

What sociodemographic factors and other important variables affect medication
compliance among hypertensive patients 50 years old and above?

By

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A thesis submitted in partial fulfillment of the requirements

for the degree of

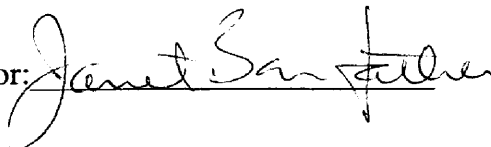
Master of Science in Nursing

The University of Michigan- Flint

March 2007

Approved:

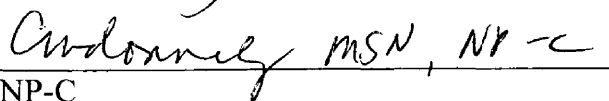
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Date 3/20/07

Abstract

One of the most prevalent chronic diseases is hypertension. Research has shown that medication non-compliance is the most important reason for poorly controlled hypertension. The objective of this study was to evaluate the socio-demographic and other important variables which may be contributing factors about why patients ages 50 years or older chose not to comply with their medication regime to manage their blood pressure. Non-compliance was defined as “the extent to which a person’s behavior does not coincide with medical or health advice” (Blackwell & Gutman, 1985,p 453).

A quantitative, descriptive study was conducted using a convenience sample. Participants were among the 160 hypertensive patients attending Dr. Jose Lopez’s primary care clinic in Burton, Michigan. After receiving approval from the Institutional Review Board at UM-Flint, a sample of 30 individuals was drawn from those who met inclusion criteria of 50 years or older, hypertension diagnosis and signed consent form. Data were collected from the 6th of March 2006 through the 3rd of April 2006 using a survey questionnaire developed by the researcher. Data included socio-demographic variables and other variables related to compliance.

Analysis of the data utilized Kendall’s tau, Mann-Whitney U and logistic regression to investigate which variables affected medication compliance. Results revealed there were no significant relationships between some of the demographic variables (age and employment) and the extent to which respondents reported taking blood pressure (BP) medications as prescribed. Health insurance prevented patients with

lower incomes from obtaining medications on time. The relationship between agreement that lack of health insurance prevents getting medications and income level had a negative correlation coefficient ($r = -.466$, $p = .003$). Gender (female) related to reports that taking BP medication was important to their health ($r = .377$, $p = .031$). Knowledge of bad side effects of not taking BP medication and doctor's advice to stay away from salty foods revealed no significant finding when correlated with demographic variables. However, doctors advice about salty foods was related to more self-reported knowledge about BP medications was related to reported knowledge about BP medications ($r = .488$, $p = .006$).

Hypertension is on the rise in America as is a greater risk for cardiovascular events such as stroke or myocardial infarction. The ultimate goal is to prevent these events and other organ damage from occurring. Knowing current treatment guidelines, understanding the different pathophysiological process and factors affecting medication non-compliance is fundamental.

It is an important role of the nurse practitioner in medical practice to teach and encourage patients about hypertension. The vast knowledge and experience of a skilled nurse practitioner should be conveyed to their patients in a simple, easy to understand format. Expanding a patient's knowledge about their disease process and treatment will result in increase compliance and improved health outcomes.

Acknowledgements

This research project could not have been written without the many individuals who have encouraged and challenged me. Never accepting less than my best efforts, I thank them all.

First, a special thank-you to my thesis chairperson Dr. Janet Barnfather, with her knowledge, dedication, patience and her continuous support in this research project. Dr. Barnfather was always there to listen, give advice and showed me different ways to approach my research problem in accomplishing my goal. Next is Dr. Jose Lopez, for his utmost support and the utilization of his office to make this research possible.

I am also greatly indebted to the faculty and staff at the University of Michigan-Flint. For the scholarship grant as well as the vast knowledge and learning experience they have instilled on me, to better prepare me as an advanced practice nurse, I am truly grateful.

Also, I would like to acknowledge my sister Erly and my thesis committee member Carol Donnelly MSN,NP-C, for their assistance with the endless research questions and providing me with insightful comments. And to those of you closest to my heart, who inspired me when times were rough and encouraged me to continue standing tall and never give up, you will never be forgotten.

Finally, but not the least, I thank my family. For the unconditional love, support and encouragement in pursuing my educational goals. This task could not have been made possible, without great sacrifices endured not only by me, but more importantly, my husband and daughter, Bryan and Nicole.

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Chapter 1

INTRODUCTION

High blood pressure is a major health problem in the United States. According to the National Heart, Lung, and Blood Institute (NHLBI, 2004) there are approximately 65 million American adults with hypertension. That equates to nearly 1 out of 3 American adults. The Centers for Disease Control and Prevention (CDC, 2002) reported that 45 million Americans or 22 percent have pre-hypertension. Thirty percent do not know they have hypertension and 36 percent either are not being treated for it or their prescribed medications failed to control their high blood pressure. Based on the 2003 guidelines provided by the Seventh Report of the Joint National Committee (JNC-7) on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (U.S. Department of Health & Human Services, 2003) a normal blood pressure (B/P) reading is a systolic B/P <120 millimeters of mercury (mmHg) and diastolic <80 mmHg. Pre-hypertension is a systolic B/P of 120-139 mmHg or diastolic B/P of 80-89 mmHg. They further classified hypertension as Stage I hypertension if systolic B/P is 140-159 mmHg or diastolic B/P is 90-99 mmHg and stage II is a systolic B/P > 160 mmHg or diastolic B/P >100 mmHg.

Sociodemographic factors that influence compliance

Non-compliance is defined as “the extent to which a person’s behavior does not coincide with medical or health advice” (Blackwell & Guttman, 1985,p 453). One of the major contributors to the large number of uncontrolled hypertensive patients appears to be non-compliance with prescribed regimens. Non-compliance is a universal characteristic and can affect all patients. However, the major problem of non-compliance is that it remains largely unrecognized in clinical practice (Burnier, 2005). On the other

hand, compliance means adherence to a drug regimen, such as taking medications correctly and on time. Compliance and adherence will be used interchangeably in this text.

