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ABSTRACT

MITIGATING RISKS TO IMPROVE HYPERTENSION
MEDICATION ADHERENCE IN A MEDICALLY
VULNERABLE POPULATION

by

Donna Hales-Teat

Chair: Carol Rossman, DNP, RN, FNP-BC, PPCNP-BC

ABSTRACT OF GRADUATE STUDENT PROJECT

Scholarly Project

Andrews University

School of Nursing, College of Health & Human Services

Title: MITIGATING RISKS TO IMPROVE HYPERTENSION MEDICATION ADHERENCE IN A MEDICALLY VULNERABLE POPULATION

Name of DNP student: Donna Hales-Teat

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Date completed: June 2023

This project assessed the effect of an evidence-based medication adherence intervention on adherence rates at a Northern Indiana clinic led by a sole nurse practitioner, receptionist, and continuous rotation of graduate nursing students from several nursing programs in the Northern Indiana area. Patient education and comprehension were poor in terms of understanding disease process, treatment options, and disease management that led to poor communication with the medical provider. The process and steps in which patients matriculate through was described by Johnson's (2002) Medication Adherence Model (MAM) with concepts of purposeful action, pattern behavior, and feedback; these helped to construct, steer, and conclude the interventional effects on medication adherence. The intervention involved a) a change to the clinic's care

process and b) 30-minute case-management educational sessions for patients scheduled at the next patient appointment concerning hypertension disease, hypertension medications, self-management, adhering-aiding tools, and provider communication. There was a statistically significant improvement in adherence rates of awareness of medication adherence.

IRB approval was obtained from La Porte Family Wellness and Andrews University, and I, the project manager, obtained survey data using the MMAS-4 questionnaire between February and April 2023.

Keywords: medication adherence, lack of adherence, medication education, vulnerable patients

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MEDICATION ADHERENCE IN A MEDICALLY
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A Scholarly Project

Presented in Partial Fulfillment

of the Requirements for the Degree

Doctor of Nursing Practice

by

Donna Hales-Teat

June 2023

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TABLE OF CONTENTS

LIST OF TABLES	vi
LIST OF FIGURES	vi
LIST OF ABBREVIATIONS	vii
Chapter	
1. INTRODUCTION	1
Background	2
Rationale	3
Significance of Project	4
Project Question	5
Purpose	5
PICOT Questions	6
2. LITERATURE REVIEW	7
Conceptual Definitions	7
Theoretical Framework	8
Purposeful Action	10
Patterned Behaviors	10
Feedback	11
Conclusion	11
Review of Literature	11
Healthcare Inequalities	12
Patient-Provider Confusion/Communication	14
Increased Adherence Interventional Components	14
Practice-Setting Adherence-Improvement Strategies	15
Measuring Adherence	16
Conclusion	16
3. METHODOLOGY	18
Project Design	18
Population	18
Setting	19
Recruitment	19

Inclusion and Exclusion Criteria	19
Inclusion	19
Exclusion	20
Sample Size	20
Ethics	20
Tools and Measurement.....	21
Variables	21
Participant Demographics.....	21
Scoring and Interpretation	22
Internal/External Validity	22
MMAS-4 Scale Reliability/Validity	23
ASK-12 Tool Reliability/Validity	23
Pill Count Adherence Ratio.....	23
Questionnaires	23
First Tool Component	24
Second Tool Component.....	24
Implementation.....	26
The Medication Adherence DNP Intervention	26
Intervention.....	27
Evaluation Procedure.....	27
Data Collection	27
Statistical Analysis.....	28
4. RESULTS.....	30
Participant Demographics	30
Statistical Analysis	32
Comparison of Blood Pressure Readings Pre- and Post-Intervention.....	35
Pill Count Adherence Ratio Analysis.....	36
5. DISCUSSION	37
Summary of Findings	38
Project Analysis and Commentary	39
Strengths.....	39
Limitations	40
Implications.....	41
Dissemination Plan	41
Recommendations.....	41
Sustainability	42
Evaluation.....	42
Self-Scholarly Analysis.....	43
Essential I.....	43
Essential II.....	43

Essential III.....44
Essential VII44

Appendix

A. QUESTIONNAIRES.....45
B. IRB LETTERS OF APPROVAL.....49
C. PROMOTIONAL MATERIALS52
D. INFORMED CONSENT LETTER.....57
E. CASE MANAGEMENT60
F. USER LICENSE AGREEMENT.....65
G. CERTIFICATE OF COMPLETION.....69
REFERENCE LIST70

LIST OF TABLES

1. Participant Demographics.....	31
2. Statistical Analysis ASK-12 Lifestyle <i>t</i> -test: Paired Two Sample for Means.....	33
3. <i>T</i> -test: Paired Two Sample for Means ASK-12 Treatment Beliefs	33
4. Statistical Analysis ASK-12 Behavior Taking Medicines	34
5. <i>T</i> -Test: Paired Two Sample Means Pre- and Post-Intervention Systolic and Diastolic Blood Pressure.....	35

LIST OF FIGURES

1. Kurt Lewin's Change Theory	9
2. Johnson's Medication Adherence Model	10
3. A Priori Analysis Matched <i>T</i> -test.....	20
4. Pill Count Adherence Ration Formula	22
5. The Medication Adherence Project Intervention	26
6. PCAR	36

LIST OF ABBREVIATIONS

ASK-12	The Adherence Starts with Knowledge-12 Tool
B/P	Blood pressure
CM	Case Management
HTN	Hypertension
MAM	Medication Adherence Model
MMAS-4	Morisky's Medication Adherence Scale-4
PICAR	Pill Count Adherence Ratio
QIP	Quality Improvement Project
WHO	World Health Organization

CHAPTER ONE

INTRODUCTION

Medication adherence is a problem. Medication adherence is taking medications as prescribed. Intervention approaches that are multifaceted (Fan et al., 2018) and patient- centered are helpful in reducing perceived health barriers to medication adherence. The focus of this project was to look at medication adherence in adult patients diagnosed with hypertension who were considered medically vulnerable. Vulnerable populations can be defined as poverty stricken, alcohol or substance abusers, disadvantaged, distressed populations, physical disabilities, individuals who do not speak English, racial or ethnic minorities, residents of rural areas, the elderly and children (Shi & Stevens, 2021) who are at higher risk for poor health. Every individual is different, and hypertension is often asymptomatic. There are many lifestyle changes that can help to prevent hypertension.

Adherence is a term that conveys that patients are taking responsibility for their medication. Another term sometimes used to describe lack of adherence is *compliance*. Patient compliance holds a negative connotation that patients inherently refuse to obey, therefore suggesting a subservient role. Adherence is a cooperative relationship.

Prescribed medications are the gold standard for managing chronic disease and help in the prevention of adverse health effects. Many patients have chronic medical problems that require them to be on many different medications. For hypertensive patients to achieve adequate blood pressure control, more than one antihypertensive medication

is often prescribed. There is a strong association between lack of adherence, polypharmacy, and increased patient-perceived barriers (Shareinia et al., 2020).

Polypharmacy issues make adherence more difficult to achieve, and providers can intervene to improve adherence using evidence-based methodologies. Poor hypertension medication adherence is associated with increased health cost, poor healthcare outcomes, comorbidities, and mortality rates (Sinan & Akyuz, 2019). The cost assessed by the American Heart Association predicted that the immediate healthcare cost for chronic hypertensive patients was \$131 billion per year higher than for non-hypertensive patients (Kirkland et al., 2018).

Background

At the site of this quality improvement project, there was no current recognized process for screening, documenting, and managing medication adherence in place. The staff consisted of a sole nurse practitioner, receptionist, and continuous rotation of graduate nursing students from several nursing programs in the Northern Indiana area. The nurse practitioner was left with little time to engage patients in effective hypertension education. Patient education and comprehension were poor in terms of understanding disease process, treatment options, and disease management that led to poor communication with the medical provider. Spanish translation was available when possible, and Spanish-speaking patients often received patient education and post-visit patient instruction information in the English language. This clinic was not involved in formal hypertension medication adherence screening efforts, and there was no formalized process in place to address lack of adherence. Time management was challenging for the solo nurse practitioner to provide effective primary care along with medication-adherence education within the 15-minute-visit window for hypertensive

patients as well as other chronic disease education management.

Lack of medication adherence causes poor patient outcomes. Much evidence-based research initiatives fundamentally support the foundation that a lack of medication adherence increases medication errors, adverse drug events, and poor patient health outcomes; however, in the outpatient clinic setting, this continues to be a challenge (Schnipper et al., 2018).

In the United States, medication errors attributed to a lack of medication adherence account for over 7,000 deaths (Douglass et al., 2018). Lack of medication adherence accounts for unnecessary emergency room visits, increased hospital admissions, and compromised patient safety (Al-Hashar et al., 2018). Multiple antihypertensive medications can escalate or potentiate a patient for experiencing physiological changes that impact cardiovascular, respiratory, neurological, and renal function (Shareinia et al., 2020). Primary care clinics are in a key position to increase patient outcomes achieved by implementing measures that can increase medication adherence.

Rationale

A primary determinant of treatment success is adherence to medication. Lack of adherence affects healthcare systems and the patient. Lack of adherence leads to increased health care costs, death, and worsening disease. This clinic served low-income Caucasian and minority patients who are primarily Hispanic and Black Americans. This population was considered medically vulnerable and at a higher risk for chronic condition prevalence with worse medication adherence rates (Fernández et al., 2017). Some studies suggested that Hispanics had a double risk since they were considered a

vulnerable population and they struggled more than any other racial group with medication adherence (Campos & Rodriguez, 2019). Vulnerable groups need increased support, increased help, increased attention, increased resources due to low levels in health literacy, more understanding, and increased academics that affect medication-adherence perceptions (Johnson, 2002).

