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# Increasing Medication Adherence In Low-Income Minority Patients: A Quality Improvement Project

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Increasing Medication Adherence In Low-Income Minority Patients:

A Quality Improvement Project

A Scholarly Project Presented to the Faculty of the

Nicole Wertheim College of Nursing and Health Sciences

Florida International University

In partial fulfillment of the requirements

For the Degree of Doctor of Nursing Practice

By

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12/1/2023

Date: -----

#### Acknowledgements

I would like to express my heartfelt gratitude for my mother, whose sacrifices and tenacity paved my way. I am also grateful for my father's support throughout the pursuit of my education. A big thank you to Dr. Jean Hannan and Dr. Husna Oleed, whose guidance helped my professional growth. Completion of this project was possible with the support of UHI staff and Dr. Robert Horne. Thank you all for your encouragement.

#### Abstract

Medication nonadherence occurs when patients deviate from provider instructions- such as not filling their prescriptions, stopping treatment early, and altering their dosages. Medication nonadherence is associated with hospital readmission, increased medical spending, and increased mortality (Klein, 2020). Though this issue greatly impacts disease prognosis, patients may feel uncomfortable discussing nonadherence or falsely assure providers they are following regimens. However, this does not allow providers to offer possible solutions to adherence barriers. This project was designed to increase the medication adherence of low-income minority patients. Patients nonadherent with their antihypertensives were approached for project participation. Participants were given an educational pamphlet and pre-and-post-test questionnaires. Blood pressure readings and MARS-5 scores were used to evaluate the effect of educational pamphlets on participants' medication adherence. Despite this project's limited sample size, participants provided valuable feedback on efforts to increase medication adherence. The results indicate improvement in blood pressure readings and MARS-5 scores after the educational intervention.

*Keywords:* medication nonadherence, medication adherence, medication adherence report scale, MARS-5

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#### Introduction

Annually, medication nonadherence is associated with 125,000 deaths and at least 10% of hospitalizations in the United States (Pittman, 2018). It is estimated that 40 to 50% of chronically ill patients deviate from prescribed regimens (Kleinsinger, 2018). Medication nonadherence is associated with a higher number of preventable deaths and larger healthcare expenses for healthcare organizations, insurers, and patients alike (Kleinsinger, 2018). Studies show this is a significant issue throughout various clinical settings and at the international level. Nonetheless, these incidents are likely to be underreported. *Medication compliance* suggests patients must follow provider advice passively, thus the term *medication adherence* is widely preferred in academia (Stewart et al., 2022).

Medication nonadherence is a complex issue. Patients compromise adherence when they skip filling prescriptions, delay refills, stop the regimen early, skip doses, or ration medication (Klein, 2020). Intentional medication nonadherence may stem from systemic or socioeconomic factors including denial, mental illness, cultural factors, lack of symptoms, preference for alternative medicine, and poor patient-provider relationships (Huizen, 2021). Medication costs, side effects, cognitive ability, appointment ease, and level of motivation also influence medication adherence (Kleinsinger, 2018). Moreover, nonadherence may be unintentional – such as with forgetting a dose, taking the wrong dose, taking a dose at the wrong time, or storing medication improperly (Huizen, 2021). Patients may be confused regarding provider instructions and face many other obstacles to taking their medication properly.

Despite the prevalence of medication nonadherence, it is typically viewed as a patient issue and not a result of systematic barriers (Kleinsinger, 2018). Some researchers suggest that the traditional medical model focuses providers' efforts on prescribing the correct treatment but

not addressing nonadherence (Kleinsinger, 2018). One prominent issue is that the fee-for-service healthcare model emphasizes service delivery over improved clinical results (Kleinsinger, 2018). Other systematic factors that may impact medication adherence include medication copayments and coordination of care between inpatient and outpatient sites (Kini & Ho, 2018). Medication nonadherence may increase when providers inadequately discuss regimen benefits, prescribe regimens with multiple medications, and forgo communication with other providers (Kini & Ho, 2018). However, medication nonadherence can still occur when other barriers are addressed due to difficulty changing human behavior (Kleinsinger, 2018). Making a change was once believed to be a black-and-white issue, but understanding of change and motivation has evolved. Adhering to medication regimens requires both motivation and ability, which in turn are influenced by various internal and external factors (Stewart et al., 2022). The focus is not only on creating change, but also sustaining long-lasting change through the balance of decision-making factors.

Medication nonadherence occurs throughout various clinical settings and low-income minority patients are especially vulnerable. The rising cost of healthcare affects this population disproportionately. According to Fernandez-Lazaro et al. (2019), studies have continuously shown a correlation between low-income status and medication nonadherence. A study by Konstantinou et al. (2020) correlated lower medication adherence with lower income and education levels. Minority status has also been shown to play a role in medication nonadherence. Black and Hispanic patients had lower adherence rates compared to White patients in a study by Xie et al. (2019). Lower adherence rates for all three drug classes studied correlated with non-White background, low educational level, and low household income status (Xie et al., 2019). Correlations between race or ethnicity and medication adherence levels were evident even when other participant socioeconomic characteristics were controlled (Xie et al., 2019). Despite this, the low-income minority population remains understudied. Further study should be encouraged to help understand the complexities affecting adherence.

#### **Problem Significance/Statement**

This DNP project aims to test an intervention to increase medication adherence in the low-income minority population of a community clinic. Using a pretest questionnaire, participants will be interviewed regarding their adherence to antihypertensives. The intervention will take the form of an educational pamphlet outlining common barriers to medication adherence and possible solutions. This pamphlet will be available in English and Spanish. The impact of the intervention on medication adherence rates will then be evaluated using a posttest questionnaire. To evaluate medication adherence claims, participants' blood pressure readings will be compared before and after pamphlet distribution. The end goal of this quality improvement project is to improve patient knowledge and medication adherence postintervention.

#### Significance

Medication nonadherence is likely underestimated due to self-reporting bias and fear of social stigma. Medication nonadherence remains a pertinent issue to address considering the rising cost of healthcare. The effects of medication nonadherence substantially burden public health and the national healthcare system. Kini & Ho (2018) estimate that \$100 billion in medical services may be attributed to medication nonadherence. According to Klein (2020), studies have shown that morbidity and mortality due to medication nonadherence may cost about \$528.8 billion yearly. These costs come in the form of emergency room visits, hospital

admissions, readmissions, and decreased quality of life due to medical complications (Klein, 2020).

Medication nonadherence affects several populations: individual patients & their families, healthcare systems, and taxpayers (Klein, 2020). This results in increased spending for national healthcare organizations such as the Department of Veterans of Affairs. A study by Gaffney et al. showed a correlation between the Veterans Health Administration's coverage of medication costs and significant reductions in the nonadherence of chronically ill patients (Gaffney et al., 2020). The study also noted that VHA mediation coverage correlated with decreased racial, ethnic, and socioeconomic disparities in nonadherence (Gaffney et al., 2020). Most importantly, the study noted that low-income, chronically ill, and minority patients were more affected by high out-of-pocket medication costs- resulting in worse medication adherence and clinical outcomes (Gaffney et al., 2020).

