Enhancing Medication Adherence for Class II Medications Aligned with the Joint Commission Standards to Improve Patient Outcomes: 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

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By

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Approval Acknowledged: 

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Abstract

This quality improvement project aims to evaluate whether implementing strategies aligned with Joint Commission standards could enhance medication adherence among patients prescribed Class II medications, ultimately improving patient outcomes. The hypothesis posited those structured interventions- such as patient education, provider engagement, reminder systems, and adherence tracking- would result in higher adherence rates and better clinical outcomes compared to initial review. A pre and post survey was used over 12 weeks in an outpatient psychiatric setting on 25 participants that are prescribed Class II medications. The methods include targeted educational sessions, implementation of medication reminder tools, and regular follow up appointments to monitor compliance and address barriers. Data was collected through medical records review, self-reported adherence assessments, and prescription refill rates. Anticipation that the results will indicate a statistically significant improvement in medication adherence post intervention, along with reported overall patient satisfaction. The project's findings support the effectiveness of structured, evidence-based strategies in promoting adherence to Class II medications and highlight the need for ongoing, multidisciplinary approaches to sustain these outcomes. The results have implications for improving adherence and populations at risk of non-compliance.

Keywords: class II medications, medication adherence, quality improvement, patient education, mental health, adherence monitoring

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Introduction

Problem Statement

There are a few challenges that patients face when prescribed Class II medications, which typically include substances with a high potential for abuse. Patients who are prescribed Class II medications often struggle with adherence due to the complex scheduling, side effects, or even possibly the stigma of being on controlled substances (Aremu et al., 2022). Poor medication adherence leads to increased health risks and suboptimal treatment outcomes. Unfortunately, many health care providers do not follow the standardized approach aligned with Joint Commission standards which leads to the inconsistency of how medication adherence is addressed. This lack of standardized practice causes gaps in patient education, follow-up appointments, and monitoring (Preuss, Kalava & King, 2023). Education is especially critical with class II medications where misuse or underuse can result in significant health complications.

Scope of the Problem

The problem of medication adherence, especially Class II medications, is bigger than we would think because these medications are often used for pain management, attention deficit hyperactivity disorder (ADHD), and other serious conditions that have a high risk for misuse and dependency (Bauer et al.,2019). It affects a large number of individuals in the United States and globally. Nonadherence is associated with increased relapses, suicidal attempts, involuntary hospitalizations, homelessness, increased healthcare costs, and emergency room visits (Bauer et al., 2019). Nonadherence will increase the risk of poor healthcare outcomes due to ineffective treatment when patients do not take their medications as prescribed, their conditions may

worsen, leading to more aggressive treatments. The misuse of Class II medications can lead to legal and ethical issues for both the healthcare provider and the patient.

Significance

By implementing an adherence survey for patients on Class II medications directly improves patient outcomes by ensuring the intended therapeutic effects of these treatments. Patients with ADHD or other conditions requiring these medications, are at risk for unmanaged symptoms, reduced quality of life, and potential complications when adherence is poor. By addressing barriers to adherence this project will promote patient empowerment, reduce adverse outcomes, and improve symptom control.

This project emphasizes the pivotal role of nurses, especially APRNs, in improving medication adherence. Expected impacts on nursing practice include enhancing patient education skills and expanding use of evidence-based practice. Nurses will gain tools to effectively communicate the importance of adherence and address patient concerns while incorporating proven interventions.

The project's impact extends to the healthcare system by reducing the financial and operational burdens associated with non-adherence. Some of the benefits that are included will be decreased healthcare costs, safe and effective use of high-risk medications, and enhancing regulatory compliance with the Joint Commission standards for medication safety, avoiding potential penalties.

Consequences of Not Addressing the Problem

If providers do not address medication nonadherence for Class II medications the cost can be profound for both individuals and societal levels. In 2022, the United States (U.S.) saw over

100,000 drug overdose deaths with opioids being a leading cause (Preuss, Kalava & King, 2023). Medications like opioids can lead to accidental overdoses which have been a major driver of the opioid crisis. In 2015, 70% of the global burden of disease associated with illicit drug use was attributable to opioid use (Harker et al .,2020) This problem can increase morbidity and mortality because there will be a decline in healthcare outcomes due to untreated chronic pain, unmanaged ADHD, or insufficient control of anxiety or other conditions that can lead to significant mental and physical health deterioration (Aremu et al .,2022). Healthcare costs are higher today because the vast majority of non-adherent patients often end up requiring more frequent medical care, including ER visits, hospitalizations, and surgeries to address the complications from poor management of their conditions. There's an estimate of 100 billion to 300 billion annual healthcare costs from patient nonadherence in the US healthcare system due to avoidable healthcare utilization (Preuss, Kalava & King, 2023). The Centers for Disease Control and Prevention believe that there is absent monitoring on the prescription and distribution of controlled substances, including those prescribed for medical use, which has the potential for abuse, and this causes the continuation of misuse to elevate (Preuss, Kalava & King, 2023).

Summary of Literature

Search Strategy of Literature

A comprehensive literature search was conducted to identify evidence-based studies, quality improvement initiatives, and clinical guidelines related to medication adherence for Class II medications, including opioids and stimulants. The search focused on identifying barriers to adherence, effective interventions, patient education strategies, and alignment with the Joint Commission standards on medication management and safety. Key databases searches include Pub Med and Google Scholar for relevant literature. Search terms and combinations include

"medication adherence", "Class II medications", "schedule II-controlled substances", "stimulants", "patient education", "The Joint Commission", and "quality improvement". Boolean operators were used to refine the search and ensure a comprehensive yield of relevant articles. Reference management software such as EndNote was utilized to organize citations and PRISMA Framework was used to document the selection and review process of the literature.

Inclusion Criteria

Patient inclusion are 25 adults over the age of 18 that have been on Class II medications for over a year. Consent needs to be signed, patients need to agree to follow through with the survey questions and attend follow-up sessions.

Exclusion Criteria

Exclusion are patients under the age of 18. Patients that have recently been prescribed Class II medication for less than a year. Those patients that don't consent or are not willing to fill out the surveys completely every month. Non-English speakers if translation services are unavailable.

