less likely to be made and far less likely to be adopted as habits. Lastly, perceived barriers are discussed. Individual's evaluations of obstacles or challenges that must be overcome to change the behavior often require work. For true change and transformation to occur, the individual must feel that the benefits of the changes and new behaviors that they are adopting outweigh the risk of the consequences of the old behavior.

An individual's perception can be based on many variables and inputs that can influence how that individual sees the disease process and makes appropriate lifestyle changes. Perception can be influenced by culture, education level, past experiences, skill, and motivation. The Health Belief Model also addresses cues to action, which are people, events, or things that cause people to change their behavior. Individuals are highly influenced by personal experience, the media, and advice from healthcare providers, family, and friends. An important element to changing behavior is self-efficacy, which addresses the individual's belief that they are able do something. Individuals typically do not attempt to do things that they do not believe they will succeed at accomplishing, which often leads to decreased participation in lifestyle modifications.

There are limitations and assumptions that accompany the Health Belief Model. One is that the model does not account for attitudes or beliefs that determine the acceptance of health behaviors and habitual behaviors. It also does not take into account behaviors that are performed for social acceptance. Environmental and economic factors and their impact on promoting or prohibiting a recommended action are also not addressed in the model. The Health Belief Model assumes that everyone has access to equal amounts of information regarding disease and illness and, lastly, assumes that the cues to action are prevalent in encouraging people to take the initiative of making better health choices.

The three main components of the Health Belief Model are individual perceptions, modifying factors, and likelihood of action. Modifying factors can include demographic factors, such as sex, age, race or gender, or sociopsychological factors, including personality and socioeconomic class. These factors influence an individual's perceptions while also affecting that individual's likelihood of taking action. Demographic and sociopsychological factors affect how an individual perceives that they are susceptible to a disease process and also the severity to which they may be affected, ultimately determining how much of a threat the disease is to that individual. These same factors influence an individual's likelihood of action based on their perceptions of the benefits of preventive action minus the perceived barriers to the preventative action. After the individual develops their perceived threat of the disease process, their likelihood of taking recommended preventative health action is determined. Factors affecting the individual before deciding to take the recommended health action are the cues to action, as previously mentioned, such as advice from others, personal experience, the advice of healthcare providers, and media (Jones & Bartlett, 2015). The flow of the model is multidirectional from the individuals' perceptions, moving through their modifying factors and perceived threat, then

influencing their likelihood of taking action. This model, as used in this QI project lead, is represented in Figure 3.

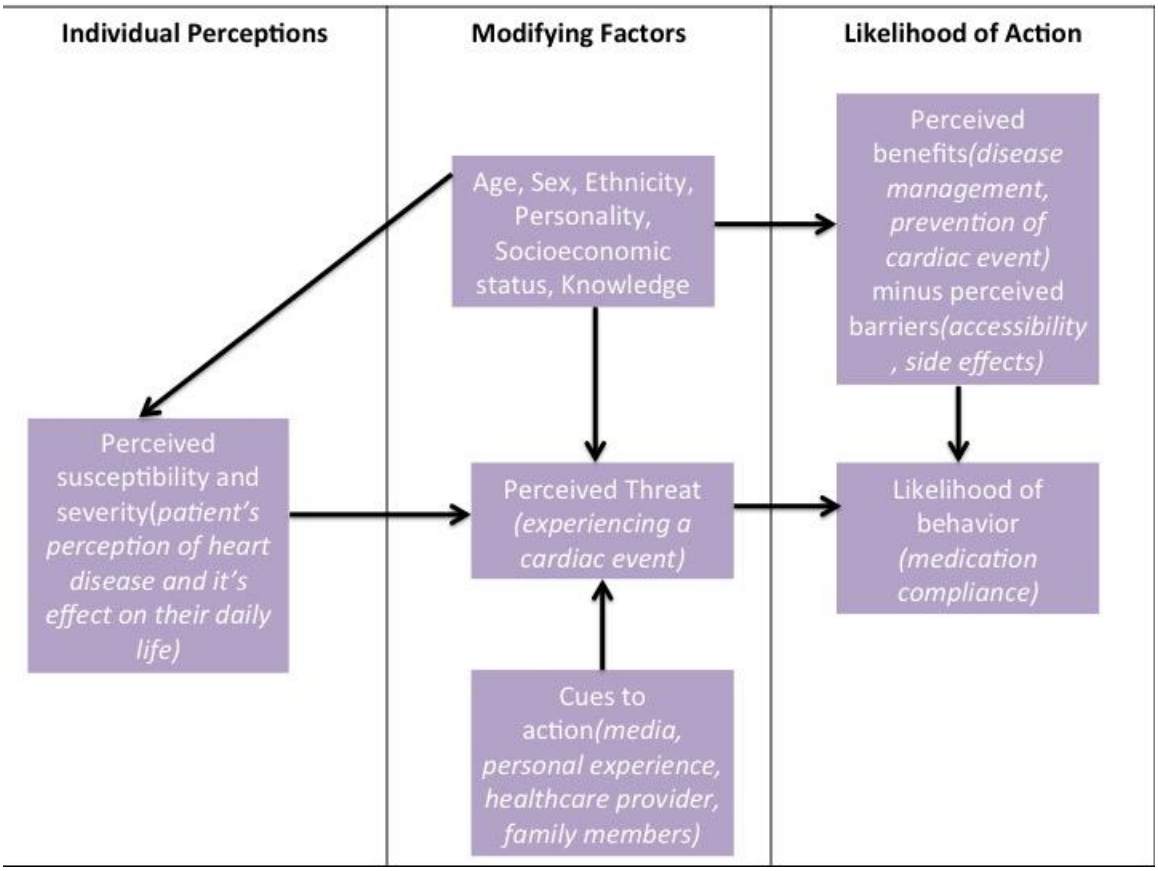

Figure 3. Health belief model visual. *Source*: Kelly (2015)

Project Objectives and Aims

Objectives

The goals of this QI project were to enhance antihypertensive medication adherence in the outpatient population and, ultimately, control hypertension. The primary objectives were to determine whether the use of medication reminders through MyMedSchedule® Plus affects adherence to antihypertensive medication, and also whether MyMedSchedule® Plus is an effective self-reporting tool in hypertensive adults. The outcome measures for these objectives were a review of self-reported medication adherence within the MyMedSchedule® Plus

application as well as a comparison between the pre and post intervention MGL scores. The secondary objective was to evaluate the correlation between the MGL score and MyMedSchedule® Plus self-reported adherence within the application. Other exploratory objectives for this QI project included evaluating the demographic trends that impact MyMedSchedule® Plus use. This was measured by looking at individuals' demographic information, and their percentage of self-reported adherence within the application. The aim of this QI project was to determine whether the MyMedSchedule® Plus application positively affects medication adherence and is an accurate self-reporting tool.