Age and gender appears to play a major factor in the prevalence of hypertension. Research has shown that men age 55 and younger are more commonly affected as compared to women in this age group. But as they age, more women 75 years and older have high blood pressure problems than men (Gardner & Knoll, 2005). Racial background also seems to have a bearing in the prevalence of hypertension. According to the American Heart Association (2005), African-Americans have the highest prevalence of hypertension worldwide. In a study comparing white women to black women, black women have an 85 percent higher rate of medical care visits for hypertension than white women (National Center of Health Statistics, 2001).

Treatment Guidelines

The current recommended guidelines formulated by JNC-7 could help reduce mortality, morbidity, and the costs of treating HTN if adhered to. Unfortunately, nearly half of the people with hypertension still go untreated and only 23% have B/P controlled to the recommended level (Hyman & Pavlick, 2002). Behavioral models suggested that medication therapy consisting of Angiotensin converting Enzyme (ACE) Inhibitors and Thiazide diuretics can be very effective in controlling hypertension, but only if the patient takes the medication as directed and maintains a healthy lifestyle.

There are many reasons for patients' noncompliance to their medications. One reason may be attributed to the fact, that hypertension (HTN) does not manifest any signs and symptoms until there are already extensive damages to the target organs such as the heart, kidneys, and eyes. Some patients do not realize these long-term consequences of uncontrolled HTN; therefore,

do not strictly follow their prescribed medication regimen. There are some who just forget to take their medications and others who refuse to take it because of its adverse effects (Medicine Net Incorporated, 2005).

Nursing Theory

Micro-range theory is defined as a set of working hypotheses or propositions. Scientist and practitioners use these working propositions to tentatively categorize, explain, or test health-related person-environment interaction. As such, they are not coded and entered into a formal theoretical system (Higgins & Moore, 2000). In this study, several possible relationships were evaluated as to which demographic variables contribute to medication non compliance among patients 50 years and older.

The objective of this study was to evaluate the sociodemographic and other important variables which may be contributing factors about why patients ages 50 years or older chose not to comply with their medication regimen to manage their blood pressure. The target population was patients in a primary care clinic in Burton, Michigan.

CHAPTER 2

REVIEW OF THE LITERATURE

High Blood Pressure as a Major Health Problem

According to the American Heart Association (2005), the number of adults in the United States (U.S.) with high blood pressure increased 30 percent from 1990-2000.

The study found that at least 65 million Americans have hypertension, defined as blood pressure of 140/90 millimeters of mercury (mm Hg) or higher or using blood-pressure lowering medications, or having been told at least twice by a physician or other health professional that they had high blood pressure (medical history). By that definition, almost a third of U.S. adults have hypertension. Reflecting the age-related association with high blood pressure, the number of people with hypertension was about 4.4 million in the 18–34 age group; 8 million in the 35–44 group; 12.7–12.8 million each in the 45–54 and 55–64 age groups; 13.2 million in the 65–74 age group, and 14.1 million in the 75-and-older age group.

Treatment of hypertension is one of the most common clinical responsibilities of U.S. physicians, yet only one fourth of patients with hypertension have their blood pressure adequately controlled making it a major health problem in our society. In a study conducted by Hyman & Pavlick (2002), data were analyzed from the third National Health and Nutrition Examination Survey to assess the role of access to and use of health care in the control of hypertension. Hypertension was defined as a blood pressure of at least 140/90 mm Hg or the use of antihypertensive medication. The study sample consisted of 16,095 adults who were at least 25 years old and for whom blood-pressure values were known. It was estimated that 27 percent of the population had hypertension, but only 23 percent of those with hypertension were taking

medications that controlled their condition. Among subjects with untreated or uncontrolled hypertension, the pattern was an elevation in the systolic blood pressure with a diastolic pressure of less than 90 mm Hg. The great majority had health insurance. Independent predictors of a lack of awareness of hypertension were an age of at least 65 years, male gender, non-Hispanic black race, and not having visited a physician within the preceding 12 months. The same variables, except for non-Hispanic black race, were independently associated with poor control of hypertension among those who were aware of their condition. An age of at least 65 years accounted for the greatest proportion of the attributable risk of the lack of awareness of hypertension and the lack of control of hypertension among those who were aware of their condition. Results show that most cases of uncontrolled hypertension in the United States consist of isolated, mild systolic hypertension in older adults, most of whom have access to health care and relatively frequent contact with physicians.

Important Predictors of Non-Compliance

Patients' non-compliant behavior with their prescribed medication regimen is a complex and multidimensional behavior. Sociodemographic variables that may be contributing to such behavior are age, gender, marital status, education and family support (Miller, 1997). Other possible contributing factors to the non-compliant behavior are social factors, treatment regimen, and the provider/client interactions (Etkin, Levkoff & Lindeman, 2002).

Independent predictors of lack of awareness of hypertension were : being 65 years of age and older, male and non-Hispanic black. Not having visited a physician within the preceding 12 months was also an independent predictor. These same variables were also seen in those patients who were aware of their poorly controlled hypertension, except for non-Hispanic black individuals. Individuals of at least 65 years old accounted for the greatest proportion of variance

in risk factor for those who lack awareness of their disease and those whose hypertension was not controlled with medications (Hyman & Pavlick, 2002).

In another study at the University of Arizona, data on background characteristics, physical health, life satisfaction, psychological distress, and medication compliance were gathered using structured interviews from randomly selected subjects ($N = 1028$) ages 55 years and older in southeastern United States who were living independently. In this study, 785 subjects admitted to taking prescribed medications, 75% were women, 83% were Caucasian, the median income was \$12,500 annually, and 66% lived alone. The mean age was 73.9 years and their mean number of years of education was 11.4. Findings revealed twenty-one percent of all respondents taking medications had been noncompliant during the month preceding the study interview (Coon, 2003).

