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**Key words:**
Hypertension; adherence; PDC; adherence barriers; 90-day; 30-day; adherence intervention; blood pressure; rural disparities; health disparities; community health center; pharmacy managed intervention

# The impact of 90-day blister pack refill and patient education on compliance and blood pressure control in a Federally Qualified Health Center

**ABSTRACT**

**Purpose:** The purpose of this study is to examine and evaluate the impact of: 1) a pharmacy managed 90-day blister package refill on adherence and 2) educational intervention on medication adherence plus blood pressure outcomes.

**Introduction**: Hypertension is one of the most common health condition amongst adults in the US. It is most often managed with the use of antihypertensive medications. Non-compliance to medication is often one of the biggest barriers in the management of hypertension and impacts health and increased health care costs. Community health centers like Mariposa Community

Health Center in rural locations often have difficulty improving their patients' medication adherence. Different strategies have been developed in order address medication adherence and improve health outcomes.

**Methods**: A prospective, randomized controlled trial study that measured and compared adherence and blood pressure (BP) values of patients enrolled in a 90-day blister pack refill who participated in an educational workshop about hypertension. Participants completed a knowledge test survey before and after the educational workshop as well as an ASK-12 survey in order to identify potential barriers that affect medication adherence. Randomization was done utilizing a block randomization method. Adherence was calculated utilizing portion of days covered (PDC) formula. BP was analyzed utilizing a paired T-test. Knowledge and ASK-12 surveys were analyzed utilizing Wilcoxon signed-rank test.

**Results**: In the first 90-day period, systolic blood pressure (SBP) was significantly decreased by mean of 6.84mmHg (p=0.05, 95% CI -.078-13.77). Diastolic had a similar decreasing trend but was not statistically significant (p=23 95% CI -2.42-9.04). 93.3% of the participants were adherent to their antihypertensive medications (PDC>80%). Pre and post knowledge surveys did not show any significant difference in the first 90 days. Questions 3 and 7 of the ASK-12 survey had a significant difference (p=0.021, p=0.15, 95% CI) in the first 90-day period.

**CONCLUSION**:

The number of patients vs those who consented yielded a less than desirable turnout limiting the intervention and making all those who consented assigned to the 90-day refill group limiting our data and having a comparison group. A significant decrease in SBP from their baseline BP was observed.

## INTRODUCTION:

According to the CDC, nearly 75 million people (1 in every 3 adults) in the United States have hypertension. One of every 3 adults also have prehypertension which means that they have blood pressures higher than normal but are not yet in the range for the diagnosis of hypertension. Hypertension puts patients at risk of developing heart disease and stroke, which is the leading cause of death amongst adults in the nation. According to the CDC, of those who have been diagnosed with hypertension, only about half (54%) have their blood pressure under control. In those who have been diagnosed with hypertension, controlling blood pressure is the best way to prevent disease progression and reduce risk of developing heart disease and stroke. It is estimated that a total of $48.6 billion is spent each year on hypertension which includes cost of medications, health care services, and missed days of work. (1) Based on data that were collected by the Arizona Department of Health for Santa Cruz County, about 31.5% of deaths in the

elderly (65 years and older) were due to diseases of the heart, the leading cause of death in this age group in Santa Cruz County. (2)

According to American Heart Association, researchers found that the risk of hospital admission, re-hospitalization, and premature death among non-adherent hypertension patients is greater than 5 times higher compared to the patients who are adherent. In addition to the health impact, non-compliance results in increased health care costs; for example, about $290 billion is avoidable cost every year if patients were adherent to their medication therapy. (1)

Studies have found many obstacles that can keep patients with hypertension from achieving or maintaining their blood pressure goals such as medication cost, lack of awareness, lack of access to care, medication side effect, nonadherence, inaccurate blood pressure measurements, and clinical inertia. (2)

Several studies have found positive impacts like increased adherence rates as a result of pharmacy-run patient education programs and 90-day refill. Since Mariposa Community Health Center currently has difficulties improving medication adherence for their patients, we will therefore, implement a pharmacy-run patient education programs along with 90-day refill service along with blister packaging at the pharmacy for patients on antihypertensive medication therapy. We will also conduct patient interviews as part of the workshop where we will identify major barrier(s) to the adherence and evaluate the understanding of the importance of adherence to medications.

