

QIP TO INCREASE MEDICATION ADHERENCE

**A QUALITY IMPROVEMENT PROJECT TO IMPROVE MEDICATION ADHERENCE
MANAGEMENT IN A CLINIC TO INCREASE MEDICATION ADHERENCE IN A
MEDICALLY VULNERABLE GROUP**

by

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DEDICATION

I dedicate this project to God, my creator, pillar of strength, the propelling force getting me to achieve this goal, despite the insurmountable challenges and obstacles. Thank you, God, for your mercy, grace, love, and unfailing presence in my life. For the divine wisdom, and your unfailing word that keeps me trusting you. I am under your control, without you nothing I do is possible.

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Abstract

This Quality Improvement Project (QIP) assessed the effect of a multi-component evidence-based (EB) Medication Adherence Intervention on adherence at a nurse-managed, student-run free clinic treating medically vulnerable adults aged ≥ 18 years who lacked health insurance and financial resources, had language barriers, low academic, health literacy, and understanding levels. The clinic staff lacked a process for screening, managing, and documenting non-adherence, estimated to be $>50\%$ by the stakeholders. Vulnerable patients, at risk for health disparities, known to need added time and attention (Viswanathan et al., 2012) did not receive adherence aid. Johnson's (2002) Medication Adherence Model (MAM) describes the process patients go through to adhere, e.g., purposeful action, pattern behavior, and feedback. MAM's concepts helped design, guide, and infer the intervention effects on adherence. The intervention involved: a) a designed online educational module to train staff on adherence and the QIP, b) a change to the clinic's care process, and c) two 1-hr case management (CM) patient educational sessions, 4-weeks apart, on disease, medications, self-management, provider communication, and adhering-aiding tools. Adherence rates improved by 141% and blood pressure (B/P) and blood sugar finger sticks (BSFS) levels decreased in two months.

Keywords: free clinic, vulnerable patients, medication adherence, self-management, literacy, medication non-adherence, medication education, multi-component adherence intervention

A Quality Improvement Project to Improve Medication Adherence Management in a Clinic and Increase Medication Adherence in a Medically Vulnerable Group

Reducing health disparities in medically vulnerable patients having multiple barriers is a complex issue of great interest to healthcare, consumers, and legislators (American Society on Aging and American Society of Consultant Pharmacists Foundation, 2012). Vulnerable groups have challenging barriers delaying access to healthcare and recommended treatment. According to Brown and Sinsky (2013) medically vulnerable patients struggle due to low incomes, no health insurance, language barriers, low to no formal education, and low health literacy levels. Barriers to medications for chronic conditions result in costly complications resulting in a poor quality of life and increased medical costs. Medically vulnerable groups need help with removing barriers to adherence to prevent complications. Prescribed medications, critical for treating chronic conditions, preventing illnesses, warding off disability, and death are the most significant advancement in medicine (American Society on Aging and American Society of Consultant Pharmacists Foundation, 2012). However, for medications to be beneficial patients must adhere. Preventing health disparities is possible when vulnerable groups gain knowledge to perceive a need to take and manage medications (Brown & Sinsky, 2013). According to Hu, Juarez, Yeborah, and Castillo (2014), to achieve outstanding health care minority groups must improve adherence. In an era where payors hold practitioners accountable for patient outcomes, adherence in the practice setting needs to be a priority (Seung, 2017).

Purpose

Healthcare teams can improve care by screening patients for barriers to adherence, offer culturally-sensitive disease, medication, and self-management education to promote adherence long-term (Brown & Sinsky, 2013; Seung, 2017). An efficient care process supports adherence efforts,

and increases disease, medication, self- management knowledge, showing potential for resolving non-adherence (Walker et al., 2014). The QIP purposed to increase medication adherence in vulnerable non-adherent patients who faced barriers. Non-adherence estimation in patients treated at the clinic was > 50% (clinic's director, personal communication, March 7, 2017). The QIP aimed to remove provider barriers by improving the clinic's care process, and remove patient barriers by offering disease, medication, communication, and self-management education to stimulate purposeful action, patterning behaviors, and supply adherence feedback.

Before the QIP, the staff did not screen, document or manage adherence. Funded by grants and donations, the clinic opens two days a week for a few hours, and the volunteer staff, made up of faculty, nurse practitioners (N/P), and Bachelor of Science in Nursing (BSN) students, work hard to treat the volume of patients seeking care. The demand for care leaves little time for practitioners to engage in effective education. Non-diabetic Spanish-speaking patients received patient education verbally and ineffective disease-specific handouts, in the English language. Also, there was no quality improvement initiative to detect the lack of medication adherence management. Provider and patient barriers contributed to non-adherence. The clinic's care process needed revising to remove provider barriers for patients to experience culturally-sensitive education, self-management aid, and increased NP communication.

Significance

Taking prescribed medications consistently benefits vulnerable groups with chronic conditions most, due to challenges faced, e.g. lack of insurance and finances (American Society on Aging and American Society of Consultant Pharmacists Foundation, 2012). As a health care professional, the DNP student is certain patient adherence is the primary solution to mitigate health disparities and improve outcomes since evidence findings consistently show a significant

correlation between adherence and improved outcomes. A study by Lopez, Bailey, Rupnow, and Annuziata (2014) found an association with poor glycemic control and medication adherence. Vulnerable adults, having little to no education, reporting non-adherence, had the worst glycemic control, while Native Americans and White participants, having higher health literacy levels, had better glycemic control and adherence (Lopez et al., 2014). Hall, Lee, Clark, and Perilla (2016) found non-adherent vulnerable adults, having low health literacy, had uncontrolled B/P, but those with disease and medication knowledge reporting adherence had controlled B/P ($p = .01$).

While medication taking may be an easy task for some patients, it is complex and challenging for vulnerable groups having limited resources, and low academic preparation (Colby, Wang, Chhabra, & Perez-Escamilla, 2012). Medically vulnerable patients, in the United States (U.S.) have the highest prevalence in chronic conditions (Walker et al., 2014), and worst medication adherence rates (Fernández et al., 2017) estimated between 17-30% (Kenya et al., 2015; Tong, Chu, Fang, Wall & Ayala, 2016). Vulnerable Latino patients with chronic conditions have the most significant struggles taking medicines than any other ethnic group (Lopez et al., 2014). Vulnerable groups need more support and help due to their low academic, health literacy, and understanding levels. Empirical studies involving patients with low academic and health literacy found they must perceive a need to take medications to adhere (Johnson, 2002). According to Zimmer, Woolf, and Haley (2015), investing efforts in patient education produces better health outcomes; however, education alone does not improve adherence (Hu et al., 2014). Research findings repeatedly show that interventions geared at improving medication adherence must include education and other EB adhering-aiding strategies, e.g. guidance with self-management, adhering-aiding tools, and increased provider communication (Hall et al., 2016; Thom et al., 2015). For NP to assess patients effectively they must communicate symptoms clearly. Colby et al. (2012) found

significant levels of adherence in patients with better health team communication and support. For best outcomes, patients need to learn the importance of open-honest provider-patient communication (Kenya et al., 2015).

Increasing adherence rates prevents health disparities, improves outcomes, care, and saves resources. According to Patterson, Holdford, and Saxena (2016), spending \$1.00 in adherence efforts saves \$37.00 in care. A systematic review of clinical practice guidelines to improve adherence recommends for providers to improve care processes by involving all staff in adherence efforts, offer education that include consequences of not adhering, and behavioral strategies, e.g. adhering-aiding tools to help patients develop patterning behaviors (American College of Preventive Medicine [ACPM], 2011; Brown & Sinsky, 2015; Ruppert et al., 2015).

Project Aims

The Quality Improvement Project (QIP) aimed to improve adherence in a vulnerable population using a multicomponent evidence-based (EB) Medication Adherence Intervention to change the clinic's care process, involve its staff in adherence efforts, and educate and support patients, to remove both provider and patient barriers to adherence in two months. The DNP student worked with the volunteer staff at the clinic, to integrate changes, using a similar process in place for screening patients for other problems. Adopting procedures in place helped the volunteer staff take part in the QIP with ease.

Project aims related to the PICOT question. The EB QIP proposed to improve medication adherence. The PICOT question asked if the intervention would influence the vulnerable group's non-adherence levels, when compared to basic medication education previously given, in two months. By designing and implementing an intervention that aimed to remove existing barriers, adherence increased. Patients were not able to adhere because they had poor

disease and medication understanding, were forgetful, had language barriers, and poor belief in the medication's efficacy and safety. Besides, the care process in place did not stimulate purposeful action in patients needed for adherence or helped them develop patterning behaviors. The PICOT question tied to the project's aim. Implementing the Medication Adherence Intervention removed barriers affecting the vulnerable group's adherence levels.

Project's Relevance

Bosworth and The National Consumers League (2016) estimated that in the U.S. 125,000 people die annually due to non-adherence. They also found a third of hospitalizations are related to medication non-adherence (Bosworth & The National Consumers League, 2016). Patients not only compromise their health with non-adherence, but it also costs the U.S. close to \$300 billion annually in expenses for visits to practitioners, the emergency room, and for complication treatment (Bosworth & The National Consumers League, 2016). Practitioners must address non-adherence to mitigate the devastating impact on patients, families, and the health care system.

QIP relevant to nurses. Nurses must translate EB findings into the care setting to improve outcomes. Also, they interact the most with patients in all settings making it possible to share disease and medication knowledge. Nurses can teach patients self-management skills, to prevent complications. This QIP was a nurse-driven opportunity to improve outcomes. Patients suffered from compromised health due to non-adherence. Nurses prevent unnecessary suffering when they help vulnerable patients obtain the necessary skills, and knowledge needed to adhere (Sutter-Barrett, Sutter-Dalrymple, & Dickman, 2015). As trained educators, nurses are in an excellent position to teach patients how to speak to providers about medications, while motivating them to engage in their care. Participants in the QIP improved medication-taking skills and knowledge. The non-prescribing staff felt empowered after efforts resulted in the patient's increased adherence,

and improved health outcomes.

QIP relevant to public health practitioners. Vulnerable populations depend on public programs to meet their needs (Sutter-Barrett et al., 2015). Public Health practitioners treating vulnerable populations can screen patients for adherence to detect barriers and mitigate costly complications in vulnerable groups lacking financial resources, saving health care dollars (Bosworth & The National Consumer League, 2016). Also, their feedback results in long-term adherence, improving the patient's quality of life.

Project Description

Project Significance and Impact

The intervention effectively increased the patient's medication adherence. Initially, the clinic staff estimated non-adherence to be more than 50%. However, the QIP preliminary findings revealed non-adherence occurred in 71% of vulnerable patients, an alarming and concerning finding since all participants had at least one chronic condition that if left untreated could have resulted in costly complications. After the QIP, adherence increased by 141% in two months. Also, non-adherent patients with hypertension (HTN), and or diabetes (DM) having elevated B/P and or BSFS pre-intervention experienced a decrease in those levels as adherence increased. The intervention effectively removed existing barriers to adherence. The DNP student recommended for the organization to expand the project to their other clinics to improve adherence and outcomes.

Significance of the problem. In a 2003 report, the World Health Organization (WHO) proclaimed medication non-adherence to be a significant public health problem (Ruppar et al., 2015). The consequences of not adhering results in excessive healthcare spending, poor outcomes, and death (Alton, March, Mallery, & Fiandt, 2015). According to Fernandez et al. (2017), medication non-adherence in vulnerable adults is a concerning problem needing immediate focus.

In the U.S., medically vulnerable populations have the highest prevalence in chronic conditions like HTN and DM (Hofer et al., 2017; Schroeder, Alaoul, & Keefe-Oats, 2015; U.S. Department of Health and Human Services Office of Minority Health, 2017), yet adhere poorly, especially Hispanics (Fernandez et al., 2017). Only 17-30% adhere to medications (Kenya et al., 2015; Tong et al., 2016). Patients, who do not adhere because of limited understanding, experience a different health outcome than those who adhere, creating health disparities (Fernandez et al., 2017). Consequently, vulnerable groups suffer complications and premature death (Bailey & Daugherty, 2014; Hofer et al., 2017). This is concerning since the number of uninsured, medically vulnerable individuals in the U.S. reached 11.7 million in 2016 (Garfield, Damico, Cox, Claxton, & Levitt, 2016), and by 2026 is expected to expand by 15 million (Center on Budget and Policy Priorities, 2016; United States Census Bureau, 2015).

Adhering to medications involves many elements in the population. Some elements include personal and cultural beliefs (Juckett, 2013), understanding the medication regimen (Brown & Sinsky, 2013), how to manage (Brown & Sinsky, 2013; Thom et al., 2015), and pay for it (Kenya et al., 2015), and transportation to get it filled (Schoenthaler et al., 2015). Prior to the QIP, patients did not perceive a need to adhere. They lacked purposeful action; which Johnson (2002) identified to be a precursor to begin adhering. When patients do not understand they do not adhere, risking complications (Bailey & Daugherty, 2014; Hofer et al., 2017).

Site's handling of the problem before the intervention. Before implementing the intervention, the clinic's director and stakeholders worked hard to increase medication access, known to impede adherence, yet non-adherence prevailed. There was no formal process in place for screening, documenting, or managing adherence. Also, the staff was not involved in adherence efforts. Patients did not get added education to understand disease, medication, self-management,

and communication with the NP was lacking. In addition, the clinic did not equip patients with adhering-aiding tools to help them manage medications. As a result, patients had poor clinical outcomes. Non-adherent patients having HTN had uncontrolled B/P ($\geq 180/140$), and non-adherent DM patients had elevated BSFS (up to 366mg/dL). The literature concurred with the DNP student's findings. In a randomized controlled trial (RCT) following 300 diverse, medically vulnerable patients (from 20 countries) having suboptimal HbA1c (> 8) levels, 83% were non-adherent (Kenya et al., 2015). Hall et al. (2016) found 49% non-adherent migrant workers treated at a federally funded clinic had uncontrolled B/P.

The EB Project

The intervention consisted of three major components, each designed to target the identified barriers contributing to medication non-adherence. Component one involved the design of an educational module to train the clinic staff on adherence and the QIP. The second component involved changing the clinic's care process to include adherence screening, managing and documenting. Finally, the third component involved patient education and self-management assistance. The following section explains each component of the QIP.

First component. The clinic's staff needed increased non-adherence awareness and involvement in adherence efforts. The first part of the QIP trained staff in adherence efforts using an online asynchronous EB training module designed to raise awareness about the importance of adherence, and the planned QIP. Once completed, staff understood the urgent need to remove barriers by screening patients and intervening with patient education and support.