Noncompliance with prescribed medications was significantly associated with higher socioeconomic status ($p < 0.01$), greater number of prescribed medications ($p < 0.01$), and higher psychological stress ($p < 0.05$). However, there were no correlations identified between compliance and living arrangements, nor between health, life satisfaction, and number of illnesses, age, or gender (Coon, 2003).

Baseline data from a clinical trial by Bosworth & Oddone (2005) assessed intentional and unintentional non-adherence using a self-report measure. Intentional non-adherence was defined as patients' understand what has been recommended, but choose not to follow the advice, while unintentional non-adherence was defined as, patients' not knowing what medication to take (knowledge deficit). Participants were presented with a list of adverse effects that were commonly associated with antihypertensive medication and asked to indicate which symptoms they had experienced. Logistic regression analyses were used to examine adjusted associations

between patient characteristics and type of non-adherence. Approximately 31% of patients reported unintentional non-adherence and 9% reported intentional non-adherence. Non-white participants, individuals without diabetes mellitus, and individuals reporting ≥ 5 adverse effects were more likely to report intentional non-adherence than their counterparts. Individuals with less than a 10th-grade education and non-white participants were more likely to report unintentional non-adherence than their counterparts. Elzubier et.al.,(2000) study revealed that a considerable proportion of patients who were non-compliant with their medication regimen were attributed to the fact that they could not afford to buy their B/P medications. Therefore, lack of medications resulted in an uncontrolled blood pressure and increased disease complications. On the other hand, there are studies that found sociodemographic factors have little or no effect on medication compliance. Findings from Dunbar-Jacob et.al.,(2003) found that sociodemographic variables did not predict compliance. Rudd et. al.,(1993) and DeGeest et.al., (1998) also support the findings that sociodemographic variables have little capacity in predicting compliance behavior.

Both of these studies have not found sociodemographic factors such as age, gender, number in household, education level, or household income to be a good predictor of compliance. Race was not found to be a significant predictor of compliance related to the percentage of days with correct dosing or timing of doses. Although income was not a significant predictor of overall compliance, it was predictive of correct timing of doses and percentage of days with correct administration.

Increased compliance has been found in studies conducted by others. According to Maclane & Zyanski, (2000) those with incomes greater than \$ 20,000 per year had a higher compliance than those with household incomes below this level. Subjects with household

incomes of \$ 20,000 to 29,000 and 30, 000 or above were no different on compliance, each exhibited higher compliance than those with incomes of less than \$ 20,000. Thus, the \$ 20,000 income level seems to be the critical income-level marking the difference between those with poor levels of compliance. It was interesting to note that approximately 43% of the sample had household incomes below \$ 20,000. Persons with lower levels of household income may have fewer resources to use and so may be more likely to be impacted by things such as co-payment for prescriptions or doctor's visits attributing to their non-compliance.

Theoretical Framework

Micro-range theory uses propositions in this study to identify, describe and organize the working conceptual relationships in practice. The investigation, although identical in process to the scientist's, differs in terms of its scope and its generalizability. That is the practitioner investigates more particular and immediate relationships in a smaller group of persons or frequently, a single person (Higgins & Moore, 2000). Development of knowledge and theoretical thinking are important to professional nursing practice. In order to build a knowledge base for advanced clinical nursing practice, micro-range theory allows direct testing of theoretical thinking from daily clinical practice.

Conclusion

Patient medication compliance is a major health care problem in the United States. Numerous studies and reports have been performed to articulate the meaning of the problem and to suggest improvements. The reviewed literature explored important facets of the current compliance situation. There is still a complex problem for clinicians and researchers who need to have better information and to understand medication compliance among hypertensive patients. This study was undertaken to better understand the compliance situation with regards to other

important variables in addition to the sociodemographic factor affecting compliance among hypertensive patients. The research question supported by the literature review is: What sociodemographic factors and other important variables affect medication compliance among hypertensive patients 50 years old and above ?

CHAPTER 3

METHODS

Sample and Setting

Approval for research was obtained through the University of Michigan Flint Institutional Review Board for the Use of Human Subjects in Research (Appendix A).

This quantitative and descriptive study, using a convenience sample, was conducted at Dr. Jose Lopez's Primary Care Clinic, in Burton, Michigan. Data collection was from the 6th of March 2006 through 3rd of April, 2006. During this interval, 160 patients diagnosed with hypertension attended the clinic. Of these patients who attended the clinic, forty met the inclusion criteria and thirty agreed to be in the study by signing the informed consent and entered the study.

Inclusion Criteria

The inclusion criteria for the participants were (1) 50 years old and above (2) can read and write English in the eight grade level (3) diagnosed with hypertension, (4) consented to participate in the study.

During the study, 10 patients who met the inclusion criteria refused to participate, verbalizing time constraints and some were not interested in the study. The 30 participants were curious and eager about the study itself including the findings. Clinic staff was very accommodating in identifying patients who met the three inclusion criteria and did a good job during the course of the study because they respected the patients' decisions to either participate or not.

Research Tool

A literature search did not reveal a research tool that fit the research question and the research setting. Some identified tools were lengthy and included many illnesses unrelated to the research question. The researcher designed a data collection tool (questionnaire) with the help of a nurse practitioner and the committee chairperson (Appendix D). The literature review supported items included in the researcher designed tool that was constructed to be administered over a short interval of time which is consistent with a busy practice setting.

The researcher designed tool has a total of 16 questions, 8 of which assessed sociodemographic variables and an 8 item survey questionnaire was used, to assess compliance with medication (Appendix D).

The answers to the questions were scored on a 5-point Likert scale with varying degree of agreement to different values from one to five. The Likert rating scale, which gauges attitudes or reactions, and measures the strength of agreement with a clear statement, was used to analyze the survey questionnaires. The independent variables were demographic variables, while the dependent variables were the medication compliance items numbered one through eight in the survey questionnaire(Appendix D).