Significance of Project

Many studies show a strong correlation between improved health outcomes and medication adherence. There is a certainty that medication adherence and improved health outcomes are primary solutions to mitigating healthcare disparities through patient centered and multiple educational interventional approaches. Taking medications as prescribed is adherence. Adherence is the gold standard. Low health literacy, poor understanding of medication importance, and needs impact a patient's daily routine and the ability to incorporate medication taking (Seung, 2017). Studies have shown that a strong association between low health literacy and poor health outcomes leads to lack of adherence, increased hospitalizations, and poor health care knowledge (Thomas & Allison, 2019). Improving medication adherence increases poor health outcomes for patients.

Investing in patients is a win-win situation for the patient-provider medication-adherence relationship (Fernández et al., 2017). Research shows that intentional interventions that are individualized and patient-centered must incorporate education, guidance with self-management of their disease, open provider communication, evidence-based adhering strategies, and helpful tools that are user friendly (Hall et al., 2016). With increased open provider communication,

patient-centered adherence levels increase significantly, which leads to positive health outcomes (Kenya et al., 2015).

Research suggests that spending \$1.00 in adherence interventions saves \$37.00 dollars for healthcare (Krumme et al., 2018). Healthcare literature suggests that clinical practice guidelines work well to improve medication adherence when clinical staff are involved, adherence-aid strategies and tools are utilized, and behavioral strategies are promoted to increase adherence (Ruppar et al., 2017). Clinic staff can help improve quality care through screening measures that address barriers to adherence by offering language-sensitive information regarding disease, treatment, and self-management education that promotes persistence (Seung, 2017).

Project Question

The question for this project suggested that medication adherence would improve if the intervention of screening for adherence risk factors then giving hypertension disease management education to those at risk influenced a medically vulnerable population's lack of adherence rates as compared to the clinic's current standard of care processes.

Purpose

The purpose of this scholarly project was to improve adherence by implementation of a medication-adherence screening-review tool to improve medication adherence and utilize case-management patient-education interventions for those who screened positively. Project objectives included the following:

1. To evaluate whether screening measures mitigated medication-adherence barriers.

2. To evaluate whether patient education offered by a case manager on disease, treatment, and self-management decreases perception barriers to increased adherence.

Screening patients for medication-adherence barriers and then discussing solutions to these barriers was expected to improve quality of care. This project implemented a process in the clinic office that screened hypertensive patients who came into the office for medication adherence; those who identified “YES” barriers were referred for a case-management patient-education intervention. The difference between the pre- and post-medication-adherence screening-tool scores would determine the effectiveness of this medication-adherence educational process for hypertensive patients.

PICOT Questions

P: In medically vulnerable adults with hypertension, **I:** will screening for risk factors, followed by individualized case management education, **C:** compared to current clinic process or standard of care, **O:** reduce perceived risks and increase hypertension medication adherence **T:** by the time of the next office visit?

CHAPTER 2

LITERATURE REVIEW

Conceptual Definitions

Adherence: According to the World Health Organization (Ogungbe et al., 2020), adherence is defined as a person's commitment to taking their medications, adhering to dietary guidelines, and lifestyle modifications as recommended by his or her primary care provider.

Barriers: Stumbling blocks that prevent forward movement.

Chronic hypertension: Diagnosed with hypertension at least three months prior.

Compliance: Obeying a command or wish.

Lack of adherence: Refers to patients who do not take their medications correctly or as prescribed.

Medication adherence: Medication adherence seeks to determine whether patients take their medications as prescribed (Ogungbe et al., 2020). Medication-adherence screening goes a step further in that it seeks to determine if and when patients understand the what, why, when, and how of taking medications correctly.

Non-compliance: Disobeying a wish or command.

Perceptions: The ability to understand or become aware of something through one's own senses.

Quality improvement: A practice that looks for ways to continuously grow and improve upon health care quality that is delivered (Berman et al., 2018).

Vulnerable: Those populations that are disadvantaged economically, racially, or by ethnicity; because of being elderly, children, homeless, or prisoners; because of having chronic health conditions, mental illness, or a low income; or for any other reason.

Theoretical Framework

There is always a need to improve medication-adherence knowledge and usage within the hypertensive patient population. Anticipated challenges with a hypertensive patient population in medication adherence and blood pressure control may include limitations; poor patient knowledge, low health care literacy, misinformation from family and friends, access to medications, patient safety, empowerment, lack of symptoms, perceived safety in skipping doses (Najimi et al., 2018), confusion about efficacy (Park et al., 2018), and poor provider-patient communication (Kvarnström et al., 2018). In order to move patients to a new way of thinking and empower them to consider changes in their life concerning taking their medication as prescribed, change will be necessary. The Change Theory by Lewin originally developed in 1951 was used as the theoretical change model for this project. (Figure 1).

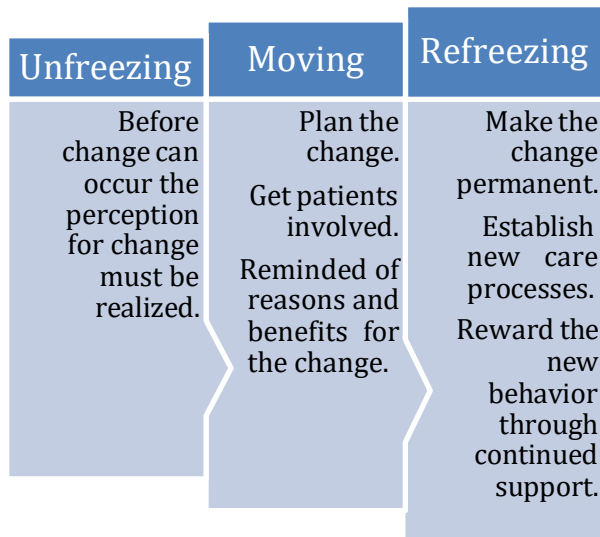


Figure 1. Kurt Lewin's change theory (Kehinde, 2020)

The use of change theory is expected to allow patients to move to a new normal where adherence rates will improve and improve patient health outcomes over time as the change becomes the norm. Change is based on the premise that before change can occur, the perception for change must be realized. Lewin's theory is based on three steps that involve unfreezing, changing, and refreezing (Kehinde, 2020). Medication adherence and blood pressure control in hypertensive patients can be effective when medication adherence challenges or limitations are recognized, acknowledged, and addressed. Change must be carefully planned, and this hypertensive population should continuously be reminded of reasons and benefits for the change. The unfreeze, change, and refreeze process suggests that education, support, time, and communication are valuable aspects of this process. This theory helps to identify strengths prior to change implementation and empowers patients to be able to find it within themselves to make changes that positively impact their own health.

Johnson's (2002) Medication Adherence Model describes the medication adherence process with hypertensive patients and will also be utilized as a theoretical framework in this study (Figure 2). This model takes the patient through the behavioral adherence journey which,

at its very core, equates to intentional or unintentional perceived need to take medications as o prescribed. Unintentional decision-making is reflected in any interruptions or barriers (Amico et al., 2018) that may cause medications not to be taken as prescribed.

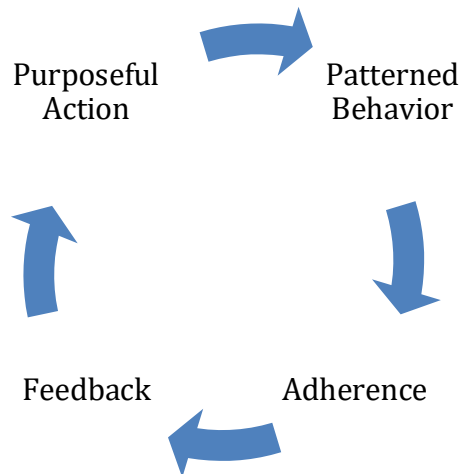


Figure 2. Johnson's medication adherence model (Johnson, 2002)

Purposeful Action

This is the process in which patients go through to decide whether to take a medication intentionally or unintentionally based on perceived need, effectiveness, and safety (Johnson, 2002). The idea is that if patients perceive a need, then they will adhere to taking their medication. This project will reinforce disease education and self- management to stimulate patient adherence through purposeful action.

Patterned Behaviors

Medically vulnerable populations can have lifestyles that challenge a medication adherence routine. Lifestyles that positively impact adherence include restrictive alcohol consumption, weight control, healthy living adherence, smoking cessation, low sodium diet, and regular exercise performance

(Kvarnström et al., 2018). Intentional decision-making or purposeful action will help patients better perceive their needs and pattern their behavior (Johnson, 2002) to meet those needs through habit-forming routines to achieve effectiveness and safety. This project helped patients who were struggling to adhere to medication regimens to develop patterning behaviors and routines by incorporating adherence-aiding tools to assist them.

Feedback

Feedback is the outcome of the patient's response results to the treatment intervention. Prompts, events, and information were evaluated. Personal responses from patients engaged in discussing the proposed case management educational intervention was postulated as a possible influence as to whether adherence to medications prescribed might improve. The adherence-aiding tools helped patients play a part in their care and increase provider communication and response.

Conclusion

These concepts of unfreezing, moving, and refreezing along with purposeful action which prompts patterned behavior will all determine to what extent adherence will be achieved. Patients have a right to self-determination, and their adherence efforts can reinforce negative or positive behaviors that lead to the success in continuing or not continuing towards adherence.

Review of Literature

Medical providers must find ways to address continued barriers to medication adherence in the vulnerable patient populations that they serve (Clarke et al., 2017). The literature suggests that health-vulnerable populations will continue to increase, and providers should be commissioned to continue addressing healthcare inequalities through patient education initiatives that increase medication adherence (Williams & Cooper, 2019). The information below details a

review of the literature that provides evidence on factors that affect adherence in vulnerable-patient populations, increased adherence-interventional components, and provides evidence-based practice-setting adherence-improvement strategies.

Health Inequalities

The common theme in much of the literature related to medication adherence was that the patient population characteristics for medication adherence in the United States tended to be Caucasian, married, and older (Fernández et al., 2017); however, these characteristics were not clinically useful predictors for medication adherence in minority hypertension patients. Anti-hypertensive medication-adherence health disparities continued to persist among racial and ethnic groups, thus increasing risk factors for morbidity and mortality among American subgroups (Schoenthaler, 2017). Patient populations identified as medically vulnerable and predominantly served at the proposed project site were low-income Caucasian, Mexican, and Black American individuals who were eligible for Medicaid.