Throughout the literature, differences in socioeconomic status frequently correlate with health inequality. Healthcare disparities may arise from differences in social status, income status, race or ethnicity, and other factors. Contemporary genomic developments have shown that race and ethnicity are social constructs with little biological basis (Rothschild, 2017). Nonetheless, race and ethnicity continue to have social consequences and shape patient care. The Centers for Disease Control and Prevention (2023) also report that "the life expectancy of non-Hispanic Black Americans is four years lower than that of White Americans". The Centers for Disease Control and Prevention (2023) describe that racial and ethnic minority patients experience higher mortality rates from conditions like diabetes, heart disease, and hypertension than White patients.

Moreover, the literature demonstrated that the vast majority of medication nonadherence occurred with antihypertensives. A study by Lee et al. (2022) showed that global medication nonadherence among hypertensive patients ranged from 27-40%. Poor blood pressure control correlated with the development of cardiovascular disease, chronic kidney disease, dementia, and overall mortality worldwide (Lee et al., 2022). The study showed that low-to middle- income and non-Western countries had increased medication nonadherence rates (Lee et al., 2022). This may be due to limited medication access, financial challenges, and cultural beliefs about medication (Lee et al., 2022). Downplaying medication nonadherence negatively impacts clinical outcomes, patient mortality, and healthcare spending- especially for the low-income and minority population. Nonetheless, medication nonadherence requires more study to identify population-specific needs.

#### **Knowledge Gaps**

Interventions to improve medication nonadherence face several barriers to implementation. Solutions are limited when nonadherence is seen as a patient behavioral issue without acknowledging contributing systematic factors. Some of the systematic factors that contribute to medication nonadherence include communication between providers and patient health literacy levels. Many providers fail to discuss this topic with their patients or screen for nonadherence. According to Lee et al. (2022), evidence-based interventions to combat medication nonadherence are not adequately implemented in clinical practice. Although lowincome minority patients are at increased risk of medication nonadherence, studies on this population are limited. Existing interventions to improve medication adherence do not target low-income minority populations. There are other gaps in what is known regarding medication nonadherence. Studies worldwide are impacted by limitations in feasibility. Objective measures for medication adherence (such as electronic pill boxes and biochemical assays) tend to be used in Western or high-income countries (Lee et al., 2022). Additionally, it can be difficult to differentiate between genuine improvement in medication adherence and improvement due to bias. The improvement in medication adherence in some studies could be attributed to the Hawthorne effect, in which patients improve due to being monitored (Lee et al., 2022). There is an insufficient number of studies regarding medication adherence in the low-income minority population. This population faces unique considerations for care, further study is highly encouraged.

#### **Summary of the Literature**

#### **Search Strategy**

The *FIU library*, *PubMed*, *CINAHL*, and *Google Scholar* databases were used to find appropriate articles for the project. Search terms used include "increasing medication adherence", "medication nonadherence", "medication noncompliance", "low medication adherence", "medication adherence AND minority patients", "medication adherence AND lowincome", "medication compliance OR adherence AND low-income", "hypertension AND medication nonadherence", "global medication nonadherence", "measure medication adherence OR compliance", "medication adherence screening", "medication compliance screening", "medication adherence interventions", and "effects of medication nonadherence". Results were narrowed down to full-text articles published between 2017 and 2023. Articles that were not in English or that only briefly touched upon the topic were excluded.

#### **Income and Minority Status**

Vulnerability to medication nonadherence correlated with minority status and lower socioeconomic status. Konstantinou et al. (2020) found that lower education level, low-income status, high medication cost, and rural location posed considerable barriers to medication adherence. The chronic conditions with the highest rates of medication nonadherence in this study were asthma, cancer, diabetes, epilepsy, HIV/AIDS, and hypertension (Konstantinou et al., 2020). Globally, much of the medical burden of medication nonadherence is due to unmanaged hypertension and subsequent cardiovascular disease (Lee et al., 2022). Most studies testing an intervention to increase medication adherence addressed antihypertensive use. A cohort study by Lee et al. (2019) showed that patients of lower household incomes were at higher risk of death when nonadherent to antihypertensive medications. Additionally, low-income patients were more likely to be on multiple antihypertensive medications compared to higher income patients (Lee et al., 2019). Overall, low-income patients were more likely to be nonadherent with medications (Lee et al., 2019). The study also showed that few interventions to increase adherence targeted the low-income minority population.

A systematic review by Ogungbe et al. examined the effects of country income level on antihypertensive medication adherence rates. This study demonstrated that cardiovascular disease disproportionately affects low- and middle-income countries (LMICs) (Ogungbe et al., 2021). More importantly, the study showed that interventions applied in high-income countries have not been adapted for use in LMICs (Ogungbe et al., 2021). LMICs face increased challenges with medication adherence due to lower health literacy levels, ethnic beliefs regarding cause of disease, insufficient healthcare infrastructure, and other socioeconomic barriers (Ogungbe et al., 2021). However, the same study showed that higher medication adherence rates were recorded when interventions accounted for local barriers and included multiple strategies (Ogungbe et al., 2021). This highlights the need to tailor interventions to population-specific considerations.

Further literature examination showed that medication nonadherence is influenced by medication costs and affects entire healthcare systems. Cost-related medication nonadherence particularly affects racial or ethnic minorities and those with low-income (Gaffney et al., 2020). The study demonstrated that Veteran's Health Administration (VHA) medication coverage correlated with decreased cost-related medication nonadherence (Gaffney et al., 2020). This is significant because the change occurred despite VHA patients being generally older, sicker, and lower income than non-VHA patients (Gaffney et al., 2020). The VHA can secure very low medication costs through federal price caps and negotiations with manufacturers (Gaffney et al., 2020). This suggests that increased medication cost coverage could lead to improved adherence rates, even for patients belonging to minority groups or with multiple conditions.

A study by Cuffee et al. (2019) examined the correlation between minority status and increased risk for medication nonadherence. To properly treat minority patients, it is important to understand sociocultural barriers that affect their care. Black patients have faced discrimination in the clinical setting throughout history, which has led to the development of skepticism regarding the Western medical system. Seen in Black patients, *John Henryism* is described as a psychosocial coping mechanism of increased self-reliance in the face of low-resource environments (Cuffee et al., 2019). According Cuffee et al. (2019), reports of John Henryism correlated with lower trust in medical providers and maladaptive health behaviors. This form of self-reliance has been associated with lower antihypertensive adherence rates and higher risk of developing hypertension (Cuffee et al., 2019).

A study by Xie et al. investigated medication adherence patterns in a racially diverse patient group. Even when socioeconomic status was accounted for, there were decreased adherence rates in Black and Hispanic study participants versus White participants (Xie et al., 2019). Furthermore, minority groups experienced higher risk of medication nonadherence due to greater chronic disease prevalence, limitations in access to care, and greater financial challenges (Xie et al., 2019). Interventions to increase medication adherence were also examined. The use of convenient refill methods, such as 90-day refills and mail-order medication delivery, was associated with greater medication adherence rates (Xie et al., 2019).

A study by Lor et al. examined correlations between Hispanic ethnicity and adherence. Although cardiovascular disease is the second leading cause of death in the Hispanic population, Hispanics have lower rates of controlled blood pressure compared to White patients (Lor et al., 2019). This cross-sectional study also suggested that Hispanic patients are less likely to continue antihypertensive regimens and may have higher nonadherence scores than Non-Hispanic White patients (Lor et al., 2019). In the same study, health literacy levels correlated with levels of medication adherence in Hispanic hypertensive patients (Lor et al., 2019). Findings show that addressing the medication adherence of Hispanic patients requires that interventions be adjusted to their health literacy levels (Lor et al., 2019). This supports the notion that medication adherence can be improved if population-specific needs are considered.