Procedures

The primary investigator (PI) was a Family Practice Nurse Practitioner graduate student. Prior to the beginning of the study, the PI gave the clinic secretary and a medical assistant minimal training on the details of the study. The PI instructed the office staff on how to ask individuals if they wanted to hear more about the study. The instruction included a script about the PI's educational affiliation and the purpose of the study. On specific dates that were selected by the PI in March, 2006, the clinic secretary was able to identify patients who

were 50 years and older with appointments on those dates. She then invited potential subjects to participate as they signed in for their scheduled appointment and handed them a flyer to read with detailed information of the study (Appendix E). The names of those who agreed to participate were given to the PI. The PI reviewed the patients' records to assure that each one met the selection criteria. Once it was determined that they met the criteria, either the principal investigator or medical assistant approached those individuals who wanted to hear more about the study and may want to participate knowing their participation is voluntary and they have a right to refuse at any time without any penalty. After obtaining a signed consent (Appendix B), the participants were taken to a quiet private room where they were asked to fill out a survey questionnaire (Appendix C and D). After completing the survey questionnaire, participants were asked to hand it back to the PI in a sealed envelope for coding, data reduction and analysis. All the completed questionnaires were confidential and kept in a secured/locked drawer only accessible to the principal investigator. The questionnaires will be shredded at the completion of the study. Remaining data files do not include any identifying information such as names of subjects who participated.

Data Analysis

Data were entered and analyzed using SPSS. Descriptive statistics are utilized to obtain the mean and standard deviation for age, while percentages are used for gender, ethnicity, marital status, education status, employment, household income and insurance. The Likert rating scale, which gauges attitudes or reactions, and measures the strength of agreement with a clear statement was used to analyze the survey questionnaires. Kendall's tau which is a non parametric test, was used to test a correlation which is different from zero and indicated the magnitude of a

relationships between ordinal level variables in this study. The values of the statistics ranges from -1.00 to $+1.00$ and their interpretation is similar to that of Pearson's r .

Type I error – alpha was set at 0.05 level of significance. The relevance of the 0.05 level indicates that the findings can be in error 5 out of 100 times, given the null hypothesis is true.

Mann – Whitney U , a non-parametric test was used in this study. This tested the difference between two independent groups (with and without insurance), since the dependent variable (8 survey questionnaires) was measured in an ordinal scale. The test involved assigning ranks to the two groups of measures and the sum was compared by calculating the U statistics. It omits less information than a median test and is more powerful (Beck & Polit, 2004).

CHAPTER 4

RESULTS

Demographics

From a total of 40 patients eligible to participate, 30 agreed to be in the study and the data on completed questionnaires were used in the analysis. The response rate was 75.0 %.

Demographic data obtained, revealed that the study sample consisted of 15 men (50 %) and 15 women (50%) (Table 1). The age of the participants ranged from 50 to 78 years with a mean age of 60.8 years and a standard deviation of 7.0. Fifty three percent of the patients were married and the remainder were single, divorced, widow or living with significant other. Most participants only had high school education. Sixty percent of the patients had insurance coverage for medications. The majority were Afro-American (43 %) followed by Caucasian (40 %), and most were unemployed (63 %) as compared to the employed (37 %). The majority of the participants income was between \$ 20,000 to \$ 29,999 (43.3%) (Table 1).

Table 1 Demographics of Study Participants (N = 30)

Characteristics	Mean/SD or Percentages
Age (years) n = 30 (50-54) n = 5 (55-60) n = 9 (61-65) n = 10 (>65) n = 6	Mean = 60.8 SD = 7.0 16.7 % 30 % 33.3 % 20 %
Gender Men n = 15 Women n = 15	50 % 50 %
Marital Status Single n = 0 Married n = 16 Divorced n = 7 Widowed n = 6 Living with significant other n = 1	0 % 53.3 % 23.3 % 20. % 3.3 %
Educational Status College n = 8 High school n = 14 Middle school n = 3 Elementary n = 5	26.7 % 46.7 % 10 % 16.6%
Ethnicity Afro-Americans n = 13 Caucasians n = 12 Others n = 4 Hispanics n = 1	43.3 % 40.0 % 13.4 % 3.3 %
Insurance Insurance (medication) *n = 18 No insurance (medication) *n = 12	60 % 40 %
Employment Unemployed n = 19 Employed n = 11	63.3% 36.7 %
Income n = 30 < 10,000 n = 6 10,000 – 19,999 n = 2 20,000 – 29,999 n = 13 30,000 – 39,999 n = 7 > 50,000 n = 2	20 % 6.6 % 43.3 % 23.3 % 6.6 %

* Insurance includes medication coverage.

Research Question

Are sociodemographic and other important variables contributing factors to non compliance with medication regimen for blood pressure management in patients 50 years old or older ?

Answering the Research Question

There were no significant findings or relationships between demographic factors investigated (age, gender, education, employment, income and insurance) and whether or not respondents reported taking BP medicines as prescribed (Question 1 from the questionnaire) (Table 2).

Financial reasons preventing patients from obtaining medications (Question 2 from the questionnaire) revealed no significant findings for the demographic variables.

Lack of health insurance and financial hardships had a significant, positive correlation coefficient. The lower the income, the more patients agree that they cannot get their medications on time (correlation coefficient -0.466 , $p = 0.003$) (Question 3 from the questionnaire) (Table 2).

Most uninsured and underinsured also face lack of insurance because of inability to afford premium co-pays or lack of employment or source of income (correlation coefficient of 0.685 , p value 0.000) (Question 2 and 3 from the questionnaire) (Table 5).

No significant findings noted between understanding / knowledge of the bad side effects of not taking medication (Question 4 from the questionnaire) for the demographic variables as well.

More females reported that taking blood pressure medication was important to their health than males (correlation coefficient 0.377 , $p = 0.031$) (Question 5 from the questionnaire).

There may be a trend, with regards to alternative medicines (Question 6 from the questionnaire) when correlated with demographic variables, but further analysis is needed.

The lower the educational level, the more likely respondents would not get medication refilled during financial hardships (correlation coefficient -0.320 , $p = 0.043$) (Question 7 from the questionnaire).

There was no significant findings between doctors advice to stay away from salty foods and demographic variables (Question 8 from the questionnaire).