Second component. To improve the clinic's care process, the DNP student added a four dichotomous questions adherence self-reporting screening tool, Morisky's Medication Adherence Scale-4 [MMAS-4] (Morisky, Green, & Levine, 1986), in English and Spanish, to the clinic's

health questionnaire intake form. Although available for use in the public domain, the DNP student secured author permission to use the tool (see Appendix A1). Any “yes” response on the MMAS-4 triggered the BSN student to give patient another adherence self-reporting screening tool to assess for barriers. The Adherence Starts with Knowledge-12 [ask-12] tool (Matza et al., 2009), available in English and Spanish, screens for barriers related to inconvenience, health belief forgetfulness, and self-management behaviors (ACPM 2011; Brown & Sinsky, 2015). The tool helps providers tailor patient education, based on barriers. Like the MMAS-4, the DNP student secured author permission to use the ask-12 tool (see Appendix A2). Once completed, the NP reviewed the forms, started the education and referred non-adherent patients to the QIP.

Third component. Finally, non-adherent patients received two, 1-hour case management (CM) patient education sessions, 4- weeks apart on disease, medication, self-management, and communication. Patients received adhering-aiding tools e.g. a pillbox, refrigerator sign, a calendar, wallet card, and notebook to journal B/P and BSFS levels, questions, or symptoms (ACPM, 2011; Brown & Sinsky, 2015; Ruppap et al., 2015). Although not initially planned, stakeholders bought digital wrist B/P devices and glucometers for HTN and DM patients given along with the rest of adhering-aiding tools bought by the DNP student. Patients learned how to use the device/s, high and low levels, actions for abnormal levels, frequency to check, and how to document results. During CM sessions, patients filled out the adherence screening tools, and the BSN students took the B/P and BSFS for patients with HTN and DM. The DNP student delivered the culturally-sensitive education using Medline Plus videos, and medication information in Spanish and English (National Institute of Health [NIH], 2017a, 2017b). The DNP student also counted the patient’s medications to obtain a Pill Count Adherence Ratio (PCAR), as an objective measure of adherence (Martin et al., 2011). The literature recommended using two or more types

of adherence measures for credible adherence results (Hu et al., 2014).

Patients taught-back (Tamura-Lis, 2013) all instructions, showed proper use of the digital wrist B/P or glucometer device/s, pre-poured their medication in the pillbox, and showed documentation of the physiological parameters recorded on the notebook for practitioner review. Patients felt “empowered” and “eager” to take part in practitioner communication.

Available Knowledge

The NP treating the vulnerable with chronic diseases must find ways to increase adherence before costly complications occur. According to the Center on Budget and Policy Priorities (2016) the number of vulnerable adults will increase in the U.S. by 2026. Kvarnström, Airaksinen, and Liira, (2018) recommend for NP to improve adherence management by offering patients education and assistance with self-management. The following section details evidence from the literature on factors affecting adherence in the patients, components in interventions that increased adherence, and strategies that improve adherence management in practice settings.

Search strategy. The DNP student reviewed the literature using computer-based searches in the English-language using Capella University’s library and an additional University’s library resources including MEDLINE (2010-2018); CINAHL (2010-2018); PUBMED (2010-2018); Agency for Research and Quality (2010-2018); PROQUEST (2010-2018); Cochrane Database of Systematic Reviews (2010- 2018); as well as GOOGLE SCHOLAR (2010-2018) yielding invaluable knowledge used to design the Medication Adherence Intervention. MeSH terms included uninsured vulnerable patients, vulnerable, low-income, parish-clinics, nurse-led clinics, free-clinics, medication adherence, medication non-adherence, compliance, clinical guidelines to improve medication adherence, predictors of adherence, provider communication, health literacy, medication self-management, measuring medication adherence, medication education, adherence

measures, adhering-aiding strategies, adhering-aiding tools, pill boxes, medication reminders, and medication lists. Also, the DNP student joined terms with keywords vulnerable groups, vulnerable patients, adherence interventions or intervention studies. A review of all retrieved citations' abstracts determined relevancy. Also reviewed full-text scholarly journal articles published between the years of 2010-2018. The searches yielded seventy-seven (77) potential sources. Screened articles in English for relevance to the PICOT question, and duplication. Retained articles included those with evidence of factors affecting medication adherence in the population, articles with evidence of useful components in adherence interventions, and articles recommending strategies to improve adherence management in practice settings. Further, hand searched article references, and specific guideline databases, and website including IMS Institute for Healthcare Informatics, Institute of Medicine, and the Agency for Research and Quality.

Exclusion/inclusion criteria. Articles excluded were those that did not add knowledge about barriers to adherence in the population, and studies involving single component to interventions studied. Empirical findings of single component interventions consistently reported no effect on adherence (Hu et al., 2014). Articles kept had evidence for barriers that impede adherence in medically vulnerable adults, components in interventions found to increase adherence or strategies that improved adherence management in the practice setting. Also, included literature reviews for the invaluable analogy done between studies that tested various interventions. Of the 77 potential sources found, 33 met inclusion criteria. Of those, 12 sources gave evidence on factors affecting adherence in the population; 19 sources provided evidence on components in interventions that increased adherence, and eight sources provided medication adherence guidelines, strategies, or recommendations on ways to improve care processes to improve adherence management.

Of the 33 sources meeting inclusion criteria six provided evidence on both factors affecting adherence in vulnerable groups, and interventions that increased medication adherence (Barkhof, Meijer, de Sonnevile, Linszen, & de Haan, 2012; Colby et al., 2012; Kenya et al., 2015; Kvarnström et al., 2018; Reh, Thomas, & Kumar, 2016; Zwikker et al., 2014).

Scheme for grading the evidence. The DNP student used a rating scale on the Worksheet for Critique of the Model for Change to EB Practice used by U.S. Preventative Services Task Force, to grade the quality of the evidence (Rosswurm & Larrabee, 1999). Robust evidence received a lower grade, e.g., Ia, Ib or IIa, and less robust a higher grade, e.g., IIb, III.

Evidence for adherence factors. A total of 12 sources looked at factors affecting adherence in vulnerable groups (Alton et al., 2015; Bailey & Daugherty, 2013; Barkhof et al., 2012; Colby et al., 2012; Coletti et al., 2015; Hall et al., 2016; Kenya et al., 2015; Kvarnström et al., 2018; Reh et al., 2016; Schroeder et al., 2015; Tong et al., 2016; Zwikker et al., 2014). Kvarnström et al. (2018) found three variables predicted adherence in medically vulnerable patients: receiving support from the physician and healthcare team; increased knowledge; and aid with self-management. The authors concluded that improvements to care processes that involve the interdisciplinary team and open communication increased adherence. Kvarnström et al. (2018) findings show that a trustful relationship between the interprofessional team and patient correlates with adherence and therapeutic outcomes. The QIP included efforts to improve the practitioner-patient relationship to improve adherence.

Four of the 12 sources found poor provider communication is a predictor of non-adherence (Kenya et al., 2015; Kvarnström et al., 2018; Reh et al., 2016; Schroeder et al., 2015). The literature named other factors to non-adherence in medically vulnerable groups. Tong et al. (2016), found patients having an annual income of < \$25,000 were twice as likely be non-adherent,

compared to patients having an annual income of > \$60,000. Also, medically vulnerable groups reported “forgetting to take medications because they felt well” (Tong et al., 2016, p. 893). Alton et al. (2015) found a third of the participants completed some grade school; the study concluded patients needing help to understand medications are three times more likely to not adhere. Studies also found when the importance or need for medications is not known it causes non-adherence (Barkhof et al., 2012; Schroeder et al., 2015; Zwikker et al., 2014).

Schroeder et al. (2015) issued national surveys to learn the reason Hispanics do not adhere (n=1712), 41% were Spanish-speaking only and claimed they did not understand the doctor. A total of 71% reported not taking their medications daily (Schroeder et al., 2015). Most patients reported needing better disease and medication information before they would adhere. Other reasons cited in the literature included forgetfulness (Reh et al., 2016), limited access to medication (Bailey & Daugherty, 2014), and medication’s cost (Kenya et al., 2015).

Of the 12 sources providing evidence, rated Ib, for factors affecting adherence one was a meta-analysis (n = 15 RCT), one a literature review (n = 12), three RCT (n = 300, 4198,123), four were comparative correlation and other descriptive studies (n = 119, 61, 328, 45), one was a qualitative study (n= 16), and two were expert reports (n = 0, 4000). The literature review source (n = 12) had a second part, a qualitative study (n=1712).

Evidence for components known to improve medication adherence. A total of 19 sources provided evidence for components in interventions known to increase adherence (Barkhof et al., 2012; Beach et al., 2015; Bruera, Barbo, & Lopez-Olivo, 2016; Colby et al. 2012; Costa et al., 2015; Fan, Ding & Sidani, 2018; Farmer et al., 2012; Fenerty, West, Davis, Kaplan, & Feldman, 2012; Foster et al., 2018; Hacıhasanoğlu & Gözümlü, 2011; Hofer et al., 2017; Hu et al., 2014; Hyrkas & Wiggins, 2014; Kenya et al., 2015; Kvarnström et al., 2018;

Najafi, Shaabani, Momennassab, & Aghasadeghi, 2016; O'Quin, Semalulu, & Orom, 2015; Reh et al., 2016; Zwikker et al., 2014).

Patient education. Of the 19 sources found for components in interventions known to improve adherence, 10 provided evidence on the effects of medication and disease education in increasing adherence (Fan et al., 2018; Farmer et al., 2012; Foster et al., 2018; Hacıhasanoğlu & Gözüm, 2011; Hofer et al., 2017; Hu et al., 2014; Hyrkas & Wiggins, 2014; Kenya et al., 2015; Najafi et al., 2016; Zwikker et al., 2014). A study by Hacıhasanoğlu and Gözüm (2011) joined medication adherence education with healthy lifestyle teaching, increasing adherence. Fan et al. (2018) studied the effects of an education intervention along with self-management and reminder tools. Patients receiving the education, and tools had increased adherence. A RCT by Hyrkas and Wiggins (2014) found education alone did not increase adherence. However, when combined with another element, education significantly increased adherence (Ruppar et al., 2015). Najafi et al. (2016) found a nurse-led adherence intervention combined with education and follow-up phone calls effectively increased adherence in elder patient's post-heart attacks. Hu's et al. (2014) reviewed studies using interventions to increase knowledge. Most studies found evidence showing education alone did not increase adherence.

Of the 10 sources having evidence, rated Ia, for educational interventions improving adherence one was a literature review (n = 20 RCT), eight were RCT (n=211, 120, 179, 100, 169, 143, 300, 123), and one a longitudinal study (n = 303).

Communication. Of the 19 sources providing evidence for components in interventions known to increase adherence, five provided evidence on the importance of provider communication in increasing adherence (Beach et al., 2015; Colby et al., 2012; Kenya et al., 2015; Kvarnström et al., 2018; Reh et al., 2016). According to Beach et al., (2015), patients who received clarification,

by speaking to providers had more to say (167 verses 128, respectfully $p=.004$). When patients communicate and obtain disease and medication education, they adhere (Kvarnström et al., 2018).

Of the five sources with evidence, rated IIa, on practitioner communication increasing adherence two were RCT ($n = 160, 300$), one cross-sectional study ($n = 61$), and one qualitative study ($n = 16$), and one expert report ($n = 4000$).

Adhering-aiding tool to improve self-management. Of the 19 sources found for components of interventions known to increase adherence, seven provided evidence on the effects adhering-aiding tools had in improving medication self-management (Barkhof et al., 2012; Bruera et al., 2016; Fan et al., 2018; Costa et al., 2015; Foster et al., 2018; O'Quin et al., 2015; Reh et al., 2016). Bruera et al. (2016), gave adhering-aiding tools, e.g. calendars, pill boxes, refrigerator reminder signs, and journaling, to patients with rheumatoid arthritis. Patients who used the tools to improve medication self-management had fewer tender joints ($p = -0.17$, $p=0.02$). The study found self-management guidance and reminder tools helped patients adhere (Bruera et al., 2016). Fan et al. (2018) conducted a RCT where the intervention group received education, self-management reminder tools, and a phone call. The comparison group received standard care. Patients who got the intervention had higher adherence rates ($> p = 0.05$). Costa et al. (2015) found patient's adherence improved with increased knowledge and medication self-management guidance. Receiving guidance with adhering-aiding tool use to improve self-management is a low-cost solution for avoiding costly consequences (O'Quin et al., 2015).

Of the seven sources with evidence, rated Ia, on adhering-aiding tool effect in increasing adherence one was a meta-analysis ($n = 15$ [RCT studies]), one a literature review ($n = 109$), three RCT ($n = 65, 169, 143$), one descriptive study ($n = 201$), and one expert report ($n = 4000$).

Strategies for improving adherence management in clinics. A total of eight sources

provided evidence on strategies, recommendations or guidelines to improve the care processes in practices to increase adherence (Balano, 2013; Brown & Bussell, 2011; Brown & Sinsky, 2013; Kvarnström et al., 2018; Ruppap et al., 2015; Seung, 2017; Starr & Sacks, 2010; Wu & Pai, 2014). Implemented guidelines effectively eradicated provider barriers in the practice setting, improving adherence management (Kvarnström et al., 2018). Practitioners, tasked with addressing adherence, do not know how to address the issue (Kvarnström et al., 2018). Health care organizations set guidelines guiding practitioners on how to prescribe medications but do not guide them on how to address non-adherence (Ruppap et al., 2015). Medication adherence guidelines recommend for practitioners to engage the clinic staff in adherence efforts (Brown & Bussell, 2011; Brown & Sinsky, 2013; Kvarnström et al., 2018; Ruppap et al., 2015; Seung, 2017; Starr & Sacks, 2010; Wu & Pai, 2014) and screen for adherence, using several types of measures. It also recommends for practice settings to educate patients, and aid with behavioral strategies to increase adherence (Balano, 2013; Brown & Bussell, 2011; Brown & Sinsky, 2013; Ruppap et al., 2015; Seung, 2017; Wu & Pai, 2014).

Of the eight sources with evidence, rated Ib, on strategies to improve adherence management in the practice setting one was a meta-analysis (n = 35 [RCT studies]), one a systematic review (n = 84), one literature review (n = 127 studies), two evidence-base provider trainings (n = 0, n = 0), and three expert reports (n = 0, n = 0, n = 0).