Methods

Setting

This was a quality improvement project performed with a convenience sample of hypertensive adults who are being managed at four different locations of a primary care practice group in northeast Florida. Each location has different patient demographics, which will enhance the variability of the demographics of the participants. The locations offer primary care services to adults provided by physicians, physician assistants, and nurse practitioners. A practice site agreement was obtained prior to patient recruitment and project implementation. Although rates of adherence to antihypertensives, or percent of nonadherent patients, are unknown within these practices, the providers and the clinical research coordinator have observed a lack of medication adherence, and are supportive of the proposed quality improvement study

Sample

The proposed sample will consist of up to 30 eligible adults with an established diagnosis of hypertension. These individuals were recruited to participate in the quality improvement

project at various primary care practice locations throughout Jacksonville, Florida, and all must meet the inclusion criteria to participate. Providers within each of the practice locations received an explanation of the project from the QI project lead. The QI project lead was available, via telephone or email, to answer questions from participants and providers throughout the implementation of the project. The clinical research coordinator who works in the primary care practice group was supporting and overseeing the project.

Inclusion criteria. Participants were

1. both males and females over the age of 18 and under the age of 75,
2. have been seen within the practice within the last 6 months,
3. have an established diagnosis of hypertension,
4. have been prescribed at least 2 antihypertensive medications and no more than 5 for three months,
5. be able to read, write, and speak English, and also have suitable vision, hearing, and dexterity to operate a mobile telephone and understand instructions,
6. have constant access to a mobile telephone or any smartphone with Internet capabilities, and
7. know, or have access to a current and accurate list of, their antihypertensive medications.

Exclusion criteria. Individuals were excluded from this study

1. if they are currently utilizing another medication reminder system or mobile phone application to assist with medication reminders,
2. are enrolled in a competing study,

3. are receiving assistance from a family member, friend, or home health assistant with their medications.
4. have a diagnosis of Alzheimer's disease or dementia, or
5. are pregnant or are planning a pregnancy during the study period.

Enrollment. Patient enrollment began with QI project lead recruitment at participating primary care practices. The QI project lead did not have access to the electronic medical record at the participating practices, so the clinical research coordinator or other staff assisted with scheduling recruiting at the four different primary care sites on days when there were a number of patients diagnosed with hypertension scheduled to be seen in the office. Individuals were approached by the QI project lead, or a staff member while in the primary care office for a previously scheduled visit and were invited to participate in the quality improvement project. A primary care staff member then introduced the QI lead to potential participants. If the potential participant was interested in participating, the QI lead explained project details, screened for eligibility, and administered consents for participants enrolling in the study. The QI project lead provided participants with a form to complete detailing their demographic information regarding age, race, gender, employment status and antihypertensive medication information, issued the MGL, assisted with installation and explanation of MyMedSchedule® Plus application, and scheduled the four-week follow up. The QI project lead also had a brief discussion with the participant guided by the four concepts of the health belief model—perceived beliefs, perceived seriousness, perceived susceptibility, and perceived benefits and barriers—to gain further insight into their current medication adherence. The enrollment visit took 15-20 minutes and took place at the time of recruitment, or at another more convenient time agreed upon by the participant and the QI project lead. A small $10 gift card for participation in the project was offered as an

incentive to the participant at the time of enrollment and was rendered at their four-week follow up visit. Patients who failed to meet the eligibility criteria were not included in the study and no further information was obtained from them.

In an effort to reduce loss to follow up, patients received a reminder telephone call prior to their follow up appointment. Patients were also be provided with a $10 gift card incentive for their time that was rendered at their follow up visit. The QI project lead was readily available by cell phone 24 hours a day to answer any questions, hear concerns, and help with any troubleshooting within the application that may have been required throughout the project.

Participants were notified that they are free to withdraw at any time without consequence. If they withdrew their consent, their information and the data obtained were no longer included in the project. Those participants were also asked whether they needed or wanted assistance removing the application from their smartphones.

Procedures

1. Patients recruited by the QI project lead from the four primary care practices who met eligibility criteria and agreed to participate in the study were either enrolled immediately or scheduled a more convenient time with the QI project lead for enrollment.
2. At the time of enrollment informed consent was obtained. The MGL was administered, demographic information was gathered, and the QI project lead assisted with MyMedSchedule® Plus set up. A brief discussion of the Health Belief Model, and the patient's current medication taking practices also took place. If the patient qualified for participation but did not have a smartphone with them, arrangements

could have been made for MyMedSchedule® Plus to be set up at another time convenient for that patient.

3. A 4-week follow up date was determined for data collection and post intervention analysis. Participants received a reminder telephone call prior to their follow-up appointment.
4. The participants documented their daily medication adherence using MyMedSchedule® Plus application for up to 28 days.
5. The 4-week follow up visit included reviewing MGL and adherence data recorded within the MyMedSchedule® Plus application. At that time, assistance was offered to remove the MyMedSchedule® application, if desired, and the patient received a gift for their participation.

Study plan for detailing procedures. The following study plan detailing the procedures for this research will be adhered to.