Young Black adults had lower variable medication-adherence routines as compared to older Black adults (Ferdinand et al., 2017). These ethnic groups have been identified as having a higher tendency to be socioeconomically disadvantaged and have poor lifestyle factors, (Thomas & Allison, 2019), higher risks for poor patient outcomes, and a greater rate of being uninsured (Schoenthaler, 2017). Hypertensive prevalence was found to be higher among Black adults (41.2%) than among White adults (28.0%), Hispanic adults (25.9%), and non-Hispanic Asian adults (24.9%) (Ferdinand et al., 2017). Blacks accounted for the highest prevalence of hypertension in average blood pressures as compared to their White counterparts (Benjamin et al., 2017; Shareinia et al., 2020); in the National Health and Nutrition Examination Survey (NHANES) 2011-2012, Blacks had higher recognition and treatment rates; however, they rated

lower in hypertension management as compared to their White counterparts (Ferdinand et al., 2017; Shareinia et al., 2020). Evidence appears to show that hypertension-medication non-adherence strongly correlates to poor hypertension management, thus contributing to cardiovascular diseases, chronic kidney disease, and stroke (Ferdinand et al., 2017; Schoenthaler, 2017; Sinan & Akyuz, 2019).

One study looking at recommended guidelines for antihypertensive management in Mexican Americans as compared to their Black and Caucasian counterparts found that there was no significant difference in medication regimes across racial groups (Blacks, 81.7%; Caucasians, 82.3%; Mexican-Americans, 79.1%), as well as no significant difference in blood pressure goal levels; Blacks were more likely to be on three or more antihypertensives compared to Mexican Americans (Perez et al., 2016). Compared to their Caucasian counterparts, Blacks had a lower rate of adherence to cardiovascular medications such as beta-blockers, statins, and angiotensin-converting enzyme inhibitors even in ideal environments that had adequate prescription access (Ferdinand et al., 2017; Shareinia et al., 2020). Hispanics also face barriers to hypertension management equity due to cultural inequalities, social factors, and the presence of other comorbidities such as obesity and diabetes (Thomas & Allison, 2019). Research studies are lacking for addressing recommended guidelines for anti-hypertensive control for Hispanic patients (Campos & Rodriguez, 2019); screening, treatment, and management must be addressed to reduce medication-adherence barriers.

Roldan et al. (2018) acknowledged that when providers communicate by using language-sensitive information and language interpretation about disease process, treatment, and management with their patients, medication adherence or care that meets the cultural and social needs of diverse patient populations increases. Language and culturally sensitive patient

education includes information on hypertension, treatment, and patient engagements or interventions (Halladay et al., 2017) that engage patients periodically along their healthcare journey that involve educational sessions, teach-back interviewing, behavioral counseling, and health coaching (Elnaem et al., 2020; Poulter et al., 2020).

Patient-Provider Confusion/Communication

Vulnerable patient populations that have a strong correlation with lack of adherence are least likely to participate in a patient-provider collaborative relationship (Bartolome et al., 2016; Schoenthaler, 2017). The evidence summarized that factors contributing to lack of adherence were due to multiple provider confusion, poor communication, and lack of timely adjustment to therapy over combination therapy (Anderson et al., 2017; Kvarnström et al., 2018; Park et al., 2018; Schoenthaler, 2017).

A patient that had multiple providers correlated to misinformation and provider confusion, poor patient knowledge, patient-perceived safety in skipping doses (Najimi et al., 2018), confusion about efficacy (Park et al., 2018), and unintentional patient decision-making (Amico et al., 2018; Shareinia et al., 2020; Sinan & Akyuz, 2019) about not taking medications as prescribed (Al-Hashar et al., 2018; Douglass et al., 2018; Schnipper et al., 2018). A trustful patient provider relationship where there is open communication correlated to increased medication adherence and positive patient health outcomes (Kvarnström et al., 2018; Najimi et al., 2018; Park et al., 2018). Research showed that when providers and healthcare teams focus on open communication, patient medication adherence increases (Schoenthaler, 2017).

Increased Adherence Interventional Components

The literature suggests that patient education interventions improve adherence. There was not one gold standard or single component of educational intervention that was identified as a one-stop fit for every patient. However, education interventions that were patient-

centered and focused on lifestyle modifications, smoking cessation, exercise, weight loss, along with self-management and patient reminder tools increased medication adherence (Fan et al., 2018; Foster et al., 2018; Hofer et al., 2017; Kvarnström et al., 2018). Nurse-led intervention models that focused on disease education, delivery design, decision support, self-management, and follow-up phone calls increased medication adherence (Halladay et al., 2017; Schoenthaler, 2017; Zhu et al., 2018).

Education alone is not enough to increase adherence. A review of the literature suggests that self-management adhering tools such as blood pressure wallet cards, blood pressure journals/notebooks, pill boxes, refrigerator reminder magnets, and pill boxes help improve medication adherence (Fan et al., 2018; Foster et al., 2018; Kvarnström et al., 2018). A study was done in which the comparison group received standard care and the interventional group received education and self-management adhering tools, reminder phone calls. This increased patient disease knowledge, adherence, and patient- provider communication (Fan et al., 2018). All these tools are examples of inexpensive solutions that can promote patient adherence.

Practice-Setting Adherence-Improvement Strategies

Clinic staff and providers must be intentional in adhering to medication adherence guidelines that promote adherence screening and awareness in relation to the patient population served (Kvarnström et al., 2018; Seung, 2017). The literature suggests that when medication adherence awareness is raised among providers and clinic staff with intentional methods to address factors that affect patient adherence, adherence increases within the patient population served, patient-provider communication increases, and positive patient health outcomes occur (Fan et al., 2018; Foster et al., 2018; Kvarnström et al., 2018; Schoenthaler, 2017; Seung, 2017). The literature also suggests that during routine follow-up office visits, patients should be

screened for medication adherence (Ruppar et al., 2017). Cultural and language-sensitive patient centered care, when promoted, is a proactive clinic or organizational approach that engages clinic staff and patients towards a win-win relationship.

Measuring Adherence

There continues to be no “gold standard” for medication-adherence measurement and two measurements are recommended to ensure credibility according to the literature (Choi et al., 2018). In the literature, validation, and reliability of the MMAS-4 (Morisky et al., 1986) and ASK-12 (Pawloski et al., 2022) have been used by many research studies as a self-reporting adherence tool used in medically vulnerable populations and with many various chronic disease populations. The challenge with self-reporting adherence scales is that the patient can embellish their answers (Thompson et al., 2017), thus causing a disconnect between patient reports and actual medication taken. These measurement tools are helpful for providers to screen, identify barriers, and promote interventional self-management behaviors that promote adherence. Taking physiological parameters such as blood pressure and pulse readings is helpful in supporting adherence during patient education interventions (Morisky et al., 1986).

Pill count is a common protocol that medical providers may use to check that medication adherence is being used correctly with the medications prescribed (Choi et al., 2018). Providers review the actual fill date and initial pill quantity dispensed, then count the pills in each bottle, subtract from the initial dispensed count, and multiply by 100 to get the pill count administration ratio (Choi et al., 2018). A cut-off value considered good for medication adherence is 80%.

Conclusion

The literature supported several recommendations to increase medication adherence in this project to increase medication adherence (Choudhry et al., 2017; Ruppart et al., 2017):

- Improvement to care process that involves the healthcare team
- Open communication opportunities
- Offering patient education on disease and medication information
- Healthy lifestyle teaching
- Patient follow-up
- Self-management assistance by giving adhering-aiding tools (e.g., calendars, notebooks, pill boxes, refrigerator magnets)
- Receiving support from the provider and healthcare team

When providers are able to screen and address barriers to adherence, vulnerable groups benefit (Ruppart et al., 2017). Multifaceted interventions (Choudhry et al., 2017) that are patient-centered will help decrease negative health outcomes that can occur with chronic health problems.

CHAPTER 3

METHODOLOGY

Project Design

This was a quality improvement project following a convenience sample, pre- post, quasi-experimental design. This design was used to assess the effect of an evidence- based medication-adherence intervention on medication adherence rates.

Population

This project involved an outpatient primary care clinic providing medical care to low-income Caucasian, Hispanic, and Black American patients in a Northern Indiana city in the United States. It had hoped to enroll primarily underserved groups, but that did not occur with the convenience sample. The clinic services were offered solely by a nurse practitioner and one receptionist. The receptionist played a dual role as receptionist and medical assistant. Eligible participants were adult male and female patients, 18 years old and above, who had had a hypertensive diagnosis within their medical record for more than three months, had clinic appointments for February and March 2023, and were taking at least one antihypertensive medication on a weekly minimum basis. Illiterate patients were assisted to complete the medical screening tools attached to the visit's health questionnaire form.

The facility IRB's approved consent was signed by each patient participant. The consent attested to the participants' voluntary decision to participate and assured them of no medical care disruption if they refused, of no obligation, and of no pressure to participate.

Setting

This project assessed the effect of an evidence-based medication-adherence intervention on adherence rates at a Northern Indiana clinic led by a sole nurse practitioner with remote physician oversight. The clinic staff included the sole nurse practitioner, a receptionist/medical assistant, and a continuous rotation of graduate nursing students from several area nursing programs.

This clinic is a federally qualified health center providing medical health care to medically underserved and uninsured populations. The clinic provides primary care on a sliding fee scale to patients of all ages who might not otherwise be able to afford quality healthcare.

Recruitment

Permission was granted to recruit patients by the project facility in which the nurse practitioner provider identified patients who had appointments for hypertension. All identified patients were called and encouraged to bring their pill bottles prior to their clinic appointment. If clinic patients with a diagnosis of hypertension answered “YES” to any of the four MMAS-4 prequestionnaires when they arrived for their clinic visit, they received an approved script and flier inviting participation in this project and were then asked to sign a written consent form.