Measuring adherence in the practice setting. After decades of medication adherence research, there is no true “gold standard” for measuring adherence, though some methods have greater limitations than others (Hu et al., 2014). Countless studies have used validated and reliable adherence self-reporting tools, like the MMAS-4 (Morisky et al., 1986) and ask-12 (Matza et al., 2009) with many populations, including vulnerable medical adults. According to the literature, a

disadvantage for using adherence self-reports is that patients tend to exaggerate responses (Spoelstra & Rittenberg, 2015). Some studies used manual pill counts as objective measures of adherence, despite it being labor intense (Martin et al., 2011). To know how many pills patients took since the fill date, practitioners counted pills in each bottle then subtracted that number by the number of pills dispensed. Practitioners then divided the number of pills taken by the number of doses dispensed, then multiplied by 100 to get the PCAR for each medication (Martin et al., 2011), used as an objective measure of adherence. Results $\geq 80\%$, meant patient adhered and $< 80\%$ meant non-adherence. According to Morisky et al. (1986), taking physiological parameters, e.g., B/P readings, BSFS levels, pulse, during interventions help support adherence findings (Morisky et al., 1986). The literature recommends for clinicians to use two or more adherence measures to ensure credible results (Hu et al., 2014; Wu et al., 2014).

Literature Review Summary

Evidence reviewed offered several recommendations pertinent to the QIP. Knowing predictors of barriers to medication adherence in medically vulnerable groups helped find EB interventions proven to increase adherence (Alton et al., 2015). According to Hu et al. (2014), interventions that increase adherence in minority groups could contribute to mitigating health disparities. In the selected site, patients had medication access, but barriers impeded adherence.

Components of EB medication adherence interventions. EB medication educational interventions alone did not improve adherence in the studies reviewed. However, when paired with other components like behavioral strategies, adherence improved. According to studies, collaborative and multi-component interventions effectively increase adherence, but interventions that are single-component and non-collaborative do not (Choudhry et al., 2017; Zimmer et al., 2015). For medically vulnerable groups to adhere, they must know the link between diseases and

medications (Zimmer et al., 2015), and ways to manage medications. Also, provider communication must improve to obtain the much-needed feedback, and support found to stimulate a desire in patients to continue adhering (Beach et al., 2015; Johnson, 2002). Support and follow-up given by practitioners, particularly feedback, showed promise as an intervention (Beach et al., 2015; Johnson, 2002) and would prove beneficial for medically vulnerable patients. Having support helps patients understand their disease, medications, and how to use adhering-aiding tools to tailor medication-taking routines (Fenerty et al., 2012). Support eases medication concerns (Thom et al., 2015), acts as reminders, and gives feedback on medication taking efforts (Colby et al., 2012). Guidelines recommend for health systems to change their care processes to improve adherence management (Ruppar et al., 2015). Providers must involve the staff in adherence efforts to screen for barriers and give patients support to ensure adherence (Brown & Sinsky, 2013).

The literature did not name a single best method for measuring adherence. Instead, it recommends for clinicians to include more than one measure, e.g., objective method (pill count) and self-reports (Hu et al., 2014). Researchers who used adherence self-reports concluded that participants exaggerated adherence rates when compared to other measures in the same study (Hu et al., 2014). Investigators using more than one measure confirmed adherence rates (Hu et al., 2014). Following recommendations in the literature, the DNP student used two adherence self-reporting tools, and pill counts, to measure adherence. Also, physiological parameters (B/P & BSFS) collected pre- and post-intervention confirmed adherence findings.

Rationale

Theoretical framework. The Medication Adherence Model (MAM) by Johnson (2002), used with verbal and written permission (see Appendix A3), helped design, guide, and infer the QIP effect on adherence. MAM theoretical framework describes the process patients go through

to adhere. The concepts in MAM guided practitioners through the process of medication adherence in patients with HTN. Johnson (2002) selected HTN due to its asymptomatic nature, which “affects about 24% of the population” (p.184), including vulnerable groups. Johnson (2002) believed if the primary adherence tenets could explain one chronic illness, then those tenets could apply to other chronic conditions. MAM focuses on two reasons patients do not adhere: (1) intentional decisions (deciding to miss, forgetting to take a dose), and (2) unintentional interruptions (lacking medication access). Johnson (2002) created MAM after finding that the Health Belief Model, Social Learning Theory, Theory of Reason Action, Self-Efficacy and Self-Regulation Theory did not focus on adherence factors in patients with chronic disease. Being adherent to medications for chronic conditions seem to have different attributes when compared to acute conditions. The QIP aimed to increase adherence, and MAM produced the concepts needed to get patients to adhere. Three core concepts of MAM helped design the intervention. The core concepts describe the theoretical framework and process patients must go through to adhere to their treatment regimen (see Figure 1.)

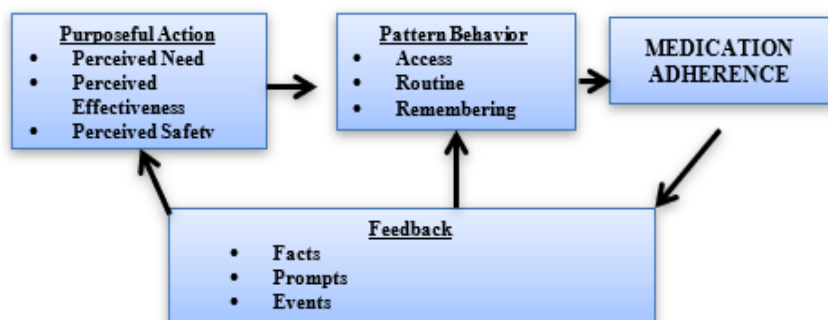


Figure 1. The Medication Adherence Model, by Johnson (2002). Copyright 2002 Springer Publishing Company. Reprinted with Written Permission.

Purposeful action. The decision process patients go through, either cognitively or intentionally, to deliberately take medication based on a perceived need, effectiveness, and safety is the first core concept of MAM, known as Purposeful Action (Johnson, 2002). If patients perceive a

need to take medications for well-being, and to ward off complications they will adhere. The QIP reinforced disease and medication education to get patients to understand its effectiveness and safety, stimulating purposeful action.

Patterned behaviors. MAM second concept deals with the ritual, habit, or pattern for taking medications that patients create after accessing and remembering to take it, called Patterned Behaviors (Johnson, 2002). The vulnerable face obstacles after accessing medications, due to their low understanding. The medically underserved often have chaotic lives making it difficult to set up realistic routines (Kvarnström et al., 2018). The QIP taught patients to self-manage medications and incorporate medication taking into their routines. Adhering-aiding tools given to non-adherent patients, helped them develop patterning behaviors. Also, some patients with cell phones learned to use the alarm as medication reminders.

Feedback. The third concept of MAM, Feedback, is the degree to which information, facts, prompts, or events reinforce the need to keep, quit, or change adherence (Johnson, 2002). The first two core concepts of MAM occur as a direct result of the patient's response to treatment. According to Johnson (2002), "feedback is the individual's outcome criteria of the need, effectiveness, and safety of the medication" (p. 187). Examples of feedback include normalizing clinical findings, e.g., B/P readings, personal responses, media messages, and comments by health care practitioners, and clinic staff. Patients use feedback to determine if they should continue adhering. Information received from sources motivate patients to continue adhering and reminds them of the importance of medications. Improvements made to the clinic's care process, as part of the QIP created increased opportunities for patients to received feedback, needed for long-term adhering. Also, the adhering-aiding tools: notebook, B/P and BSFS devices, served to engage patients in their care and increased provider feedback.

To summarize, purposeful action triggers pattern behavior determining the degree of adherence. The patient's adherence efforts create a positive or negative reinforcement that feeds back to both purposeful action and pattern behaviors, leading patient to continue adhering.

QIP variables. The QIP primary outcome of interest was adherence. A secondary outcome of interest was improvements to the patient's physiological parameters (B/P & BSFS) in patients with HTN and DM, as adherence increased. A review of the staff responses on the training module evaluation, created using Kirkpatrick's Evaluation Model for measuring the success of training programs (Dorri, Akbari, & Dorri-Sedeh, 2016) determined needed module changes, before permanent implementation. The survey measured staff reaction, learning, level of knowledge gained, and behavior, to assess their opinions, essential for making changes. It also informed if the learner found the information helpful, and relevant to practice. Fortunately, the staff found the training module educative, engaging, interactive, relevant, and useful to the practice setting. The staff did not recommend any changes (n =29).

Assumptions. To minimize potential threats to the QIP success the DNP student supervised, supported, encouraged, and promoted the QIP. The DNP student ensured all staff took part in adherence efforts. Feedback from the staff showed they believed the intervention was easy to implement. Teamwork motivated the staff to find other nurse-led initiatives to improve quality care empowering them to find research to support their projects. The School of Nursing supported the clinic's efforts to improve patient adherence and decrease health disparities. Without staff involvement, the QIP would have been difficult to implement. The designed intervention called for an interdisciplinary and collaborative effort to increase adherence. Involving every staff member was vital to the success of the QIP. Trained staff received their assigned task, ongoing praise for their efforts, and constant reports for the outcomes achieved

helping to keep the momentum going. The excellent outcomes inspired staff to continue adherence efforts. As a result, the DNP student eradicated potential threats to the QIP related to minimal staff participation.

Specific Aims

The QIP specifically aimed to increase medication adherence and improve physiological parameters in HTN and DM patients. To increase adherence in the clinic, targeted provider and patient barriers for removal, by training the staff in adherence efforts, changing the clinic's care process to screen patients for adherence, and offer non-adherent patients culturally-sensitive disease, medication, communication, and self-management education, and aid using adhering-aiding tools. Also, patients diagnosed with HTN and DM received a digital wrist B/P device and glucometer, and notebook to document results for the practitioner to review. At the end of two months, adherence changed from 29% to 70%, adherence increased by 141%, and patients with HTN and/or DM experienced a drop in their elevated B/P and BSFS levels.

Purpose of the project. The purpose of the QIP was to remove provider and patient barriers contributing to non-adherence in the clinic. Only 29% of patients adhered before the QIP. After the intervention adherence increased by 141%, in two months. According to Bernstein (2015), lacking an understanding of the importance and need for medications, and having low health literacy affects a person's ability to incorporate medication taking into daily routines. In a study by Schroeder et al. (2015), vulnerable patients reported non-adherence if they did not know the medication's purpose, efficacy, importance, and complications of not taking it. Improving adherence rates mitigated potential costly complications for patients, their families, and healthcare system. The QIP helped save healthcare resources by preventing complications, e.g., stroke.

Connecting the QIP goals and PICOT to MAM. The QIP aimed to improve adherence.

The PICOT question tied in directly to the projects aim. For adherence rates to increase the practitioner barriers needed eliminating. The clinic needed to include adherence screening, documenting and management to its care process. Also, patient barriers needed removal. Patients needed added time, and culturally-sensitive education to understand their disease and medications, for purposeful action to occur (Johnson, 2002). Patients with limited understanding needed guidance on how to develop pattern behaviors (Johnson, 2002) to add medication taking into their routines using adhering-aiding reminder tools. Finally, patients needed to learn how to communicate with practitioners to obtain feedback needed for long-term adherence (Johnson, 2002). Equipping the population with knowledge, and self-managing skills helped motivate adherence. The QIP addressed MAM core concepts needed for patients to adhere, (Johnson, 2002). The response to the PICOT question is yes, a Medication Adherence Intervention removed barriers effecting the vulnerable group's adherence levels, in two-months.

Context

Participants Characteristics

Participants were mostly uninsured Hispanics (> 90%), living in a City with a population of 147,294, where 50.9% (74,973) are Hispanics, and 42% (61,863) considered poor. This vulnerable group lacked the residence status needed to secure legal employment. If working, participants reported earning less than minimum wage, limiting their financial resources. Participants reported migrating from foreign Latin countries, e.g., Honduras, Guatemala, El Salvador, Mexico, and Cuba, leaving their family behind. Most relied on friends, and neighbors met in the U.S. for support.

All Participants were adults \geq 18 years of age, with incomes < 200% of the Federal Poverty level (The SANDAG Service Bureau, 2013), who form part of the 22.31% of uninsured

residents in the community (Kiernan, 2016). They also had low academic education, health literacy, and comprehension levels, language barriers, and illegal U.S. residency status (Health and Human Services Agency, 2017). Despite having chronic conditions, participants were overweight and did not exercise or follow any diet restrictions.

Prevalent health conditions found among participants included uncontrolled HTN and DM. Despite having medications prescribed for their conditions, participants did not follow the regimen. Non-adhering participants having HTN had elevated B/P, and those with DM had elevated BSFS, before receiving the intervention.

Benefits to populations. The culturally-sensitive education appeared to be the precursor needed to motivate patients to adhere. Improving provider communication allowed patients to obtain help with removing barriers to adherence. Obtaining aid with medication self-management involved patients in their care and ensured adherence. Besides, adhering-aiding tools served as reminders for patients to take medications. Ongoing provider feedback motivated patients to adhere for two months. Mitigating health disparities and complications is possible when vulnerable groups get needed knowledge, and skills to adhere (Colby et al., 2012; Juckett, 2013; Thom et al., 2015). Patients with increased knowledge and self-management skills are less dependent on the health care system and use it less (ACPM, 2011; Costa et al., 2015).

Organizational Characteristics

The nurse-managed student-run free clinics serve uninsured and low-income patients at risk for healthcare disparities. Patients receive holistic care by healthcare students, who train at the site. The site affords students a community practice setting. The clinics are 501(c)(3) tax-exempt, not funded by the federal government. Instead, the clinics rely entirely on donations and grants for funds. According to the clinic's director (personal communication, March 7, 2017)

in 2017, the clinics had over 4000 patient encounters, saving the County over \$800,000 in healthcare resources. Without free clinics, uninsured populations would not access the same level of care and prevention as insured patients; their conditions would go untreated (Birs et al., 2016). Free clinics treating vulnerable groups must ensure quality care by educating patients about their medications and the importance of adhering (Birs et al., 2016). The selected site is committed to delivering quality care. They are always seeking ways to improve care.

Organizational structure. The clinic's director administers and manages all clinics and keeps the School of Nursing informed of all activities, expenditures, savings, and outcomes. Every semester several BSN students serve as clinic managers. Additionally, other BSN students work in the clinics as part of their community clinical rotation, giving care ordered by NP students practicing under their faculty supervision and guidance. Nursing faculty supervise the BSN students guiding and enforcing their nursing skills, ensuring safe care. The NP students with faculty assistance, assess, screen, diagnose, prescribe, and treat patients.

Organization's culture. The clinic runs on grants, donations, and volunteers, limiting the operating time. When opened, the demand for support and service is great, limiting the practitioner visit. Patients needing more time with the NP due to language barriers, and low comprehension levels, do not get it. The NP spend 15-30 minutes with patients, despite the patient's language barriers, and low comprehension limiting screening, and education shared.