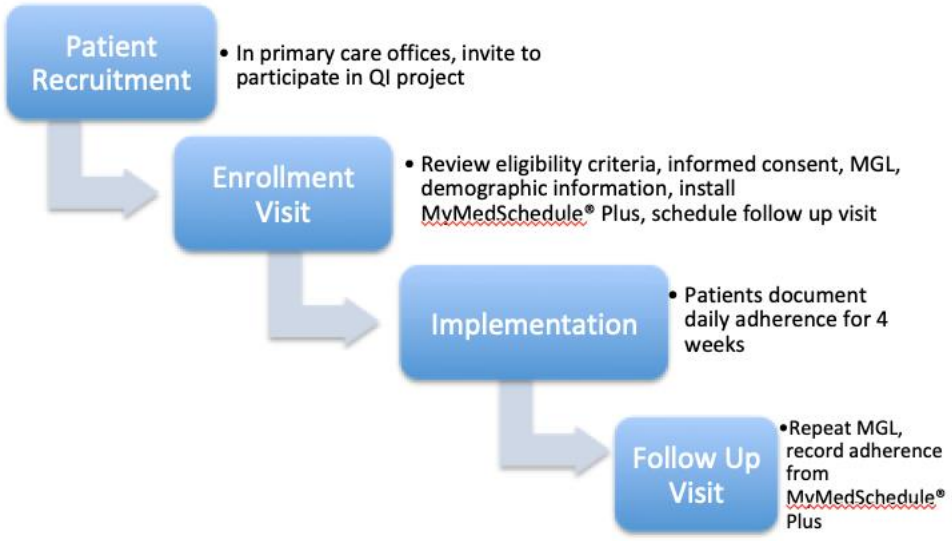

Figure 4. Study plan for procedures. *Source:* Kelly (2019)

Study period and final visit. The study took place over a 90-day period. This timeline allowed for patient recruitment and enrollment at the various facilities within the first 60 days and adequate time for 28 days of data collection. Enrollment was rolling, and each participant started on the day on which they are enrolled. Once enrolled, participants provided 28 days of medication adherence data through the utilization of the MyMedSchedule® Plus application, as directed. After four weeks of data collection, the participants returned to the site of their enrollment for a final visit. A confirmation call was given by the QI project lead to the participant within five days of the scheduled follow-up visit to either confirm or reschedule. At the final visit, the participant took the MGL again, and the MyMedSchedule® Plus data was shared with the QI project lead. After information was obtained, the participant was offered assistance with deleting the MyMedSchedule® Plus application and received their gift for participation.

Measures

The tool used to measure self-reported medication adherence at the initial visit and also at the final visit was the MGL, as previously described. The MyMedSchedule® Plus application was also evaluated to determine whether the percentage of doses taken meets the definition of either adherence or nonadherence. Although the MGL measure is in the public domain, the author Dr. Donald Morisky was contacted and consulted for its use in this QI project (Appendix D).

Procedure for the Protection of Human Subjects

Monitoring of the study. Throughout the study, the QI project lead had regular contact with Jacksonville University DNP Project Chair Dr. Mary Gipson, as well as Dr. Kim M. Barbel-Johnson, who works in clinical research at the chosen facilities, to ensure the protocol was

adhered to and to assist with any questions that arose throughout the study process. The informed consent (Appendix E) approved by the IRB was adhered to throughout the study. No changes were made that required submission of an amendment or resubmission and approval through IRB.

Confidentiality. Informed consent was obtained from participants on printed forms for them to sign. Those forms contained the participants' names as well as a participant identification number by which they were identified and were kept in the clinical research office at one of the participating primary care practices. Participant demographic information was collected on a form tracked with the unique number that corresponds to the number on the participant consent forms to ensure privacy and safety of the patient information. Both of these forms were kept separately in a locked cabinet in the designated office with access limited to employees with keys. The patient was only identifiable to the QI project lead by the assigned number. All electronic information was stored on a password-protected computer and saved to an encrypted university cloud-based network. MyMedSchedule® Plus requires a username and password that were chosen by the patient and the application is operated on a HIPAA approved cloud-based server.

The MGL was printed with one indicating "pre" and the other "post" for initial and final evaluation, and it was attached to the de-identified patient demographic sheet. The MyMedSchedule® Plus application information was also collected by the QI project lead through an evaluation of the MyMedSchedule® Plus application on the participant's smartphone at the final visit. This information was input into an Excel spreadsheet (Appendix B) that was then forwarded to a statistician for data analysis.

Ethical Considerations

This study required approval by an IRB before its implementation. The IRB approved the QI project protocol as well as written materials such as the informed consent, patient demographic information collection sheet, spreadsheet for recording results, and the MGL. The patient recruitment procedure was also approved before the study implementation. Other ethical considerations included voluntary participation without coercion, the privacy and protection of patient information, and honesty about the study's objectives and outcomes.

Data Analysis Plan

Demographics (i.e., age, sex, and race), employment status, number of medications per day, drug information (i.e., drug, dose, and frequency), and pre- and post-survey data (i.e., MGL) were summarized using descriptive statistics and/or frequency tables. Continuous variables were summarized by *n*, the mean, standard deviation (*SD*), median, minimum, and maximum. Categorical variables were summarized by frequency counts and the percentage of participants within each category. Bar charts, pie charts, histograms, and box and whisker plots were considered for data visualization.

The MGL was summarized individually by intervention period (pre versus post-intervention). MGL scores were calculated for each participant as the number of "No" responses. The scores ranged from 0 to 4, with 0 representing the lowest level of medication adherence and 4 the highest level of medication adherence. The scores were summarized using frequency tables by intervention period. Wilcoxon signed rank tests were used to test for the differences between the pre (baseline) and post (4-week) scores.

To evaluate the effect of the implementation of MyMedSchedule® Plus on increasing the level of medication adherence, MGL scores were analyzed using a multinomial regression model for repeated measures. Demographics, employment status, number of medications per day, and

drug information were included in the regression analysis to evaluate their effects on the level of medication adherence. Unless otherwise specified, all statistical tests were two-sided. Further exploratory analysis were undertaken, if necessary, at the discretion of the QI project lead.