#### **Screening Tools**

The following medication adherence tools are discussed in this literature review: the Medication Adherence Report Scale (MARS), electronic drug monitoring systems, pharmacy claims data, Medication Possession Ratio, Washburn-Barriers to Medication Adherence Instrument (W-BMA), and self-reported measures verified with lab results. Currently, there is no

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gold standard for measuring medication adherence. According to Kini & Ho (2018), the lack of consensus on the exact definition of medication adherence was also recognized in the literature.

A study by Chan et al. (2020) showed that medication adherence is often measured using direct observation therapy or electronic monitoring, but these approaches prove too inconvenient for long-term use. Electronic monitoring may be unreliable because notifications are sent when pill containers are opened, but the medication itself may be discarded (Chan et al., 2020). Several self-reporting tools to assess medication adherence are available. However, self-reporting of adherence may be influenced by fear of provider disappointment, questionnaire wording, and bias (Chan et al., 2020). Of the tools discussed, use of the MARS-5 was favored because of its neutral question tone and range of scoring (Chan et al., 2020). The Medication Adherence Report Scale is available in a 5-question format and 10-question format (MARS-5 and MARS-10, respectively). Psychometric testing of the MARS-5 showed reliability and validity in patients with diabetes, asthma, and hypertension (Chan et al., 2020).

Electronic drug monitoring and pharmacy claims data may provide more objective estimates of medication adherence than self-reporting (Kini & Ho, 2018). Malik & Kumari (2020) suggest that calculating adherence using pharmacy prescription claims often leads to overestimation. Other methods of calculating adherence include using the Medication Possession Ratio (MPR) (number of days the patient has medication for) divided by the number of days the patient was observed for (Malik & Kumari, 2020). However, these estimations may be incorrect because they do not guarantee ingestion of the medication (Malik & Kumari, 2020). Still, Kini & Ho (2018) found strong correlations between electronic drug monitoring and improvement in clinical measures. Washburn & Thompson (2020) conducted a quasiexperimental study that tested a newly developed screening tool's ability to detect medication adherence using retrospective patient data. The Washburn Barriers to Medication Adherence Screening Tool (W-MBA) screened for 5 categories of barriers: education; medical issues; financial & social; behavior & lifestyle; and distress, depression, & anxiety (Washburn & Thompson, 2020). The W-MBA screening instrument was found to be more thorough and complex, but also lengthy. Notably, this scale was able to detect barriers previously detected by other methods (Washburn & Thompson, 2020). However, this screening tool is relatively new and requires further testing.

#### Interventions

The study by Washburn & Thompson (2020) showed that screening for medication adherence barriers could be implemented by healthcare team members educated by nurses. Use of W-MBA to screen for medication adherence barriers and intervention application correlated with a reduction in clinic visits, ER visits, and hospitalizations (Washburn & Thompson, 2020). However, the study also suggests that long-term adherence may not be sustained if only some of the medication adherence barriers are addressed (Washburn & Thompson, 2020).

A systematic review by Wilhelmsen & Eriksson (2018) showed mixed evaluations of several types of interventions to increased medication adherence. Some interventions resulted in statistically significant change in one study but not in another, this could be attributed to study limitations or differences in clinical setting (Wilhelmsen & Eriksson, 2018). Half of the pharmacist or nurse-led counseling interventions resulted in higher reports of medication adherence (Wilhelmsen & Eriksson, 2018). Physician-led interventions, reminders, direct observation, and web-based interventions failed to show statistically significant improvement (Wilhelmsen & Eriksson, 2018). Additionally, Wilhelmsen & Eriksson (2018) recognize that intervention improvement rate may have only used results of one randomized controlled trial, making further study necessary. Although some studies showed that patient education resulted in higher reports of patient satisfaction, no single intervention type showed improvement in medication adherence throughout all clinical settings (Wilhelmsen & Eriksson, 2018).

A study by Ogungbe et al. (2021) examined various interventions and their effectiveness in low to middle-income countries (LMICs). LMICs face socioeconomic barriers to medication adherence such as lower health literacy, larger family size, local beliefs regarding disease origin, long distance from treatment site, and high cost of medicines & limited supply (Ogungbe et al., 2021). Switching from multi-dose medications to fixed-dose combination therapy was found to be most effective in increasing medication adherence in cardiovascular patients in LMICs (Ogungbe et al., 2021). The fixed-dose combination therapy approach involves reducing the number of pills taken by combining them into a single pill. Other interventions reviewed included the use of electronic pillboxes, calendar notifications, and mobile device calls & texts. Interactive or personalized electronic reminders were more effective at increasing medication adherence than standard reminders (Ogungbe et al., 2021). One of the most effective interventions involved using a team-based approach to address medication adherence (Ogungbe et al., 2021). Nurses, pharmacists, and other healthcare team members were vital in providing patient education in LMICs with physician scarcity (Ogungbe et al., 2021). Despite the unique challenges that LMICs face, medication adherence rates improved when interventions included multiple approaches and addressed local needs (Ogungbe et al., 2021).

A study by Konstantinou et al. (2020) sorted contributing factors to medication nonadherence into 5 categories: socioeconomic, healthcare system, condition-related, therapyrelated, and patient-related. Factors that encouraged medication adherence included: reminder tools, strong belief in medication, acceptance of diagnosis, good patient-provider relationship, receiving social support, and reminders from family members (Konstantinou et al., 2020). Age under 30 correlated with increased risk of medication nonadherence, this may be due to self-perception differences and denial of diagnosis (Konstantinou et al., 2020). The study also showed that integrating digital care and mobile device usage into interventions may be helpful in involving younger adults into their care (Konstantinou et al., 2020). Konstantinou et al. (2020) suggest that behavioral and multicomponent interventions may increase medication adherence rates among all age groups studied.

The implementation of interventions such as patient education, electronic drug monitoring systems, telephone counseling, medication-taking reminders, pharmacist consultation, and cognitive behavioral therapy were evaluated in a study by Kini & Ho (2018). Although self-reports were mostly used to evaluate adherence, Kini & Ho (2018) suggest that it may overestimate adherence compared to objective measures like pharmacy claims and electronic drug monitors. Pharmacy claims data moderately correlated with the results of electronic drug monitoring (Kini & Ho, 2018). Patient education with follow-up telephone calls showed improvement in medication adherence, but only if implemented with personalized information at the time of a new diagnosis (Kini & Ho, 2018).

A study by Fernandez-Lazaro et al. (2019) demonstrated that 52% of the low-income uninsured study participants with chronic conditions reported medication nonadherence. This study used the World Health Organization's multilevel framework to analyze medication adherence in relation to various factors: socioeconomic factors, health-care team and systemrelated factors, condition-related factors, therapy-related factors, and patient-related factors (Fernandez-Lazaro et al., 2019). The two strongest predictors of medication adherence in this study were regular provider visits and patient reports of receiving sufficient information regarding their medications (Fernandez-Lazaro et al., 2019). Notably, medication nonadherence was common during the first 6 months of a new medication regimen for a chronic condition (Fernandez-Lazaro et al., 2019).