Education, self-management aid, and adhering tools. The clinic did not offer patient support to reinforce disease, medication, or communication education. Both NP and BSN students did not help patients with medication self-management or adhering-aiding tools. Instead, the NP gave patients medication education, and BSN students (who mostly spoke English) repeated the instructions or gave ineffective educational information from the internet in English, to Spanish

speaking patients. The clinic staff (NP and BSN students, and faculty) placed minimal effort in getting patients to adhere. To help non-adherent diabetics the clinic offers a diabetic nurse educator to support and educate patients, and still, some did not adhere. The NP did not have the needed time to get patients to take medications.

Screening, documenting, and adherence management. Before the QIP, tracking adherence at the site was a problem. There was no process for screening, documenting or managing adherence. The free electronic health record (EHR) platform, Practice Fusion, did not have a way for BSN students to enter adherence status prior to patient's appointment. The NP students documented non-adherence in their SOAP notes, but it was not readily accessible in the EHR (clinic's director, personal communication, March 7, 2017). To get actual non-adherence rates involved a time-consuming chart review, which staff could not perform due to the workload.

Adherence efforts. Before the QIP, the BSN and NP students worked hard to remove one of the most significant barriers to adherence experienced by medically vulnerable patients, medication access. The NP faculty secured medication samples from drug manufacturing companies and found pharmacies that filled generic medications for \$4.00 and paid the copay, using grants and donor funds. In addition, BSN students aided patients with completing applications to drug company's patient assistance programs (PAP) to gain access. However, the clinic did not screen, document, or manage adherence, after patients accessed their medications.

Care process in place. Prior to the QIP, the clinic's care process involved screening vulnerable patients for other issues/symptoms, e.g., depression, anxiety, domestic violence, using dichotomous questions on the clinic's health questionnaire intake form. The responses served as a trigger for BSN students to give patients specific evidence-based (EB) assessment tools relevant to the identified issue. A BSN student then gave the NP student the form and tools for review. Once

the appointment ended, the BSN students uploaded all forms to the EHR. Depending on the patient's ongoing needs e.g., insurance or PAP, the NP referred patients to either community resources or for a clinic case management (CM) appointment.

Unfortunately, the clinic's care process did not include adherence screening. Instead, the NP students practicing under severe time constraints had the challenge of discussing adherence with patients who needed added time to understand. It was unrealistic to expect the NP students to examine, treat, and screen for adherence, provide in-depth education and help patients with self-management in a culturally-sensitive way in the limited time. It is not surprising that the rushed educational session about complex diseases and medication was ineffective in motivating adherence. Both practitioner and patient barriers contributed to non-adherence.

Overcoming barriers. At the start of the QIP, the NP students did not engage in the new clinic's care process, even after completing the online educational training. The DNP student quickly noted the disinterest and devoted added time to promote and reinforce the QIP with each NP student, praising their efforts, each time a non-adherent patient requested to be a part of the QIP. However, after sharing preliminary intervention findings, the NP students engaged. An added barrier met dealt with getting initial participants to keep their CM appointments. Even after repeated reminder calls, and encouragement nine participants did not keep both or the last CM appointment. To mitigate attrition, the DNP student shared preliminary intervention results with non-adhering patients, to motivate them to complete the program.

Organizational support. The organization supported the QIP because it was an EB, interdisciplinary, collaborative initiative, affording students an opportunity to practice their education and quality improvement skills. The clinic also supported the QIP because it had the potential of mitigating costly complications and improving health outcomes for at-risk patients.

Improving the clinic's quality care improved the clinic's chances for future funding.

QIP financial support. The clinic's stakeholders bought digital wrist B/P and glucometers for patients having HTN or DM. They requested for the DNP student to document and report physiological parameter changes to note clinical improvements as adherence changed. The DNP student, who implemented the project as part of the DNP degree requirement, solely funded the QIP, and bought the adhering-aiding tools given to patients.

Stakeholders. The interest generated by the QIP on the stakeholders was impressive. They understand the difference the clinic makes, and the absolute need to continue giving care. Besides, stakeholders are interested in future funding opportunities that undoubtedly will require proof of quality care. Sharing the QIP preliminary outcomes with the stakeholders resulted in their immediate search for funding. As a result, the stakeholders applied and secured a grant for \$25,000.00 to expand the intervention to the rest of the University's clinics.

QIP benefits to the clinic. The QIP helped improve the clinic's care process, which now includes adherence screening, documentation, and management. Also, patient outcomes improved, resulting in added funding to expand the initiative to the other four clinics. Improvements achieved at the other clinic sites will place the organization in an excellent position to compete for added funding. The clinic's director and stakeholders have already started adopting the new care process at the other sites. All clinics now use the adherence screening tool added to the healthcare questionnaire intake form. The designed online educational module now trains all the clinic staff and will continue to train new practitioners and students each semester. In addition, the School of Nursing already selected Eight (8) BSN interns to help deliver culturally-sensitive education and medication self-management aid. Finally, the faithful stakeholders who work diligently to support the clinics, bought more adhering-aiding tools, digital wrist B/P and

and glucometers for 600 patients.

Intervention

The QIP involved a multicomponent intervention designed to remove provider and patient barriers impeding medication adherence in medically vulnerable adults aged ≥ 18 years (see Appendix B). The intervention consisted of three separate components: an educational training module designed to train the staff; a change to the clinic's care process to add medication adherence screening, documenting and management; and culturally-sensitive education, self-management aid, and adhering-aiding tools to increase adherence. Although complex, the intervention addressed the barriers impeding adherence.

First Component: The Educational Module

The DNP student designed an online, convenient, EB asynchronous training module as a slide presentation and added it to the clinic's training website for the clinic staff to learn about barriers to adherence, and planned changes to the clinic's care process. The selected time and cost-saving lesson delivery is the most efficient method to present and keep information (Siew-Chin & Williams, 2006; Lai, Tsai, & Yu, 2011). Using the Holistic Learning Environment Framework for designing online lessons by Siew-Chin and Williams (2006) the DNP student created the foundation of the instructional strategy. The framework addressed the needs of learners, promoted engagement, reflection, and active construction of knowledge.

Content for the module incorporated advice from the Medication Adherence–Time Tool for Healthcare Providers (ACPM, 2011) and Clinical Practice Guidelines recommended in the literature (Ruppar et al., 2015). The Tool used EB findings for recommending strategies to providers proven to increase adherence in outpatient settings (ACPM, 2011). Atreja et al. (as cited in ACPM, 2011) grouped simple, effective adhering-aiding interventions into an easy to remember mnemonic

SIMPLE: **S**implify the regimen, **I**mpart knowledge, **M**odify patient beliefs and human behavior, **P**rovide communication and trust, **L**ease the bias, **E**valuate adherence. For adherence to improve in outpatient settings, all staff must be involved in adherence efforts that includes screening patients for adherence and managing adherence (Ruppar et al., 2015; Starr & Sacks, 2010). The staff training module goals included:

- State the importance of medication adherence in achieving the best outcomes
- Name current practitioner-barriers leading to medication non-adherence
- Name barriers to adherence in the population
- Describe changes to the care process to remove barriers and support adherence
- List EB strategies planned to support and help patients take medication.

Also, a web link (<https://www.stepsforward.org/modules/medication-adherence>) for an interactive presentation by the American Medical Association (AMA) STEPS Forward program, equipped staff with strategies to remove barriers (Brown & Sinsky, 2015). Staff learned how to:

- Identify non-adherent patients
- Determine reasons for non-adherence
- Promote a blame-free environment where patients can discuss non-adherence
- Tailor adherence solutions specific to each patient

Summative assessment. Once staff completed the module, they completed a 10-item quiz. Results determined key concept, changes to the clinic's care process, and adherence understanding. The quiz consisted of five multiple choice questions and five fill-in responses. A passing score of $\geq 80\%$ showed content proficiency. A $< 80\%$ meant staff needed more time with the content to pass the quiz. All staff completed and passed the quiz.

Module evaluation. The evaluation survey measured the staff's perceived module's

usefulness, based on Donald Kirkpatrick's Model for Measuring Success of Training Programs (Dorri et al., 2016). The model worked well in obtaining the learner's feedback. A review of the staff responses helped the DNP student determine if the module needed changes, before permanent use. Fortunately, the staff found the module relevant and useful. The clinic's medical director, five NP faculty, four BSN faculty, sixteen BSN students, and 3 NP students, who treat 20-40 patients weekly completed the module and did not suggest changes (n =29).

Second Component: Improving Intake Form and Screening

The second part of the intervention changed the clinic's care process to add adherence adherence screening, involving all staff in adherence efforts. Modeling after the clinic's usual screening process to inform the practitioner of patient issues, the DNP student included a validated and reliable EB adherence self-reporting tool MMAS-4 (Morisky et al., 1986) to the clinic's health questionnaire intake form. The process at the clinic changed from having practitioners ask patients about adherence during the visit, to having the patient screened, and adherence documented in the EHR. The BSN student gave patients the intake form to fill out, then evaluated the patient's responses to the four questions on the MMAS-4:

- Do you ever forget to take your medications? Y or N
- Are you careless at times about taking your medications? Y or N
- When you feel better do you sometimes stop taking your medications? Y or N
- Sometimes if you feel worse, do you stop taking it? Y or N

Any "Yes" triggered patients to complete the ask-12 tool. Patients reported medication use by answering 12 questions (Matza et al., 2009). The ask-12, derived from the ask-20, is short and effective (Matza et al., 2009). The tool has three subscales: adherence behavior, health beliefs, inconvenience and forgetfulness, allowing practitioners to assess for adherence barriers and

non-adherence risks, helpful when designing interventions (Matza et al., 2009). Once completed, the BSN students gave the forms to the NP for review, who started the education and referred patient for the QIP.

The DNP student explained the QIP to patients using the site's Institutional Review Board (IRB) approved QIP informed consent (created in English and Spanish) then had patient re-state the QIP information to verify understanding before signing. A BSN student scheduled two, 1-hour CM sessions, 4-weeks apart based on patient's availability, and called patients the day of each CM session.

Third Component: Two CM Sessions

The final part of the Medication Adherence Intervention involved increasing the patient's knowledge about their disease, medication, self-management, and the importance of provider communication. Patients also received help with self-management and adhering-aiding tool use, to stimulate purposeful action and patterning behaviors, needed to stimulate adherence. The two, 1-hour CM sessions 4-weeks apart with the DNP student offered culturally-sensitive education using culturally-sensitive animated online videos offered by the National Institute of Health [NIH] (2017a) to the public, titled MedlinePlus Health Topics/Información de Salud para Usted, and medication educational website titled Drug, Herbs, and Supplements / Medicinas, Hierbas y Suplementos (NIH, 2017b). Patients also received education on the importance of practitioner communication, and strategies to start conversations, e.g., use a notebook with physiological parameters, and information for practitioner review. Also, patients received instructions on the use of a wallet card, noting the patient's diagnoses and medications, for providers in any care setting to review. Improvements to communication gave the patient the needed feedback, a precursor to long-term adherence (Johnson, 2002). The DNP student counted the prescribed

medication/s as the patient watched the videos, obtain an objective measure of adherence. To get the PCAR (Martin et al., 2011), the DNP student subtracted the total doses dispensed from the total doses remaining, yielding the total doses taken (see Figure 2.). The DNP then divided the total doses taken by the total doses dispensed, then multiplied by 100.

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

Figure 2. Pill Count Adherence Ratio [PCAR] (Martin et al., 2011)

Patients classified as being 1= adherent for taking $\geq 80\%$ of the medication or 2= non-adherent for taking $< 80\%$ (Martin et al., 2011). Also, patients considered 100% adherent if all doses taken since the fill date. Patients received aid with self-management to develop patterning behaviors, medication-taking with established routines. They also received adhering-aiding tools, and instruction on its use to help with medication reminders, e.g., pill box, refrigerator sign, calendar. Teaching patients with cell phones how to set the alarm as a reminder (Agency for Healthcare Research and Quality [AHRQ], 2016) proved difficult for some to understand.

Finally, patients received instructions on the consequences of not adhering (Costa et al., 2015; Ruppert et al., 2015). The DNP student, fluent in English and Spanish delivered instruction in a culturally-sensitive manner, using proper language and nonprofessional terms comparable to a fourth-grade education level, while actively listening, respecting patients, and not interrupting or being judgmental (Brown & Sinsky, 2013; Schroeder et al., 2015). The “teach-back” method help evaluate the patient’s comprehension level (AHRQ, 2016; Tamura-Lis, 2013). Listening to the patient “teach-back” confirmed understanding; showed gaps in knowledge, and areas needing reinforcement. Also, HTN and DM patients demonstrated how to take their B/P and BSFS, pre-pour medications using the pill box, and documented parameter findings in the notebook.

Setting

The selected site treats vulnerable uninsured patients having limited funds and language barriers. The clinic does not receive formal government funding, instead relies on grants and donors, which limits the days and time patients access care. When opened the demand for care is high, limiting the practitioner's time with patients. The clinic's care process did not include adherence screening, documenting or managing. Patients did not receive culturally-sensitive disease and medication education, self-management aid or adhering-aiding tools.

QIP Population Sample Inclusion/Exclusion Criteria

Since one of the components of the QIP involved changing the clinic's process to screen all patients for medication adherence, there was no formal recruiting. Instead, all patients, aged ≥ 18 years, non-adherent to at least one chronic condition medication receive an invitation to join the QIP by the NP. Patients included needed to follow verbal instruction. They also needed to decide on their own to take part, verbally repeat the QIP information to show understanding and sign the informed consent. Patients excluded were either younger than 18 years, had cognitive deficits preventing them from giving consent, or did not take medications for chronic conditions.

QIP participants needed power analysis. To increase the chance of detecting a post-intervention difference in adherence means, a statistical power analysis-G Power 3.1.9.2 version, developed by Faul, Erdfelder, Buchner, and Lang (2009), estimated the number of participants needed for the QIP. A power analysis completed before the QIP decreased the risk of Type II errors (a false negative finding) and strengthened the statistical conclusion validity (Polit & Beck, 2012). The number of patients needed for the QIP was determined by using an A priori analysis for t-tests means difference between two dependent means [matched pairs] (see Table1).

Table 1

A Priori Analysis: Compute Required Sample Size

t tests - Means: Difference between two dependent means
(matched pairs)

Input: Tail(s) = One

Effect size dz = 0.5

α err prob = 0.05

Power (1- β err prob) = 0.95

Output: Non-centrality parameter δ = 3.3541020

Critical t = 1.6802300

Df = 44

Total patients needed for QIP = 45

Actual power = 0.9512400

Note: G Power 3.1.9.2 version, developed by Faul et al. (2009).

A Power: .80, Effect Size: .35, $p = < 0.05$, yielded a total of 45 patients needed for the QIP.

However, the DNP student added another 10% for attrition, $n = 45 + 5$, increasing the total of participants needed to 50.