Self-reported adherence recorded via the MyMedSchedule® Plus application was also evaluated. The total number of participants with 80% reported adherence or above was calculated. The demographics of those participants were then compared with those below the 80% adherence threshold to determine which factors had the most impact on medication adherence in the sample.

All statistical analyses will be conducted using R version 3.5 or higher (R Foundation for Statistical Computing, Vienna, Austria) and/or SPSS and SAS version 9.4 or higher (SAS Institute Inc., Cary, NC).

Timeline

The timeline for the project began with submission for Jacksonville University IRB approval. Once approval to begin the QI project was granted, patient recruitment at the primary care practices began, and patients consented to the study as soon as they were identified as meeting the appropriate inclusion criteria. Recruiting took place on scheduled days at the four different primary care practices and was ceased when the providers and clinical research coordinator felt voluntary research studies were no longer responsible due to COVID-19. Participants did not all start at the same time and each was followed independently for four weeks. Once the data was collected, it was submitted to the statistician for data analysis and the summary of findings was completed. The projected date of completion is June 2020.

Fiscal Considerations

Fiscal considerations for the completion of this study were minimal as the MyMedSchedule® Plus application to be used for the reminders is free. The patients were recruited while already within the office, so no visit fees applied. All additional visits for the project only involved the participant and the QI project lead; therefore, no payment from the participant was due. Implementation of this project did not take up any time for a regularly scheduled office visit, so prolonged appointments with the provider or missed office visits were not a factor for the practice. Recruitment and enrollment visits took place within the office in a designated space outside of the patient care areas. Participation in the study came at no monetary cost to the patient because their time with the QI project lead was not considered an office visit. There were small monetary incentives rewarded to the patients upon the completion of their participation in the study in the form of a $10 gift card financed by the QI project lead. The MGL has cost the QI project lead $79.00, and it included a number of published articles where the questionnaire has been used in the outpatient antihypertensive population as well as direct consultation with the author, Dr. Donald Morisky. Jacksonville University requires submission to an editing service at the cost of $312.00 which was covered by the QI project lead. The QI project lead applied for grants and the Schroeder Scholarship through Jacksonville University to cover the costs of the gift card incentive. The total expected cost was:

1. Consultation with Dr. Donald Morisky and MGL = $79.00
2. Incentives for participants $10 X up to 30 participants = $300.00
3. Total cost to QI project lead = $379.00

The total actual cost to the QI project lead was only $169.

Sustainability

This project was sustainable, as the intervention is electronically managed and could be implemented by office staff or by individual patients who choose to continue or join after the project has ended. If participants saw improvement in medication adherence due to the MyMedSchedule® Plus reminders, research shows that they will be more likely to continue positive chronic disease management behaviors (Dayer et al., 2013). The use of technology is also becoming a way for providers to communicate with their patients and bill for services without having a face-to-face interaction.

System wide. Utilization of these tools may become a standard of care for initial and ongoing monitoring among hypertensive patients based on the strength of the results and the findings of the data analysis. The data did not yield statistically significant results, but these tools may still be recommended or utilized by other providers who are part of the larger practice network seeking enhanced antihypertensive medication adherence, or medication adherence in any chronic disease management.

Politically. Although there are currently no political ties to the study, large health insurance companies and those who provide government funded services may recommend or require the utilization of a smartphone application or reminder tool, assuming that resources are available, to aid in improving health outcomes and preventing or slowing the progression of chronic disease.

Analysis and Results

A statistician was consulted to evaluate the data and provide input regarding the statistical data analysis. Those findings are described below.

Statistical Analysis

There were a total of 9 participants in this quality improvement project. There were 7 males (77.8%), 6 were Caucasian (66.7%) and two (22.2%) were African American. Similarly, 6 (66.7%) of the participants were retired, while 2 (22.2%) were employed, and one participant was disabled. The age of the participants ranged from 55 to 74, with an average (SD) of 66 years. Six of the participants (66.7%) were taking a total of two antihypertensive medications, and the remaining three participants (33.3%) were taking three antihypertensive medications. The average number of total doses of medication taken per month was 78.6 doses. Refer to Table 1 for more details regarding patient demographics and medication information.

Table 1

Summary of Patient Demographics and Medication Information. Source: Toubouti (2020).

Variable	Total N=9
Age (in years)	
n	9
Mean (SD)	65.9 (4.81)
Median	66.0
Min - Max	55.0 - 73.0
Sex [n(%)]	
Male	7 (77.8)
Female	2 (22.2)
Race [n(%)]	
African American	2 (22.2)
Caucasian	6 (66.7)
Hispanic	1 (11.1)
Employment Status [n(%)]	
Disabled	1 (11.1)
Employed	2 (22.2)
Retired	6 (66.7)
Number of Antihypertensive Medications [n(%)]	
1	0 (0.0)
2	6 (66.7)
3	3 (33.3)
4	0 (0.0)
Pre MGL Score	
n	9
Mean (SD)	3.2 (0.83)
Median	3.0
Min - Max	2.0 - 4.0

Post MGL Score	
n	9
Mean (SD)	3.4 (0.88)
Median	4.0
Min - Max	2.0 - 4.0
SD: standard deviation, Min: Minimum, Max: Maximum, % = 100 x (n/N).	

Variable	Total N=9
Change in MGL score (post-pre)	
n	9
Mean (SD)	0.2 (1.09)
Median	0.0
Min - Max	-2.0 - 2.0
Number of Doses per Month	
n	9
Mean (SD)	78.6 (17.73)
Median	83.0
Min - Max	56.0 - 110.0
Number of Doses Taken per Month	
n	9
Mean (SD)	70.3 (25.01)
Median	79.0
Min - Max	32.0 - 110.0
Ratio of Adherence	
n	9
Mean (SD)	0.871 (0.1536)
Median	0.919
Min - Max	0.542 - 1.000
SD: standard deviation, Min: Minimum, Max: Maximum, % = 100 x (n/N).	