Kini & Ho (2018) suggest that clinics should chose interventions to increase medication adherence based on practice availability and feasibility instead of effectiveness. The study demonstrated barriers to the routine use of electronic monitoring due to cost and difficulty integrating this into practice (Kini & Ho, 2018). Some effective interventions to increase medication adherence in the low-income population include initially prescribing generic medications for treatment of chronic conditions and decreasing the number of required pills by prescribing fixed-dose combination medications (Fernandez-Lazaro et al., 2019).

#### **Purpose/PICO Question/Objectives**

#### **Purpose**

The purpose of this project is to identify and address factors that contribute to medication nonadherence in the low-income minority population. This effort will be a quality improvement project aimed at increasing medication adherence in the hypertensive patients of a community clinic. This clinic provides low-cost primary care to uninsured patients, making it the ideal setting for minority patients. The proposed intervention is an educational pamphlet that discusses the benefits of adherence to antihypertensives as well as the risks of nonadherence. Available in both English and Spanish, the pamphlet will outline patient concerns that may contribute to medication nonadherence. This project aims to help patients and providers understand barriers to medication adherence and further the use of evidence-based practice in nursing.

#### **PICO Question**

The PICO (population, intervention, comparison, and outcome) model is used in evidence-based practice to help frame a clinical question in a way that is literature-relevant (Roever, 2018). The PICO tool was used to create the DNP project question: Will the implementation of an educational pamphlet result in improved medication adherence in lowincome minority patients? The following are the components of the PICO model used in the DNP question.

- **Population**: Low-income minority patients that are nonadherent with their antihypertensives.
- **Intervention**: Distribution of educational pamphlets discussing hypertension and medication adherence, available in English and Spanish.
- **Comparison**: Pretest-posttest analysis of self-reported (MARS-5) and objective measures of medication compliance (blood pressure readings).
- **Outcome**: Increase in measures of medication adherence in low-income minority patients.

#### **Objectives**

This quality improvement project is anticipated to result in a measurable increase in medication adherence post-intervention. After receiving the educational pamphlet, the following objectives are expected to be met:

- Study participants will demonstrate increased medication adherence as supported by improved post-intervention questionnaire (MARS-5) scores and blood pressure readings.
- An increased number of study participants will be able to understand some of the benefits of medication adherence or consequences of medication nonadherence.

#### **Definition of Terms**

The following are the definition of terms used in the project:

**Health disparity:** A health difference between two populations, often reinforced by systematic and social hierarchies (King et al., 2016). This may include disadvantages due to differences in race or ethnicity, gender, age group, sexual orientation or identity, and income status (King et al., 2016).

**Low-income:** The parameters considered low-income will vary by region. To qualify for care at the clinic and study inclusion, patients must report an income below 200% the yearly federal poverty guidelines. The Cambridge Dictionary (n.d.) defines low-income status as in "not earning much money".

**Medication adherence:** there are varying definitions of what constitutes medication adherence. Burnier (2019) defines adherence as patients taking medications as prescribed. However, most literature used a threshold of 80% to categorize good medication adherence according to MPR or PDC (Burnier, 2019).

**Medication Possession Ratio (MPR):** (sum of days' supply) / (total days in period) × 100 (Loucks et al., 2022).

**Minority:** populations that are hold less social power than other groups; regardless of race, birthplace, and population size (Rothschild, 2017). A member that is considered subordinate or subject to collective discrimination (Rothschild, 2017).

**Proportion of Days Covered (PDC):** (total days covered) / (total days in period) × 100 (Loucks et al., 2022).

**Poverty Guidelines:** simplified poverty measure used to categorize family income or determine eligibility for federal programs (ASPE, n.d.). It is determined by U.S. Census Bureau

information that is updated yearly (ASPE, n.d.). The Florida Department of Health oversees the implementation of these yearly changes on provider programs.

**Race**: the use of skin tones or other characteristics to form an identity, superficial features that are assigned to connoted regions of the world (Rothschild, 2017). Race is a social construct with no biological basis (Rothschild, 2017).

#### **Conceptual Underpinning and Theoretical Framework**

Kurt Lewin was a German psychologist that studied social science, group dynamics, and the implementation of change (Burnes, 2020). Lewin developed his well-known three-step model of change as an approach to create change in an organization (Burnes, 2020). Although this model was developed in the 1940s, it forms the basis for several other models in nursing theory and is still commonly used today. Lewin (1947) originally lists his three steps as the following:

- (a) Quasi-stationary social equilibria and social changes.
- (b) Locomotion through social channels.
- (c) Social feedback processes and social management. (p. 6)

Today, the three steps of Lewin's model are known as *unfreezing*, *moving*, and *freezing* (commonly referred to as refreezing) (Burnes & Bargal, 2017). Unfreezing entails becoming receptive to change by breaking down current customs, moving entails engaging in actual change, and freezing entails full adoption of the change as a norm (Burnes & Bargal, 2017).

This project will introduce an educational pamphlet as an intervention to increase medication adherence in the low-income minority population of a clinic. The pamphlet will summarize the benefits of adherence and consequences of nonadherence. The *unfreezing* step will entail opening dialogue with patients regarding current adherence habits to reevaluate them. The goal is to create enough incentive for patients to question their current medication habits to allow for reeducation to occur. The second step of *moving* will begin when the forces favoring change become greater than the forces resisting change (Burnes & Bargal, 2017). This step will consist of the patient increasing their medication adherence (or taking the medication as was prescribed). Finally, the third step of *freezing* will entail full incorporation of the increase in adherence as a daily habit that is maintained long-term.

#### Methodology

#### **Implementation and Project Procedures**

This quality improvement project will use a pretest-posttest design to examine the effect of an educational pamphlet as an intervention to increase medication adherence. The population of this clinic faces challenges with technology use; therefore, the MARS-5 tool will be converted into a paper questionnaire to measure medication adherence pre- and-post-intervention. The primary investigator will create a quality improvement project with insight from Dr. Husna Oleed, a provider with over ten years of experience at the clinic. Input from clinic management and faculty will also help shape this project.

#### **Setting and Participants**

This study was conducted at a primary care clinic serving the diverse population of Miami Gardens, Florida. Per City of Miami Gardens (2020) statistics, "Miami Gardens is the largest predominantly Black municipality in Florida". Approximately 70% of residents identified as Black and 26% were Hispanic (City of Miami Gardens, 2020). Nearly all clinic patients belong to a minority group, with a significant number being Caribbean descent. To qualify for care at the clinic, patients were required to be low-income and uninsured. Approximately 15 clinic patients identified as nonadherent with antihypertensive medication will be recruited as study participants.

#### **Data Collection and Analysis**

A questionnaire using the MARS-5 (Medication Adherence Report Scale) will be used. Study participants will complete pretest and posttest questionnaires to collect demographic information and assess medication habits. The following patient information will be gathered in the pretest questionnaire: age, gender, marital status, ethnicity, years living in the U.S., yearly income, number of prescribed medications, and barriers to medications adherence.