Inclusion and Exclusion Criteria

Inclusion

- Adult patients 18 years of age and older
- Lack of adherence as determined by the MMAS-4 screening tool
- Hypertension diagnosis and taking at least one hypertensive medication weekly
- Able to follow instructions by verbally repeating information
- Willing to sign the consent form

Exclusion

- Less than 18 years of age
- Answered “NO” to all questions on the MMAS-4 questionnaire
- Unable to follow directions
- Not taking medications for hypertension
- Possibility of cognitive deficits and unable to sign consent

Sample Size

A Power .80, Effect Size: .35, $p < 0.05$, yielded a total of 45 patients needed for the project (Kang, 2021). However, another 10% was added for attrition, $n = 45 + 5$, increasing the total participants needed to 50. The convenience sampling goal of 50 patients was desired for project participation. This was an unrealistic goal due to inadequate potential participants, thus decreasing the participant sample to 31 for project participation, as shown below.

t test – Means: Difference between two dependent means (matched pairs)

Input: Tail(s) = One

Effect size $d_z = 0.36$

α error prob = 0.05

Power ($1 - \beta$ err prob) = 0.80

Output: Non-centrality parameter $\delta = 2.546$

Critical t = 1.677

Df = 49

Total Patients Needed for QIP = 50

Actual Power = 0.807

Source: *G*Power 3.1.9.7*

Figure 3. A priori analysis matched *t*-test.

Ethics

Training on the Federal guidelines and Human Subject Basic Research training as required by Andrews University was completed by the project manager. Proof of this

completed training met the IRB project application submission requirement. Ethical care was taken to ensure that the project design was structurally sound in meeting the goals of the project and minimized risks to the project participants:

- Andrews University and project facility IRB review endorsement
 - Explanation of project aims and objectives to participants prior to obtaining informed consent
 - Signed participant informed consent form
 - Patient privacy protection
 - Delivery of educational information using video and printed materials
- The Institutional Review Board for the Northern Indiana outpatient clinic and Andrews University were consulted for project study approval. Patients provided written consent (Appendix D) to participate in this project.

Tools and Measurement

Variables

The independent variables were case-management, hypertensive health education. The dependent variable was the identified patient-medication-adherence barriers.

Participant Demographics

Participants completed a participant demographic questionnaire that included variables on age, sex, race, language, education level, employment status, medical insurance, marital status, number of medications taken, and number of chronic diagnoses.

Scoring and Interpretation

The first tool used was the MMAS-4 questionnaire scale which is generic self-

reported and can be used for high blood pressure or other specified health issues on medication-taking behaviors. The scale entailed a scoring of four items of “Yes” = 0 or “No” = 1. The sum of the range of scores would be 0 to 4.

The Adherence Starts with Knowledge (ASK 12) is a survey which measures medication adherence by answering 12 questions. These questions are grouped into three sections: lifestyle, treatment beliefs, and behavior. The questions are given five potential answers which are then converted into ordinal data from 1 to 5 with 5 reflecting greater barriers to adherence to medication usage. These ordinal data were then converted to numeric data with the assumption that the rankings of 1 through 5 are evenly distributed and an overall score is then calculated.

The Pill Count Adherence Ratio (PCAR) is calculated by subtracting total doses remaining from total dose dispensed divided by total doses dispensed and multiplied by 100 (Figure 4). If all the doses since the fill date have been taken, 100% adherence is considered. Adherence medication was classified as 1 = >80% (Forbes et al., 2018), and lack of adherence medication was classified as 2 = <80%.

$$\frac{[\text{Total Doses Dispensed}] - [\text{Total Doses Remaining}]}{\text{Total Doses Dispensed}} \times 100 = \text{PCAR}$$

Figure 4. Pill count adherence ration formula (Forbes et al., 2018).

Internal/External Validity

Multiple measures are recommended by the literature to measure adherence (Choi et al., 2018). The MMAS-4 and ASK-12 were the patient self-report adherence tools that were utilized, along with the PCAR in which I requested that patients bring in their

antihypertensive medications and individually counted the pills to measure adherence objectively during the case management session.

MMAS-4 Scale Reliability/Validity

The MMAS-4 (Morisky et al., 1986) has many advantages since it can be used in various populations, diseases, countries, and electronic monitoring devices and has a lesser response burden. This scale is available in Spanish and English. This scale has a good test-retest reliability (intraclass correlation of 0.79 and a Cronbach's alpha reliability of 0.61, a specificity of 0.44, and 0.81 good sensitivity rate (Graffigna et al., 2017).

ASK-12 Tool Reliability/Validity

The ASK-12 (Pawloski et al., 2022) has Cronbach's alpha reliability of 0.75 good internal reliability and has a strong correlation with the MMAS-4 (Graffigna et al., 2017; Matza et al., 2009; Morisky et al., 1986: $r = 0.74$; $p < 0.001$) which showed convergent validity. As a brief measure, the ASK-12 can be helpful in measuring behavior adherence. In scores ranging from 12–60, the ASK-12 can help differentiate between self-reported adherence patient-response indicators on number of adherence days, treatment satisfaction, and missed doses.

Pill Count Adherence Ratio

Research suggested that for adherence to be credible with reliability and validity when using the PCAR method, at least a minimum of two additional measures are recommended (Bazargan et al., 2017).

Questionnaires

The project made use of Johnson's (2002) Medication Adherence Model (MAM) which described the matriculation process that patients encounter for medication adherence

that included purposeful action, pattern behavior, and feedback concepts. This helped to design and guide the intervention and theorize the adherence assumptive conclusion.

First Tool Component

The first screening tool component utilized MMAS-4 (Graffigna et al., 2017) and was given at the patient's scheduled appointment. This scale was provided in English and was attached to the intake health questionnaire form at the patient's scheduled appointment. This scale was accessible for use in the public domain. This 4-item questionnaire screening tool that was composed of "yes" and "no" questions was helpful in assessing medication non-adherence in a hypertensive patient in a smaller sample size. This scale addressed the reasons why patients do not adhere to taking medication in four main domains that include carelessness, stopping the medication when feeling better, forgetfulness, and stopping the medication when feeling worse. The MMAS-4 (Graffigna et al., 2017) evaluated patient's responses in a four-question format:

- Do you ever forget to take your medicine? Y or N
- Do you ever have problems remembering to take your medicine? Y or N
- When you feel better, do you sometimes stop taking your medicine? Y or N
- If you feel worse, do you sometimes stop taking your medicine? Y or N

Only patients who answered "YES" to any of these questions were then eligible to participate, and all questionnaires who received "NO" answers were discarded. A note in the patient's chart indicated that the screening was completed, and the results of the screening were either positive or negative. Positive results were any "YES" answers.

Second Tool Component

Any "YES" responses on the MMAS-4 (Graffigna et al., 2017) prompted a second adherence screening tool to be given to patients who agreed to participate: the ASK-12 tool

(Pawloski et al., 2022). Permission from the author was secured to use this scale in English (see Appendix I). This tool was developed to increase patient- intervention effectiveness by asking identified barrier questions indicated by patients so that health care providers could quickly identify those influencing patient medication adherence. There are three components of the ASK-12 that address inconvenience, beliefs, and behaviors. The information gathered allowed the case manager to tailor education, treatment, and follow-up management in a patient-centered model. The ASK- 12 Medication adherence tool (Pawloski et al., 2022) evaluated patient’s responses in a 12-question format ranging from strongly agree, agree, neutral, disagree, and strongly disagree:

Lifestyles Questions

- I just forget to take my medicines some of the time.
- I ran out of medicine because I didn’t get refills on time.
- Taking medicines more than once a day is inconvenient.

Treatment Beliefs Questions

- I feel confident that each one of my medicines will help me.
- I know if I am reaching my health goals.
- I have someone I can call with questions about my medicines.
- My doctor/nurse and I work together to make decisions.

Behavior Questions

- Have you taken medicine more or less often than prescribed?
- Have you skipped or stopped taking medicine because you didn’t think it was working?
- Have you skipped, stopped, not refilled, or taken less medicine because of the cost?
- Have you skipped, stopped, not refilled, or taken less medicine because of the cost?
- Have you not had medicine with you when it was time to take it?

Implementation

The Medication Adherence DNP Intervention

The medication adherence project intervention (Figure 5), from start to finish, was in a planned order which yielded an understanding of the project's steps as to how the research data were obtained.

Revise the clinic's health questionnaire intake form by adding the MMAS-4 form.

Initiate QIP in Clinic

Appointment, check-in for all diagnosed chronic HTN patients.

DNP student hands patient's the intake forms, collects, reviews MMAS-4, any "Yes" answers triggers the DNP student to talk with the patient about the QIP, obtain participation consents, and then administer to patient's the demographic and ASK-12 questionnaire. Obtain blood pressure values. The DNP student collects the forms and sends the patient onto the provider appointment.

Patient Provider Visit

End of Provider Visit

All "YES" patients meet for 30 minutes individualized session with project manager in the case management role giving hypertension education/self-management tools. Project manager collects all intake hypertension adherence screening questionnaires and patient receives next scheduled provider appointment and are encouraged to bring medication bottles to the next appointments.

Case Management Role Session

Review MMAS-4 & ASK-12 questionnaires. Show Medline hypertension videos. Obtain pill counts of HTN medications. Encourage patients to bring pill bottles at next provider visits. Give medication adherence toolbox/self-management tools.

Next Provider Visit

Blood pressure recheck. Retake ASK-12 questionnaire and PCAR.

DNP Student Gathers Data Collected From:

Demographic questionnaire, ASK-12 pre/post, PCAR pre/post, Blood pressure values pre/post visits. Complete data analysis to determine effect of this project on medication adherence.

Figure 5. The medication adherence project intervention.

Intervention

The project manager worked as case manager in helping to deliver language-sensitive hypertensive education using Medline Plus videos. The case manager's educational medication adherence toolkit included patient-provider open communication and conversation starter strategies that were given to patients (e.g., physiological parameters journal, notebooks, wallet cards, pillbox, calendar, refrigerator signs, and questions for provider review).