Advanced Literature Review

Common Medication Adherence Disorders

Medication adherence remains a significant challenge across multiple chronic disease states, with considerable implications for patient outcomes and healthcare systems (Preuss, Kalava & King, 2023). Among the most affected conditions is hypertension, where poor adherence contributes to inadequate blood pressure control and heightened risk of cardiovascular morbidity and mortality (Preuss, Kalava & King, 2023). Similarly, type II Diabetes mellitus

demonstrates suboptimal adherence rates, often due to complexity of pharmacological regiments, polypharmacy, and the necessity for concurrent lifestyle modifications. Psychiatric disorders, including schizophrenia, bipolar disorder, and major depressive disorder, are particularly susceptible to not adherence, frequently influenced by factors such as impaired insight, cognitive deficits, adverse medication effects, and societal stigma (Aremu et al .,2022). In the contents of chronic respiratory diseases such as asthma and chronic obstructive pulmonary disease (COPD), patients commonly underutilized inhaled therapies, leading to preventable exacerbation and hospitalization (Aremu et al., 2022). Moreover, chronic pain disorders often exhibit medication adherence challenges stemming from concerns about long term toxicity, treatment fatigue, or potential or dependency (Harker et al .,2020). Recognizing these patterns of non-adherence is essential for developing targeted, evidence-based interventions that align with regulatory standards and promote sustained therapeutic engagement.

Purpose

The purpose of this study is to determine whether implementing strategies aligned with Joint Commission standards to enhance medication adherence in patients prescribed Class II medications improves patient outcomes.

PICO

This study focuses on a **Population** of 25 adult patients who have been prescribed Class II medications, such as stimulants, which are known for their therapeutic importance but also carry a high risk for misuse and non-adherence. The primary **intervention** involves implementing structured strategies aimed at enhancing medication adherence, including patient education, follow up reminders, and medication counselling aligning with evidence-based

guidelines. The effectiveness of these strategies will be evaluated by **comparing** adherence levels before and after implementation, using data gathered from a pre impulse survey. The intended **outcome** is to improve overall patient adherence to their prescribed medication regimen, thereby promoting better health outcomes, reducing the risk of adverse events, and aligning with the Joint Commission standards for medication safety and patient centered care.

Definition of Terms

Medication adherence- the extent to which a person's behavior or actions corresponds with taking a medicine optimally agreed with their health professional (While, 2020).

Class II medications- also known as Schedule II drugs, are at high risk for both physical and psychological dependence. They have a high capacity for both use disorder and misuse (Preuss, Kalava, & King, 2023).

Medication compliance- the degree or extent of conformity to the recommendations about the day-to-day treatment by the provider with respect to the timing, dosage, and frequency.

Conceptual Underpinning and Theoretical Framework of the Project

The theoretical framework that aligns with medication adherence is the Health Belief Model (HBM). The Health Belief Model helps explain the reasoning why patients may or may not take their medication consistently and it offers insights into designing interventions that address these factors (Parwati et al.,2021). HBM is based on the idea that personal beliefs and perceptions about one's health condition are the reasons why individual health-related behaviors occur (Parwati et al.,2021). HBM provides a structured approach for identifying and addressing the psychological and practical factors that influence adherence (Parwati et al.,2021).

HBM will inform medication adherence by identifying the patient's belief about their condition, the reasoning behind the prescribed medication, and any perceived barriers to adherence, like cost, inconvenience, or side effects (Parwati et al.,2021). HBM focuses on creating targeted educational and motivational strategies. Encouraging and educating patients on how adherence reduces health risks and improves outcomes will shift perceptions to increase patient engagement. To adhere to medications, the HBM framework uses cues to action, which are like reminders that prompt behavior. Pill organizer tools, text messages, and scheduled follow-ups with providers can ensure patients are receiving ongoing personalized cues to adhere to their medications (Parwati et al.,2021). Healthcare providers who are aware of the HBM framework principles better understand the patient's struggle with medication adherence. With this knowledge providers can address patients' specific beliefs and encourage adherence through positive framing and supportive conversations. Surveys and adherence rates gathered through feedback on patients will provide their perceptions around susceptibility, severity, beliefs, and barriers to medication adherence (Parwati et al.,2021).

A conceptual framework that focuses on improving medication adherence is the Capability-Opportunity-Motivation-Behavior (COM-B) Model of Behavior Change. This framework emphasizes behavior (medication adherence) is influenced by three major components: Capability, Opportunity, and Motivation (Buchanan et al.,2021). Capability refers to the physical and psychological ability to adhere to prescribed medications, meaning patients can understand the purpose of taking a medication and how to follow the dosing instructions (Buchanan et al.,2021). Opportunity alludes to external factors that enable or prevent medication adherence. Motivation allows patients to reflect on their beliefs by acknowledging the importance of adherence and better health outcomes (Buchanan et al.,2021).

Educational material and follow-up sessions will improve psychological capability, so patients have a better understanding of the medications prescribed. COM-B model uses motivational interviewing and reinforcement to strengthen both reflective and automatic reasoning to adhere to medications more intentional and habitual behavior (Buchanan et al.,2021). Using the COM-B model provides a holistic framework addressing psychological, environmental, and behavioral factors in medication adherence.

Methodology

Setting

Parent's Information & Resource Center, Inc (PIRC) is a community medical clinic that offers expert mental health services, support, and resources to help adults and children with mental health issues.

Sample/ Participants

Dr. Michele Byrd PMHNP-BC and Dr. Fred Jean MD- as a healthcare provider their role is vital to educating, communicating, and supporting the patients with class II medication adherence. Providers should ensure that patients understand their treatment and address any questions or concerns that may impact adherence. Providers should adjust treatments or offer alternative options if adherence is an issue. Healthcare providers can implement motivational interviewing to address barriers and assist patients in setting achievable adherence goals.

Patient inclusion are 25 adults over the age of 18 that have been on Class II medications for over a year. Consent needs to be signed, and patients need to agree to follow through with the survey questions. Exclusion are patients under the age of 18. Patients that have recently been prescribed Class II medication for less than a year. Those patients that don't consent or are not

willing to fill out the surveys completely every month. Non-English speakers if translation services are unavailable.

Project Design

The quality improvement project employed a quasi-experimental, pre-survey/ post-survey study designed to evaluate the effectiveness of an educational intervention aimed at enhancing medication adherence among adults prescribed Class II medications. This methodological approach allowed for the measurement of participant knowledge before and after the intervention, providing a structured means of assessing the impact of the educational content. The pre-survey was administered in-person using a paper-based format prior to the intervention, serving as a baseline to gauge participants' existing understanding and perceptions of medication adherence.

The educational intervention was delivered through an in-person PowerPoint presentation developed by the researcher, incorporating evidence-based information obtained from an extensive literature review. One month following the presentation a post survey was administered -again in person and on paper-to assess changes in knowledge and attitudes related to adherence practices. This design not only enabled a direct comparison of pre and post intervention data but also allows the researcher to evaluate the overall effectiveness of the intervention in a real-world clinical setting. The integration of original survey instruments and educational materials to ensure that the content was relevant, targeted, and reflective of the current best practices in medication adherence education.