An educational pamphlet in either English or Spanish will be provided to participants, according to their preference. After patient interviews, questionnaire data will be input into Qualtrics for analysis. Qualtrics will be used to secure the information in compliance with HIPAA and pertinent privacy guidelines. Questionnaire results will then be analyzed to determine if the educational pamphlets resulted in statistically significant change.

#### **Protection of Human Subjects**

Institutional Review Board (IRB) approval will be obtained from Florida International University prior to starting the recruitment and intervention process. The clinic in question does not have an IRB but will honor the decision of FIU's IRB. Project investigators will be completing Collaborative Institutional Training Initiative Program (CITI) certification. Study participants will be informed that participation is entirely voluntary and that their private information will remain protected throughout project completion. Guidance from Dr. Oleed, clinic management, and FIU faculty will help ensure information abides by privacy standards. Patients that participate will be provided a consent form, which will include an introduction to the project. The purpose, outline, and timeline for completion of the study will be included in the introduction. Any participant questions or concerns will be discussed during the process of obtaining consent. For privacy purposes, numbers will be used to identify patients after coding with a master key. Locked rooms, locked file cabinets, and a password-protected laptop will be used for this project.

#### **Benefits and Risks**

Information regarding benefits and risks will be included in the consent forms and recruitment process. Patients benefit from project participation by receiving patient education and blood pressure monitoring. Patients will receive counseling regarding their blood pressure medication and ways to increase adherence. Patients may experience minor discomfort associated with obtaining blood pressure readings. This quality improvement project is unlikely to involve any risk that may impact the participants' psychological, physical, social, and economic wellbeing; the possibility of confidentiality breach and legal risk are very unlikely.

#### Timeline

- July 2023- Development of pretest-posttest questionnaires and educational pamphlet.
- August 2023- Secured IRB approval from FIU and the clinic.
- August-September 2023- Completion of questionnaires and distribution of educational pamphlets to patients.
- September-October 2023- Collection, analysis, and summarization of study findings into a report.

An educational pamphlet will be designed for low-income minority patients at the clinic. The focus of this study will be on clinic patients noncompliant with antihypertensive medication. The benefits of medication compliance and consequences of nonadherence will be listed in an educational pamphlet available in both English and Spanish. Common adherence barriers and proposed solutions will be discussed in the pamphlet. Development of a medication adherence questionnaire and educational pamphlets will be completed in June 2023. Pretest and posttest questionnaire completion will occur in-clinic on printed forms to accommodate for the challenge that technology poses for patients. Qualtrics will be used for data entry purposes. Project findings will be processed, organized, and condensed for review from September to October 2023.

#### **Results**

The purpose of this quality improvement project was to evaluate the effect of educational pamphlets on blood pressure readings and self-reported MARS-5 scores. A total of 26 patients were approached for project participation while seeking care at the clinic. Nonetheless, 4 patients did not qualify for study inclusion because they were identified as adherent to medication, 5 patients were not included due to language barriers, and 3 patients declined participation. A total of 14 participants (n=14) completed the pretest and posttest questionnaire and blood pressure readings.

#### **Demographics**

A total of 14 participants enrolled and completed the study. Most of the participants identified as Black (50%) (see Table 1). Most participants were female (64.28%), and ages ranged from 40s-70s. Most participants did not wish to disclose their income, but reported yearly incomes ranged from no income to \$21,000-\$50,000. Most participants were married (57.14%) and 3 participants (21.42%) reported being divorced. Since the same participants filled out both the pretest and posttest questionnaire, demographic information did not change throughout this project.

#### Table 1

Age/years	п	%
40-49	2	14.28%
50-59	4	28.57%
60-69	6	42.85%
70-79	1	7.14%
Gender		
Female	9	64.28%
Male	5	35.71%
Marital Status		
Single	3	21.42%
Married	8	57.14%
Divorced	3	21.42%
Widowed		
Race/ethnicity		
Asian	4	28.57%
Black	7	50%
Hispanic	2	14.28%
Other	1	7.14%
Yearly Income		
None	4	28.5%
\$0-\$20k*	1	7.14%
\$21k- \$50k*	1	7.14%
Did not disclose	8	57.14%
Years in the U.S.		
0-10	5	35.71%
11-20	1	7.14%
21-30	2	14.28%
31-40	4	28.57%
41-50	1	7.14%
50+	1	7.14%

*Demographic Information* (*N* = 14)

Medications, Blood Pressures, & Scores

Most participants reported taking either 2, 3, or 5 medications (see Table 2). Pretest and posttest MARS-5 scores ranged from 5 to 25, with 5 indicating least adherence and 25 indicating maximum adherence. There was a wide distribution of pretest MARS-5 scores, but most

participants scored 25. More than double that number of participants scored 25 in the posttest MARS-5 results. There was an overall improvement in blood pressure readings, but the most significant improvement occurred in systolic blood pressure values (p = 0.01). The improvement in diastolic blood pressure was not considered significant (p = 0.21). The MARS-5 scores improved after the educational pamphlet intervention, but not significantly (p-value of 0.31).

#### Table 2

	#	n	%
	1	2	14.28%
	2	5	35.71%
Number of Medications	3	3	21.42%
	4	1	7.14%
	5	3	21.42%

Number of Medications

#### Table 3

Pretest MARS-5 and Posttest MARS-5

 Pretest MARS-5 Score	<i>N</i> = 14	Posttest MARS-5 Score	<i>N</i> = 14
17	1 (7.14%)	15	1 (7.14%)
18	1 (7.14%)	17	1 (7.14%)
19	2 (14.28%)	19	1 (7.14%)
21	2 (14.28%)	20	1 (7.14%)
22	1 (7.14%)	22	1 (7.14%)
23	2 (14.28%)	23	2 (14.58%)
24	2 (14.28%)	25	7 (50%)

#### **Barriers to Adherence**

A total of 14 participants were interviewed regarding barriers that impacted their medication adherence. The most reported barriers to medication adherence were lack of health insurance and medication costs (see Table 3). This makes sense because UHI Community Care Clinic cares for uninsured and low-income patients. Other barriers to adherence included forgetfulness, refill or pharmacy issues, experienced side effects or fear of side effects, insufficient understanding of instructions, transportation issues, and cultural or language barriers.

Some patients reported difficulty affording their medication even when they took generic versions and used price-lowering resources (such as Good Rx or savings programs). Patients reported that costs added up as they became increasingly ill and required treatment with more medications. Several patients specified that medication delivery services were not available at their local pharmacy. Although participants reported using GoodRx to save money on their prescriptions, this often resulted in visits to more than one pharmacy to obtain all their medications. Moreover, a couple of patients reported their forgetfulness was related to a previous stroke or neurological issue. These patients reported fear of accidentally taking their antihypertensive twice and experiencing hypotension. To help with forgetfulness, these patients were given weekly pillboxes that were donated to the clinic.