Table 2 Kendall's tau (Correlation between major study variables)

		Age in Years	Gender	Educa- tion	Employ- ment	Income	Insu- rance for Rx
I take my BP med every day as prescribed	Correlation Coefficient	-0.009	-0.013	0.133	0.120	0.141	-0.066
	Sig. (2-tailed)	0.951	0.944	0.435	0.512	0.404	0.720
Question 1	N	30	30	30	30	30	30
Financial reasons prevent me from getting my meds on time	Correlation Coefficient	0.016	-0.063	-0.283	0.220	-0.282	0.110
	Sig. (2-tailed)	0.910	0.710	0.075	0.196	0.072	0.518
	N	30	30	30	30	30	30
Question 2							
Health insurance prevents me from getting my meds on time	Correlation Coefficient	0.100	-0.158	-0.214	0.317	-.466(**)	0.287
	Sig. (2-tailed)	0.480	0.345	0.171	0.058	0.003	0.088
	N	30	30	30	30	30	30
Question 3							
I understand the bad side effects of not taking my BP med	Correlation Coefficient	-0.217	-0.032	0.107	-0.173	0.149	0.061
	Sig. (2-tailed)	0.156	0.858	0.526	0.339	0.370	0.738
	N	30	30	30	30	30	30
Question 4							

Table 2 (continued)

Taking my BP med everyday is important for health	Correlation Coefficient	-0.132	.377(*)	-0.014	0.233	-0.067	0.135
Question 5	Sig. (2-tailed)	0.372	0.031	0.932	0.184	0.676	0.441
	N	30	30	30	30	30	30
Health products are just as effective as meds	Correlation Coefficient	0.195	-0.277	-0.186	0.187	-0.181	0.037
Question 6	Sig. (2-tailed)	0.170	0.099	0.235	0.267	0.241	0.827
	N	30	30	30	30	30	30
If I had enough money I would use it to refill my prescriptions	Correlation Coefficient	-0.158	0.284	-.320(*)	0.035	-0.147	-0.035
Question 7	Sig. (2-tailed)	0.272	0.095	0.043	0.835	0.350	0.838
	N	30	30	30	30	30	30
If my doc told me to stay away from salty foods I would	Correlation Coefficient	-0.113	0.093	0.084	-0.102	0.104	-0.016
Question 8	Sig. (2-tailed)	0.463	0.612	0.620	0.579	0.537	0.931
	N	30	30	30	30	30	30

* Correlation is significant at the 0.05 level (2- tailed).

** Correlation is significant at the 0.01 level (2 -tailed).

According to the Mann-Whitney U test (Table 3), there was no significant findings on having insurance or not for medication compliance which was measured by each item in the Questionnaires (Appendix D).

The results also were non significant as well, using the Wilcoxon signed rank test. The Z value were all lower than one and the asymmetric and exact sig were not in normal distribution and therefore not symmetrical in graph (Table 4).

Table 3 Correlation between with and without insurance and other study variables.

	Insurance	N	Mean Rank	Sum of Ranks
Financial reasons prevent me from getting my meds on time	Have insurance for medication	18	14.69	264.50
	No insurance for medications	12	16.71	200.50
	Total	30		
Health insurance prevents me from getting my meds on time	Have insurance for medication	18	13.33	240.00
	No insurance for medications	12	18.75	225.00
	Total	30		
I understand the bad side effects of not taking my BP med	Have insurance for medication	18	15.19	273.50
	No insurance for medications	12	15.96	191.50
	Total	30		
Taking my BP med everyday is important for health	Have insurance for medication	18	14.58	262.50
	No insurance for medications	12	16.88	202.50
	Total	30		
Health products are just as effective as meds	Have insurance for medication	18	15.22	274.00
	No insurance for medications	12	15.92	191.00
	Total	30		
If I had enough money I would use it to refill my prescriptions	Have insurance for medication	18	15.75	283.50
	No insurance for medications	12	15.13	181.50
	Total	30		
If my doc told me to stay away from salty foods I would	Have insurance for medication	18	15.58	280.50
	No insurance for medications	12	15.38	184.50
	Total	30		

Table 3 (continued)

	Finances prevent me from getting meds on time	Insurance prevents me from getting meds on time	Understand bad side effects of not taking my BP med daily	Taking my BP meds everyday is important keeping me health	Health products are just as effective as BP meds	If I had money to get by this month I would use it to get refill	If doc told me no salt I would stop eating salted foods
Mann-Whitney	93.500	69.000	102.500	91.500	103.00	103.500	106.500
Z	-.647	-1.708	-.334	-.771	-.219	-.204	-.086
Asymp. Sig.(2-tailed)	.518	.088	.738	.441	.827	.838	.931

According to logistic regression (Table 4), the dependent variable (taking or not taking blood pressure (BP) medications) did not have significant predictors by the independent variables (employment, income and insurance). The group was created from item number one in the survey questionnaire, where the group taking BP medication were the people who answered strongly agree and somewhat agree. The group not taking BP medication were the people who answered strongly disagree, somewhat disagree and undecided.

Table 4 Predictors for taking or not taking BP medications.

Variables not in the Equation

Step	Variables	Empl	Score	df	Sig
0		Income	1.787	1	.181
		Insurance	.008	1	.930
			.690	1	.406
	Overall Statistics		2.671	3	.445

Variables not in the Equation (continued)

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 1a	Employment	51.145	11998.677	.000	1	.997	1.6E+022
	Income	17.319	4993.469	.000	1	.997	33246311
	Insurance	17.063	8783.638	.000	1	.998	25717437
	Constant	-119.068	27290.107	.000	1	.997	.000

Table 5 Kendall's Tau (Correlation between study variables)

			Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8
Kend all's Tau_B										
Q1	Take BP med everyday as prescribed by doctor	Correlation Coefficient Sig.(2-tailed) N	1.000 . 30							
Q2	Finances prevents me from getting meds on time	Correlation Coefficient Sig.(2-tailed) N	.367* .029 30	1.000 . 30						
Q3	Insurance prevents me from getting meds on time	Correlation Coefficient Sig.(2-tailed) N	.219* .186 30	.685** .000 30	1.000 . 30					
Q4	Understand bad side effects of not taking my BP med daily	Correlation Coefficient Sig.(2-tailed) N	.109 .541 30	-.163 .328 30	-.183 .263 30	1.000 . 30				
Q5	Taking my BP meds everyday is important keeping me healthy	Correlation Coefficient Sig.(2-tailed) N	.076 .662 30	.094 .559 30	.101 .525 30	.214 .211 30	1.000 . 30			
Q6	Health products are just as effective as BP meds	Correlation Coefficient Sig.(2-tailed) N	.146 .379 30	.459** .003 30	.350* .022 30	-.288 .079 30	.250 .115 30	1.000 . 30		

Table 5 (continued)

			Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8
Q7	If I had money to get by this month I would use it to get refill	Correlation Coefficient Sig.(2-tailed) N	.082 .624 30	.398* .011 30	.233 .130 30	.014 .934 30	.308 .056 30	.040 .796 30	1.000 .30 30	
Q8	If doc told me no salt I would stop eating salted foods	Correlation Coefficient Sig.(2-tailed) N	.869 .030* 30	.385* .022 30	-.259 .117 30	.488** .006 30	.000 1.000 30	-.175 .290 30	-.075 .656 30	1.000 .30 30

* Correlation is significant at the 0.05 level (2- tailed).

** Correlation is significant at the 0.01 level (2 -tailed).

According to Kendall's Tau (Table 5), poor finances and lack of insurance had a significant positive correlation coefficient (correlation coefficient of .685, p value .000). The use of health products (as effective as BP medications), when correlated with poor finances and insurance, showed a positive correlation coefficient (correlation coefficient of .459, p value .003) (correlation coefficient of .350, p value .022). The physicians advice of no salt intake, when correlated with understanding the bad side effects of not taking BP medication, showed a positive correlation coefficient (correlation coefficient of .488, p value .006).

Conclusion

The one important sociodemographic factor that shows direct relationship to reported medication compliance for treatment of hypertension, is income. The lower the income the more

agreement that participants cannot get their medications on time. Although compliance items regarding insurance and finances had a moderate significant relationship (Table 2), the results are mixed because, individuals who reported having insurance coverage versus those who did not showed no difference in compliance (Table 3).

People who tend to use health products were more likely to have problems with their finances and insurance. Females showed a significant finding as they reported that taking BP medications was more important to their health and keeping their BP controlled than males. Other investigated factors, including age and employment had no impact on respondents decision to take blood pressure medications as prescribed to them.

CHAPTER 5

DISCUSSION OF RESULTS AND SUMMARY

The primary objective of this study was to evaluate the socio-demographic and other important variables which may be contributing factors about why patients ages 50 years or older chose not to comply with their medication regimen to manage their blood pressure in a primary care clinic in Burton, Michigan. This chapter has the interpretation and summary of the results related to the theoretical / conceptual framework. The validity of the conclusion and its implication of research for nursing practice, theory, research and policy are analyzed. Alternative explanations and limitations are expressed and recommendations are brought up.

Interpretation of Results related to Theoretical/Conceptual Framework

Micro-range theory is the least formal and most tentative of all the theoretical levels. It is also non-restrictive in terms of time and scope or application. However, its particularistic approach is invaluable for scientists and practitioners as they work to describe, organize and test ideas. In nursing, our “reality” is clinical practice, and we construct theories about probable truths related to the experience of health in the person-environment interaction (Higgins & Moore, 2000). In this study, the practitioner investigates more particular and immediate relationships in a smaller group of persons.

Opposing views exist regarding socio-demographic factors that affect patient’s medication compliance. From the literatures reviewed, Miller, Etkin et al., Hyman and Pavlick, Coon and Elzubier et al., all have found out that various socio-demographic factors affect compliance. These factors include age, gender, marital status, educational level, provider-client relationships, number of prescriptions, psychological stress and presence of co-morbidities.

This study found gender, educational level and provider-client relationships (physicians advice of no salt intake), showed significant findings with medication compliance.

On the other hand, studies by Dunbar-Jacob et al., Rudd et al., and DeGeest et al., have found that these very same socio-demographic factors (age, gender, number of household, education level and household income) do not predict medication compliance. The one significant sociodemographic factor identified was income, but not directly with overall compliance. Although income was not a significant predictor of overall compliance, it was predictive of correct timing of doses and percentage of days with correct administration.

The results of this study partly agree with Dunbar-Jacob, et al. There was no significant relationship between medication compliance and demographic factors such as age and employment. Other factors investigated such as doctors' advice and knowledge of effects of non-compliance, were significant. Specifically, doctor's advice about salt intake (Question 8), had a significant correlation with understanding the bad side effects of not taking BP medications (Question 4).

Financial status and health insurance were factors found to have direct correlation with reported medication compliance.

Validity of Conclusions

Selection bias is a threat to the internal validity of this study because convenience sampling was used to recruit study subjects. While there was a study inclusion criteria, subjects included were those who agreed to participate and who are most accessible to the researcher. The external validity of the study is also threatened by the limited number of study participants (N=30). The fact that they all belong to the same primary care practice and more likely to reside

in the same or nearby geographic location, are issues that could affect the generalizability of the findings.

Implications of the Study

The results of this study emphasize the need to assess each individual patient's ability to afford their medications: whether or not they have health insurance, have prescription coverage, pay premiums or co-pays.