Protection of Human Subjects

Data will be securely stored on an encrypted HIPAA compliant server. This ensures adherence to healthcare data privacy regulations. Any paper-based data will be kept in a locked file cabinet in a restricted access area at PIRC. By maintaining confidentiality patient identifiers will be removed or replaced with unique participant codes. To ensure confidentiality the surveys will only have patient initials and date of completion. There will be no personal information on surveys. Only authorized personnels will have access to the data.

Data Collection

The data collection and initial handling will be collected through surveys, electronic health records, and qualitative interviews. With preparation for coding, we will ensure that all data is de-identified to maintain confidentiality. Regarding data coding, the information obtained will be assigned a numerical value for ease of analysis from our closed-ended survey responses. Any missing responses are coded as unique values(eg.NA). The scores from validated instruments (MMAS-8) are calculated using their respective algorithms. Any paper-based data, trained data entry personnel will manually input responses into a secure database or spreadsheet and use double entry verification to minimize errors.

Data Analysis/ Management

Data will be securely stored on an encrypted HIPAA compliant server. This ensures adherence to healthcare data privacy regulations. Any paper-based data will be kept in a locked file cabinet in a restricted access area at PIRC. By maintaining confidentiality patient identifiers will be removed or replaced with unique participant codes. Only authorized personnels will have access to the data.

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Nursing Practice Dissemination

Findings from the study were presented to the psychiatric outpatient clinic involved. Following the successful implementation of the adherence enhancing strategies among adults prescribed class to medications, the clinic took into consideration the notable improvement in patient engagement and treatment compliance. A few of the positive outcomes were the improved patient understanding of their treatment regimens and a reduction in reported adverse events related to missed or misused doses. These findings were disseminated through interdisciplinary staff meetings and integrated into the clinical protocols, allowing for sustained practice change. This process not only validated the nursing role in quality improvement but also fostered a culture of collaboration and accountability, reinforcing the importance of evidence-based practice and outpatient psychiatric care. These findings were also presented at Florida International University's DNP symposium.

Results

Participant Demographic Information

A total of 12 participants were engaged in the process, categorized into four groups based on their level of participation and outcome: Confirmed, Denied, No Show, and Telehealth (See graph 1). Out of the 12 participants: Six participants (50%) confirmed participation in the adherence initiative. All six participants voluntarily completed the project entirely, which included an anonymous consent to complete the QI project, the completion of a pretest, a 15-minute educational presentation, and a post test. Of these six participants, 4 demonstrated improvements in adherence following a follow-up appointment, indicating the effectiveness of continued engagement and follow-up. Three participants (25%) denied participation, citing reasons such as prior experience with similar initiatives or confidence in their current regimen. One participant (8.3%) did not show up for their scheduled appointment, highlighting a gap in engagement. Three participants (25%) were transitioned to Telehealth appointments, a flexible approach that maintained continuity of care, though follow-up results varied. Two participants identified as male (33.33%) and four identified as female (66.67%) (See graph 2). The majority of the samples were between the ages of 18-40 (80%), while the remaining samples were above the age of 41(20%) (See graph 3).

Importantly, one of the confirmed participants failed to schedule a follow-up, which limits the ability to assess long-term adherence changes in that case. This points to a need for stronger systems to ensure follow-up compliance. The results show that adherence improved in 33% of the total participants (4 out of 12)—a promising outcome considering the challenges in patient engagement and the controlled nature of Class II medications. These findings suggest that

consistent follow-ups, personalized communication can positively influence adherence behavior (See graph 4).

However, the data also highlights areas for improvement, such as increasing follow-through for initial confirmations, minimizing no-shows, and re-engaging those who are initially hesitant. Future efforts might benefit from more structured tracking systems, educational support, and motivational interviewing strategies to reinforce the importance of adherence and patient involvement.

Participants Opinions on Medication Adherence in the Clinical Setting

Participant feedback from the group of 12 individuals revealed diverse opinions and barriers related to the medication adherence within the clinical setting. One participant (8%) declined to partake in the project, explaining that she had been on Class II medications for many years and did not feel the need for additional education. Two participants (17%) also opt-out, stating that they had previously participated in a similar study and were concerned that this project would be too time-consuming. One participant (8%) expressed concerns about the stigma associated with taking Class II medications, specifically mentioning fears of addiction and judgement, which led to inconsistent medication use. Additionally, three participants (25%) reported that they often forgot to take their medications daily due to their busy lifestyles and lack of consistent routines.

Presurvey and Postsurvey Score Analysis

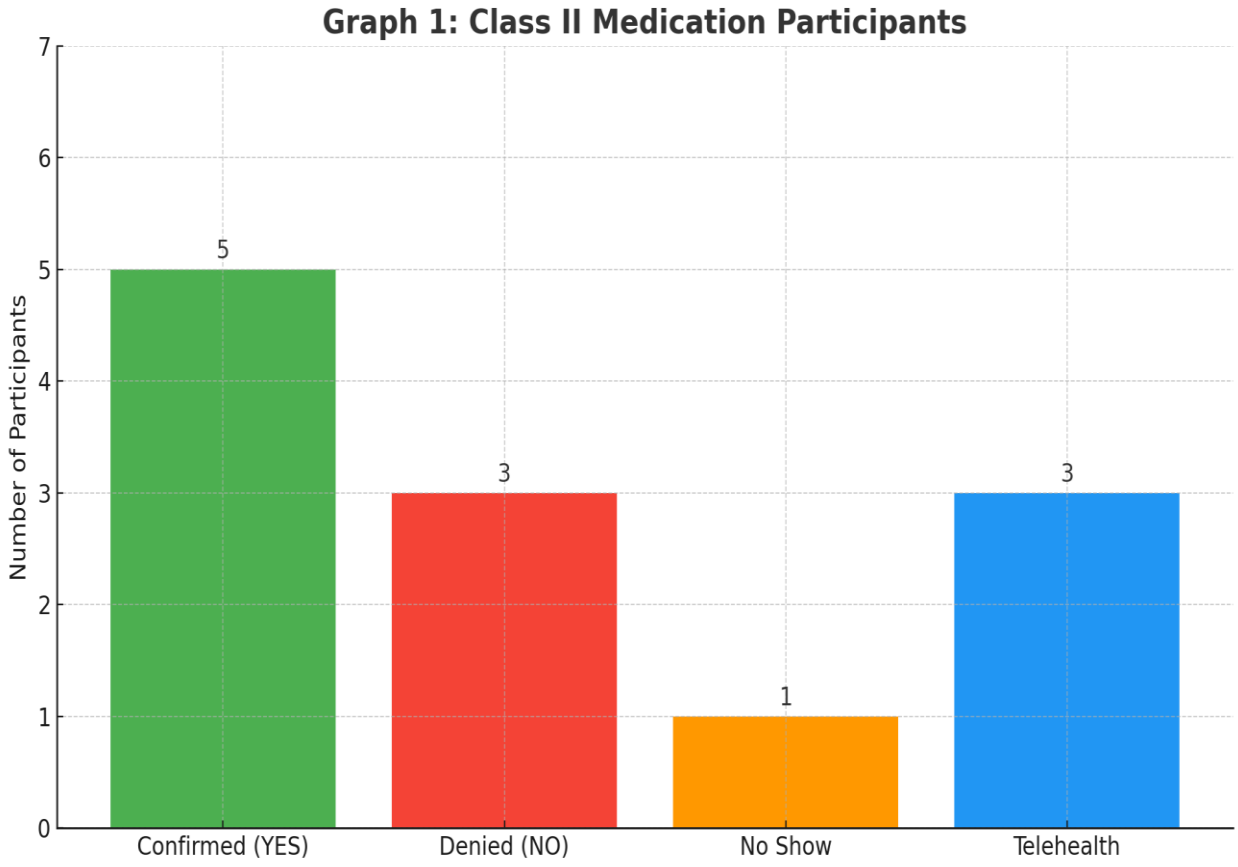
The pre survey scores among six participants were converted to percentages and analyzed. The mean score (M) was 40.56 %, indicating a low baseline level of adherence knowledge or practice period. The standard deviation (SD) was 23.52%, reflecting a wide