Practice Recommendations

Barriers contributed to medication non-adherence levels in the clinic. The care processes needed revising to screen, document and manage adherence. Tools to screen for adherence needed implementing in a way that did not increase the overworked staff's workload. Provider barriers impeding adherence ceased once the care process changed to promote adherence. Also, meeting the patient's educational needs, and giving self-management aid helped remove barriers to adherence. Once patients began adhering, those with HTN and DM had improved B/P and BSFS levels. The DNP student recommends for adherence efforts to continue for ongoing improved outcomes, and to keep patients involved in their care.

DNP Student's Role

The DNP student's role in the QIP included completing a root cause analysis to find the gap in practice, designing an EB intervention to remove provider and patient barriers to adherence, and searching the literature for EB solutions, a theoretical framework, and recommended practice guidelines. Also, the DNP student bought the EB adhering-aiding tools

to teach patients how to self-manage medications. In addition, the DNP student gave the adherence self-reporting tool to the clinic's director to add to the clinic's health questionnaire intake form. The DNP student also found EB culturally-sensitive educational videos and medication information to educate patients. The DNP student created the participant consent and sent it to the sites IRB for approval; created the data collection sheets; delivered both CM sessions and obtained each medication PCAR. Throughout the project, the DNP student shared updates, facilitated inter-disciplinary collaboration, staff engagement, and motivation. The DNP student also clarified and delegated the staff's tasks, while keeping the channels of communication flowing, and analyzed the data collected. By the end of the QIP, the DNP student solidified leadership abilities needed to design, implement, and complete a QIP in the practice setting to improve patient outcomes and save healthcare resources.

As a leader, the DNP student found that supervising, supporting, encouraging, and motivating the staff influenced their interest in the practice change. The DNP student also found ways to motivate staff who did not initially engage, successfully recruiting their efforts. The project allowed the DNP student to:

- translate research into practice, while reporting, and integrating new knowledge;
- collaborate with multiple disciplines to improve the clinic's quality of care
- engage in clinical scholarship applying research findings to the practice setting
- used technology to design the staff's online training module and internet-based videos to educate patients, use a computer and programs to document, analyze, and infer data;
- improved the health of vulnerable adults susceptible to health disparities.

The Clinic's Medication Adherence Team

There was no need to form any special team or group to implement the QIP. Instead, all clinic staff took part in the QIP (Ruppar et al., 2015). Also, the DNP student adopted existing

clinic processes to make it easier for all clinic staff to take part in the QIP. The clinic's director added the adherence screening tool to the health questionnaire intake form, uploaded the designed online educational module to train staff, and bought the wrist digital B/P and BSFS devices. To avoid disrupting the clinic's care process, the DNP student enhanced it by adding an adherence screening self-reported tool to the intake form, using the clinic's existing process as a strategic way to secure the staff's buy-in and QIP participation. BSN students who already assessed patient's responses on the intake form and gave patients screening tools, based on their responses, kept the same role when screening for adherence. They also obtained the physiological parameters for patients with HTN and DM. NP students, who reviewed the intake form and screening tools did the same when assessing adherence and referred non-adherent patients to the QIP. BSN students scheduled both 1-hour CM session, 4-weeks apart and called patients before each session reminding them to take medications. The DNP student delivered the culturally-sensitive education, helped patients with self-management and adhering-aiding tool use, counted the medication/s, and gathered data at each CM visit.

Study of the Intervention

Assessing QIP Impact

The DNP student used multiple methods to measure the impact of the QIP, e.g., objective and self-reported measures. Past studies have found that adherence self-reported tools over reported results (Wu et al., 2014). However, the literature did not share any specific foolproof adherence measure. Instead, it found that multiple measuring methods yield greater credibility to adherence findings (Hu et al., 2014; Wu et al., 2014). For the QIP, self-reported adherence and PCAR scores measured adherence, and physiological parameters confirmed adherence findings.

Evaluation Plan

A review of the staff responses on the educational module evaluation survey

(Dori et al., 2016) helped determine if the module needed changes before its permanent use. The adherence self-reporting tools and PCAR data (Martin et al., 2011) gathered at each CM session evaluated adherence before and after the intervention. Also, the physiological parameters (B/P & BSFS) taken at each CM visit for patients with HTN and DM, determined changes to the patient's clinical status. Finally, the patient satisfaction survey post-intervention evaluated the patient's feelings about the QIP and changes to the care process. There was a change in means in the data gathered pre and post-intervention showing the QIP influenced adherence levels.

QIP Intended/Unintended Impacts

The QIP directly increased the patient's adherence levels. Non-adherent patients did not adhere because they experienced barriers. The intervention targeted barriers to adherence. Once the clinic's care process improved, barriers ceased. Patients developed purposeful action, patterning behaviors and obtained practitioner feedback to motivate ongoing adherence. Patients also began communicating with the practitioner and involved themselves in their care and treatment. Patients found the notebook helpful in starting practitioner conversations.

The QIP also had unintended impacts, specifically to the patient's physiological parameters. Since the designed intervention allowed all non-adherent patients access to the QIP, and most patients had HTN and or DM, stakeholders requested for BSN students to take B/P and or BSFS at each CM session to evaluate the effects of adherence on elevated B/P and BSFS. Also, the stakeholders bought digital wrist B/P and glucometer devices for HTN and DM patients to check levels at home, and document findings for NP review. Checking physiological parameters on patients having HTN and or DM, pre- and post-intervention, provided unplanned credible data supporting improvements to the patient's clinical status, as adherence increased.

Measures

Project Design

The DNP student designed the QIP targeting existing barriers to adherence. After reviewing the literature for common barriers in vulnerable patients (Alton et al., 2015; Barkhof et al., 2012), components of interventions proven to increase adherence (Beach et al., 2015; Bruera et al., 2016), clinical guidelines for improving adherence in the practice setting (Ruppar et al., 2015), and a theoretical framework detailing the process of adherence (Johnson, 2002), the DNP student designed a multicomponent intervention, needed to address the various types of barriers. Providers needed help with screening, documenting, and managing adherence. Patients were missing knowledge to stimulate adherence and did not get added support to know how to manage and remember to take medications. The designed QIP addressed and removed the barriers,

QIP Measures

The measures chosen for the data analysis included the scores obtained from the patient's self-reported adherence tools, PCAR, and physiological parameters collected pre and post-intervention. Also, manual reviews of the educational training module survey completed by staff, determined module changes needed before permanent implementation. Finally, manual review of the patient satisfaction surveys provided patient's feelings about the QIP and changed to the clinic's care process.

Data Collection

Data and demographic information gathered during both CM sessions, given 4-weeks apart, produced the needed QIP data. Patients completed the MMAS-4 to determine adherence status, then the ask-12, if found to be non-adherent, when arriving at the clinic for their CM sessions. The BSN students checked B/P and or BSFS, documenting findings; and the DNP student counted the patient's medications to obtain PCAR.

Tool Validity/Reliability/Permission

To measure adherence, the literature recommends using multiple measures to achieve the best credible results. The MMAS-4 and ask-12 measured the patient's self-reported adherence. In addition, the DNP student counted pills to use as the objective measure of adherence.

MMAS-4 reliability and validity. The MMAS-4, used with author permission, had an alpha reliability of 0.61, good sensitivity of 0.81, and specificity of 0.44 (Morisky et al., 1986). The MMAS-4 has been successful in national and international studies, and various clinics to screen multiple populations, including vulnerable groups (Morisky et al., 1986). The tool is available in English and Spanish.

Ask-12 tool's reliability and validity. The ask-12 (Matza et al., 2009) tool, used with author permission, showed internal consistency reliability (Cronbach's α 0.75) and test-retest reliability (intra-class correlation 0.79). Strong correlation with the MMAS-4 (r -0.74; $p < 0.001$), and with self-report measures and objective measures showed convergent validity (Matza et al., 2009). Scores for responses on the ask-12 can range from 12-60, with higher scores showing greater adherence barriers. Learning about the individual's barriers helped the DNP student tailor the education and help participants develop patterning behaviors and medication self-management skills.

Evaluation Criteria

Using inferential statistics, the DNP student evaluated the effects of the intervention on adherence levels by comparing the means of the quantitative data gathered from the ask-12 adherence self-reported tool and PCAR scores. The DNP student also evaluated the means of the B/P and BSFS to determine improvements, as adherence increased. A difference in means showed the intervention had an effect in increasing the vulnerable group's adherence rates. Further, a review of the educational module survey completed by the staff after the online training, and the patient satisfaction

survey completed by participants after completing the intervention, gave much needed feedback to tweak and improve the training module and intervention before permanent implementation.

Specifically, using a one-tailed dependent t-test (directional), the DNP student found that the quantitative data analyzed pre and post-intervention resulted in a change in means. The intervention effected adherence rates. Also, as adherence improved patients having uncontrolled B/P and BSFS levels before the intervention experienced decreased levels after the intervention, confirming increased adherence. Sharing the findings with participants solidified the importance of adhering, which motivated patients to continue taking medication. Although labor intensive, needing staff involvement, the complex intervention effectively removed barriers to adherence.

Analysis

Data Analysis

It took the DNP student two-months to gather the QIP data, at each CM session. The primary outcome of interest was medication adherence. To measure adherence, the DNP student used two adherence self-reporting tools (one to screen adherence, the other to measure adherence) and PCAR. The second outcome of interest focused on changes to B/P and BSFS in patients with HTN and DM, as adherence increased. The DNP student gathered adherence quantitative measures using the ask-12, which yielded interval data. Scores range from 12-60, with higher scores showing more significant barriers to adherence and lower scores fewer barriers/greater adherence. The PCAR quantitative data yielded ratio data to determine the percent of medication taken, since the fill date. Patients considered adherent if they took $\geq 80\%$, and non-adherent if they took $< 80\%$ (Martin et al., 2011). The ask-12, and PCAR scores tallied provided the pre/post-intervention means to determine changes to adherence.

The B/P and BSFS levels yielded ratio quantitative data calculated pre-/post-intervention to obtain the means to evaluate changes to clinical status as adherence changed. Additionally, the

DNP student evaluated the staff responses on the module evaluation surveys (n = 29) and patient satisfaction surveys (n = 50), manually, to determine if the module or intervention needed changing before permanent implementation. Fortunately, the staff and participants did not make suggestions for to either the training module or intervention.

Statistical Analysis

To determine the effects of the intervention on adherence levels, the DNP student calculated the quantitative data produced by the ask-12, PCAR, B/P and BSFS, pre and post-intervention obtaining the means and standard deviation (SD) for each of the two repeated measures. Then statistical significance testing, specifically, a one-tailed dependent t-test (directional) compared the means, using a significance level $p = 0.05$. A change between the pre and post-intervention means signified the intervention effected medication adherence.

Ethical Considerations

The intervention, designed for a vulnerable, at-risk group having language barriers, low academic, understanding, and health literacy levels, needed IRB review. Before the project's implementation, the DNP student sent the project for review to both Capella University (CU) and the site's IRB. Both entities reviewed the QIP ensuring it followed regulations and guidelines put in place by the federal, state, local, and university to protect participants.

Human Subject Protection Method

According to Ross et al. (2010), federal laws protect human participants in research and outlines nine ways to ensure protection. CU IRB determined the QIP did not meet the federal regulation's definition of human subject research. Instead, CU IRB approved the project as non-human subject research, stipulating it did not need IRB full review or oversight. However, the site's IRB approved the project as human subject research and needed participants to sign an

informed consent, before project participation. Once both IRB confirmed approvals the DNP student implemented the project, following nine ways to ensure participants protection.

Minimizing risks. To mitigate participants risks, the DNP Student gave patients culturally-sensitive explanations of the QIP and had them restate information, before signing, to confirm patient's understanding of the QIP, intervention, and time needed to achieve benefits. Patients understood participation was voluntary and they could quit at any time without a need to explain or be afraid care at the clinic would cease. Including only adults aged ≥ 18 years mitigated risks, as they could consent independently. Also, delivering the education and self-management aid in a culturally-sensitive, easy to understand manner ensured understanding. To prevent imposing on the patient's time, they scheduled the CM sessions based on availability. The DNP student took care to offer the intervention during and after business hours, based on the clinic's operating times, to accommodate the patient's availability.

Throughout the QIP the DNP student kept the participant's confidentiality and privacy. The DNP students accessed the EMR using a computer kept in a doubled locked office, using several protected passwords. During the QIP each participant received a unique number, and the DNP student documented all data findings as aggregate data to keep anonymity. Lastly, the organization approved for the DNP student to conduct the project at the site. All efforts taken ensured the intervention posed minimal risks to participants.

Ensuring reasonable benefit-risk ratio. The identified problem had the potential for causing patients debilitating, life-threatening consequences, including death. The intervention was beneficial to participants. Participants received disease, medication, and self-management education, which increased their knowledge. Also, they received information on ways to improve practitioner communication and use adhering-aiding tools as medication reminders. The intervention removed barriers, increasing patient adherence. By increasing the patient's knowledge

and improving their medication self-management they took medications, minimizing costly complications. The benefits of the intervention outweighed the risks. The selected population had low academic, health literacy, and understanding levels. They needed effective culturally-sensitive educational instruction and self-management aid before perceiving a need to adhere. Staying in a non-adherence state would have resulted in severe, life-threatening complications for patients, common in uncontrolled chronic conditions. Equipping the patients with knowledge and medication self-management skills improved adherence and patient health.

Subjects fair participation. Practitioners referred all non-adherent adult patients aged ≥ 18 years, able to consent, teach-back, and follow instructions to take part in the QIP. The educational part of the intervention aimed to increase disease, medication, and self-management knowledge. It was imperative that patients could learn. Therefore, patients with cognitive deficits or those who did not manage their medications could not take part in the QIP.

Data monitoring. The DNP student watched the data for suggested risks, adverse events, or breeches to confidentiality that if present would have required halting the QIP. To prevent errors, the BSN and DNP students followed the same process for collecting and documenting the data. Physiological parameters found to be out of normal ranges required a faculty instructor to recheck the findings, ensuring correct data gathering.

Informed consent. One of the components of the intervention involved meeting with participants face to face to provide culturally-sensitive education and aid with self-management. The site's IRB determined each patient needed to sign an informed consent attesting to their volunteered decision to partake in the QIP, without feeling pressured, obligated, or fearful that medical care would cease at the clinic if they refused. The informed consent designed in both English and Spanish, approved by the site's IRB, needed signing from each participant.