While stressing the importance of controlling blood pressure and educating patients about their medications are good ways of encouraging medication compliance, these are not good indicators that they will follow the doctor's order. This study revealed that there is a relationship between financial hardships and patients filling their prescriptions. The health care practitioner who implements the treatment and care plan, and who writes for or order the medication needs to find out the least expensive way to control blood pressure. Knowledge of brand name medications that the patient's health insurance would cover and pay for, as well as generic formulation would be a big help to patients. Alternatively, non-pharmaceutical interventions such as lifestyle changes would not be as costly to patients. Also important to consider is the number of medications patients are placed on. While it is necessary for many patients with uncontrolled hypertension to be placed on multiple blood pressure medications, health care providers might find it cheaper to use combination drugs so that patients can avoid exorbitant co-pays for numerous prescriptions. The nurse practitioner can also be aware that women valued taking their blood pressure medicine more than men. As the nurse practitioner educate their clientele, more time and emphasis would be given to men with regards to medication compliance to avoid negative sequelae or complications of hypertension. Also, the nurse practitioner, may want to assess what "health products" patients are using by asking questions such as: If finance

or insurance prevents you from getting your medications on time, do you use any other health products for your blood pressure control?

Alternative Explanations for Findings

Because this study was conducted in a single primary care practice, the study participants are homogenous in nature as far as their geographic residence. Living in the same city or county and facing similar economic situations, study subjects were more apt to have the same opinions regarding the impact of their living standards to their health care.

The City of Burton where the primary care office was located, along with the neighboring City of Flint and entire Genesee County, has seen economic difficulty with the collapse of the automobile industry. Many have lost their jobs and consequently are more unable to pay for health care. These are two major concerns in these communities and could have affected the study participants' belief on what could explain for their inability to comply with their doctor's order.

Limitations

The small sample size and single primary care practice investigated are the major limitations to this study. These may have also affected the analysis of the data and resulted non-significant correlations between variables.

Medication compliance was also not well-defined for study participants. Also, it was not clear if health products referred to alternative medicine and / or over the counter medications or other nutrients. In addition, this was measured based on patient's self-reporting. Medication compliance could be more accurately measured if this study reviewed medical records including medication refill from pharmacies, or used a questionnaire to test knowledge of participants

regarding what, when and how much medication they take vis-à-vis what was prescribed, instead of relying on participant's self admission of medication.

Another limitation of this study, was marital status and ethnicity were not analyzed because of a coding problem which was related to level of measurement. Hence, these variables were not used in the analysis for predicting compliance.

Another important factor not investigated, that could have a big impact on medical compliance, is the quality of patient and health care provider relationship and methods of providing health care to patients.

Recommendations

Hypertension is one of the most common health disorders in the world. Long term trials have repeatedly shown that the use of anti-hypertensive drugs reduces both morbidity and mortality resulting from hypertension and non-compliance results in the reduction of benefits provided by those drugs. The quiet nature of hypertension often encourages the tendency of patients to be non-compliant, although factors such as the nature of the treatment regimen, side-effects of the drugs, sociodemographic factors and factors related to the patients' milieu are also involved.

Further study is recommended to investigate if other sociodemographic factors can in fact affect medication compliance, using longitudinal design with larger randomized samples in more than one geographic location with a broader population. It would be interesting to find out the type of provider, whether physician, nurse practitioner, or physician assistant also have a bearing on medication compliance. More importantly, the quality of provider, the patient relationship, and level of trust / confidence in the provider could have more impact on patient medication compliance.

Value system, health beliefs, knowledge level and patient-provider relationship are a few examples that could also play a role on patient medication compliance. In order to assess all these factors, it is necessary to conduct further research with more study participants and controls both extraneous and confounding variables.

A qualitative research design could also explore new concepts identifying other factors for medication compliance not investigated in this study.

Conclusion

This study found significant relationship between medication compliance and demographic factor such as gender and other important variables including insurance, finances, education and provider relationship. However, medication compliance is a multi-factoral behavior. Factors such as age and employment were investigated, but without significant findings. However, there are plethora of factors that could affect medication compliance. There may be a trend with regards to health products when correlated to demographic variables as shown in the result of this study, that further warrants analysis.

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APPENDICES

Appendix A (UM-Flint IRB Approval Letter)

Appendix B (Consent Form- Rights and Responsibilities of Participants)

Appendix C (Demographic Questionnaire)

Appendix D (Survey Questionnaire)

Appendix E (Flyer)

Appendix F (Physician Permission Allowing Patients to Participate)

Appendix A

(Approval from University of Michigan Flint Institutional Review Board)

(Appendix A)

Approval from University of Michigan Flint Institutional Review Board



Flint Institutional Review Board (IRB) • 530 French Hall, 303 E. Kearsley St, Flint, MI 48502 • phone (810) 762-3383 • fax (313) 593-0526 • research@umflint.edu

Date: 2/7/2006

To: Dr. Janet Barnfather

Cc: IRB Flint

Subject: Initial Study Approval

The Flint Institutional Review Board (IRB) has reviewed and approved the research proposal referenced below. The IRB determined that the research is compliant with applicable guidelines, state and federal regulations, and the University of Michigan's Federalwide Assurance with the Department of Health and Human Services (HHS).

Any proposed changes/amendments in the research (e.g., personnel, procedures, or documents), no matter how minor, must be approved in advance by the IRB unless necessary to eliminate apparent immediate hazards to research subjects.

The approval period for this project is listed below. Please note your expiration date. If the project is scheduled to continue beyond this date, submit a Scheduled Continuing Review application **at least two months prior** to the expiration date to allow the IRB sufficient time to review and approve the project. **If the approval lapses, no work may be conducted on this project until appropriate approval has been obtained, except as necessary to eliminate apparent immediate hazards to research subjects.**

The IRB must be informed of all unanticipated or adverse events (i.e., physical, social, or emotional) or any new information that may affect the risk/benefit assessment of this research.

The online forms for amendments, adverse event reporting, and scheduled continuing review can be obtained by accessing the eResearch workspace for this approved study at <https://eresearch.umich.edu>.

It is expected that only the current IRB-approved version of the informed consent document(s) will be used in conjunction with this research. To obtain and download a copy of the current IRB-approved informed consent document(s), PIs and Study Staff should access the eResearch workspace for this approved study and view the "Documents" tab.