variation in responses, and the standard error (SE) was 9.60%, suggesting moderate variability in the samples mean estimate. The range of scores spanned from 16.67% to 73.33%, further highlighting the inconsistency in adherence behaviors across individuals.

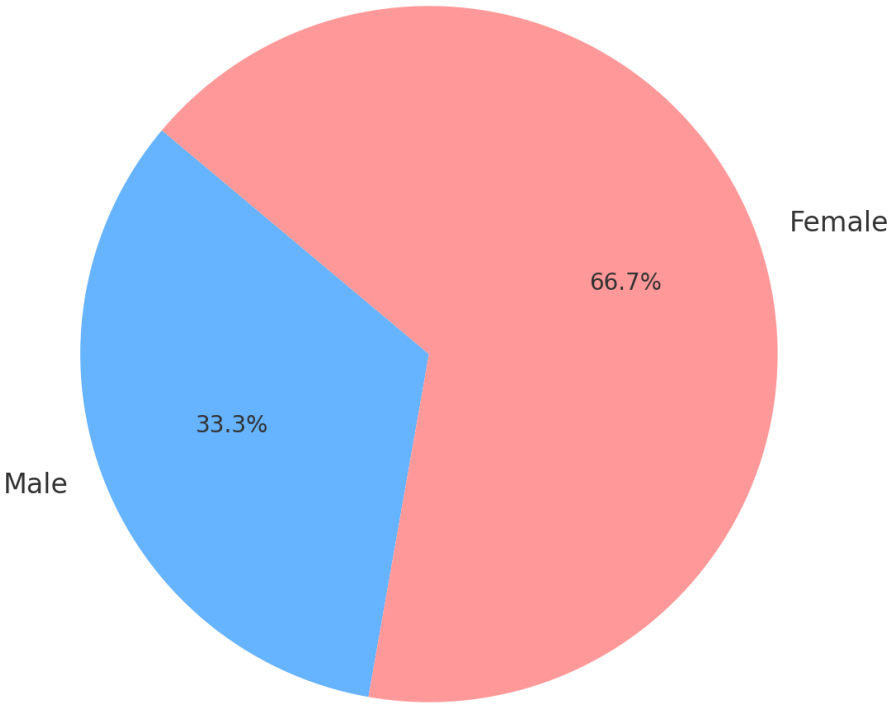
The post survey results among six participants showed a mean score of 6.67%, reflecting an overall low level of post intervention adherence understanding. The standard deviation was 9.19%, indicating some spread in scores, while the standard error was 3.75%, suggesting limited precisions in the average due to sample size. The score range spanned from 0.0% to 20%, with several participants scoring at the lowest possible level. Despite the overall low average, four participants demonstrated improvement when compared to their pre survey scores. This suggests that while the intervention did not result in uniform success across the group, it had a positive impact on a subset of individuals. The improvement seen in these participants may highlight the importance of tailoring interventions to individual readiness, learning styles, or motivational factors to enhance medication adherence outcomes more broadly.

A paired samples *t*-test was done through Microsoft Excel to determine if there were statistical evidence that the means are different between the pre-survey and post-survey. In this study the p-value of the two-tailed survey was 0.016, which is less than the specified significance level of 0.05. This indicates a statistically significant difference between the pre-survey and post-survey scores, and the null hypothesis is rejected. In this case the post-survey scores were significantly lowered, suggesting that the intervention may not have been effective overall, despite improvements in four participants. Further analysis and a revised intervention approach are recommended to support adherence across all participants