The ratio of antihypertensive medication adherence was calculated as the number of doses marked as taken over the total number of doses anticipated to be taken per month. A 95% confidence interval was used to provide the descriptive statistics of the antihypertensive medication adherence rate summarized in Table 2. The ratio of medication adherence ranges between 54.2% and 100% with the average being 87.1%. A 95% confidence interval places the lower limit of adherence at 75.3%, with the higher limit at 98.9%. For this quality improvement project, an adherence rate of 80% was considered to be adherent, so taking the 95% confidence interval into account, it is concluded that the adherence rate is not statistically superior to 80%.

Table 2

Ratio of Antihypertensive Medication Adherence. Source: Toubouti (2020).

	Mean ± SD	**Median**	**Min-Max**	**95% Lower**	**95% Upper**
Ratio (%)	87.1 ± 15.36	91.9	54.2-100	75.3	98.9

To evaluate the MGL scores, Wilcoxon signed rank and paired t-tests were used for ordinal and normal data respectively at 5% significance to test for no difference between pre and post MGL scores. Both tests were unable to reject the null hypothesis, showing no significant difference in the pre and post scores (p value > 0.05). For the purposes of this quality improvement project, a score of 3 or greater was considered to show medication adherence. The pre and post MGL scores are demonstrated in the table below.

Table 3

Comparison Between Pre and Post MGL Scores. Source: Toubouti (2020).

MGL	**Pre-score n(%)**	**Post-score n(%)**	**P-value**
0	0 (0.0)	0 (0.0)	0.7500
1	0 (0.0)	0 (0.0)	
2	2 (22.2)	2 (22.2)	
3	3 (33.3)	1 (11.1)	
4	4 (44.4)	6 (66.7)	
Mean ± SD	3.2 ± 0.83	3.4 ± 0.88	W

In summary, this quality improvement project showed an adherence rate of 87.1% using a 95% confidence interval. As demonstrated above, although the adherence rate was over 80%, there was no statistical significance due to the lower limit being below 80%. As for the pre and post MGL scores, these also both had an average that showed adherence, but could not be considered statistically significant with a p-value of 0.7500.

Conclusion and Recommendations

Discussion of Findings

This quality improvement project was designed to explore various factors that contribute to medication adherence. These include participant demographics, the use of technology through the smart phone application MyMedSchedule® Plus for medication reminders, and also the Morisky Green Levine self-reported medication adherence questionnaire. All of these variables were explored separately, and also evaluated together to ultimately determine their effect on medication adherence in the outpatient adult hypertensive population.

Participant demographics. There were three participants who reported 100% adherence within the MyMedSchedule® Plus application. Two of those participants were 66-year-old retired Caucasian males, and the third was a 55-year-old disabled Hispanic woman. The participants who reported the next highest adherence rates were a 66-year-old retired African American male reporting 92% of doses taken, followed by a 65-year-old employed Caucasian male, and a 73-year-old retired Caucasian male both reporting 91% of doses taken within MyMedSchedule® Plus. The last participant with a self-reported adherence rate above 80% was a 65-year-old employed Caucasian male, reporting 83% of doses taken. The final two participants had a self-reported adherence below the 80% definition of adherence for the QI project. The first participant was a 69-year-old retired African American woman reporting 73% of doses taken, followed by a 68-year-old retired Caucasian man reporting only 54% of doses taken within MyMedSchedule® Plus. When comparing the average percentage of adherence between African American participants and Caucasian participants, their adherence rates are 82.5% and 86.5% respectively. Participants who were retired averaged an adherence rate of 85%, whereas the employed participants had a self-reported average adherence of 87%. All participants were taking either two or three antihypertensive medications. The average

medication adherence for participants taking three antihypertensive medications was 94%, compared to an adherence rate average of 83.5% for the remaining participants who were prescribed only two antihypertensive medications. When evaluating adherence by gender, males were only slightly more adherent than females, averaging 87.2% adherence and 86.5% adherence respectively.

The participants for this study were primarily retired Caucasian males with an average age of 66 years old who were taking two antihypertensive medications. This participant population is quite specific, making the findings of this quality improvement project difficult to generalize. The participants for this project fail to represent a diverse group of both males and females of other races with a wide range of ages or adults who are still employed and taking more than two or three antihypertensive medications.

MyMedSchedule® Plus. The data collected regarding the number of antihypertensive medication doses marked as taken within the MyMedSchedule® Plus smart phone application had a wide range of variability between participants. All participants were assisted in downloading and inputting their medications into the MyMedSchedule® Plus smart phone application, and also received in person education on how to use the application to record the data necessary for the project. Participants verbalized understanding and performed return demonstration of how to utilize the application at the enrollment visit. The percent of medication adherence is calculated within the MyMedSchedule® Plus smart phone application by counting the number of doses marked taken by the participant compared to the total number of medication doses scheduled. The lowest rate of adherence recorded within the MyMedSchedule® Plus application was 54.2% and the highest rate of medication adherence was 100%.

Morisky Green Levine self-reported medication adherence questionnaire. The Morisky Green Levine self-reported medication adherence questionnaire was administered at both the enrollment visit, and the follow up visit. The goal of the pre and post MGL questionnaire was to determine whether a self-reported medication adherence questionnaire is an effective tool for measuring medication adherence, and also to determine the effect the MyMedSchedule® Plus smart phone application has on self-reported medication adherence. The questionnaire is scored by the number of questions answered "yes" and "no". A "no" answer is worth 1 point, and a "yes" answer is worth zero points. The highest possible score is a 4, reflecting the highest rate of medication adherence. For the purpose of this quality improvement project, a score greater than 3 is considered to be adherent. Although the mean pre and post MGL scores for the participants were both above 3, the statistical data analysis demonstrates a p-value of 0.7500, therefore rejecting the null hypothesis indicating that there was no statistically significant change between the pre and post MGL scores.