The purpose of this study was to examine and evaluate the impact of; 1) a pharmacy managed 90-day blister package refill on adherence and 2) educational intervention on medication adherence plus blood pressure outcomes. It was expected that patients who consent to 90-day blister package refill would have a higher adherence rate and lead to a higher percent of patients who met BP goals. It is also expected that patients upon receiving an education intervention on the importance of adherence would have an increase in knowledge of the importance of their antihypertensive medication treatment, which would lead to a positive effect on adherence rate; measured by PDC. We hoped to see an increase in the understanding of managing hypertension after educational services were provided.

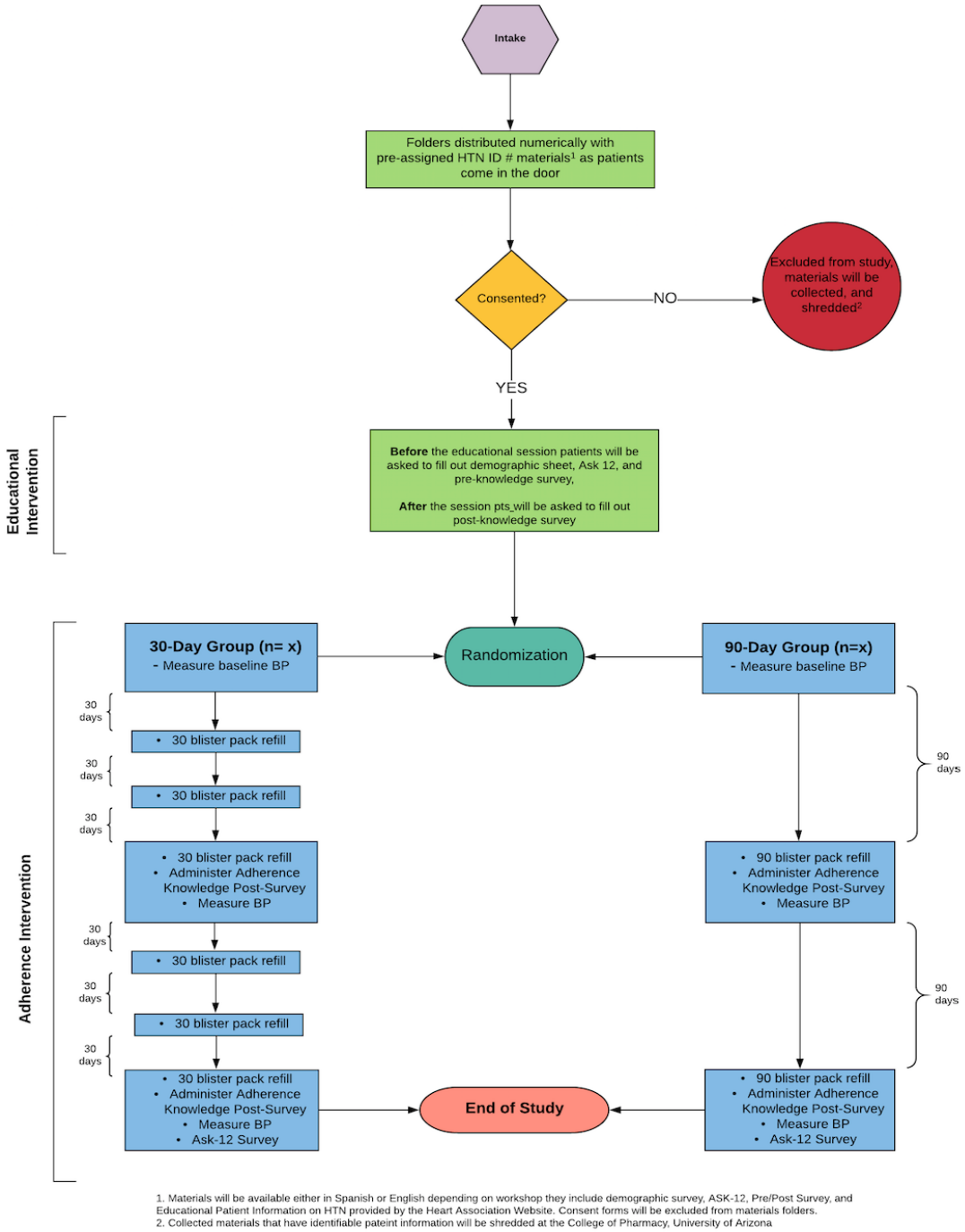
## METHODS:

### Design

This interventional, randomized control trial, prospective study measured and compared adherence rate of patients enrolled in a 30-day (control group) and 90-day (test group) blister pack refill. The randomization was done utilizing a block randomization method. This was done by first generating a random number list using excel's rand() function. The participants were then

divided into blocks (homogeneous subgroups) of four people in each block. The first 2 people in each block were designated as 30-day refill group while the last 2 people were designated as 90-day refill. The random numbers that were generated and then organized in ascending order for each block. This generated a second randomization of the order of the groups that each participant in each block is assigned to. As potential participants lined up to turn in their signed consent form, their name was assigned to a HTN ID#. Only project investigators had access to code book that identified the participant's name and assigned HTN ID#. Refer to project flowchart below.