Teach-back instructions (Zabolypour et al., 2020) were given to patients showing how to use the pillbox pre-pouring of medications and how to record blood pressure in their journals/notebooks, as well as conversation starters to engage with me in open dialogue and review.

The PCAR (Forbes et al., 2018) was utilized for me to count the patient's antihypertensive medications pill bottles. Evidence-based practice suggested that a minimum of two measures should be utilized for credible adherence results (Bazargan et al., 2017).

Evaluation Procedure

Data Collection

The project data were collected from the demographic information questionnaire, the two ASK-12 questionnaires, and information gathered from the case management individualized interventional sessions to determine the degree of adherence. The medication pills in each bottle were tallied according to the PCAR calculations. Blood pressures were obtained pre- and post-clinic visits using a non-invasive automatic blood pressure cuff on the patient's bare upper arm resting on the side tray table, sitting in an upright position with feet uncrossed and flat on the floor. The bottom of the cuff was 1-2 inches above the bend of the elbow and patients were encouraged not to talk. According to the American Heart Association (Virani et al., 2020), blood pressure guidelines are as follows:

- Normal: Less than 120/80 mm Hg,
- Elevated: Systolic between 120-129 and diastolic less than 80,
- Stage 1: Systolic between 130-139 or diastolic between 80 and 89,
- Stage 2: Systolic at least 140 or diastolic at least 90 mm Hg, and
- Hypertensive crisis: Systolic over 180 and/or diastolic over 120, with patients needing prompt changes in medication if there are no other indications of problems, or immediate hospitalization if there are signs of organ damage.

Statistical Analysis

The data analyzed from the project was collected over three months. The data analyzed sought to determine hypertension medication adherence which was the focus of this project. Two self-reporting adherence tools were utilized: one to screen hypertension medication adherence and the other to measure hypertension medication adherence. The self-reporting adherence screening tool of the ASK-12 (Pawloski et al., 2022) was a quantitative measure which yielded interval data. Utilized in conjunction with the ASK- 12 was the PCAR (Forbes et al., 2018) which also yielded quantitative ratio measurements that determined fill date and the amount of medication taken with the goal of 80% or greater for determining adherence, and a score of less than 80% when adherence was lacking. These combined scores from the ASK-12 and PCAR provided the means to determine changes to adherence from the pre-/post-intervention. The ASK-12 questionnaire was graded on a 1–5 scale for 12 specific questions with an overall mean value generated for each survey. The lower the number, the better, and the higher the number, the worse. The scale was 1–5 for 12 specific questions with an overall mean value generated for each patient. The best potential score was 12, and the worst score was 60. Blood pressure physiological parameters were

analyzed to determine whether clinical adherence increased through quantitative data calculations on the pre- and post- intervention.

Calculations of the quantitative data retrieved from the pre- and post-ASK-12, PCAR, and blood pressure physiological parameters helped to determine the mean and standard deviation for the measures repeated. A one-tailed dependent (directional) *t*-test compared the means using statistical significance testing level $p = 0.05$. The proposed project change between the pre- and post-intervention signified that the medication-adherence intervention was effective.

CHAPTER 4

RESULTS

Participant Demographics

A total of 31 patients consented to participate in this project (see Table 1). Of the 31 patients, 58.1% were female, 38.7% were male, and 3.2% marked neither. The participants ranged in age between 21 and 93 years of age with the largest mean group of 41.9% being between the ages of 41 and 60. Of the participants, 39% were employed and 48% were married. Of the convenience sampling, 94% were Caucasians and 6% were Black Americans. Of the participants, 39% were identified as taking at least 1–3 prescribed medications. All the participants had a diagnosis of chronic hypertension, followed by obesity (48%) and diabetes (35%). Fifty-four percent of the participants had between a fifth grade and twelfth grade education.

Table 1

Participant Demographics

Demographics		All Participants n=31
Age (Years)		
	21 – 40	6 (19%)
	41 – 60	13 (41.9%)
	61 – 80	9 (29%)
	>80	3 (9.7%)
Sex		
	Male	12 (38.7%)
	Female	18 (58.1%)
	Transgender	1 (3.2%)
Race		
	Black	2 (6%)
	White	29 (94%)
Language		
	English	31 (100%)
Education Level		
	5 th Grade	1 (3%)
	11 th Grade	2 (6%)
	12 th Grade	14 (45%)
	GED	2 (6%)
	Associates	4 (13%)
	Bachelors	3 (10%)
	Masters	4 (13%)
	Doctorate	1 (3%)
Employment Status		
	Disability	1 (3%)
	Full Time	12 (39%)
	Part Time	7 (23%)
	Retired	8 (26%)
	Unemployed	2 (6%)
	Student	1 (3%)
Medical Insurance		
	Yes	31 (100%)
Marital Status		
	Married	15 (48%)
	Single	10 (32%)
	Widow	5 (16%)
	Divorce	1 (3%)

Table 1—Continued.

Number of Medications Taken	
1 to 3	12 (39%)
4 to 6	11 (34%)
7 to 9	5 (16%)
10 to 12	1 (3%)
13 to 15	2 (6%)
Number of Chronic Diagnoses	
1	3 (10%)
2	5 (16%)
3	7 (23%)
4	9 (29%)
5	3 (10%)
6	3 (10%)
9	1 (3%)
Chronic Diagnosis Reported	
HTN	31 (100%)
Obesity	15 (48%)
DM	11 (35%)
HLD	10 (32%)
Anxiety	8 (26%)
Depression	7 (23%)
COPD	3 (10%)
Alcohol Abuse	2 (6%)
PTSD	2 (6%)
Smoker	2 (6%)
Other	22 (71%)

Note. HTN – Hypertension; DM – Diabetes; HLD – Hypersensitivity Lung Disease

Statistical Analysis

Adherence Starts with Knowledge (ASK-12; Pawloski et al, 2020) screened for barriers related to lifestyle, treatment beliefs, and behaviors. The ASK-12 uses a Likert scale numbered from 1 to 5. With a Likert scale, a lower number means a better score, and a higher number means a worse score. A paired t-test was used to evaluate the change, comparing pre- and post-results. The ASK-12 Lifestyle Changes showed that the survey results were not significantly changed based on the medication adherence intervention program (see Table 2).

Table 2

Statistical Analysis ASK-12 Lifestyle t-test: Paired Two Sample for Means

The ASK-12 uses a Likert Scale numbered from 1 to 5.
 With a Likert Scale the lower the number = better and the higher the number = worse.

	Pre	Post
Mean	9.225806	9.290323
Variance	5.180645	9.946237
Observation	31	31
df	30	
t Stat	-0.15561	
P value	0.4387	

This paired t-test showed that there was a statistically significant improvement in the ASK-12 Treatment Beliefs survey responses post-intervention (see Table 3). The change between pre-and post-ASK-12 Treatment Beliefs scores signified that the medication adherence intervention was effective at decreasing perceived barriers to taking hypertension medication.

Table 3

T-test: Paired Two Sample for Means ASK-12 Treatment Beliefs

	Pre	Post
Mean	9.806451613	6.032258065
Variance	3.961290323	1.432258065
Observations	31	31
df	30	
T Stat	11.90822989	
P value <	0.001	

The change between pre- and post-ASK-12 scores signified that the medication adherence intervention was effective at decreasing perceived barriers to taking hypertension medication. What was particularly striking was that the variation was also significantly reduced. This would indicate that there was a high level of variation in treatment beliefs for the 31 participants prior to the intervention, and the project was able to reinforce the importance of medication adherence for the entire group which both reduced the mean value and reduced the variation in responses.

Behavior Taking Medicines questions were statistically significantly worse; however, this may have showed an understanding that patients became more aware that the perceived adherence to the regular dosage was not as accurate as they may have initially believed (see Table 4).

Table 4

Statistical Analysis ASK-12 Behavior Taking Medicines

	Pre	Post
Mean	8.709677	10.12903
Variance	17.07957	22.44946
Observations	31	31
df	30	
t Stat	-3.5395	
P value	0.001	

This data showed that there was strong statistical evidence that the group positively responded to the intervention. What is particularly striking is that the variation was also significantly reduced. This indicated that there was a high level of variation in treatment beliefs for the 31 patients prior to the intervention, and the program was able to reinforce the importance of medicine adherence for the entire group, which both reduced the mean value

and reduced the variation in responses.

Comparison of Blood Pressure Readings Pre- and Post-Intervention

Thirty-one patients were analyzed to see whether their blood pressure reading improved after participating in the adherence intervention. A paired t-test was used to compare the readings of individual patients before and after the intervention to see whether there was any change in performance. However, there was not enough statistical evidence to show that the intervention had reduced systolic and diastolic blood pressure. Overall changes in blood pressure often take weeks, and we found that in this population, the blood pressure data did not show dramatic results with a convenience sampling in a short amount of time. Below are the statistical results in Table 5.

Table 5

T-Test: Paired Two Sample Means Pre- and Post-Intervention Systolic and Diastolic Blood Pressure

Systolic Blood Pressure	Pre-	Post-
Mean	80.19354839	80.77419355
Variance	44.29462366	34.51397849
Observations	31	31
df	30	
T Stat	-0.419050607	
P Value	0.339082238	
Diastolic Blood Pressure	Pre-	Post-
Mean	100	100
Variance	0	0
Observations	31	31
df	30	
T Stat	N/A	
P Value	N/A	

There was not enough statistical evidence to show that the intervention had reduced systolic or diastolic blood pressure.

Pill Count Adherence Ratio Analysis

A methodology that can be used to assess the effectiveness of the medicine adherence intervention is assessing the PCAR. This measure was designed to calculate the adherence to a prescription dosing plan. Thirty-one participants PCAR scores were measured pre and post the medication adherence intervention. The PCAR scores for each of the participants pre and post medication adherence was 100%. There was a potential for bias as when the participants purchased the prescriptions near the start of the research project, it could have contributed to the results being 100%. The PCAR is calculated using the following formula shown in Figure 6.

$$\frac{(\text{Total Doses Dispensed}) - (\text{Total Doses Remaining})}{(\text{Total Doses Dispensed})} \times 100 = \text{PCAR}$$

Figure 6. PCAR.