Aims and Objectives

The aim of this project was to determine whether the use of medication reminders through the MyMedSchedule® Plus smart phone application enhances adherence to antihypertensive medication and is an effective self-reporting tool in hypertensive adults in the outpatient setting. For the purposes of this quality improvement project, a reported adherence rate of 80% or greater within the MyMedSchedule® Plus smart phone application was considered to be adherent. As outlined in the statistical analysis above, the average rate of adherence was 87.1% which is above the 80% benchmark for adherence, but the results were not statistically significant as the lower limit of the 95% confidence interval was below the 80% benchmark. Of the nine total participants in the quality improvement project, seven of the nine

participants self-reported adherence rates greater than 80% within the MyMedSchedule® Plus application on their smart phone.

When evaluating the relationship between the pre and post MGL questionnaire, three participants demonstrated an improvement in their medication adherence between the pre and post score, four participants had the same self-reported medication adherence on the pre and post MGL scores, and one participant received a lower score on their self-reported adherence at the time of the follow up visit. These results do not demonstrate a statistically significant positive change in medication adherence after the implementation of the MyMedSchedule® Plus smart phone application.

Based on the findings through the statistical data analysis, the aim of the project was not met and the null hypothesis was rejected. The findings also demonstrate a lack of correlation between self-reported medication adherence within the MyMedSchedule® Plus smart phone application, and the rate of self-reported adherence evaluated through the pre and post MGL questionnaires.

Limitations

The primary limitation of this quality improvement project is the small sample size of participants and their lack of diversity. During participant recruitment, the government encouraged all non-essential workers to stay home and non-emergent medical appointments be delayed due to the COVID-19 global pandemic. The facilities that were stakeholders in this quality improvement project decided that continuing with patient recruitment would be irresponsible during that time.

Another limitation to the quality improvement project was the high reliance on self-reported measures. As previously outlined in the literature review, the use of self-reporting to

measure medication adherence often leads to over reporting and it lacks validity and precision even when utilizing a tool that has been deemed valid and reliable. In addition, seven of the nine participants had a telephone call follow up visit instead of the in-person visit, so the four item MGL questionnaire was asked to them and they were to provide a "yes" or "no" answer versus filling out their response on the printed questionnaire. Stirratt et al., (2015) note that interview-based assessment tends to lead to over reporting of adherence which may have had an impact on the final MGL scores gathered. The use of self-reporting is still frequently used in clinical practice due to its low cost and ease of use but is recommended to be used in combination with another adherence measurement tool to establish convergent validity. When looking at the statistical significance of the self-reported data gathered through MyMedSchedule® Plus, in combination with the self-reported data gathered through the pre and post MGL, there is no evidence to support increased medication adherence through the use of the MyMedSchedule® Plus smart phone application.

Conclusions

This quality improvement project did not demonstrate that the use of the MyMedSchedule® Plus smart phone application had a significant effect on increasing antihypertensive medication adherence in the hypertensive outpatient population. This conclusion is based on the combination of all of the data for each of the participants, although some participants did demonstrate an increase in their self-reported adherence within the MyMedSchedule® Plus smart phone application, as well as the MGL questionnaire. These conclusions are similar to findings in previous studies that were highlighted throughout the review of literature. Although the results of this quality improvement project are not significant enough to support a change in clinical practice, they do yield opportunities for further research.

In addition to the data that was collected for statistical analysis, discussion with participants at their follow up visit also provided some insight into the quality improvement project, specifically the MyMedSchedule® Plus smart phone application. Of the nine participants, eight of them chose to continue to use the MyMedSchedule® Plus smart phone application beyond their follow up visit. Participants stated that they planned to add the rest of their medication regimen to the smart phone application in order to receive reminders, maintain an accurate and accessible list of their medications, and also keep track of doses taken. Participants were also inquiring about the ability to track vital signs related to their medications – such as heart rate and blood pressure – and whether there was a way to communicate with their providers through the MyMedSchedule® Plus application.

Recommendations for Future Research

Based on the findings in this quality improvement project, there are a number of opportunities for future research. This quality improvement project only focused on adults with hypertension, but these concepts of enhancing medication adherence can be applied to a broader population of adults living with any chronic disease. One opportunity for future research could be a much larger, public study evaluating the effectiveness of the self-reported adherence questionnaire such as the MMAS-8 used in combination with a different smart phone application for measuring adherence. Given that self-reported adherence is known to be over-reported, exploring a new method to track medication adherence that would be simple, cost effective, and more accurate would provide superior data regarding rates of medication adherence in the outpatient setting. Although the MyMedSchedule® Plus smart phone application was used for this quality improvement project, there are a number of other medication reminder applications available. Further research into other smart phone applications and how their features compare to

those found in MyMedSchedule® Plus would also provide data that could lead to improvement in the smart phone medication reminder applications. With technology being easily accessible to many adults across the world, more research into how to utilize it to improve health outcomes and increase access to care could have a significant impact on decreasing the rates of morbidity and mortality for those living with chronic disease.

Another area for future research could include providers and whether they feel that applications such as MyMedSchedule® Plus provide meaningful interactions with patients outside of an in-person office visit. This feature of the MyMedSchedule® Plus application has not been well-researched but would provide valuable feedback on whether smart phone applications are beneficial for medication reminders and management from both the patient, and also the provider point of view. If the provider encourages the patient to keep a blood pressure log from home, or is titrating medication doses, smart phone applications can be an effective way for simple communication that would not require in-person visits. If future research does support such interactions that do not require in office visits, it would then be important to determine how providers will be reimbursed for their interactions with patients through the use of smart phone applications.