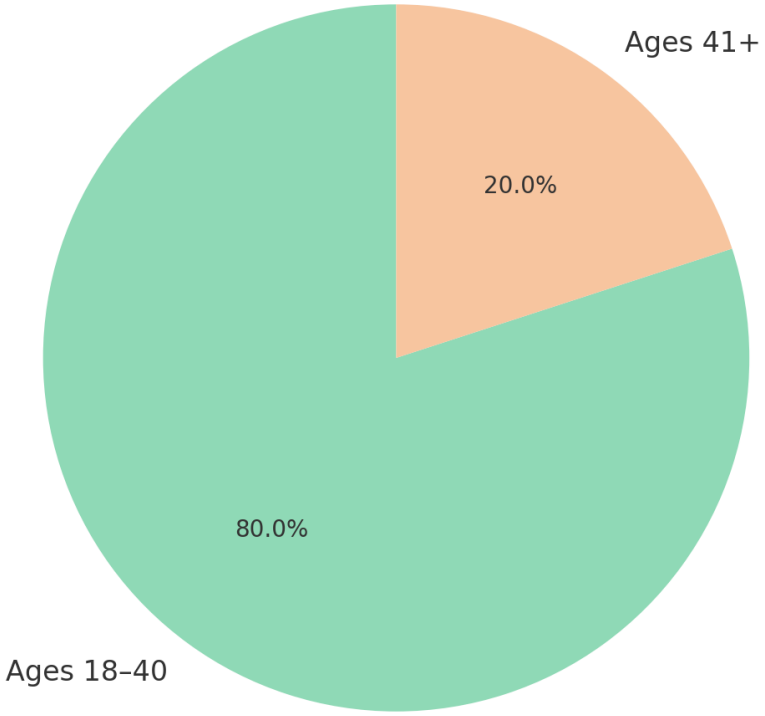
Graphs and Tables

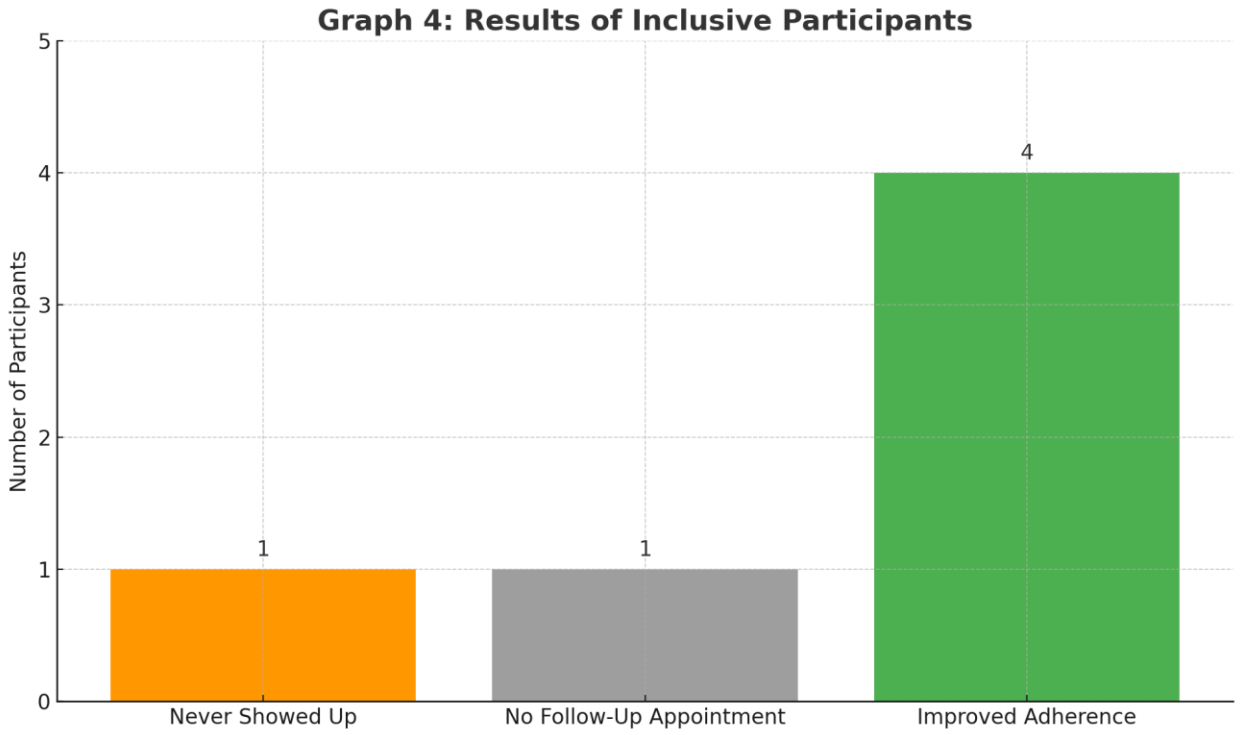


Graph 2: Participant Gender Distribution



Graph 3: Participant Age Distribution




Graph 4: Results of Inclusive Participants
Number of Participants
0
1
2
3
4
5
1
1
4
Never Showed Up
No Follow-Up Appointment
Improved Adherence

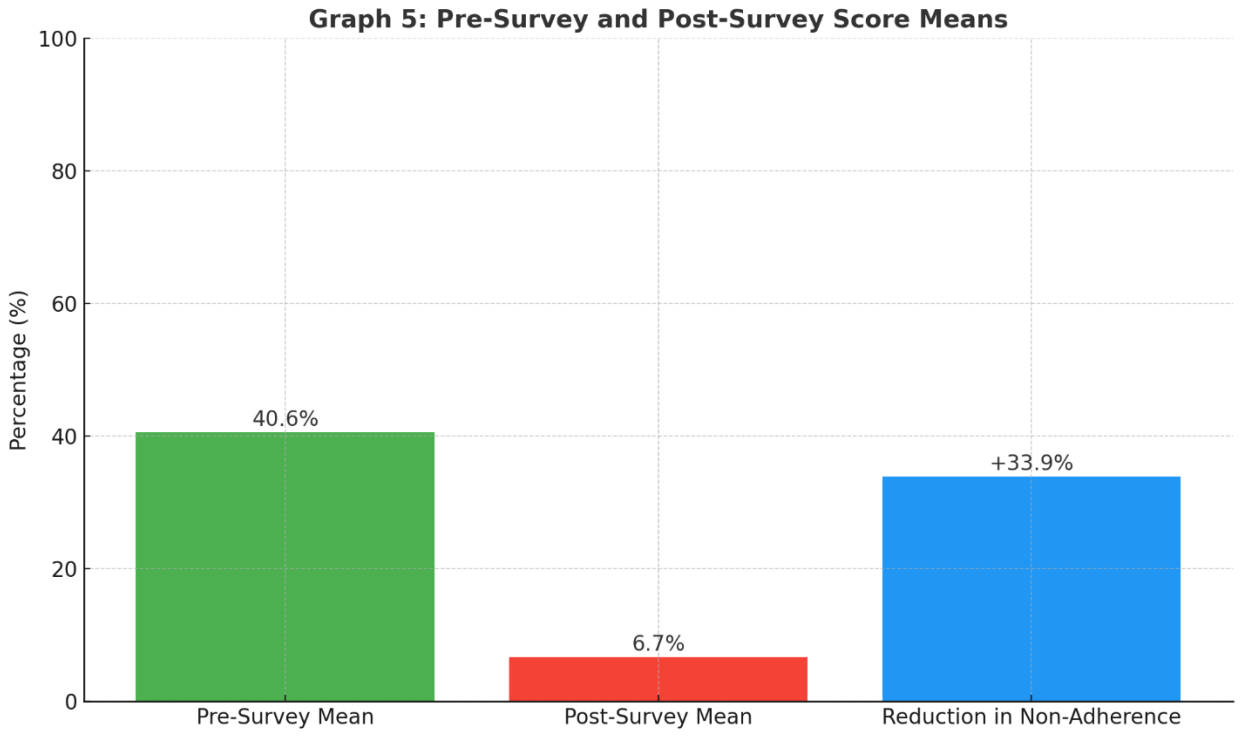

Graph 5: Pre-Survey and Post-Survey Score Means
Percentage (%)
0
20
40
60
80
100
40.6%
6.7%
+33.9%
Pre-Survey Mean
Post-Survey Mean
Reduction in Non-Adherence