Ensuring privacy and confidentiality. The DNP student and preceptor completed the

CITI Program online training. The staff at the clinic did not need to take the CITI online training because the project was not a research study. The DNP student de-identified identifiers and was the only person able to re-name the information. The completed MMAS-4, ask-12 tool, and PCAR scores were all scanned to the EHR, and laptops secured in a locked cabinet and locked room at the clinic. The DNP Student was the sole individual involved in a retrospective review of the patient records, once the QIP culminated and avoided discussions about the participants both outside, and in the site. Data gathering occurred in a private quiet room on the second floor of the clinic that is well lighted, with office/home furnishings creating a warm and welcoming ambiance, away from patients and clinic staff.

Conflicts of interest. The DNP student's primary interest in implementing the QIP at the clinic was to full fill an academic requirement. A secondary interest was to implement a much-needed QIP to change the clinic's care process to improve adherence management and adherence in a vulnerable group at risk for expensive complications. There were no financial conflicts of interest between the academic institution, community members, stakeholders, or site related to the QIP. All wished to improve the care of the population. The QIP was self-funded by the DNP student, with donations from stakeholders for participants in the form of digital wrist B/P and glucometer devices. There were no financial gains or benefits to any entity, eradicating potential third-party influences or interests in the information or outcomes reached.

Vulnerabilities addressed. The selected population was medically vulnerable due to a lack of health care insurance and financial resources. They also lacked English skills, had low academic, health literacy, understanding levels, and no self-advocacy skills. Non-adherence exposed patients to debilitating, life-threatening consequences, including death. To be able to adhere patients needed an intensive intervention to help them understand and initiate medication adherence. The QIP offered patients an opportunity to increase knowledge, and gain skills needed

to manage medications, and learn to exercise their autonomy. The population received confidential, non-judgmental treatment that was caring, respectful, and empathetic.

Human subject protection training. To ensure participant protection, the DNP student followed Federal guidelines and took the Human Subject Basic research training. The IRB required proof of training completion with the project review application submitted. Once the DNP student completed the online training modules, the certificate providing proof of training completion full filled the IRB requirement.

QIP Ethical Consideration

The DNP student took extra care to ensure the designed QIP was methodologically sound and properly structured to achieve the intended aims to help the population. Anticipated and mitigated minimal risks by:

- obtaining IRB review and project approval,
- securing the participant's signed informed consents;
- protecting the patient's privacy,
- keeping all patient information confidential,
- and ensuring patients understood the purpose of the QIP, before signing consent.

The DNP student delivered the education at a fourth-grade level in a respectful, and culturally-sensitive manner, using multiple teaching methods, print, video, and audio.

Results

A total of 59 patients signed a consent to take part in the QIP. However, seven did not keep their scheduled CM appointment, and two completed only the first CM session. A total of nine patients did not complete the QIP. Only 50 patients, more females than males, took part in the QIP (for demographic data see Appendix C Table C1). Participants were between 41-80 years of age,

Hispanics, who spoke did not speak English. Many participants reported having none to only a fifth-grade education level. Patients were mostly unemployed, married, and had up to three chronic conditions, for which they took three to six prescribed medications. HTN and DM were the top two medical diagnoses prevalent among participants. It was not surprising that at the start of the QIP non-adherent patients with HTN and DM had elevated B/P and BSFS levels. Also, the ask-12, and PCAR findings correlated with the patient's reports of non-adherence, and uncontrolled physiological parameters.

After the intervention ended, the DNP student analyzed the means for the ask-12, PCAR, B/P, and BSFS data, obtained pre and post-intervention, to determine statistical significance. A paired t-tests (95% CI, $p = 0.05$) compared the means for the repeated measures. A difference in means signified the intervention effected adherence. The analysis showed a difference in means for the *ask-12 tool* ($M = 23.10$, $SD = 8.79$); $t(49) = 14.46$, $p = .000$ (see Appendix D, Table D1 & D2); and *PCAR* ($M = .701$, $SD = .204$); $t(49) = 12.32$, $p = .000$ (see Appendix D, Table D3 & D4) pre- and post-intervention. Also, significant differences were found to the patient's *Systolic B/P* ($M = 124.52$, $SD = 14.16$); $t(41) = 8.366$, $p = .000$ (see Appendix D, Table D5 & D6); *Diastolic B/P* ($M = 74.14$, $SD = 9.99$); $t(41) = 8.389$, $p = .000$ (see Appendix D, Table D7 & D8); and *BSFS* ($M = 123.33$, $SD = 34.97$); $t(20) = 4.59$, $p = .000$ (see Appendix D, Table D9 & D10), pre- and post-intervention. The intervention led to significant improvements in medication adherence from a rate of 29% pre-intervention, to increasing by 141% post-intervention. Further, increases in adherence resulted in decreased B/P and BSFS levels in patients with HTN and DM, supporting the need for culturally-sensitive disease, medication, self-management, and provider communication education, and adhering-aiding tool use.

The DNP student manually reviewed the staff feedback on the completed Evaluation Module Surveys ($n = 29$), to determine needed changes to the module. Fortunately, the clinic staff

did not make suggestions for changes to the module. The DNP student also manually reviewed the completed post-intervention Patients Satisfaction Surveys (n = 50), to determine needed changes to the intervention. Feedback received included that patients found the culturally-sensitive education helped them understand the disease and medication. They also found getting organized and planning to take medications around their routines was helpful, and using the tools helped them “remember” to take medicines. Further, patients rated the adhering-aiding tool as reminders aids. The refrigerator sign, B/P and glucometer devices, and notebook for documenting results and questions for practitioner were rated as most helpful.

Achieved Project Outcomes

The intervention effectively mitigated barriers contributing to the high non-adherence levels. After the intervention, adherence levels increased dramatically by 141%, in two months. Also, the intervention effected the participant’s uncontrolled HTN and DM. As adherence increased B/P and BSFS levels decreased. Patient’s clinical status positively improved.

Outcomes, intervention, and relevant contextual elements. Before the intervention, non-adherence was excessive in vulnerable patients. The clinic did not have a process in place for managing adherence or aiding patients in getting them to adhere. There was a direct association between the perceived barriers and high levels of non-adherence.

To increase adherence levels, the DNP student involved the entire staff in the adherence efforts. The staff trained using the designed online educational module. The EB Medication Adhering Intervention targeted the provider and patient barriers to adherence. Once the care process at the clinic improved, patients received effective education, and self-management skills aid, adherence increased. Also, patients understood the importance of communicating with practitioners to obtain feedback needed to continue to adhere. According to Bernstein (2015), for patients to adhere they need to know why medications are essential. By the end of the QIP, there

were notable improvements to medication adherence levels. Also, the controlled B/P and BSFS levels post-intervention, lent credibility to adherence findings, giving evidence that the QIP improved the vulnerable group's health significantly.

Unintended results. The patient's reports of feeling "empowered, with the responsibility of managing and monitoring" their health is an unintended result of the QIP. The project aimed to increase medication adherence, and not to specifically stimulate empowerment in patients. Teaching patients with HTN and DM how to check their levels at home and document the results for practitioner review, caused patients to feel "excited to be involved" in their care. They also reported "looking forward" to communicating with the NP, also an unintended result of the QIP. At the start of the intervention, patients reported they usually "felt rushed during appointments" going in and out of the exam room "fast" at times "forgetting to share their questions and concerns" during the appointment. Also, most patients reported feeling "intimidated" by how bright the practitioners are, and "embarrassed" to speak around them. However, patients were excited with idea of writing their questions beforehand and having their B/P or BSFS levels written in the notebook for practitioner review. They found "prior preparation" made the appointment more "productive". After receiving basic communication education and tools, patients "felt prepared" to speak to the NP.

Missing Data

Although a total of 59 patients signed the participant consent agreeing to take part in the QIP, only 50 completed the QIP. Seven patients did not take part or completed the QIP. Since there was no way to determine if the intervention effected adherence in the two patients who completed only the first CM session, the DNP student did not include the data in the analysis.

Facilitators/Barriers

Facilitators helped propel project implementation with ease and efficiency. However, barriers

had the potential of hindering the QIP progress. When present, the DNP student strategized quickly to mitigate barriers keeping the project progressing forward.

Facilitators. Before the QIP, the clinic had a convenient online asynchronous training site to train staff. Also, the clinic's care process included screening tools for various issues on the health questionnaire intake form. The staff screened patients for depression, anxiety, food insecurities, and insurance qualification, which practitioners then addressed during the appointment. The staff then scanned the screening documentation into the patient's EMR. These facilitators enabled the DNP student to design the intervention using adopting existing processes, and the health questionnaire intake form. The strategy used allowed the staff to engage in the QIP, following the steps of the intervention with ease, with close to no disruption to the clinic's usual flow. Another facilitator was the availability of a private room on the second floor of the clinic. Using the room for the CM sessions protected the patient's privacy and confidentiality. Also, the stakeholders and the clinic's director supported the QIP and helped to enhance the planned adhering-aiding tools for patients. They showed a commitment to share staff, time, and resources to implement the QIP. Finally, all clinic staff engaged in patient safety and high-quality care needed to keep adherence efforts implemented long-term.

Barriers. Initially, the clinic had barriers to adherence that could have impeded the projects' progress and success. The staff and the practitioners' practice under severe time constraints, and as a result they did not screen, manage or document the patient's adherence. Also, the NP students did not have time to aid patients with self-management or to deliver effective culturally-sensitive education to stimulate purposeful action in patients. Also, on some days the clinic lacked Spanish-speaking BSN and NP students who communicate with patients, affecting the patient's comprehension. Further, the clinic did not have a quality process in place to address adherence, and the staff was untrained in adherence efforts. The DNP student took note of existing

barriers to adherence and designed an effective intervention that was easy to implement, without disrupting processes in place or burdening the overworked staff.

Initially, implementing the intervention at the clinic was slow. The DNP student noticed the NP students did not engage in the new clinic's care process, even after completing the educational training. The DNP student strategized a way to promote the intervention to each NP student and praised their efforts each time a non-adherent patient requested to take part in the QIP. However, after sharing the preliminary effects of the intervention on adherence, the NP students increased their efforts. Another barrier met dealt with getting initial participants to keep their CM appointments. Even after repeated reminder calls and encouragement nine participants did not keep both or their last CM session. To prevent further attrition, the DNP student shared preliminary findings with non-adhering patients taking part in the QIP, serving to motivate an interest in patients to complete the program. Tackling unforeseen barriers helped to keep the QIP progressing. The clinic has the potential for making a difference by using EB measures to improve vulnerable patient's health.

Sustainability

After completing the QIP, the medication adherence screening section added to the clinic's healthcare questionnaire intake form remained on the form and clinics use it. The organization's clinics also adopted the intervention's care process. Key staff members trained and involved in adherence efforts continued their role. The online educational module remained in the clinic's online training website and now educates new NP and BSN students each semester. Eight Spanish-speaking BSN intern students now help patients with needed education and medication self-management. Finally, the clinic's director bought more adhering-aiding tools, e.g., pill box, refrigerator sign, calendar, notebook, wallet card, wrist digital B/P and glucometer, using a \$25,000 grant awarded to the clinic for expanding the QIP to all clinics.

Reproducing The QIP

Replicating this QIP is possible in any outpatient clinic treating any population. Medication non-adherence is a global epidemic. Studies have found the most effective interventions used to combat the complex problem of non-adherence are complex, multi-component, and intensive (Farmer et al., 2012; Ruppap et al., 2015). Outpatient practices have processes followed for prescribing but do not have directions on how to help patients adhere. The method used in this QIP can apply to other outpatient settings to determine adherence levels or change the clinic's care process to address adherence or to use culturally-sensitive technological tools to educate patients. Clinical guidelines recommend for providers to promote efficient adherence efforts in the practice to help patients adhere (Ruppap et al., 2015).

Recommendations

The QIP effectively increased adherence rates in non-adhering patients treated in a free clinic. Participants will continue to require ongoing support and feedback for adherence to continue long-term. Also, the organization serves other vulnerable populations in other low socioeconomic communities, who like the participants can benefit from culturally-sensitive education, self-management assistance and adhering aiding tools. In addition, future planned QIP should focus on additional repeated measures to ensure long-term adherence.

Future practice. The clinic must continue adherence efforts, and refer non-adherent patients for added disease, medication, and self-management education. Further, continued support must continue to be culturally-sensitive, at an appropriate grade-level. Patients should receive continue education, aid with self-management, and adhering-aiding tools to stimulate purposeful action and patterning behaviors. Also, provider communication should continue by encouraging patients to take notebooks to appointments for patients to get needed feedback.

Future practice inquiry. The QIP design and findings added to current research and helped deliver quality patient care by increasing medication adherence resulting in controlled B/P and BSFS in patients with HTN and DM, mitigating costly complications. Future practice inquiry should involve a medication adherence QIP that includes various repeated measures over six months to a year, to determine persistence to adherence, with ongoing support.

Summary

Provider and patient barriers suggested an opportunity to implement practice changes in the clinic to remove barriers to improve adherence. Using an interdisciplinary approach to involve all staff in adherence efforts lightened the load for practitioners, who lacked time to provide effective patient education and aid with self-management. Changing the clinic's care process to screen, document and manage adherence removed provider barriers. Offering non-adherent patients culturally-sensitive education, adhering-aiding tools, and self-management aid, helped remove patient barriers. The QIP efforts increased adherence levels in a medically vulnerable group and improved clinical status.

According to Johnson (2002), patients need purposeful action, patterning behaviors, and feedback for adherence to occur. The selected population lacked purposeful action because they had not received culturally-sensitive disease, medication, communication, or self-management education. Also, the clinic did not offer adhering-aiding tools, or self-management aid to help patients develop patterning behaviors. Finally, NP-patient communication was lacking; patients did not get effective feedback. The QIP success was due to the interdisciplinary involvement.

Project Strengths

The QIP had several notable strengths. The DNP student designed a multicomponent intervention that was theoretical and EB to address the concerning problem of non-adherence. According to Farmer et al. (2012), effective interventions found in the literature to improve

medication adherence and clinical outcomes have been complex, multi-component and intensive. No single effort or education-only intervention has effected adherence rates, especially in vulnerable groups (Hu et al., 2014). According to Ruppap et al. (2015), practice guidelines recommend for all staff in the primary care setting to involve themselves in adherence efforts. Another project strength involved the inclusion of the interdisciplinary team in adherence efforts. Staff received training on adherence to effectively engage in adherence efforts.

An added strength of the QIP is that it offered patients the intervention twice. According to Barkhof et al. (2012), interventions longer in duration, offering more sessions on adherence are more successful. The B/P and glucometer devices issued to HTN and DM patients to check levels at home and document results for practitioner review strengthen the QIP. Patients felt empowered, ready to take part in their care.