CHAPTER 5

DISCUSSION

There is always a need to improve medication knowledge and usage within the hypertensive patient population. Anticipated challenges with this population in medication adherence may include many limitations: poor patient knowledge, low health care literacy, misinformation from family and friends, access to medications, patient safety, empowerment, lack of symptoms, perceived safety in skipping doses (Najimi et al., 2018), confusion about efficacy (Park et al., 2018), and poor provider-patient communication (Kvarnström et al., 2018). Medication adherence in hypertensive patients can be effective when adherence challenges or limitations are recognized, acknowledged, and addressed.

Johnson's (2002) Medication Adherence Model described purposeful action, pattern behavior, and feedback, which is the process patients journey through to adherence, along with the proposition for Lewin's Change Theory (Kehinde, 2020) that also rationalized that once the change theory has been defined, then adherence outcomes will impact intervention outcomes. Change was based on the premise that before change could occur, the perception for change had to be realized. Change (Kehinde, 2020) must be carefully planned, and this population needed to be reminded continuously about the reasons and benefits for the change. Lewin's Change Theory of unfreeze, change, and refreeze process (Kehinde, 2020) suggested that education, support, time, and communication are valuable aspects of the

adherence process. This process helped to identify weaknesses and strengths prior to change implementation.

Summary of Findings

The purpose of this statistical analysis was to evaluate whether the medication-adherence intervention was able to produce statistically significant outcomes for the groups of patients in the study. Thirty-one patients were surveyed prior to and after a medication-adherence intervention improvement, and there was statistically significant improvement in the awareness of medication adherence. The area of the most improvement was in attitudes and beliefs towards following a rigorous medication dosage program. What is interesting is that we see both a lowering of scores and reduction in variation in *Behavior Taking Medicine*. What is truly impressive is the reduction in variation responses. Variation is typically more difficult to improve and shows that this intervention program was extremely effective in educating the 31 participants in the importance of hypertension medication adherence. Based on this limited subset, a larger study, potentially funded by the Indiana Department of Health and Human Services, is warranted to see whether this reduction in variation can be reproduced. If so, this is an opportunity to create a periodic process of educating patients within the healthcare system on the importance of medication adherence.

In terms of blood pressure, there was not enough data to see differences in the blood pressure readings pre- and post-intervention. There was not enough data to demonstrate that the intervention had a positive effect on blood pressure. Neither value improved to a great enough degree to demonstrate that the intervention had had a positive effect. This is not surprising since medicine adherence, while important, is not the only factor driving blood pressure readings, and it would be unlikely that an improvement in this one area would cause

an overall improvement in results. It is more likely that we would see an improvement over a long-duration study evaluating those who had lack of adherence versus those who had improved their adherence.

In terms of PCAR analysis, since the data from pre- and post-intervention were both 100% adherence, we cannot do a statistical study on these data. However, we can conclude that the data show a general trend where the PCAR results were not negatively impacted by the medication-adherence educational intervention program.

One overall concern of this analysis is that we calculated the required number of patients at 50 but only reviewed 31 based on resources. However, based on the data collected from the ASK-12 post-survey results, the results were strong enough for us to conclude that the intervention was successful.

Project Analysis and Commentary

Strengths

Project strengths included an improved care process in which patients received effective hypertensive education, self-management skills, and patient-provider communication tips that helped to increase medication-adherence behavior. When patients could understand the information gathering from questions of who, what, where, when, and how through intentional methods to address medication-adherence awareness, then adherence increased within the targeted patient population (Seung, 2017) with the added benefit of positive patient health outcomes and increased patient-provider communication (Kvarnström et al., 2018). Patients felt empowered as a result of the intervention and helped to improve patient-provider communication opportunities, thus leading to patient feedback that helped to set the tone for continued adherence.

Limitations

The clinic initially lacked a screening, documentation, and management plan for patients' medication adherence in the care process. The nurse practitioner was the sole provider, and the graduate nursing students and receptionist/medical assistant were not trained in adherence efforts. On many of the clinic days, it was slow due to appointment no-shows, canceled, and rescheduling which allowed for a smaller number of participants to be recruited within the project timeline.

The convenience sampling goal of 50 patients was desired for project participation. This was an unrealistic goal due to inadequate potential participants, thus decreasing the participant sample to 31 for project participation. The sample size was small. The research project timeline was for 2–3 months and extending the timeline to an unknown number of months to increase participant contact was a limitation, thus creating a small amount of time between pre- and post-intervention measures. Under-served groups were not represented by using the convenience sampling.

Another limitation was that self-reporting scales have limitations because the participants' recall became less and less specific and their answers became embellished, causing incompatibility between actual medication taking and patient reports (Thompson et al., 2017). Research also showed that patients tend to participate in research when encouraged by their providers, and there is no one way or gold standard to medication adherence measurements (Giardini et al., 2016).

The risk of bias affecting reliability and validity can be introduced with assessor oversight when low-literacy patients cannot self-administer or complete the survey by themselves (Basu et al., 2019). Also, the association among poor health literacy, higher numbers of health diagnoses,

and the use of multiple medications strongly affects adherence. Adherence varies with time.

Implications

Prior to this project, the clinic did not have a care process in place to screen for adherence issues in their hypertensive patient population. The association between adherence and perceived barriers was direct. With the care process in place and tools to help increase patient-provider communication, that is, patients receiving self- management skills and effective hypertension education, adherence behaviors increased.

Dissemination Plan

The project results were made available to this Northern Indiana outpatient clinic, to Andrews University, and were presented in poster format to both entities. The care process protocol used at this outpatient clinic was made available to the staff to help implement continuous educational interventional efforts on medication adherence.

Recommendations

Adherence efforts must be continued in every outpatient clinic setting. The end-product deliverables of this project show, through much data research support, that improved provider-patient communication is a result of improved sharing of disease- process information, improved patient support, increased patient involvement, patient engagement, patient trust, patient satisfaction, and medication adherence (Ruppar et al., 2017). Adherence efforts must be on a continuum. Patient-centered care works when patients are informed and supported, care is individualized through various interventions, and medication adherence is increased.

Sustainability

At the project site, staff and patients demonstrated complete “buy-in” to the project’s goals and aims. However, there was a concern how undertaking this project would impose upon the time constraints of being a sole provider who wore many hats, along with the challenge of dedicating time to training revolving graduate nursing students who were there for only a limited amount of clinical time. Replicating this project is possible in treating a hypertensive population in any clinic setting.

The sustainability plan for any project is for the project to live on (Moran et al., 2019) or to have a future. The plan for sustainability would be that the medication-adherence screening tool would continue to remain a part of the clinic’s use and that the organization would embrace and adopt the interventions used in this project within the clinic. A designated staff member or graduate nursing student who could be trained in the educational components of medication adherence would continue to remain a part of the clinic’s use and the clinic would embrace and adopt the interventions used in this project. Students trained in the educational components of medication adherence would continue their role and become liaisons as “train-the-trainers” for new and upcoming graduate nursing students completing their clinical rotations and assuming the case management role. Grants would be obtained by the onsite program director to purchase self- management adherence tools such as digital B/P wrist monitors, BP wallet cards, and other tools that would aid in adherence with the identified vulnerable population for this clinic.

Evaluation

The purpose of this project was to reduce hypertension medication barriers. The hypothesis of this project was that by mitigating risk in a medically vulnerable population,

hypertension medication adherence would improve. This project was successful in screening patients, offering educational intervention on hypertension, and offering self-management adhering tools to increase adherence. Increased patient- provider communication and patient feedback on the educational efforts promoting adherence that were reinforced helped to energize purposeful action and patterning behaviors. This vulnerable patient population will need ongoing adherence support and feedback to continue the behavior long-term.

Self-Scholarly Analysis

The DNP essentials are curriculum core competencies that prepared DNP students must articulate successfully through their project completion of the scholarly research project (Moran et al., 2019). The following DNP essentials were reflected within my scholarly proposed project.

Essential I

Scientific Underpinnings for Practice were reflective of the complex issues in health care practice with this identified hypertensive population as they relate to their human interactive behavior correlated to life stressors, life events, and environment. Customizing a program that is focused on addressing blood pressure management and medication adherence through education and self-management interventions helped to identify improved patient outcomes in medication adherence (Marseille et al., 2021).

Essential II

Organizational and Systems Leadership for Quality Improvement and Systems Thinking was reflected in helping to adhere to culture and population sensitivity within this identified patient population. Telephone calls and case management visits helped to further meet patient population needs within this hypertensive group. The O'Brien (2018) cultural model for caring

suggests that in identifying cultural needs, the process involves becoming aware, making sense, figuring out meaningfulness, and intentional caring which can be compared to the steps involved in conceptualizing new practice strategies (p. 364) within the DNP Essential II framework.

Essential III

Clinical Scholarship and Analytical Methods for Evidence-Based Practice were reflected in care delivery approaches and interventions that were developed, implemented, and evaluated to meet the identified needs of this hypertensive population in an outpatient clinic setting. Evaluations and results were applicable in helping to develop guidelines for practice improvement.

Essential VII

Clinical Prevention and Population Health for Improving the Nation's Health involved cultural diversity, environmental data, determinants of health, and patients' knowledge regarding chronic disease. The intervention helped to guide my knowledge of health prevention and the identified population's health. Activities that increased medication adherence with supportive self-management intervention tools were utilized with this hypertensive population. These tools or measurements were effectively implemented within the clinic environment in order to test for small change evaluations (Polancich et al., 2018).

APPENDIX A

QUESTIONNAIRES

MMAS-4 Questionnaire

Morisky Medication-Taking Adherence Scale-MMAS (4-item)

English Version

(Please check one box on each line)

- | | Yes | No |
|---|-----------------------|-----------------------|
| 1. Do you ever forget to take your (name of health condition) medicine? | <input type="radio"/> | <input type="radio"/> |
| 2. Do you ever have problems remembering to take your (name of health condition) medication? | <input type="radio"/> | <input type="radio"/> |
| 3. When you feel better, do you sometimes stop taking your (name of health condition) medicine? | <input type="radio"/> | <input type="radio"/> |
| 4. Sometimes if you feel worse when you take your (name of health condition) medicine, do you stop taking it? | <input type="radio"/> | <input type="radio"/> |
-

The Morisky Medication-Taking Adherence Scale-MMAS is not copyrighted, is in the public domain, and does not require a fee for license.