Table 1. Descriptive Statistic Analysis

Survey Type	N	Mean	SD	SE
Pre-Survey	**6**	**12.17**	**7.05**	**2.88**
Post-Survey	**6**	**2.00**	**2.76**	**1.13**

Discussion

The results of this project are presumed to show a measurable improvement in medication adherence among patients prescribed Class II medications following the implementation of strategies aligned with Joint Commission Standards. These findings are strongly supported by existing literature, which highlights the effectiveness of structured interventions such as patient education, reminder systems, and provider-patient communication and improving adherence.

The findings of the quality improvement project on enhancing medication adherence among patients prescribed Class II medications aligned with several key points discussed in the reported literatures. The article “Medication adherence and compliance: recipe for improving patient outcomes” and the quality improvement project both emphasize the critical role of patient and provider education, effective communication strategies, and the use of reminder systems in improving medication adherence. Regarding the differences this literature addresses in general patient factors affecting adherence, it does not delve deeply into strategies tailored for patients with specific mental health challenges. While the quality improvement project is specifically

targeted towards those prescribed Class II medications, often found to be patients with comorbid mental health conditions, such as cognitive impairments, severe depression, and ADHD.

The article “Exploring the value of real time medication adherence monitoring: a qualitative study” and the quality improvement project share a common objective which is improving medication adherence to support better patient outcomes. Both highlight the importance of engaging stakeholders such as patients, caregivers, and health care providers in the adherence process and acknowledge the value of technology aid like reminders and monitoring systems. However, the two differ in their approach and scope. The quality improvement project takes a practical, clinical approach by implementing structured educational interventions and communication strategies in a real-world health care setting. In contrast the article adopts a qualitative research design to explore stakeholders’ perceptions of advanced real-time adherence monitoring technology, such as smart pill bottles or wearable devices. While the project uses tools like appointment reminders and patient education to improve adherence, the article emphasizes the potential of continuous data collection for timely interventions and broader health care system applications. Additionally, the article includes perspectives from insurance companies and policymakers, whereas the project focuses primarily on the provider-patient dynamic.

The literature a “Health belief model based motivational interviewing for medication adherence and treatment success and pulmonary tuberculosis patients” and the quality improvement project share the common goal of improving patient adherence through patient-centered approaches. Both implement structured interventions and emphasize increasing self-efficacy to help patients manage their medications more effectively. However, there are a few key areas that differ between the two. The article targets tuberculosis patients, focusing on

preventing transmission and resistance, while the quality improvement project addresses adherence issues related to Class II medications. Intervention delivery also differs, with the literature utilizing multiple counseling sessions delivered remotely, compared to in person education and digital reminder systems in the quality improvement project. The outcome measures vary as well, the literature uses pill counts and sputum test results, while the quality improvement project uses patient self-reports.

The potential reasoning for the similarities across all projects lie in the shared goal of improving medication adherence and ultimately enhancing patient outcomes. Each study acknowledges the complexity of adherence behaviors and emphasizes the importance of patient centered interventions, were through education, communication, reminders, or motivational support. They also all recognize the improving adherence requires active engagement for both patients and providers and that technology or structured approach can play a crucial role in this effort. However, differences merge based on the specific health conditions being addressed and different health contexts naturally shape the intervention strategies and outcome measures. Technology integration also differed with one literature highlighting advanced digital tools to collect adherence data continuously, while the quality improvement project uses simpler, more accessible methods like reminders and follow up calls. These variations highlight the importance of tailoring adherence interventions to the unique needs of patient populations, health care settings, and resource availabilities.

Limitations

While the quality improvement project demonstrated positive outcomes in enhancing medication adherence among adults prescribed Class II medications, there were several limitations that must be acknowledged. First, the small sample size of 25 participants limits the generalizability of the findings to larger or more diverse populations. Second, the reliance of self-reported adherence and survey responses introduces the potential for bias, as patients may overreport compliance due to social desirability or misunderstanding. Third, the short duration of the intervention. may not fully capture long-term adherence behaviors or sustainability of outcomes. Additionally, external factors such as changes in insurance coverage, pharmacy access, or mental health status were not controlled for or may have influenced adherence independently of the intervention. Finally, the single site design within a psychiatric outpatient setting may not reflect the challenges placed in other clinical environments, such as primary care or inpatient facilities. These limitations highlight the need for future studies with larger, more diverse samples, and longer follow-up periods to validate and expand upon the findings.

Implications for Advanced Practice Nursing

Developing and implementing a Class II medication adherence survey project will have an impact on patient education, policy development, interdisciplinary collaboration, and improve clinical care. The results may highlight gaps in patient understanding of their medications which allow advanced practice nurses to use the information to refine and tailor patient education efforts. This project will improve patient outcomes by identifying barriers to adherence and implementing effective interventions. Adherence strategies will provide insight into individual and systematic barriers to adherence that helps advanced practice nurses adopt a more patient centered approach.

Conclusion

Non-adherence to Class II medications-commonly prescribed for mental health and chronic pain- can lead to poor health outcomes, increase hospitalizations, and higher health care costs. Many patients struggle with following their prescribed regimens due to lack of education, forgetfulness, or concerns about side effects. The purpose of this quality improvement project is to determine whether implementing a structured strategy aligned with Joint Commission standards can significantly enhance medication adherence in patients prescribed Class II medications, thereby improving overall patient outcomes.

The project involves implementing evidence-based adherence strategies such as patient education, medication reminders, standardized providers patient communication, and regular follow-ups. Data will be collected through patient feedback and chart reviews. The project focuses on adult patients at PIRC who are prescribed Class II medications. A Psychiatrist, Psychiatric mental health nurse practitioner and project's DNP student are involved in the implementation and monitoring process. By improving medication adherence, this project aims to reduce avoidable complications and improve patient quality of life. It also contributes to institutional goals for patient safety, compliance with accreditation standards, and cost-effective care delivery.