Using several types of adherence measures strengthen the project's findings. Self-reported adherence measures alone would not have yielded an accurate adherence measure. The literature has repeatedly found self-reported adherence to be unreliable as a sole measure (Hu et al., 2014). According to Wu et al. (2014) using more than one measure yields credible results.

Finally, the DNP student's ability to deliver the education in both English and Spanish strengthen the QIP. Having a bilingual ability allowed the DNP student to deliver education that was culturally-sensitive at a proper grade level ensuring the patient's disease, medication, and self-management knowledge increased. Patients were receptive and welcomed the information presented in their language.

Interpretation

Adherence increased as patients began taking their medications. Also, increased adherence stabilized the patient's clinical status. The intervention successfully removed barriers

to adherence. Patients became more knowledgeable, learned self-management skills, and started engaging in communication with the practitioners.

According to MAM (Johnson, 2002), patients need to understand the importance of the medication. If the education provided to patients is not enough to help them understand their disease and medication purpose, they will not develop purposeful action, needed to adhere. Practitioner's alone were not able to give patients added time needed by patients to understand. The intervention, however, involved all staff in adherence efforts, which lightened the load for practitioners, and removed provider barriers. Besides, offering culturally-sensitive education to patients, that included consequences of not adhering caused patients to understand the importance of adherence, thus stimulating purposeful action. Medication self-management and the adhering-aiding tools helped patients develop patterning behaviors needed to adhere. Finally, increased practitioner communication resulting when patients used their prewritten notes enabled the practitioner to give patients the much-needed feedback needed to adhere long-term. The intervention successfully removed patient barriers to adherence. The removal of both provider and patient barriers caused adherence levels to increase, and clinical outcomes to improve.

QIP Outcomes - Literature Finding

The QIP outcomes compared to similar projects in the literature using multi-component interventions to increase adherence rates. Foster et al. (2018), found adherence to medication improved after patients received a multicomponent intervention consisting of education and reminder tools. Participants in Foster et al. (2018) who received an intervention had significantly higher odds of adhering (OR, 1.66, 95% CI, 1.15-2.39). Fan et al. (2018), successfully increased adherence rates in a migrant worker population having HTN. The intervention involved culturally-sensitive education, medication information cards, a pill box, and follow-up calls to patients resulting in increased adherence rates ($p < 0.05$) and controlled B/P (Fan et al., 2018).

In a RCT, a multicomponent intervention to train providers on the importance of medication adherence, and patient communication, along with education, patient coaching, and self-management assistance successfully increased adherence (Beach et al., 2015).

QIP Impact on People/Systems

The QIP yielded improvements to patient outcomes. The removal of existing barriers to adherence enabled patients to adhere to medications positively improving their health. Also, the patient's knowledge increased, and they learned ways to remember to take their medication. As a result, patients developed patterning behaviors, which according to MAM (Johnson, 2002) they need to adhere. Further, patients improved communication with the NP to obtain feedback needed for long-term adherence. Adherence resulted in improvements to the vulnerable group's health, mitigating costly complications and health disparities related to non-adherence.

The QIP yielded improvements to patient outcomes and better the quality of care. The clinic must always show it provides quality care to secure much-needed funding to stay operable. One of the most critical benchmarks potential funders seek is the quality of patient outcomes. Funding is difficult to secure if potential funders do not see efforts are in place to improve quality of care. Improvements to care will translate into future funding for the clinic.

Finally, the QIP saved healthcare resources by mitigating costly complications, common in non-adherent medically vulnerable populations. According to Brown and Sinsky (2013), non-adherence adds up to billions in preventative health care expenditure. The intervention helped save health care dollars and resources, even though it cost money to implement.

QIP Cost and Strategic Trade-Offs/Opportunity costs

Although the complex multicomponent Medication Adherence Intervention involved a financial investment (see Appendix E) the resulting opportunity costs, e.g., increased adherence, and improved B/P and BSFS, made the investment worthwhile. The cost to implement the QIP

equaled \$2,062. The DNP student spent a total of \$1,312.00, and the stakeholders spent \$750.00. The small expenditure strategically traded-off preventable use of the healthcare system, poor patient outcomes and quality of life, and costly consequences including death. The intervention effected adherence and controlled chronic conditions like HTN. According to Alton et al. (2015) improving adherence to HTN medications can prevent around 90,000 deaths each year.

Non-adherence is a costly health care problem. Bernstein (2015) estimated preventable hospitalizations, emergency room visits and other complications due to non-adherence costs billion dollars annually. Efforts to improve adherence even on a small-scale result in savings to health care resources. If Patterson et al. (2016), estimated that for every dollar spent trying to improve adherence saves \$37.00 in care, the multi-component Medication Adherence Intervention was cost beneficial, yielding a positive return on investment. The cost of the QIP (\$2,062) saved an estimated \$76,294.00 ($\$2,062 \times \37) in healthcare expenses to treat complications of non-adherence. Actual savings is larger when factoring improvements to the patient's quality of life and preventable early demise. However, it is impossible to equate a monetary figure to a patient's improved quality of life or extended lifespan. Finally, the QIP inspired stakeholders to secure a \$25,000 grant to expand the intervention to an additional 600 patients treated at the organization's other four clinics. It will cost the organization an estimated \$24,744.00 but it has the potential of saving \$915,528 ($\$24,744 \times 600$) almost one million healthcare dollars. Imagine the severe positive impact the project would have in all outpatient settings in the U.S. The theoretical and EB QIP is not only effective in improving adherence, it is also significant, and relevant in saving valuable healthcare dollars.

Limitations

Unfortunately, the project had limitations, but efforts minimized and adjusted for the limitations. First, the sample included patients having many chronic conditions. The QIP could

not be disease-specific due to a risk of not getting enough participants. A total of 50 patients needed to take part in the QIP to detect a difference in adherence after the intervention. The free clinic treats underinsured, uninsured, medically vulnerable adults having limited resources, and low academic, health literacy, and understanding levels. A risk already existed in the number of patients at the clinic who would express an interest in the QIP, potentially decreasing the already small sample size. To increase the chances of getting non-adherent patients interested in the QIP patients having any chronic condition could take part in the QIP. According to Johnson (2002), primary adherence tenets could explain adherence in any chronic conditions. Therefore, the QIP did not need to be disease-specific mitigating minimal participation.

Using validated adherence self-reported tools to screen patients could have limited the QIP findings due to the potential exaggerated responses. However, the DNP student included multiple methods for measuring adherence: self-reported adherence measures, and objective measures, e.g., PCAR to obtain greater credibility to adherence findings after the intervention.

Another limitation of the project was the two-month time limit. Although participants received adherence education reinforcement and self-management aid in two separate CM sessions, it was not enough time to capture the participant's long-term adherence. In a population known to not adhere due to low academic, health literacy, and understanding levels, as well as poor self-management skills repeated CM visits, would ensure adherence continued long-term after the project ended. Further, if patients must take medications indefinitely, then adherence efforts should also continue to be indefinite. According to Barkhof et al. (2012), adherence improving interventions that are longer in duration, offering more sessions to focus on adherence tend to be more successful than short duration interventions. To minimize the probability of adherence levels decreasing once the project ended, the clinic's director and stakeholders kept the clinic's new care process going. The clinic continued using the designed online adherence

education module to train/orient new BSN and NP students. Also, adherence screening continued, using the same QIP self-reporting tools MMAS-4 and ask-12, and NP continued referring non-adherent patients for CM sessions delivered by Spanish-speaking BSN students.

This project may generalize to other clinics treating vulnerable groups. The health of vulnerable populations improves when they receive disease, medication, and self-management education along with aid in a culturally-sensitive manner. The intervention itself can generalize to any out-patient practice setting lacking effective adherence care processes. Although medication non-adherence is a complex problem, implementing a complex multi-component intervention can successfully mitigate non-adherence.

Limited Internal Validity

Instrumentation used to measure self-reported adherence could have limited internal validity, if not presented or measured in the same way each time. Staff put the effort in ensuring that patients answered the MMAS-4 when completing the clinic's health questionnaire intake form, and the ask-12 in the same order at each CM visits to minimize threats to internal validity. In addition, the BSN students helped patients having difficulty with the tools.

Conclusion

The QIP enhanced efforts previously started by NP faculty who removed medication barriers related to cost. Although prior strategies helped patients access medications, 71% did not adhere. The QIP successfully removed barriers by training the staff in adherence efforts, screening patients for adherence, offering culturally-sensitive education, and self-management adhering-aiding tools. The multi-component intervention stimulated purposeful action, and patterning behaviors, and increased NP communication, giving patients feedback on adherence efforts. The QIP achieved its aim, adherence increased, and B/P and BSFS levels improved.

Findings in this QIP are useful to the practice setting. A multi-component intervention that targets provider and patient barriers effectively increased adherence. The project's theoretical framework is useful and significant in any setting wishing to improve adherence. Culturally-sensitive education and self-management efforts are effective in getting Spanish-speaking patients to adhere. The project supports adherence guidelines for providers to involve all staff in adherence efforts and use various measures to obtain correct adherence levels. The QIP offers a chance to decrease the burden of chronic conditions, improve medication-taking, and save healthcare resources. Non-adherence cost to human and social costs is tremendously high, and many entities have taken notice. Organizations offer health care provider grants for initiatives aimed at increasing adherence in the practice setting. Providers can apply for grants to offset the cost of sustaining adherence.

The intervention used in this QIP is useful in any out-patient setting looking to improve adherence screening, rates, or change the care process to address adherence. Although complex, the intervention tackled the complex problem of non-adherence, while including all disciplines in the effort. Screening patients for adherence, finding barriers and strategizing ways to remove barriers are necessary steps to mitigate non-adherence. Further study in the field of medication adherence should investigate the effects of a multi-component Adherence Intervention long-term. When patients take medications indefinitely, adherence support must continue indefinitely. The QIP findings will be disseminated at conferences, organization presentations and journals.

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Appendix A

Written Approval to Use Tools/MAM

A1- Approval to use MMAS-4

From: Donald Morisky <dmorisky@gmail.com>**Sent:** Tuesday, April 25, 2017 11:22 PM**To:** VDelgado**Subject:** Re: Requesting a license agreement to use the 8- item Morisky Medication Adherence scale in Spanish

Thanks Ms. Delgado for getting back to me regarding your interest in using the MMAS-8 diagnostic adherence instrument.

Since the cost of the widget is probably more, **I suggest that you use the Morisky, Green and Levine Adherence Scale (MMAS-4) which is in the public domain and does not require a license fee. Also, you can make your own translation of this scale as it is not copyrighted.** Please let me know if you are still interested in using the widget and my Chief Investigator will be in touch with you. I have attached the MGL publication for your reading enjoyment. Thank you again for your interest in using my validated diagnostic adherence tool.

Sincerely,

Donald E. Morisky, Sc.D., M.S.P.H., Sc.M.

Professor and Former Chair Distinguished Chair Professor at Kaohsiung University, Taiwan

Department of Community Health Sciences

UCLA Fielding School of Public Health

650 Charles E. Young Drive South Room 46-071 CHS

Los Angeles, CA 90095-1772

email: dmorisky@ucla.edu

Phone: (310) 825-8508

Fax: (310) 794-1805

A2 - Approval to use the ask-12



May 18, 2017

Via Email to

V. Delgado, MSN-Ed., PHN, DSD, BSN, RN

RE: Permission to use The Adherence Starts with Knowledge Surveys (ASK-12 and ASK-20)

Dear Ms. Delgado,

Thank you for your email of May 17, 2017 requesting permission to use the Adherence Starts with Knowledge Survey (ASK-12) (the "Instrument") in English and Spanish. We understand you are interested in using the Instrument as part of your quality improvement project to fulfill the academic requirement for the Doctor of Nursing Practice degree at the Capella University. Specifically, you would like permission to implement the Instrument as part of an intervention to improve medication adherence and health literacy in a Spanish-speaking, uninsured, low-income, and low-literate population who is currently non-adherent.

GlaxoSmithKline is pleased to grant you permission to use, reproduce and distribute paper and electronic pdf copies of the Instrument in English and Spanish as part of the above clinical study, subject to the following conditions:

1. You may not modify the Instrument or combine it with other instruments without prior written approval;
2. You must use the Instrument in its entirety, with the questions appearing verbatim and in order;
3. You must not remove any trademark ownership statements or copyright notices that appear on the Instrument;
4. You must use the Instrument only for the specific purposes stated in your request;
5. You must use only the most current version of the Instrument, which, for ease of reference, is enclosed with this letter (current as of the date of this letter).

There is no charge for the foregoing permission. You have permission to use the Instrument for the specific purposes described in your request. GlaxoSmithKline strictly prohibits the reproduction or use of this Instrument for any other purpose without prior written consent. We reserve the right to revoke our permission at any time; however, such revocation will not affect any use by you of the reproduction in accordance with the permission granted herein prior to such revocation. Please be advised that we cannot make, and hereby disclaim, any representations or warranties about this Instrument, including any warranties as to additional permissions that may be required for its use. Thank you for your interest in GlaxoSmithKline. If you have any questions regarding this matter, please contact me at your convenience.

Sincerely,

Matthew S Lau, PharmD, MSCR
Manager, US Value, Evidence & Outcomes
US Medical Affairs

GlaxoSmithKline

A3 - Approval to use Medication Adherence Model (MAM)

From: MARY JANE JOHNSON <mary_jayne_johnson@msn.com>

Date: Sunday, Jun 4, 2017 at 8:53 AM

Subject: RE: Request permission to use your Medication Adherence theoretical framework, concept map and questionnaires

To: V DELGADO

Hi Virgie,

I hope this finds you well. I am more than happy for you to use the Medication Adherence Model, concept map, and needed tools. Good luck with your project.

Mary Jayne Johnson PhD

From: VIRGIE DELGADO

Date: Saturday, April 15, 2017 at 12:1 PM

Subject: Request permission to use the concept mapping of your Medication Adherence Model

To: MARY JANE JOHNSON <mary_jayne_johnson@msn.com>

Hello Dr. Johnson,

My name is Virgie S. Delgado. I am a DNP student at Capella University approaching the implementation of my doctoral practice immersion project. I am interested in implementing a quality improvement project at a University sponsored, nurse-managed, student-run free clinic to improve medication adherence in a vulnerable population of adults aged ≥ 18 years, uninsured, low-income adults who are currently non-adherent.

I would like to respectfully request written permission to use your Medication Adherence Model (MAM) as the guiding theoretical framework to design, guide, and infer the intervention's findings. I would also like to use the conceptual map (as it appears on the framework's article). If you agree, full credit will be given for your work, in all in-text citations and on the reference list for the conceptual map, and framework's core concepts.

I am particularly interested in using MAM after noting its behavioral component (important in medication adherence).