Participant Demographics Questionnaire

Participant Demographic Questionnaire. Please answer each question.

What is your age?	
What is your gender?	
What is your race?	
What is your primary language?	
What is the highest level of education?	
What is your employment status?	Full-time Part-time Unemployed
Do you have health insurance?	Yes No
What is your marital status?	Single Married Widowed Divorced
What is the number of medications you take?	
What <u>are</u> your chronic medical diagnosis?	

ASK-12 Questionnaire



Taking Medicine—What Gets in the Way?

Think about all of the medicines you take. Mark one answer for each item below.

INCONVENIENCE/ FORGETFULNESS

Lifestyles

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1 I just forget to take my medicines some of the time.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2 I run out of my medicine because I don't get refills on time.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3 Taking medicines more than once a day is inconvenient.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

TREATMENT BELIEFS

Attitudes and Beliefs

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
4 I feel confident that each one of my medicines will help me.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5 I know if I am reaching my health goals.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Help From Others

6 I have someone I can call with questions about my medicines.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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Talking With Healthcare Team

7 My doctor/nurse and I work together to make decisions.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
--	-----------------------	-----------------------	-----------------------	-----------------------	-----------------------

BEHAVIOR

Taking Medicines

Have You...

	In the last week	In the last month	In the last 3 months	More than 3 months ago	Never
8 Taken a medicine more or less often than prescribed?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9 Skipped or stopped taking a medicine because you didn't think it was working?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10 Skipped or stopped taking a medicine because it made you feel bad?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11 Skipped, stopped, not refilled, or taken less medicine because of the cost?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12 Not had medicine with you when it was time to take it?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If you checked any answers in the dark blue boxes, talk with your doctor or healthcare professional.



Using ASK-12SM

- Ask your patients to complete ASK-12SM on paper, over the telephone.
- Identify potential barriers by reviewing any answers in dark blue boxes.
- Discuss with your patient any potential barriers.
 - If several barriers are identified, ask the patient which one matters most to him or her.
- Provide ASK resources (www.takingmeds.com) to address specific adherence barriers.
 - Consider any social support or services that may benefit the patient.
 - Counsel and follow up with the patient as needed.

APPENDIX B

IRB LETTERS OF APPROVAL

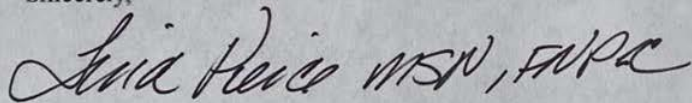
October 30, 2022

Institutional Review Board
Andrews University
4150 Administrative Drive Room 322
Berrien Springs, MI 49104-0355

I approve and submit this letter of supportive intent on behalf of LaPorte Family Wellness for Donna Hales-Teat, RN Doctor of Nursing Practice (DNP) student. She is proposing to conduct a project entitled Mitigating Risks to Improve Hypertension Medication Adherence in a Medically Vulnerable Population at LaPorte Family Wellness in La Porte, Indiana. The proposed project will be a quality improvement project to determine if implementation of a hypertension screening tool along with implementation of an educational interventional tool will improve hypertension medication adherence in a medically vulnerable population. To execute this project, I grant Donna Hales-Teat full access to space, patient medical records and all resources LaPorte Family Wellness.

The project will provide evidence that will address important risks in the area of patient hypertension medication adherence. This practice serves a high population of hypertension patients. Strategies to improve the clinical outcomes for our patients are embraced, valued, and appreciated.

Sincerely,



Tina Pierce, MSN, FNP-C
LaPorte Family Wellness
1700 Lincolnway Pl, Suite 8
La Porte, IN 46350
219-393-9072
Fax#219-325-0855
Psychconsults2@gmail.com

February 8, 2023

Donna Hales-Teat,
Tel. 574-876-5248
Email: halesteat@andrews.edu

RE: APPLICATION FOR APPROVAL OF RESEARCH INVOLVING HUMAN SUBJECTS
IRB Protocol #:23-005 **Application Type:** Original **Dept.:** Nursing
Review Category: Exempt **Action Taken:** Approved **Advisor:** Carol Rossman
Title: Mitigating risks to improve hypertension medication adherence in a medically vulnerable population.

Your IRB application for approval of research involving human subjects entitled: *"Mitigating risks to improve hypertension medication adherence in a medically vulnerable population"* IRB protocol # 23-005 has been evaluated and determined Exempt from IRB review under regulation CFR 46.104 (2)(i): Research that include survey procedures and in which information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subject. You may now proceed with your research.

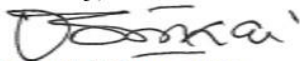
Please note that any future changes made to the study design or informed consent form require prior approval from the IRB before such changes can be implemented. In case you need to make changes please use the attached report form.

While there appears to be no more than minimum risks with your study, should an incidence occur that results in a research-related adverse reaction or physical injury, this must be reported immediately in writing to the IRB. Any research-related physical injury must also be reported immediately to the University Physician, Dr. Katherine, by calling (269) 473-2222.

We ask that you reference the protocol number in any future correspondence regarding this study for easy retrieval of information.

Best wishes in your research.

Sincerely,



Mordekai Ongo, PhD.
Research Integrity and Compliance Officer

Institutional Review Board – 8488 E Campus Circle Dr Room 234 - Berrien Springs, MI 49104-0355
Tel: (269) 471-6361 E-mail: irb@andrews.edu

APPENDIX C

PROMOTIONAL MATERIALS

Flier



Nursing Research Project

Increasing Medication Adherence

Andrews University School of Nursing

LaPorte Family Wellness, 1700 Lincolnway Suite 8, La Porte, Indiana

Improving Medication Adherence for Hypertensive Medication Through Individualized Case Management Education

Who Can Participate?

- Anyone who is 18 years old or older
- Anyone who has a Hypertension Diagnosis for at least 3 months

What is Required of Me?

- Completing a pretest survey
- Individual case management session 30 minutes in length
- Completing a post-test survey

Risks/Benefits?

- No associated risks
- Benefits include increased health knowledge and future benefit to community health education programs.

How Do I Sign Up?

Keep your scheduled clinic appointment in February

What If I Have Questions?

Call, Text or Email Donna Hales-Teat at 574-876-5248 or halesteat@andrews.edu

Brochures

[National Institutes of Health / National Library of Medicine](#)



[Home](#) → [Medical Encyclopedia](#) → High blood pressure in adults - hypertension

URL of this page: //medlineplus.gov/ency/article/000468.htm

High blood pressure in adults - hypertension

Blood pressure is a measurement of the force exerted against the walls of your arteries as your heart pumps blood to your body. Hypertension is the term used to describe high blood [pressure](#).

Untreated high blood pressure can lead to many medical problems. These include heart disease, stroke, kidney failure, eye problems, and other health issues.

Blood pressure readings are given as two numbers. The top number is called systolic blood pressure. The bottom number is called diastolic blood pressure. For example, 120 over 80 (written as 120/80 mm Hg).

One or both of these numbers can be too high. (Note: These numbers apply to people who are not taking medicines for blood pressure and who are not ill.)

- Normal blood pressure is when your blood pressure is lower than 120/80 mm Hg most of the time.
- High blood pressure (hypertension) is when one or both of your blood pressure readings are higher than 130/80 mm Hg most of the time.
- If the top blood pressure number is between 120 and 130 mm Hg, and the bottom blood pressure number is less than 80 mm Hg, it is called elevated blood pressure.

If you have heart or kidney problems, or you had a stroke, your doctor may want your blood pressure to be even lower than that of people who do not have these conditions.

[Home](#) → [Medical Encyclopedia](#) → Controlling your high blood pressure

URL of this page: //medlineplus.gov/ency/patientinstructions/000101.htm

Controlling your high blood pressure

Hypertension is another term used to describe high blood pressure. High blood pressure can lead to:

- Stroke
- Heart attack
- Heart failure
- Kidney disease
- Early death

You are more likely to have high blood pressure as you get older. This is because your blood vessels become stiffer as you age. When that happens, your blood pressure goes up.

When is Your Blood Pressure a Concern?

If your blood pressure is high, you need to lower it and keep it under control. Your blood pressure reading has 2 numbers. One or both of these numbers can be too high.

- The top number is called the **systolic blood pressure**. For most people, this reading is too high if it is 140 or higher.
- The bottom number is called the **diastolic blood pressure**. For most people, this reading is too high if it is 90 or higher.



[Home](#) → [Medical Encyclopedia](#) → Low-salt diet

URL of this page: [//medlineplus.gov/ency/patientinstructions/000109.htm](https://medlineplus.gov/ency/patientinstructions/000109.htm)

Low-salt diet

Too much sodium in your diet can be bad for you. If you have high blood pressure or heart failure, you may be asked to limit the amount of salt (which contains sodium) you eat every day. These tips will help you choose foods that are lower in sodium.

Salt and Your Diet

Your body needs salt to work properly. Salt contains sodium. Sodium helps your body control many functions. Too much sodium in your diet can be bad for you. For most people, dietary sodium comes from salt that is in or added to their food.

If you have high blood pressure or heart failure, you will likely be asked to limit how much salt you eat every day. Even people with normal blood pressure will have lower (and healthier) [blood pressure](#) if they lower how much salt they eat.

Dietary sodium is measured in milligrams (mg). Your health care provider may tell you to eat no more than 2,300 mg a day when you have these conditions. A measuring teaspoon of table salt contains 2,300 mg sodium. For some people, 1,500 mg a day is an even better goal.

Limiting Salt in Your Diet

Eating a variety of foods every day can help you limit salt. Try to eat a balanced diet.