Appendix A

FLORIDA INTERNATIONAL UNIVERSITY

Office of Research Integrity
Research Compliance, MARC ٤١٤

MEMORANDUM

To: Dr. Victor Delgado
CC: Rosanne Charles

From: Maria Melendez-Vargas, MIBA, IRB Coordinator

Date: March ١٧, ٢٠٢٥

Protocol Title: "Enhancing medication adherence for class II medications aligned with the Joint Commission Standards to improve patient outcomes: A quality improvement project"

The Florida International University Office of Research Integrity has reviewed your research study for the use of human subjects and deemed it Exempt via the Exempt Review process.

IRB Protocol Exemption #: IRB-٢٥-٠١١٤ IRB Exemption Date: ٠٣/١٧/٢٥
TOPAZ Reference #: ١١٥٣٢٧

As a requirement of IRB Exemption you are required to:

١) Submit an IRB Exempt Amendment Form for all proposed additions or changes in the procedures involving human subjects. All additions and changes must be reviewed and approved prior to implementation.
٢) Promptly submit an IRB Exempt 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.

Special Conditions: N/A

٣) Submit an IRB Exempt Project Completion Report Form when the study is finished or discontinued.

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

MMV/em

Appendix B

Parent's Information & Resource Center, Inc.

Parent's Information & Resource Center, Inc.
817 Dixie Highway
Pompano Beach, FL 33060
Telephone: 954-785-8285
DATE: 1/23/2025

Dr. Victor Delgado
Associate Professor
Nicole Wertheim College of Nursing & Health Sciences
Florida International University

Dear Dr. Delgado,

Thank you for inviting the Parent's Information & Resource Center Inc. (PIRC) to participate in Rosanne Charles's DNP Project. I understand that this student will be conducting this project as part of the requirement for the Doctor in Nursing Practice program at Florida International University. After reviewing the proposal of the project titled," *Enhancing medication adherence for class II medications aligned with the Joint Commission Standards to improve patient outcomes: A quality improvement (QI) project."* I have warranted her to conduct the project in this facility.

We understand that this project will be developed in the PIRC's setting and will occur in multiple sessions over the next six months. We are also aware of our staff's participation in supporting the student in completing this project, warranting access to the PIRC facility, giving consent, and delivering the pre-survey, educational intervention, and post-survey questionnaire after the initial four weeks and monthly for the six months of research. We will provide a peaceful environment to safeguard our participants' privacy and provide an adequate area for conducting the educational training.

Parent's Information & Resource Center, Inc.

This project will be conducted with the participants giving their consent. Florida International University Institutional Review Board will evaluate and approve the procedures for conducting this project. The educational intervention will be delivered in two formats:

Classroom Setting – A brief in-person 20-minute session will be conducted where the key elements of Class II medication management and information regarding cost-effective adherence programs or resources will be discussed.

Online educational Modules—For providers who prefer online learning or cannot attend the in-person session, a concise PowerPoint module that outlines the same educational content will be provided, ensuring flexible and convenient access to the material.

Given the importance of maintaining participants' confidentiality and adhering to clinic protocols, all data collected during this QI project will remain de-identified and will be used exclusively for educational and quality improvement purposes. The data will be stored on a secure laptop protected by a password. We will work closely with your team to ensure compliance with the facility policies and any necessary approvals.

We expect Rosanne Charles to behave professionally, follow office standards of care, and not interfere with typical office performance. As the clinical director of PIRC, I support the participation of our providers and staff in this project and look forward to working with you.

Sincerely,

Judith Thony (Clinical Director),

jthony@pircinc.org

Appendix C

Rosanne Charles
Florida International University
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March 24, 2025

Institutional Review Board
Parent's Information & Resource Center, Inc.
817 N. Dixie Highway, Pompano Beach Fl. 33060

Dear Members of the Institutional Review Board,

- I am writing to request a waiver of the IRB requirement for the clinical site involved in my research study titled **"Enhancing medication adherence for class II medications aligned with the Joint Commission Standards to improve patient outcomes: A quality improvement project"**. The purpose of this study is to determine whether implementing strategies aligned with Joint Commission standards to enhance medication adherence in patients prescribed Class II medications improves patient outcomes. By enhancing adherence, the study aims to reduce medication errors, prevent complications, and improve overall patient health outcomes. The study employs a quasi-experimental design with a pre- and post- intervention survey. The interventions include provider training, patient education, follow-up assessments, and medication reminder systems. Participants include Psychiatric Mental Health Nurse Practitioner, Psychiatrist, and 25 adult patients that are prescribed Class II medications.

The reason for requesting this waiver is that this study has minimal risk to participants because there are no invasive procedures, experimental medications, or significant changes to a patient's treatment. This study involves educational and behavioral interventions that pose no more than minimal risk to any participants. Participation in the intervention is voluntary, and patients can opt out without affecting their standard of care. Confidentiality and privacy are strictly maintained, with no personal identifiable information collected or disclosed.

Specifically, this study is primarily a quality improvement initiative rather than human subject research. It focuses on enhancing medication adherence through standardized strategies aligned

with Joint Commission Standards. Patients receive education, reminders, and follow-up assessments, which are standard best practices in clinical settings. Obtaining IRB approval at this clinical site would require extensive administrative processes, which could delay implementation and impact timely quality improvement efforts.

In accordance with 45 CFR 46.114, I believe that the following criteria for a waiver of IRB requirement are met:

1. **Minimal Risk**: The research involves no more than minimal risk to the participants.
2. **No Adverse Effects**: The waiver will not adversely affect the rights and welfare of the participants.
3. **Impracticality**: The research could not practically be carried out without the waiver.
4. **Equivalent Protections**: The study will still be conducted under the oversight of the primary IRB, ensuring equivalent protections for participants.

I have attached all relevant documents, including the study protocol and any supporting materials, for your review. I am happy to provide any additional information or clarification as needed.

Thank you for considering my request. I look forward to your favorable response.

Sincerely,

Rosanne Charles, MSN PMHNP-BC
DNP student
Florida International University

Appendix D

Patient Pre and Post Survey questions

Class II medication

Introduction

The primary aim of this quality Improvement project is to enhance the knowledge of adherence to Class II medication towards providers and patients to improve patient education and patient outcomes in this population.

Please answer the questions below to the best of your ability. The questions are in a variety of formats from multiple choice, true/false, open-ended questions etc…. These questions are meant to measure knowledge and perception on identification, management and patient education about adherence with Class II medications.