The intended intervention will consist of disease, medication, self-management and communication skills education, and self-management aid using adhering-aiding tools to be disseminated to increase adherence in the population, within a period of two months.

I thank you in advance for your consideration, response, and support. I look forward to hearing from you soon.

Warm regards,

V Delgado, MSN-Ed., BSN, RN, PHN, DSD

Appendix B

The Medication Adherence Intervention

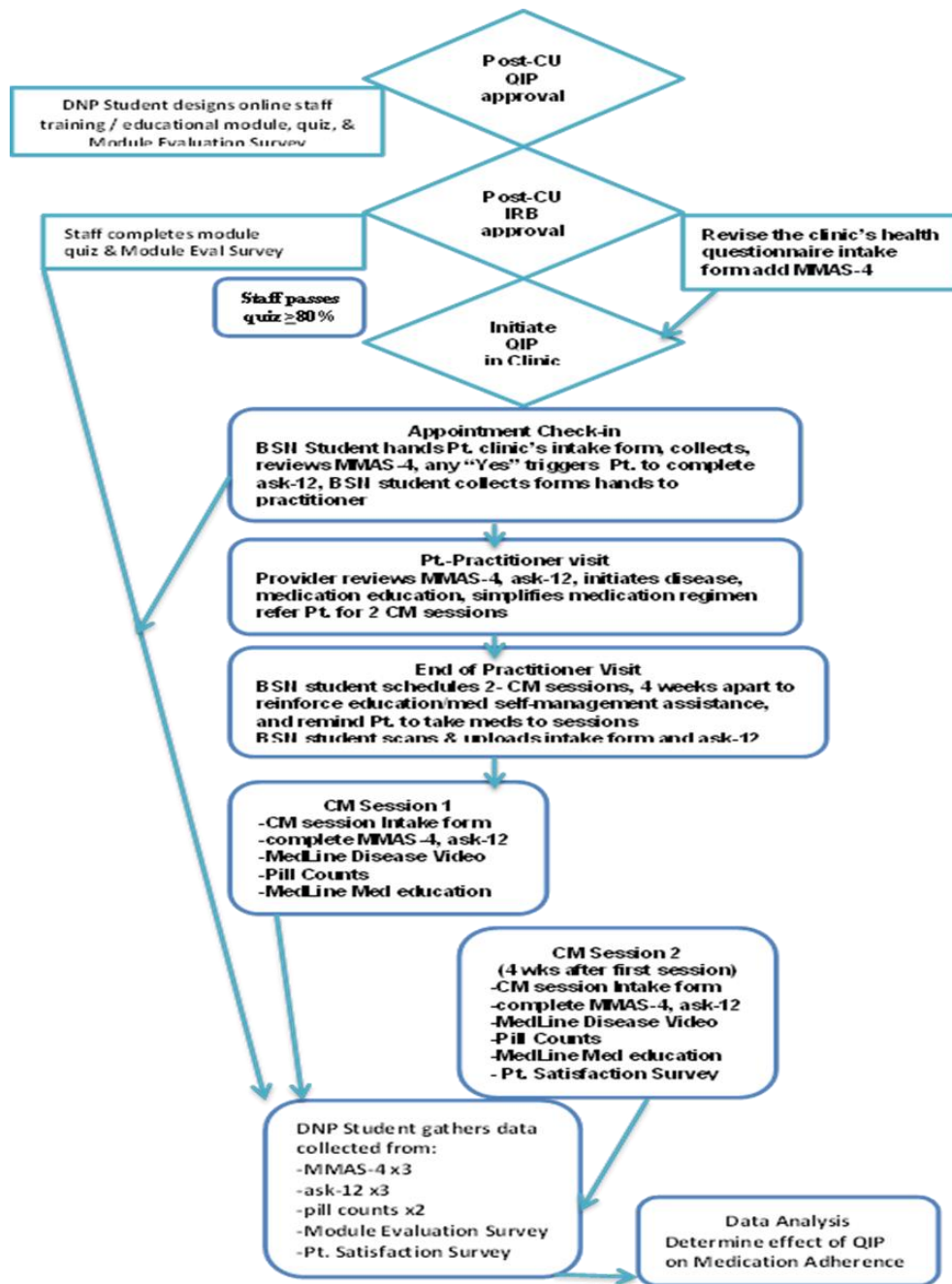


Figure B1. Medication Adherence Intervention Flow Chart

Appendix C

QIP Participants Demographic Data

Table C1

QIP Participant Demographics All Participants n = 50 (%)

Age (years)	
21-40	3 (6%)
41-60	13 (26%)
61-80	27 (54%)
81-90	7 (14%)
Sex	
Male	16 (32%)
Female	34 (68%)
Race	
Hispanic	44 (88%)
Asian Pacific Islander	1 (2%)
White	5 (10%)
Language Understood	
Spanish-Only	44 (88%)
English-Only	6 (12%)
Education Level	
None	17 (34%)
K-5 th grade	17 (34%)
6-8 th grade	3 (6%)
9-12 th grade	9 (18%)
Other	4 (8%)
Employment Status	
Unemployed	42 (84%)
Full Time	4 (8%)
Part Time	4 (8%)
Medical Insurance Status	
None	50 (100%)
Marital Status	
Married	26 (52%)
Divorced	8 (16%)
Widowed	4 (8%)
Single	12 (24%)
Number of Medications taken	
1-3	28 (56%)
4-6	19 (38%)
7-9	3 (6%)
Number of Chronic Diagnoses	
1	7 (14%)
2	14 (28%)
3	21 (42%)
4	6 (12%)
5	2 (4%)
Chronic Diagnosis Reported	
HTN	42 (84%)
DM	21 (42%)
Hypercholesterolemia	10 (20%)
Hyperlipidemia	11 (22%)
Hypothyroidism	11 (22%)
Asthma	2 (4%)
Anemia	2 (4%)
Depression	9 (18%)
Anxiety	2 (4%)
Traumatic Brain Injury	1 (2%)
Post-Traumatic stress Disorder	1 (2%)
Benign Prostatic Hypertrophy	2 (4%)
Congested Heart Failure	1 (2%)
Other	14 (28%)

Note: HTN – Hypertension; DM -Diabetes

Appendix D

Paired Sample Statistics and Test

Table D1

Paired Sample Statistics (ask-12)

	n	Mean	SD	Std. Error Mean	t	df	Sig. (2- tail)
Pair 1 ask-12					14.462	49	.000
Pre-test	50	44.06	9.803	1.386			
Post-test	50	23.1	8.794	1.244			

Note: Results for the ask-12 tool scores showed statistically significant decreases in barriers to adherence.

Table D2

Paired Samples Test (ask-12)

	t	df	Sig. (2- tailed)	Test Value = 0 Mean Difference	95% Confidence Interval of the Difference	
					Lower	Upper
Pair 1 (ask-12)	14.462	49	.000	20.96	18.048	23.872

Note: *p < .05

Table D3

Paired Sample Statistics (PCAR)

	n	Mean	SD	Std. Error Mean	t	df	Sig. (2- tail)
Pair 1 PCAR					12.327	49	.000
Pre-test	50	.2912	.178	.02519			
Post-test	50	.7018	.204	.02897			

Note: Results for the PCAR scores showed a statistically significant increase in adherence.

Table D4

Paired Samples Test (PCAR)

	t	df	Test Value = 0			
			Sig. (2-tailed)	Mean Difference	95% Confidence Interval of the Difference	
					Lower	Upper
Pair 1 (PCAR)	12.327	49	.000	-.41060	-.47753	-.34367

Note: *p < .05

Table D5

Paired Sample Statistics (Systolic B/P)

	n	Mean	SD	Std. Error Mean	t	df	Sig. (2-tail)
Pair 1 Systolic B/P					8.366	41	.000
Pre-test	42	138.17	12.844	1.982			
Post-test	42	124.52	14.160	2.185			

Note: Results for the Systolic B/P showed statistically significant decreases in Systolic B/P levels.

Table D6

Paired Samples Test (Systolic B/P)

	t	df	Test Value = 0			
			Sig. (2-tailed)	Mean Difference	95% Confidence Interval of the Difference	
					Lower	Upper
Pair 1 (Systolic B/P)	8.366	41	.000	13.643	10.349	16.936

Note: *p < .05

Table D7

Paired Sample Statistics (Diastolic B/P)

	n	Mean	SD	Std. Error Mean	t	df	Sig. (2-tail)
Pair 1 Diastolic B/P					8.389	41	.000
Pre-test	42	85.74	12.593	1.943			
Post-test	42	74.14	9.994	1.542			

Note: Results for the diastolic B/P showed statistically significant decreases in diastolic B/P Levels.

Table D8

Paired Samples Test (Diastolic B/P)

	t	df	Test Value = 0			
			Sig. (2-tailed)	Mean Difference	95% Confidence Interval of the Difference	
					Lower	Upper
Pair 1 (Diastolic B/P)	8.389	41	.000	11.595	8.804	14.387

Note: *p < .05

Table D9

Paired Sample Statistics (BSFS)

	n	Mean	SD	Std. Error Mean	t	df	Sig. (2-tail)
Pair 1 BSFS					4.593	20	.000
Pre-test	21	180.86	59.285	12.937			
Post-test	21	123.33	34.975	7.632			

Note: Results for the BSFS scores showed statistically significant decreases in BSFS levels.

Table D10

Paired Samples Test (BSFS)

	t	df	Test Value = 0			
			Sig. (2-tailed)	Mean Difference	95% Confidence Interval of the Difference	
					Lower	Upper
Pair 1 (BSFS)	4.593	20	.000	57.524	31.398	83.650

Note: *p < .05

Appendix E

QIP Cost and Benefits

Table E1

Itemized Program Cost Outline for Physical Materials

Items Descriptions	Cost
Medication Info Sheet printed from Medline Plus (NIH, 2017b)	\$0.00
Medication Refrigerator Sign x50	\$0.00 DNP(c) created
Medication List Wallet Card x50	\$0.00 DNP(c) created
One Ream of Orange Colored Paper	\$17.00 DNP (c)
Three Reams of White Paper	\$20.00 DNP(c)
Ink for HP Printer	\$125.00 DNP(c)
Plastic CD covers (used as the Wallet Card holder) x50	\$25.00 DNP(c)
Pill Box x 50	\$50.00 DNP(c)
Calendars x50	\$50.00 DNP(c)
Notebooks x50	\$50.00 DNP(c)
Wrist Digital B/P Device x42	\$630.00 Stake Holders
Glucometers (for newly diagnosed patients) x3	\$120.00 Stake Holders
Total Physical Material Cost	\$1087.00

Table E2

Itemized Program Cost for Outline for Computer Information Systems

Item Description	Cost
Practice Fusion EHR	\$0.00 Clinic
Medline Videos	\$0.00 NIH (2017b)
Medline Medication Info Sheets	\$0.00 NIH (2017b)
Personal Laptop with current Microsoft Programs	\$0.00 owned by DNP(c)
Total Computer Information Systems	\$0.00

Table E3

Itemized Program Cost Outline for Transportation and Travel

Item Description	Cost
Project Manager [DNP(c)] (.17 x 70 x 82 days)	\$975.00 DNP(c) [CA reimbursable volunteer mileage]
Total Travel Cost:	\$975.00

Table E4

Itemized Program Cost Outline for Personnel

Item Description	Cost
Clinic's Director	\$0.00 Volunteer
BSN Students-x16	\$0.00 Clinical Assignment
Faculty (supervise BSN Students) x3	\$0.00 Volunteer
Faculty (supervise NP students) x5	\$0.00 Volunteer
NP Students x3	\$0.00 MSN Practicum
Diabetic Educator-1	\$0.00 Volunteer
Total Personnel Cost	\$0.00

Table E5

Itemized Program Cost Outline for Project Space and Implementation

Item Description	Cost
Clinic Room- site of intervention	\$0.00
Clinic Office- Data tallying	\$0.00
Home Office- Data Analysis	\$0.00 DNP(c)
Total Space for Implementation:	\$0.00

Table E6

Overall Project Cost

Item Description	Cost
Total Physical Material Cost	\$1087.00
Total Computer Information System	\$0.00
Total Travel Cost	\$975.00
Total Personnel Cost	\$260.00
Total Space for Implementation	\$0.00
Total Program Cost	\$2062

Table E7

Project Expense Breakdown

DNP(c) Expense Incurred	\$1312.00
Stakeholder Expense Incurred (Wrist B/P & Glucometers - Donated to QIP for patients)	\$750.00

Table E8

Project's Cost and Benefit

Cost to Increase Medication Adherence:	\$2062.00
Savings to the Healthcare System: (Patterson et al., 2016)	\$76,294.00

STATEMENT OF ORIGINAL WORK

Academic Honesty Policy

Capella University's Academic Honesty Policy ([3.01.01](#)) holds learners accountable for the integrity of work they submit, which includes but is not limited to discussion postings, assignments, comprehensive exams, and the dissertation or capstone project.

Established in the Policy are the expectations for original work, rationale for the policy, definition of terms that pertain to academic honesty and original work, and disciplinary consequences of academic dishonesty. Also stated in the Policy is the expectation that learners will follow APA rules for citing another person's ideas or works.

The following standards for original work and definition of *plagiarism* are discussed in the Policy:

Learners are expected to be the sole authors of their work and to acknowledge the authorship of others' work through proper citation and reference. Use of another person's ideas, including another learner's, without proper reference or citation constitutes plagiarism and academic dishonesty and is prohibited conduct. (p. 1)

Plagiarism is one example of academic dishonesty. Plagiarism is presenting someone else's ideas or work as your own. Plagiarism also includes copying verbatim or rephrasing ideas without properly acknowledging the source by author, date, and publication medium. (p. 2)

Capella University's Research Misconduct Policy ([3.03.06](#)) holds learners accountable for research integrity. What constitutes research misconduct is discussed in the Policy:

Research misconduct includes but is not limited to falsification, fabrication, plagiarism, misappropriation, or other practices that seriously deviate from those that are commonly accepted within the academic community for proposing, conducting, or reviewing research, or in reporting research results. (p. 1)

Learners failing to abide by these policies are subject to consequences, including but not limited to dismissal or revocation of the degree.

Statement of Original Work and Signature

I have read, understood, and abided by Capella University's Academic Honesty Policy ([3.01.01](#)) and Research Misconduct Policy ([3.03.06](#)), including the Policy Statements, Rationale, and Definitions.

I attest that this dissertation or capstone project is my own work. Where I have used the ideas or words of others, I have paraphrased, summarized, or used direct quotes following the guidelines set forth in the *APA Publication Manual*.

Learner name
and date

Virgie Stella Delgado, DNP(c), MSN Ed., RN  1/31/19

Mentor name
and date

Linda Royer, PhD, RN  1-31-19