APPENDIX D

INFORMED CONSENT LETTER

Andrews University, Department of Nursing Improving Medication Adherence for Hypertensive Medication Through Individualized Case Management Education

Project Manager: Donna Hales-Teat

Faculty Advisor: Carolyn Rossman, DNP, APRN-BC

Project Goal: To determine if screening patients with hypertension for medication adherence, then implementing individualized case management education to all patients who lack medication adherence, improve medication adherence among hypertensive adult patients in a primary clinic.

Consent to Participate in Research

Participation is completely voluntary

- I voluntarily agree to participate in this research study.
- I understand that even if I agree to participate now, I can withdraw at any time without any consequences.

Definition of Participation

I understand that participation in this research project involves the following:

- Taking a pre-test
- Attending a 30-minute case management session
- Taking a post test

Risks of participating in this project are minimal. There are no significant risks associated with this research project outside of normal day to day risks.

Benefits

- Increase in knowledge related to topics relevant to hypertension.
- Benefit to community health education in the future based on results of research.

Protecting the privacy of participants is a priority

- All data will be de-identified prior to analysis.
- Surveys will be stored in separate folders on the project manager's password protected computer.

If you have any questions regarding this project, please contact

Donna Hales-Teat, RN, BSN, Andrews University Student
at (574) 876-5248 or at halesteat@andrews.edu.

For any other concerns or questions about your rights as a project participant, please contact Dr. Carolyn Rossman, DNP, APRN-BC, DNP Program Director of Andrews University Department of Nursing at (269) 471-3614 or rossman@andrews.edu or Andrews University Institutional Review Board at (269) 471-6361 or irb@andrews.edu.

Conflicts of Interest – Donna Hales Teat, the project manager, declares no conflicts of interest.

“I have read and recognized that by completing and returning this survey that I am giving my informed consent to participate, agree that I am at least 18 years old and that I agree to the terms listed above.”

Print Name

Date

Signature

APPENDIX E

CASE MANAGEMENT

Case Management Tool Kit

Indication—Effectiveness—Safety—Adherence Indication Reason why I should take this medication.

Effectiveness What I should expect from taking this medication

Safety: What are the potential interactions or side effects of taking this medication

Adherence: Cost, case management self-management toolkit; memory aids, pill boxes, helping to set reminders, refrigerator magnets, calendars, journal, notebook, and wallet cards.

Tool Kit

Memory Aids: Patients are encouraged to keep medications together and in visible locations such as a kitchen pantry, medicine bag, and a medicine cabinet.

Association strategies like taking medications around daily events of brushing teeth or eating breakfast.

Pill boxes are medication organizers that separate sections labeled for the day of the week or more detailed versions that reflect time of day such as breakfast, lunch, dinner, and bedtime.

Reminders: Patients are encouraged to set their timers, wrist watch alarms, sticky notes on the bathroom mirror or use of phone alarms to remember when to take medications, what quantity to take, how to properly take medications, medication start and end dates, what medications look like, and side effects.

Refrigerator Magnet These are visual cues to remind patients to take their medications placed in a highly visible area.

Calendars: A calendar, noticeboard, and wall charts placed where seen frequently can help as a reminder to take medications. Crossing the day's date off the calendar before going to bed helps to reinforce what has been accomplished that day and the certainty of the date when you get up the next day.

Journals: Daily journals can be used to remind patients on how they felt or what they have done surrounding the taking of their medications. A journal can be used as conversation starters with their primary care providers.

Notebooks: A notebook is helpful in keeping lists of things to do or tasks accomplished. It is also helpful to keep the notebook near the phone or in a fixed place in the kitchen.

Wallet Cards: Can be used to list all medications and also as a walking diary of daily blood pressure recordings. This is often helpful to keep up to date and readily available to give when called upon by the medical doctors seen. This card also helps the patient track forward mobility towards their blood pressure goals.

Case Management Adherence Lesson Plan

Objective: Increase the patient’s knowledge about hypertension disease, medication, self-management, and provider communication importance.

Specific Objectives:

1. Participants will gain awareness of hypertension risks through knowledge and facts.
2. Patients will gain a sense of perceived risk through knowledge, facts, and striking statistics.
3. Patients will gain a sense of awareness of adhering-aiding tools/self- management importance.
4. Patients will begin to associate their own perceived risks with medication adherence.

30 MINUTE CASE MANAGEMENT SESSION OVERVIEW

Minutes 5

minutes

- Get situated, introductions, and restate objectives.
- Define Medication Adherence -is the act of filling and taking medications as prescribed.
- Show Hypertension Overview MedLine Plus Health Topic Animated Video offered by the National Institute of Health (22 seconds in length)

English <https://medlineplus.gov/ency/anatomyvideos/000072.htm>

Spanish <https://medlineplus.gov/ency/anatomyvideos/000072.htm>

- *(Project Manager to complete PCAR while patient is watching video)*

15 minutes

- Recap MedLine Plus Hypertension video
- Review MMAS-4 and ASK-12 questionnaire perceived patient risks.
- Give and review MedLine Plus Handouts on Hypertension disease, medication, and self-management.
- Teach back strategies such as asking open-ended questions “I want to be sure I explained why hypertension medication adherence is so important. Can you please explain it back to me so I can be sure I did?”

10 minutes

- Patients receive help with self-management adhering-aiding tools to stimulate adherence.
- Patient receives strategies on the importance of provider communication:
 - a) Make a list of your concerns in advance and keep track of how you felt and the symptoms you experienced when taking medications.
 - b) Speak up and make your key concerns are known from the onset of your doctors' visit.
 - c) Listen. Take a few deep breaths and focus on what the doctor is saying. Bring a tape recorder and ask the doctor if it is okay to record the visit. Bring a family member or friend to help listen, clarify or ask questions that you may neglect to remember.
 - d) Ask questions. If information is unfamiliar ask the doctor to repeat or explain information so that you can understand.
 - e) Do not minimize the symptoms or situation that you are experiencing. For example, "it's just a little cough" may lead the doctor to conclude that this is not serious.
 - f) Share what you know. You are the best source of information about what is going on with you and share the information or resources with your doctor that has been helpful to you.
- Make taking medication a habit
 - a) Help with organizing medications by using pillboxes.
 - b) Encourage patients to store medications together.
 - c) Attach the timing of medications around an existing habit like breakfast or when brushing teeth.
- Conclude and encourage patients to return to the next provider appointment and bring their medication bottles.

APPENDIX F

USER LICENSE AGREEMENT

SPECIAL TERMS No75838

These User License Agreement Special Terms (Special Terms) are issued between Mapi Research Trust (“MRT”) and Donna Hales-Teat (User).

These Special Terms are in addition to any and all previous Special Terms under the User License Agreement General Terms.

These Special Terms include the terms and conditions of the User License Agreement General Terms, which are hereby incorporated by this reference as though the same was set forth in its entirety and shall be effective as of the Special Terms Effective Date set forth herein.

All capitalized terms which are not defined herein shall have the same meanings as set forth in the User License Agreement General Terms.

These Special Terms, including all attachments and the User License Agreement General Terms contain the entire understanding of the Parties with respect to the subject matter herein and supersedes all previous agreements and undertakings with respect thereto. If the terms and conditions of these Special Terms or any attachment conflict with the terms and conditions of the User License Agreement General Terms, the terms and conditions of the User License Agreement General Terms will control, unless these Special Terms specifically acknowledge the conflict and expressly states that the conflicting term or provision found in these Special Terms control for these Special Terms only. These Special Terms may be modified only by written agreement signed by the Parties.

1. User information

User name	Donna Hales-Teat
Category of User	Student
User address	8975 Old 31, Berrien Springs, 49104, United States
User VAT number	
User email	halesteat@andrews.edu
User phone	5748765248
Billing information	8975 Old 31, Berrien Springs, 49104, United States

The User undertakes to use the COA solely in the context of the Stated Purpose as defined hereafter.

4.1 Stated Purpose

Other project

Title	Quality Improvement Project to Increase Medication Adherence
Disease or condition	Hypertension
Planned Term*	Start: 10/2022 End: 12/2022
Description (including format or media)	

4.2 Country and languages

MRT grants the License to use the COA on the following countries and in the languages indicated in the table below:

Version/Module	Language	For use in the following country
ASK-12_AU1.0	English	the USA

The User understands that the countries indicated above are provided for information purposes. The User may use the COA in other countries than the ones indicated above.

5. Specific requirements for the COA

- If the COA has not already been translated into the Licensed Language, the User is entitled to translate the COA or have it translated in such language, provided that the User complies with the methodology and requirements set-out in section 4.2.2 of this WO
- In case the User wants to use an e-Version of the COA, the User shall send the Screenshots of the original version of the COA to MRT or ICON LS for review and approval. The Screenshots review may incur additional fees.
- The Copyright Holder of the COA recommends that each new translation of the COA undergoes a full linguistic validation process according to standard recognized methodology of translation, as described in the ISPOR guidelines by Wild et al. 2005. Value in Health 8 (2): 94-104.

By accepting these Special Terms, the User acknowledges and confirms that it has read and approves the User Agreement General Terms.

Title MITIGATING RISKS TO IMPROVE HYPERTENSION MEDICATION
ADHERENCE IN A MEDICALLY VULNERABLE POPULATION

Disease or condition Hypertension

Planned Term* Start: 02/2023
End: 06/2023

Description (including format or media) project exploration

4.2 Country and languages

MRT grants the License to use the COA on the following countries and in the languages indicated in the table below:

Version/Module	Language	For use in the following country
ASK-12_AU1.0	English	the USA

The User understands that the countries indicated above are provided for information purposes. The User may use the COA in other countries than the ones indicated above.

APPENDIX G

CERTIFICATE OF COMPLETION



CERTIFICATE OF COMPLETION

PHRP Online Training, Inc. certifies that

Donna Hales-Teat

has successfully completed the web-based course "Protecting Human Research Participants Online Training."

Date Completed: **2022-11-04** Certification Number: **2984541**



PHRP
Protecting Human
Research Participants
Online Training

REFERENCE LIST

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