PERSONAL INFORMATION

1. **Gender**: Male Female Other
2. **Date of Birth**: _____
3. **Ethnicity**:

Hispanic Caucasian African American Asian Other

1. How often do you miss taking your medication as prescribed?

- o Never
- o Rarely (1-2 times per month)
- o Sometimes (1-2 times per week)
- o Often (3+ times per week)

2. In the past week, how many doses have you missed?

- o 0
- o 1-2
- o 3-5
- o More than 5

3. Have you ever missed a dose? Yes why?

4. Do you ever stop taking your medication without telling your doctor?

- o Yes
- o No

5. Do you understand the purpose and proper use of your medication?

- o Yes, completely
- o Somewhat, but I have questions
- o No, I need more information

6. Do you experience any side effects that discourage you from taking the medication as prescribed?

- o Yes
- o No

7. Has your health care provider explained how to take your medication properly (e.g. timing, food interaction)?

- o Yes
- o No

8. How satisfied are you with the communication and education provided by your healthcare provider? (0=Not satisfied at all , 10=Extremely satisfied)

- o 0-2: I receive little to no help with my medication regimen, and I often feel confused about how to take my medications properly.
- o 3-5: I sometimes receive helpful advice, but I still have questions about how to manage my medications correctly.
- o 6-8: I receive good support most of the time and generally understand how to follow my medication plan, but there are occasional gaps.
- o 9-10: I am very satisfied with the level of support, and I feel confident in managing my medication with the help of my healthcare provider.

9. Do you find it difficult to afford or refill your medications?

- o Yes
- o No

10. Have you ever skipped doses or cut pills in half to make your medication last longer?

- o Yes
- o No

11. Do you always refill your prescription on time?

- o Yes, always
- o Sometimes, I forget
- o No, I have trouble keeping track

12. Have you run out of medication before refilling?

- o Yes
- o No

13. Do you have reliable transportation to pick up your prescriptions?

- o Yes
- o No

14. Would reminders (text, phone calls, app notifications) help you remember to take your medication?

- o Yes
- o No

15. How likely or often do you use tools like reminders or apps to help you remember to take your medication?

- o Never
- o Sometimes, 2-4 times a week
- o Always, everyday

Appendix E

CITI PROGRAM

Completion Date 31-Aug-2024
Expiration Date 31-Aug-2027
Record ID 59719419

This is to certify that:

Rosanne Charles

Not valid for renewal of certification through CME.

Has completed the following CITI Program course:

Basic/Refresher Course - Human Subjects Research
(Curriculum Group)
Biomedical Human Research Course
(CourseLearner Group)
2 - Refresher Course
(Stage)

Under requirements set by:

Florida International University

CITI
Collaborative Institutional Training Initiative
101 NE 3rd Avenue, Suite 320
Fort Lauderdale, FL 33301 US
www.citiprogram.org

Generated on 16-Jul-2025. Verify at www.citiprogram.org/verify/?wfd38df67-5263-414c-bce2-ff30dd79eafa-59719419

Appendix F

FIU | FLORIDA INTERNATIONAL UNIVERSITY

CONSENT TO PARTICIPATE IN A QUALITY IMPROVEMENT PROJECT
"Useofastructurededucationalprogramorproviders toimprovepatient'sadherencetoClas II medications."

PURPOSE OF THE PROJECT

You are being asked to be in a quality improvement project. The goal of this project is to increase patients' adherence to Class II medication through a structured intervention targeting primary care providers to identify tools and guidelines that could be implemented in the primary care setting to improve patient's adherence.

NUMBER OF PROJECT PARTICIPANTS

Ifyoudecideto beinthisproject، youwillbeone of twenty-five people participating in this research project.

DURATION OF THE PROJECT

Yourparticipationwill require about١٠-٢٠ minutes of your time in the first session and ٥-١٠ minutes in the second session that will occur four weeks after your first session.

PROCEDURES

Ifyouagree to bein the project، we will ask you to do the following things:

Providers:

١. At your first session، you will complete a demographic questionnaire، which includes general information such as age، gender، position in practice، and a pre-survey with the Class II medication management guideline.
٢. In the first session، you will receive a ١٠ minutes educational program about Class II medication management guidelines، medication adherence، and patient centered care.
٣. Four weeks later، you will be asked to complete the Class II medication management post-survey.

Patient Participants:

١. At your first session، you will complete a pre-survey questionnaire، which includes Class II medication management questions and will be educated on medication adherence benefits and risks for approximately ١٠ minutes.
٢. Four weeks later، you will be asked to complete the Class II medication management post-survey.

RISKS AND /OR DISCOMFORTS

Therearenoforeseeablerisks withyou for participating in this project.

BENEFITS
The following benefits may be associated with your participation in this project: An increase in Class II medication management knowledge, which will help you to better assess medication adherence and guidelines implementations to reduce the risk of cardiovascular events. The overall objective of the program is to increase the quality of healthcare delivery, improving the health indicator of our patients, and increase patient engagement.

ALTERNATIVES
There are no known alternatives available to you other than not taking part in this project. However, if you like to receive the educational material given to the participants in this project, it will be provided to you at no cost

CONFIDENTIALITY
The records ofthis project will be kept private and will be protected to the fullest extent provided by law. If, in any sort of report, we might publish, we will not include any information that will make it possible to identify you as a participant. Records will be stored securely, and only the project team will have access to the records.

COMPENSATION & COSTS
Thereis nocostorpaymenttoyou for receiving the health education and /or participating in this project.

RIGHT TO DECLINE OR WITHDRAW
Your participation in this projectis voluntary. You are free to participate in the project or withdraw your consent at any time during the project. Your withdrawal or lack of participation will not affect any benefits to which you are otherwise entitled. The investigator reserves the right to remove you without your consent at such time that they feel it is in the best interest.

RESEARCHER CONTACT INFORMATION
If youhaveany questions aboutthe purpose, procedures, or any other issues relating to this research project, you may contact Rosanne Charles at rchar٠٧١@fiu.edu or Dr. Victor Delgado at٣٠٥-٣٤٨-٧٧٤١, vadelgad@fiu.edu.

IRB CONTACT INFORMATION
Ifyou would liketo talk with someone about your rights of being a subject in this project or about ethical issues with this project, you may contact the FIU Office of Research Integrity by phone at٣٠٥-٣٤٨-٢٤٩٤ or by email at ori@fiu.edu.

PARTICIPANT AGREEMENT
Ihave read the information inthis consent form and agree to participate in this project. I have had a chance to ask any questions I have about this project, and they have been answered for me. Iunderstand that I will be given a copy of this form for my records.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

_____ _____

Signature of Person Obtaining Consent Date

References

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