Figure 1. Project Flow-Chart




Secondary clinical outcomes included the following: proportion of participants that meet BP goals and the knowledge maintained that was provided during the workshop which may or may not impact adherence. This was assessed using a knowledge test survey (pre-survey & post-survey). The post educational survey (retest) was administered to the patient during their first and second refill pick up.It aimed to determine if the educational intervention had a longitudinal impact on patient's understanding and knowledge in regard to their antihypertensive treatment.

Due to the limited sample size, the original proposed protocol was scaled back in order to address the challenges of recruitment. All consented study participants were assigned to the 90-day blister pack refill group. The flow-chart shown in figure 1 was followed as shown in accordance to the 90-day group.

Subjects:

Patients who had established primary care treatment with MCHC, were 18 years of age or older, had a diagnosis of hypertension, were on at least 1 antihypertensive medication treatment, and utilize MCHC Pharmacy were eligible for the study. Exclusion criteria included any patient who: was pregnant, under 18 years of age, not on hypertensive medication treatment, and did not have a diagnosis of HTN. Based on feedback from the pharmacists at MCHC we anticipated that approximately 80 patients would attend the educational workshop, but that 60 would consent to enroll and participate in the adherence study. After extensive recruitment efforts, only 15 people consented to participate in the study opposed to our anticipated sample size of ~60. Since the population of Nogales includes a large proportion of individual who speak Spanish, the educational workshop was given in both English and Spanish; the consent form, demographic survey, and all workshop educational materials was also provided in both English and Spanish. Bilingual investigators were available to answer any questions or concerns during the educational program, consenting process, and data collection procedures.

Instruments & Variables:

Instruments included a form collecting demographic data, a pre and post-survey to measure impact of education of blood pressure on patient knowledge, the Ask-12 survey to identify barriers that affect medication adherence, 90-day and 30-day blister package enrollment form and data collection sheet to record adherence and blood pressure to track any improvements. The treatment (independent) variables were the 30-day and 90-day blister packaged refills and the educational workshop. The dependent variables was any change in the adherence rate from baseline among and between the two groups. Adherence was measured utilizing PDC, which is the current gold standard. The industry-accepted adherence threshold in most therapeutic categories is 0.8(80%) according to the Pharmacy Quality Alliance (PQA) (3).

Figure 2. Equation for PDC

$$PDC = \left( \frac{\text{Number of days in period "covered"}}{\text{Number of days in period}} \right) \times 100\%$$

Descriptive variables included the demographic data that was collected (i.e. sex, race/ethnicity, age, education level, etc). Other descriptive variables include those collected in the pre and post-survey and ASK-12 survey data.

Data Collection:

The data that was collected was de-identified using the randomly assigned HTN # discussed in the design section. The data that was collected included the following; demographic, pre and post-survey, ASK-12 survey, BP measures, and PDC/adherence data. Only authorized data collectors, including the MCHC pharmacists, PI and Co-PI collected adherence intervention data at MCHC pharmacy. Investigators and data collectors only had access to the data collection forms that were locked up in safe filing cabinet and the forms on the clipboard were covered with a white sheet to protect patient data collected. After data was collected for each instance, the clipboard was put back into the safe.

Data analysis:

Demographic data was analyzed by frequencies and percentages. Differences in BP from baseline and 90-day period were analyzed using a paired T-test to assess for difference. Adherence was measured using the formula for PDC and analyzed with a mean, standard deviation, and paired T-test to assess for any difference. Descriptive and categorical data from the pre/post-knowledge survey and pre/post ASK-12 survey were analyzed using the Wilcoxon signed-rank test to assess if they differed. All statistical analysis was completed using SPSS statistics software. An alpha level of 0.05 for significant was utilized in the analysis.