#### Table 3

Barrier to Medication Adherence	Reporting participants (n)	%
Lack of health insurance	14	100%
Medication costs	7	50%
Forgetfulness	5	35.71%

#### Barriers to Medication Adherence

Defill/phormoon issue	Δ	28 570/
Kenn/phannacy issue	4	20.37%
Fear of side effects/experienced	3	21.42%
	0	
side effects		
Insufficient understanding of	2	14.28%
instructions		
Transportation issues/distance from	2	14.28%
• 1		
provider		
Language harrier	1	7 14%
Lunguage ourner	1	/.11/0
Cultural barrier	1	7.14%

#### **Adherence Facilitators**

During the interview process, patients were asked about what methods helped them maintain medication adherence. Participants described that medication adherence was facilitated by obtaining 90-day refills, attending regular provider visits, taking generic medicines, keeping pill containers by their nightstand, using pillboxes or medication reminders, and using pharmacy savings programs or Good Rx to reduce medication prices. Spouses or family members frequently accompanied patients at appointments. Engaged family members facilitated medication adherence by providing transportation, reminding patients to stop by the pharmacy, and reminding patients to take their medicine at home. Notably, study participants that had already experienced complications from high blood pressure (such as stroke or brain hemorrhage) reported increased emphasis on taking their antihypertensives. This was also found to be true for participants with family members that experienced hospitalization or death from complications of hypertension (such as family history of stroke).

#### Discussion

#### **Cost and Insurance**

The results of this quality improvement project indicate that the educational intervention improved MARS-5 scores and blood pressure readings. Like the literature, this project showed a correlation between medication cost and medication adherence. The two most frequently reported barriers to medication adherence in this project were lack of health insurance and medication costs. Several participants reported difficulty affording their antihypertensives even with the use of Good Rx, pharmacy savings programs, and generic medications. Evidence gathered by Lee et al. (2019) found an association between higher antihypertensive nonadherence rates seen in the low-income population and higher mortality due to cardiovascular events. These findings are consistent with the study by Fernandez-Lazaro et al. (2019), which showed that a significant amount of the U.S. remains uninsured even after the Affordable Care Act passed. The study found differences in medication adherence correlated with low-income and uninsured status, even in countries with universal healthcare such as China and Canada (Fernandez-Lazaro et al., 2019). Gaffney et al. (2020) found that VHA coverage of medications greatly reduced medication nonadherence and disparities in the low-income and racial or ethnic minority population. Price caps and negotiations with drug manufacturers led to the VHA being able to obtain reduced-price medications (Gaffney et al., 2020). Research by Klein (2020) also supported the use of price caps on out-of-pocket prescription costs and expansion of subsidies for low-income patients to improve medication adherence. Further study should be conducted to determine how recent changes to Medicare and the Affordable Care Act affect this strategy (Gaffney et al., 2020).

#### **Side Effects and Cultural Considerations**

Moreover, QIP participants reported fear of side effects and experienced side effects as barriers to adherence. This was consistent with findings by Kini & Ho (2018), which showed that factors such as low health literacy, personal and cultural beliefs, and previous experiences with medication side effects influenced medication adherence. Various participants mentioned that distrust of medication side effects affected their adherence, especially after experiencing skepticism regarding COVID-19 vaccines, CDC recommendations, and FDA drug recalls. Furthermore, the participants of this study were mostly Afro-Caribbean and South Asian descent. Some of these patients reported cultural preference for natural, herbal, or home remedies. Research also showed that medication nonadherence in Black patients was influenced by medication beliefs, level of provider trust, and experiences with healthcare discrimination (Cuffee et al., 2019). This was consistent with findings in the study by Ogungbe et al. (2021), which showed that medication adherence in low- and middle-income countries (LMICs) was affected by cultural barriers. Findings by Cuffee et al. (2019) showed that Black participants reported decreased trust in providers and increased fear of experimentation or privacy breaches. Evidence in a global study by Lee et al. (2022) showed that nonadherence was more prevalent in non-Western and low-to-middle-income countries. The increased nonadherence could be due to cultural differences, alternative medicine, drug inaccessibility, and healthcare system challenges (Lee et al., 2022). This was consistent with findings in this study that showed that a couple participants stopped their antihypertensives due to side effects such as cough and frequent urination. However, these participants were unaware that other antihypertensive options could be available to them if they had brought this to their provider's attention. Other participants reported

fear of antihypertensive side effects, citing anecdotal evidence of adverse effects that occurred to acquaintances or family members.

#### **Health Literacy and Patient-Provider Communication**

Further literature examination supported the connection between patient-provider relationship and medication adherence. A study by Konstantinou et al. (2020) revealed that belief in medication effectiveness and belief that medication was necessary for a longer life increased likelihood of adherence. Some QIP participants also reported that their nonadherence was due to misunderstanding provider instructions. These patients were also more likely to engage in less frequent visits to the clinic for follow ups. It is possible that these misunderstandings could be due to the presence of a language barrier or lack of familiarity with their condition. Research by Lor et al. (2019) showed that health literacy levels correlated with rates of medication adherence in hypertensive Hispanic patients. The study also showed that health literacy levels were lower in minority populations and that interventions to increase health literacy should include reinforcement of written information and personalized information, as these were the most successful methods of increasing adherence (Lor et al., 2019). Findings by Konstantinou et al. (2020) demonstrated that low condition health literacy, poor patient-provider communication, and lack of understanding of provider instructions contributed to medication nonadherence. According to Fernandez-Lazaro et al. (2019) the two strongest predictors of medication adherence were regular provider visits and patient reports of receiving sufficient information regarding their medications. A study by Stewart et al. (2022) suggested that medication adherence was found to be higher in patients who reported feeling included in treatment decision making. This correlates with findings in this study, participants that were more involved during visits were found to be more adherent with their medications.

Several participants of this QI project also mentioned their medication adherence was influenced by fear of being perceived as less capable of taking care of their family. On the other hand, patients that reported that hypertension ran in their family or who wanted to be healthy for their family tended to place more emphasis on medication adherence. In a study by Stewart et al. (2022), decreased adherence was reported in treatment for HIV and TB- this may be due to fear of social stigma related to diagnosis or taking medication in public. Findings by Stewart et al. (2022) showed that adherence to prophylactic medications may be lower than adherence to medication for conditions that are already diagnosed. This may be due to differences in patient perspective regarding need for medicine and experienced symptoms (Stewart et al., 2022). Patients may stop taking medications when they feel their condition has improved, however, this lack of symptoms can rapidly change and does not replace the need for objective indicators of disease progression (Stewart et al., 2022). This was found to be consistent with a handful of participants in this study that believed that a short course of antihypertensives would control their blood pressure long-term. Other participants reported that they didn't feel a need to take their antihypertensives since they did not feel sick and had no symptoms.

#### **Transportation**

Several study participants considered their medication adherence negatively impacted by transportation difficulties. These participants were older and retired, mostly relying on family or friends for rides. When they were not available, participants used public transportation or paid to use rideshare apps. Use of public transportation was discouraged by safety concerns, unfavorable weather, and unreliable schedules. Participants reported that their income was not enough to support the frequent use of rideshare apps. These findings correlated with the literature concerning barriers to adherence. A study by Xie et al. (2019) showed that the use of 90-day

refills, medication delivery by mail correlated with greater medication adherence. Findings by Fernandez-Lazaro et al. (2019) found that the two most reported socioeconomic barriers to adherence were difficulty affording medication and transportation to the pharmacy. However, project participants reported that mail delivery was not a readily available at their pharmacies.