Implications for Practice

This quality improvement project supported the literature stating that most adults have a smart phone that they have at least a basic understanding how to use. Although there was concern that older adults may be resistant to the use of technology, this quality improvement project demonstrated that with hands on assistance and explanation that barrier can be easily overcome. The MyMedSchedule® Plus smart phone application used in this quality improvement project has the capability to coordinate automatic refills with pharmacies, and also

be used as a platform for patients to interact with their providers without having an in-person office visit. These features provide opportunities for a more streamlined approach to medication refills, and also enhance the opportunity for patient and provider interaction. Due to the ease of use of the MyMedSchedule® Plus smart phone application, encouraging patients to use the application to keep track of their medications, and coordinate the services outlined above with their providers and pharmacists would seem beneficial. MyMedSchedule® Plus also contains lots of patient education regarding their medications and provides opportunities for them to feel as though they are active participants in their care. This can be empowering and enhance their feelings of self-efficacy towards managing their health.

Overall, this quality improvement project did not demonstrate statistically significant improvements in the use of medication reminders through MyMedSchedule® Plus in the hypertensive outpatient population. Participants did see the benefit of a medication reminder smart phone application and also liked being able to maintain an accurate medication list within their smart phone which they had with them most times. Data collected from this quality improvement project did demonstrate that there are opportunities for improvement when it comes to self-reporting medication adherence and also how to most efficiently utilize technology, specifically smart phone applications in the management of chronic diseases.

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Appendix A

PATIENT DEMOGRAPHIC FORM

Patient ID #: _____ Telephone #:_____

AGE / DOB:_____

Sex: M F Race:_____

Employed Unemployed

Antihypertensive Medications:

Medication Name, Dose & Frequency

1.
2.
3.
4.
5.

Pre Survey Score_____ Post Survey Score_____

Informed Consent Completed_____ Start Date_____

Appendix B

EXCEL SPREADSHEET FOR DATA COLLECTION

ID #	CELL PHONE #	DOB	AGE	SEX	RACE	EMPLOYMENT STATUS	PRE MGL SCORE	POST MGL SCORE	Rx (drug, dose, freq)	TOTAL % ADHERENCE weekly /drug	TOTAL % ADHERENCE monthly /drug	% OVERALL ADHERENCE (all drugs, all doses)
Participant 1									1			
Start Date/End Date									2			
F/U Call Date									3			
F/U Date									4			
									5			
Participant 2												

Appendix C

MORISKY GREEN LEVINE MEDICATION ADHERENCE QUESTIONNAIRE

1. Do you ever forget to take your medicine? YES NO

2. Are you careless at times about taking your medicine? YES NO

3. When you feel better, do you sometimes stop taking your medicine? YES NO

4. Sometimes if you feel worse when you take your medicine, do you stop taking it?

YES NO

Appendix D

Dr. Donald Morisky Consultation and MGL Tool Permission

Thank you Meredith, for your note regarding your interest in using my copyrighted and trademarked intellectual property, the MMAS-8. Since only institutions can use this, I am willing to let you use another adherence scale I developed. I can put together a package consisting of two articles I published. This includes the original article of the scale and an article on the long-term outcomes, a five-year study that assessed morbidity and mortality. In a randomized clinical trial, I compared patients who received an educational intervention and educational consultation to patients in a standard care group. This article has been cited over 3000 times. I will also send you citations of published articles that have used the adherence article in their research. The processing fee for this package amounts to $79.00. Please let me know if you wish to receive this package. You also can make your own translation if you need. I also will provide you with consultation time for any questions you may have related to your research protocol, analyses of adherence data and evaluation of your study variables.

Best wishes,

Professor Donald Morisky, ScD, ScM, MSPH
UCLA Fielding School of Public Health
Department of Community Health Sciences

Thanks Meridith for your note and I will process your MGL package today. Sorry for any delay.

Professor Donald Morisky, ScD, MSPH, ScM
UCLA Fielding School of Public Health

Appendix E

Informed Consent

Quality Improvement Project Summary

The Effect of MyMedSchedule® Plus Smartphone Application on Antihypertensive Medication Adherence in Hypertensive Adults in the Outpatient Setting

PRINCIPAL INVESTIGATOR/STUDENT PROJECT LEAD
Meredith Kelly, mkelly3@jacksonville.edu 904-310-0760
Jacksonville University, 2800 University Blvd. N., Jacksonville, FL 32211

FACULTY ADVISOR/CHAIR PROJECT LEAD:
Co- Investigator: Dr. Mary Gipson, mgipson@ju.edu, 904-256-7257
Jacksonville University, 2800 University Blvd. N., Jacksonville, FL 32211

You are invited to participate in a quality improvement project. In order to participate, you must be at least 18 years old with high blood pressure and taking blood pressure medication.

The purpose of the project is to learn about medication-taking of patients with high blood pressure and the use of a medication reminder application on a smartphone.

If you agree to take part, you will be asked to provide some information – including age, sex, race, employment status and a list of your blood pressure medications. You will also take a four-question survey about taking your medications. You may skip any question you do not wish to answer. Next, the project lead will help you download a smartphone application, MyMedSchedule® Plus and set up your medication reminders. Over four weeks, you will mark when you take your medicine in the MyMedSchedule® Plus application. After four weeks, you will come back for a follow up visit with the project lead. You will be asked to re-take the survey and the medication information in your MyMedSchedule® Plus application will be reviewed. The first and follow up visits are each expected to take about 20 minutes.

At the final visit you will receive a $10 gift card for participating in this project.

The data collected will be linked to the last four digits of your cell phone number, and we will not be using these de-identified data in future projects. All information will be stored on Jacksonville University's protected server to protect privacy.

There are few risks expected with the project. Those risks may include a loss of privacy or confidentiality. To reduce risk, the MyMedSchedule® Plus application is password protected and any papers with your personal information will be stored in a locked cabinet in the clinical research department, identifiable only with the code number. Only the informed consent, which will be kept separate from all other papers, will have your name on it. Any data stored on a computer will be password-protected and saved to a secure cloud-based server.