**RESULTS:**

Figure 2. Study Demographics

| | n (%) |
|---|---|
| Gender | |
| Male | 6 (40) |
| Female | 9 (60) |
| Race/Ethnicity | |
| African American/Black | |
| American Indian/Native American | |
| Asian | |
| Hispanic/Latino | 15 (100) |
| Other Pacific Islander | |
| White | |
| Education Level | |
| Elementary | 4 (28.6) |
| Some High School | 3 (21.4) |
| High School Degree/GED | 2 (14.3) |
| College | 5 (35.7) |
| Primary Language | |
| English | 1 (6.7) |
| Spanish | 14 (93.3) |
| Other | |
| Age | |
| 18-24 | |
| 25-34 | |
| 35-44 | |
| 45-54 | 1 (6.7) |
| 55-64 | 5 (33.3) |
| 65-74 | 6 (40.0) |
| ≥ 75 | 3 (20.0) |
| # Antihypertensive Medications | |
| 1 | 5 (35.7) |
| 1-3 | 8 (57.1) |
| 4-6 | 1 (7.1) |
| >6 | |
| Primary Pharmacy | |
| Mariposa | 15 (100) |
| Mail Order | |
| Retail | |
| Other | |
| Active Insurance | |
| No | |
| Yes | 15 (100) |
| Without Insurance in past 12 months | |
| No | 15 (100) |
| Yes | |
| Insurance Type | |
| Current Employer | |
| Former Employer | |
| Government | 7 (50.0) |
| Self-Funded | 4 (28.6) |
| Other | 3 (21.4) |

A total of 120 eligible patients were invited to participate in the educational workshop that was also used to recruit people interested in participating in the study. A total of 32 participants attended one of the four recruitment workshops held. Of those 32 people, a total of 15 consented to participate in the study. As previously stated, all participants were assigned to the 90-day group in order to address the challenges of recruitment. Refer to figure 2 for study participant demographics. The study is still ongoing until all participants have completed a 180-day period. For the first 90-day period, systolic blood pressure (SBP) was significantly decreased by a mean of 6.84mmHg from baseline ($p=0.05$, 95% CI -0.078-13.77). Similarly, diastolic blood pressure (DBP) had a similar decreasing trend of 3.31mmHg from baseline, however was not statistically significant ($p=0.23$, 95% CI -2.42-9.04). For the first 90-day period, 14 out of 15 (93.3%) of the participants were adherent to their me antihypertensive medication according to the industry-

accepted adherence threshold of 0.8(80%). The mean adherence (PDC) measure for all the participants was 115.1(SD=41.7). When comparing the pre and post-knowledge surveys, there was no statistically significant difference in any of the questions during the first 90-day period (Q1 p=0.31, Q2 p=1.0, Q3 p=0.31, Q5 p=.18, Q6 p=.46, Q7 p=.78, Q8 p=.31, Q9 p=.65, Q10 p=.31, Q11 p=.31, Q12 p=.59). When comparing the ASK-12 survey from day 0 and day 90, there was a statistically significant difference in question 3 and 7 (p=0.021, p=0.015 respectively). Question 3 asked participants if they thought that it was inconvenient to take medications more than once a day. This can be interpreted as participants changing their mind whether they felt it was inconvenient to take medications more than once a day during the first 90-day period. Question 7 asked participants if they felt that they work together with the doctor/nurse to make decisions on their healthcare. This can be interpreted as participants changing their mind on whether they felt they work together with their doctor/nurse to make decisions during the first 90-day period.

**CONCLUSION:**

In conclusion, the number of patients vs those who consented yielded a less than desirable turnout limiting the intervention and making all those who consented assigned to the 90-day refill group limiting our data and having a comparison group. There was a significant decrease in SBP from their baseline BP, whereas there was no statistical difference in DBP from their baseline.

**DISCUSSION:**

Some notable limitations were identified in this study. Due to the limited participation of consented individuals the project was limited and therefore no other comparison groups were able to be formed. The study compared the 90-day blister pack refill to their baseline scores instead of other possible interventions (e.g, those who fill 30-day blister pack) if we yielded more consented patients. Even though patients were invited personally by the healthcare institution and were called to confirm attendance, the majority of potential did not show up to the education workshop. More creative, strategic ways for recruitment can be employed in this particular population such as having provider involvement since this population is highly receptive to the input of healthcare providers. Other advertising efforts can also be employed to increase awareness and convince people to attend. There was highly positive feedback from people who did attend the educational workshop about the information they were given and many stated that they would be interested in attending an future workshops on different topics.

Attitude of the 90-day blister pack refill overall was positive from the patients perspective. While speaking to the pharmacist, data collector in this case, they were able to interact with the patients during one-on-one to 5-minute discussions. It gave the patients an opportunity to ask questions in

regards to their blood pressure and medications overall. Some of the comments expressed to the study investigator by the data collections include “we enjoy talking to the pharmacist during pick up” and “it has helped me take my medications”.

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