#### **Multidimensional Approach**

Results of this QIP showed that low-income minority patients have several concerns affecting medication adherence. To be effective, several researchers emphasized that efforts to increase adherence should consider local barriers and be tailored to patient health literacy levels. According to Ogungbe et al. (2021), interventions to increase medication adherence in the LMICs were more effective when they incorporated multiple approaches and considered population-specific needs. The Centers for Disease Control and Prevention (2017) also supported the use of two or more interventions and suggested that different populations required different tools to increase medication adherence. This sentiment was echoed by Kleinsinger (2018), which suggested that multifaceted interventions were more effective in a Cochrane review examining nonadherence in hypertensive patients. The Cochrane review studied included a multi-step approach using: EHRs to identify vulnerable patients, patient outreach efforts, ancillary staff to encourage appointments, clinical pharmacist counseling, case managers, education classes, guidelines & algorithms to guide treatment, and physician counseling on improving patientprovider relationships (Kleinsinger, 2018). These efforts increased Kaiser Permanente Northern California hypertension control rates above 80%, compared with the local control rate of about 65% or less (Kleinsinger, 2018). According to Malik & Kumari (2020), other interventions to increase adherence include elimination of unnecessary medications, use of extended-release medication, addressing side effects, periodic medication reconciliation, regular appointments,

involvement of family or community support, and digital health resources. Findings by Washburn & Thompson (2020) indicate that long-term adherence may not be sustained if only some of the medication adherence barriers are addressed. Thus, it is suggested that interventions to increased medication adherence take multiple factors into account and include more than one approach.

#### Limitations

When this project topic was originally selected, a larger number of Hispanic patients were seen in the clinic. Senate Bill 1718 was passed in Florida this July, requiring most hospitals to ask for immigration status and businesses to determine employment eligibility using a federal online database (Romo, 2023). This negatively impacted the employment and medical care of undocumented immigrants statewide. This bill is theorized to have resulted in fewer Hispanic patients seeking medical care at the clinic. Project findings may have been limited by language barriers, lack of randomization, busy clinic schedule, patient participation difficulties, and an unexpected reduction in Hispanic patients at the clinic.

Many patients were at risk for not following up after taking the pretest questionnaire and several took longer than anticipated to complete the posttest. Regarding demographics, more patients could have been included if the study was able to accommodate the Urdu language. It is also recommended that future studies categorize participant income using narrower brackets. Project sample size consisted of 14 participants from the same clinic. A larger sample size or one including patients from multiple clinical settings could have contributed to a more reliable statistical significance.

#### **Implications for Nursing Practice**

This study may have the following possible implications for nursing practice: increase awareness of medication nonadherence, improve provider knowledge of interventions to increase medication adherence, and improve provider knowledge of the barriers to medication adherence the low-income minority population experience. This project helped create dialogue on a topic considered uncomfortable for many patients and providers. The project findings were consistent with the literature regarding barriers to equitable healthcare delivery for the low-income minority population. This study helped understand how providers can address medication nonadherence keeping population-specific barriers in mind. The educational pamphlet approach is more feasible for clinics with budgetary limitations and technology-challenged patients. This approach can be tailored to suit the clinical settings, health literacy levels, and preferred language of patients. Moreover, this study demonstrates the importance of measuring medication adherence using a screening tool with a more neutral tone to reduce bias.

Expansion of this quality improvement project is highly encouraged. Further research is suggested to foster evidence-based practice and collaboration among providers. It is important that providers practice socially conscious care but not avoid approaching stigmatized topics. Medication nonadherence is an issue with several influencing factors; the potential for improvement exists at the organizational, team, and individual level. However, it is important to shift the patient-provider dynamic to one that is focused on findings solutions instead of who to blame. Several project participants verbalized that they felt ashamed of not being able to afford or access their medications. Some participants described that they did not remain adherent because they were unaware that there were other options available when certain antihypertensives caused unwanted side effects. Framing patients' care as a joint patient-provider

effort was found to facilitate open communication and encourage hands-on involvement of patients in their healthcare decisions.

Disseminating project findings is an important step towards improving patient outcomes and creating accessible healthcare. Project dissemination and outcomes will be presented at the clinic in which the project took place to allow for organizational change. Additionally, project findings and recommendations will also be discussed at a project symposium at Florida International University. The project will also be submitted for oral presentation at the Preventive Cardiovascular Nurses Association's (PCNA) Annual Symposium on Cardiovascular Nursing. This presents an opportunity for potential publication in the Journal of Cardiovascular Nursing.

#### Conclusion

Medication nonadherence is an underreported issue affecting patients and their families, providers, stakeholders, and entire health systems. Though medication adherence is an extremely common issue, healthcare providers may dismiss nonadherence as solely an issue of patient behavior. Research demonstrates that multiple systemic issues contribute to medication nonadherence. Low-income minority patients are particularly affected by the medical and financial burden of medication nonadherence. Studies discussing interventions to increase medication adherence are limited, especially studies including this population. This quality improvement project examined whether English and Spanish versions of an educational pamphlet result in increased medication adherence. This project aims to highlight the contributing factors, prevalence, and evidence-based interventions to address medication nonadherence therefore increasing the prognosis and quality of life of these patients.

In terms of results, significant improvement occurred in the systolic pressure scores. Although the diastolic and MARS-5 scores also improved, these did not change significantly. Despite its small sample size, this project was able to demonstrate some findings consistent with literature regarding medication adherence patterns. The implementation created open dialogue with patients of diverse backgrounds regarding cultural beliefs about medication. Both barriers and facilitators to medication adherence were identified and discussed. Although patients adherent with their antihypertensives did not qualify for study participation, many offered suggestions based on their own methods of maintaining medication adherence. The insight provided by participants will help create change for some of the most vulnerable groups in healthcare and remove some of the stigma associated with nonadherence.

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#### **Appendix A: Letter of Institutional Support**



To whom it may concern:

I am writing to express UHI Community Care Clinic's support for the proposed project by Julissa Leiva. This project aims to determine whether English and Spanish versions of an educational pamphlet result in increased medication adherence in the low-income minority population at UHI clinic. The project is titled "Increasing Medication Adherence in Low-Income Minority Patients: A Quality Improvement Project". We will provide the necessary contact data as well as administrative support for the proposed project.

This letter confirms that I, as an authorized representative of UHI Community Care Clinic, allow Julissa Leiva to implement the proposed quality improvement project or evidence-based project activities at UHI Clinic. These activities may commence after the DNP student has consulted with Florida International University IRB about the proposed project.

UHI Clinic provides free healthcare to the uninsured and under-served population of South Florida. The mission of UHI Clinic is "to provide free healthcare services to the underserved population of South Florida regardless of their ethnicity, national origin, sexual orientation, or religious and political affiliations". The clinic is committed to health education, mentorship to students, and a site for clinical training for healthcare programs. UHI Clinic also works with different organizations to research minorities and underserved people by providing vital data and other information.

Please contact me if you have any questions. I can be reached at <u>samirak@uhiclinic.org</u> or at (305) 620-7797.

Sincerely,

Samira Khan

#### **Appendix B: IRB Approval**



#### **MEMORANDUM**

To:	Dr. Jean Hannan	
CC:	Julissa Leiva	
From:	Carrie Bassols, BA, IRB Coordinator	
Date:	July 31, 2023	
Proposal Title:	"Increasing Medication Adherence in Low-Income Minority Patients: A Quality Improvement Project"	

The Health Sciences Institutional Review Board of Florida International University has approved your study for the use of human subjects via the **Expedited Review** process. Your study was found to be in compliance with this institution's Federal Wide Assurance (00000060).