This project may or may not benefit you. The MyMedSchedule® Plus application includes medication reminders, a way to track doses taken, information on medication side effects, and ability to communicate with your health care providers. These features may be helpful for encouraging and tracking medication and decreasing heart disease risk factors. Outside of this project, the MyMedSchedule® Plus application can be used for all medications. Others may benefit from any knowledge found in this project regarding medication taking applications for people who have high blood pressure. The $10 gift card is a show of appreciation for your participation.

If you decide to take part in this project, it should be because you want to volunteer. You will not lose any services you would normally have if you choose not to volunteer. If you are a patient, nothing about your medical status or services will change no matter what you decide.

The project is explained in further detail below. If you are interested in being a participant, please continue to read and ask questions at any time. If you are not interested stop here.

Thank you.

PARTICIPANT'S NAME (Print): _____

TITLE OF THE PROJECT: The Effect of MyMedSchedule® Plus Smartphone Application on Antihypertensive Medication Adherence in Hypertensive Adults in the Outpatient Setting

QUALITY IMPROVEMENT PROJECT LEADS:

- Meredith Kelly, Doctoral Nursing Student: mkelly3@jacksonville.edu 904-310-0760
- Dr. Mary Gipson, Nursing Faculty Chair: mgipson@ju.edu 904-256-7257

Jacksonville University Keigwin School of Nursing, 2800 University Blvd. N., Jacksonville, FL 32211

INVESTIGATOR'S STATEMENT:
We are asking you to be in a quality improvement (QI) project. The purpose of this consent letter is to give you the information you will need to help you decide whether to be in the project or not. Please read this form carefully. You may ask questions about the purpose of the QI project, the possible risks and benefits, and anything else about the project or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the project or not. This process is called "informed consent." We will give you a copy of this form for your records.

THE PURPOSE OF THE PROJECT: The purpose of the project is to learn about medication-taking of patients with high blood pressure and the use of a medication reminder application on a smartphone.

PROCEDURES: You will be asked to provide some information – including age, sex, race, employment status and a list of your blood pressure medications. You will also take a survey about taking your medications. You may skip any question you do not wish to answer. Next, the project lead will help you download a smartphone application, MyMedSchedule® Plus and set up your medication reminders. Over four weeks, you will mark when you take your medicine in the MyMedSchedule® Plus application. After four weeks, you will come back for a follow up visit with the project lead. You will be asked to re-take the survey and the medication information in your MyMedSchedule® Plus application will be reviewed. The first and follow up visits are each expected to take about 20 minutes.
Up to 30 men and women between the ages of 18 and 75 will take part in this project.

If you decide to be in the study, the investigators will collect the following information: Your age, sex, race, employment status, a list of your blood pressure medications, and your self-reported medication adherence within the MyMedSchedule® Plus application.

If you have any questions now or at any time during the project, you may contact anyone listed under Project Leads.

BENEFITS OF THE PROJECT: This project may or may not benefit you. The MyMedSchedule® Plus application includes medication reminders, a way to track doses taken, information on medication side effects, and ability to communicate with your health care providers. These features may be helpful for encouraging and tracking medication and decreasing heart disease risk factors. Outside of this project, the MyMedSchedule® Plus application can be used for all medications. Others may benefit from any knowledge found in this project regarding medication taking applications for people who have high blood pressure.

RISKS OF THE PROJECT: Ther risks of taking part in this study include a loss of privacy or confidentiality. To reduce risk, the MyMedSchedule® Plus application is password protected and any papers with your personal information will be stored in a locked cabinet in the clinical research department, identifiable only with the code number. Only the informed consent, which will be kept separate from all other papers, will have your name on it. Any data stored on a computer will be password-protected and saved to a secure cloud-based server.

COSTS / COMPENSATION: You will not have to pay any amount for taking part in this study. A $10 gift card is provided to you at the return visit as show of appreciation for your participation.

ALTERNATIVE TO BE IN THE PROJECT: The alternative participating in this project is not to participate.

CONFIDENTIALITY: The people in charge of this project and/or The Jacksonville University's Institutional Review Board may review records or data you provided in this project. Anyone who reviews that data is required by law to protect your privacy. The only time personal identification information will be shared is if law requires it. Jacksonville University officials have the legal right to review quality improvement project records, and they will protect the privacy as the law allows. Otherwise, your quality improvement records will not be released without your permission. If we learn that you intend to harm yourself or others, we must report that to the authorities.

We plan to publish the results of this project. Privacy will be protected by not including any information that may identify you. The last four digits of your cell phone number will be used to identify you and the information you provide. To further protect your privacy will store data on the Jacksonville University password protected server. All paper documents will be kept at the clinical research department, and then destroyed at the end of the project. We may share your quality improvement data with other investigators without asking for your consent again, but it will not contain information that could directly identify you.

CONFLICT OF INTEREST: There are no conflicts of interest. Presenting the data gathered in a scientific meeting or published in a journal will help other providers and patients in the health care field.

RIGHT TO PARTICIPATE OR WITHDRAW: You are free to drop out of this project at any time without penalty and without losing any benefits to which you are entitled. Once you withdraw, any data collected will be destroyed and not included in the final results of the project. If there are

any new findings developed during the project that may increase your desire to continue, they will be shared with you.

If you decide to stop taking part in this quality improvement project for any reason, you should contact Meredith Kelly at 903-310-0760. If you choose to tell the project leads why you are leaving the project, your reasons may be kept as part of the project record. If you decide to withdraw from the project, any data collected from you will be destroyed and not included in the final results of the project. If you have any questions about your rights as a quality improvement participant, you may call the JU Office of Research & Sponsored Programs at (904) 256-7151.

CONSENT TO PARTICIPATE: You have been informed about this project's purpose, procedures, possible benefits, and risks; and the alternatives to being in the project. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time.

I understand that my consent does not take away any legal rights. I understand that nothing in this consent form is intended to replace any applicable federal, state, or local laws.

By signing this form, you voluntarily agree to take part in this project. You are not waiving any of your legal rights. You will receive a copy of this form.

Participant's Name Printed	Participant's Signature	Date

Person Obtaining Consent and Authorization:

Name Printed	Signature	Date