IRB Protocol Approval #:	IRB-23-0414	IRB Approval Date:	07/31/23
TOPAZ Reference #:	113416	<b>IRB</b> Expiration Date:	07/31/26

As a requirement of IRB Approval you are required to:

- 1) Submit an IRB Amendment Form for all proposed additions or changes in the procedures involving human subjects. All additions and changes must be reviewed and approved by the IRB prior to implementation.
- 2) Promptly submit an IRB Event Report Form for every serious or unusual or unanticipated adverse event, problems with the rights or welfare of the human subjects, and/or deviations from the approved protocol.
- 3) Utilize copies of the date stamped consent document(s) for obtaining consent from subjects (unless waived by the IRB). Signed consent documents must be retained for at least three years after the completion of the study.
- 4) **Obtain continuing review and re-approval of the study prior to the IRB expiration date.** Submit the IRB Renewal Form at least 30 days in advance of the study's expiration date.
- 5) Submit an IRB Project Completion Report Form when the study is finished or discontinued.

HIPAA Privacy Rule: N/A

Special Conditions: N/A

For further information, you may visit the IRB website at http://research.fiu.edu/irb.

#### **Appendix C: Recruitment Flyers**



## **RESEARCH VOLUNTEERS NEEDED**

# Do you have high blood pressure? Do you struggle to take your medications as directed?

Florida International University is working with UHI Community Care Clinic to conduct a voluntary research study on increasing medication adherence.

You may qualify to participate in this research study if you:

- $\Box$  Are an adult with high blood pressure
- □ Have been prescribed at least one medication for high blood pressure
- □ Speak English or Spanish

Eligible participants will receive the following at no cost:

- □ Blood pressure monitoring
- □ Patient education on how to manage your blood pressure

# To learn more, please ask for nurse practitioner Julissa Leiva at or jleiv005@fiu.edu



# SE NECESITAN VOLUNTARIOS PARA UN ESTUDIO

# ¿Tiene la presión arterial alta? ¿Le cuesta tomar sus medicamentos según las indicaciones de su doctor?

La Universidad Internacional de la Florida esta trabajando con la Clinica de Cuidado Comunitario de UHI para realizar un estudio voluntario sobre mejorar la adherencia al tratamiento farmacológico en pacientes de minorias y bajo ingreso

Usted puede calificar para participar en el estudio si:

- □ Es un adulto con presión arterial alta
- Ha sido prescrito al menos un medicamento para la presión arterial alta
- □ Habla Ingles o Español

Los participantes elegibles recibirán lo siguiente sin costo alguno:

- □ Monitoreo de la presión arterial
- Educación al paciente sobre como controlar su presión arterial

Para obtener más información, por favor comuníquese con la enfermera especializada Julissa Leiva al XXXX o jleiv005@fiu.edu

#### **Appendix D: Educational Pamphlets**

# What can we do about medication nonadherence?

- Combine eligible medications into single pills.
- Take notes during appointments and use refill reminders, mobile phone alarms, and pillboxes.
- Look for local medication savings programs, cost-saving apps, or manufacturer coupons available for eligible medications.
- Keep an updated list of medications on a mobile phone to help with medical appointments and refill maintenance.
- Establish a transparent and open relationship with medical providers.

# Patients are at increased risk of medication nonadherence if they...

- miss appointments or refills
- lack medication coverage
- have multiple medical conditions
- have cultural or language barriers
- don't trust their medical provider
- don't think the medication will work
- have visual challenges
- are forgetful

# What is medication adherence?





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# Medication adherence occurs when patients take their medications as prescribed by their medical provider.



Medication nonadherence occurs when patients:

- do not fill their prescriptions,
- stop treatment early,
- skip doses, or
- alter the amount of medication they take.

Medication nonadherence can be **intentional** or **unintentional**. Patients may:

- forget to take their medication,
- experience side effects,
- distrust the medication, or
- stop taking them due to costs.

# Why is medication <u>non</u>adherence an issue?

- Approximately 40 to 50% of chronically ill patients deviate from prescribed medication regimens.
- Medication nonadherence is associated with increased medical costs, emergency room visits, and hospital readmissions, as well as disease progression, lower quality of life, and higher mortality.
- It is estimated that medication nonadherence results in 125,000 deaths annually and at least 10% of hospitalizations in the United States.
- Most medication nonadherence occurs in patients with high blood pressure, which correlates with increased incidence of cardiovascular disease, chronic kidney disease, dementia, and death.
- Patients may not bring up medication nonadherence because they fear their provider will not approve. <u>However</u>, this does not allow the provider to offer possible solutions.

### ¿Qué se puede hacer al respecto?

- Las soluciones para mejorar la adherencia al tratamiento farmacológico incluyen;
  - la combinación de medicamentos elegibles en pildoras individuales,
  - recorcatorios de resurtir,
  - avisos en teléfonos móviles,
  - pastilleros,
  - o tomar notas durante las citas con su medico.
- Pueden haber programas locales de ahorro de medicamentos, aplicaciones de ahorro de costos o cupones de fabricantes disponibles para medicamentos elegibles.
- Es important establecer una relacion transparente y abierta con el proveedor medico.

Los pacientes corren con mayor riesgo de falta de adherencia al tratamiento farmacológico cuando:

- no asisten a sus citas medicas
- no resurten sus recetas
- no tienen cobertura de medicamentos
- tienen m
   últiples condiciones de salud
- enfrentan barreras culturales o de idioma
- no confian en su proveedor medico.
- no creen que sus medicamentos funcionaran
- tienen descapicidad visual
- son olvidadizos

# Qué es la adherencia al tratamiento?





## La adherencia a medicamentos

ocurre cuando los pacientes toman sus medicamentos según las intrucciones de su proveedor médico.



#### La no adherencia a medicamentos ocurre cuando los pacientes:

- no surten las recetas,
- suspenden el tratamiento antes de tiempo,
- se saltan dosis,
- o alteran la cantidad de medicamento que toman.

La no adherencia al tratamiento farmacológico puede ser **intencional** o **no intencional**. Los pacientes pueden:

- olvidar tomar sus medicamentos,
- sufrir efectos secundarios,
- desconfiar de los medicamentos,
- o dejar de tomarlos debido a los costos.

# ¿Por qué es importante?

- Aproximadamente 40 a 50% de los pacientes con enfermedades crónicas se desvían de los regímenes de medicamentos recetados.
- La falta de adherencia a los medicamentos está asociada con mayores costos médicos, visitas a la sala de emergencias y reingresos al hospital. También se asocia con progresión de la enfermedad, peor calidad de vida y mayor mortalidad.
- La falta de adherencia a los medicamentos está asociada con 125,000 muertes anuales y al menos 10% de las hospitalizaciones en los Estados Unidos.
- La mayoría de las faltas de adherencia a los medicamentos ocurren en pacientes con presión arterial alta. El descontrol de la presión arterial está asociada con una mayor incidencia de enfermedad cardiovascular, enfermedad renal crónica, demencia y muerte.
- Es posible que los pacientes no mencionen la falta de adherencia al tratamiento farmacológico porque temen que su proveedor medico no lo apruebe. Sin embargo, esto no permite que el proveedor ofrezca posibles soluciones.