Submission Information:

Title: Smith, Maria Victoria: Sociodemographic Factors and Other Important Variables of Medication Non-Compliance among Hypertensive Patients

IRB File Number: HUM00001915

Initial IRB Approval Date: **2/7/2006**

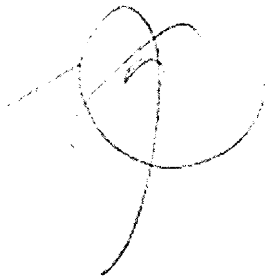
Current IRB Approval Period: **2/7/2006 - 2/6/2007**

Expiration Date: **2/6/2007**

eResearch workspace: Smith, Maria Victoria: Sociodemographic Factors and Other Important Variables of Medication Non-Compliance among Hypertensive Patients

UM Federalwide Assurance: FWA00004969 Expiration 6/12/06

Sincerely,

A handwritten signature in black ink, appearing to be 'M. McGrath', with a large loop and a trailing line.

Marianne McGrath

Chair, IRB Flint

Appendix B

(Consent Form- Rights and Responsibilities of Participants)

(Appendix B)

Consent Form

- 1.) The patient agrees to participate in the research project, titled “Sociodemographic Factors and other Important Variables of Medication Non-Compliance among Hypertensive Patients”. This is being conducted by Maria Victoria L. Smith, RN, BSN, who is a graduate student at the University Of Michigan-Flint. The research question is designed to find out some reasons that prevents patients ages 50 years and older, from taking their blood pressure medications on a regular basis. This study may help reduce and prevent the epidemic of uncontrolled high blood pressure in our society.
- 2.) The patient has been informed that their participation is voluntary, and poses no risk or discomforts. He/she may withdraw at any time and if he/she chooses not to participate, and will not have any effect on his/her receiving services through Dr. Jose Lopez Clinic.
- 3.) The patient understands that this study is in the form of a short multiple-choice questionnaire, that will take about 20 minutes or less to complete. The patient understands that his/her name will remain confidential in this study. The patient understands that the questionnaires will be the property of the director of the project (principal investigator-Maria Victoria Smith) and will not be shared with anyone else. The patient understands that upon the completion of the project in May 2007, all materials and questionnaires will be destroyed by the project director to insure patient confidentiality. The patient understands that although he/she may not receive direct benefit from their participation, others may ultimately benefit from the knowledge obtained in this study. There is no cost to the client in participating in this study.
- 4.) The patients name will not be shared with the primary care clinic. Information that is shared will only be discussed as group data to assist with primary health care. The patient will not be identified in any reports on this study. Records will be kept confidential to the extent provided by federal, state, and local law. However, the Institutional Review Board, university and government officials responsible for monitoring this study may inspect these records. The patients name will remain confidential.
- 5.) Upon request, the patient may receive results of this study which may impact the medical condition of the patient.
- 6.) One copy of this document will be kept together with the research records of this study and the patient will be given a copy to keep.
- 7.) The patient has read and understands the information given above. Maria Victoria L. Smith has offered to answer any questions that the patient may have concerning the study. The patient hereby consents to participate in the study.

Print Name

Date

Signature

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Appendix C
(Demographic Questionnaire)

(Appendix C)

Demographic Questionnaire

Please read each item and answer by filling in the blank or putting an X on the answer that is appropriate for you.

1.) Age

_____ years

2.) Gender

_____ male

_____ female

3.) Ethnicity

_____ Caucasian

_____ Afro-American

_____ Native American

_____ Hispanic

_____ other (please specify _____)

4.) Marital Status

_____ single

_____ married

_____ divorced

_____ widow

_____ living with significant other

5.) Education (highest grade level completed)

_____ elementary school

_____ middle school

_____ high school

_____ college

6.) Employment status

☐ employed
☐ unemployed

7.) Household income

☐ less than \$10,000
☐ 10,000-19,999
☐ 20,000-29,999
☐ 30,000-49,999
☐ greater than \$50,000

8.) Insurance coverage for medications

☐ yes
☐ no

Appendix D
(Survey Questionnaire)

(Appendix D)

Survey Questionnaire

Put an x next to the answer that best expresses your opinion.

1.) I take my high blood pressure medication everyday as prescribed by my doctor.

- ☐ 1 Strongly disagree
- ☐ 2 Somewhat disagree
- ☐ 3 Undecided
- ☐ 4 Somewhat agree
- ☐ 5 Strongly agree

2.) I think financial reasons(money) prevent me from getting my medication on time.

- ☐ 1 Strongly disagree
- ☐ 2 Somewhat disagree
- ☐ 3 Undecided
- ☐ 4 Somewhat agree
- ☐ 5 Strongly agree

3.) My health insurance prevents me from getting my medication on time.

- ☐ 1 Strongly disagree
- ☐ 2 Somewhat disagree
- ☐ 3 Undecided
- ☐ 4 Somewhat agree
- ☐ 5 Strongly agree

4.) I have a good understanding of the bad side effects of not taking my blood pressure medication everyday.

- ☐ 1 Strongly disagree
- ☐ 2 Somewhat disagree
- ☐ 3 Undecided
- ☐ 4 Somewhat agree
- ☐ 5 Strongly agree

5.) I think that taking my blood pressure medication everyday is important in keeping me healthy and away from the hospital.

- ___ 1 Strongly disagree
- ___ 2 Somewhat disagree
- ___ 3 Undecided
- ___ 4 Somewhat agree
- ___ 5 Strongly agree

6.) I think health products (example garlic, red pepper etc.)are just as effective or better than my prescribed blood pressure medication ?

- ___ 1 Strongly disagree
- ___ 2 Somewhat disagree
- ___ 3 Undecided
- ___ 4 Somewhat agree
- ___ 5 Strongly agree

7.) If I only have enough money to get by this month, I would use it to refill my prescription.

- ___ 1 Strongly disagree
- ___ 2 Somewhat disagree
- ___ 3 Undecided
- ___ 4 Somewhat agree
- ___ 5 Strongly agree

8.) If my doctor told me to stay away from salty foods, I would stop eating those foods.

- ___ 1 Strongly disagree
- ___ 2 Somewhat disagree
- ___ 3 Undecided
- ___ 4 Somewhat agree
- ___ 5 Strongly agree

Appendix E

(Flyer)

(Appendix E)

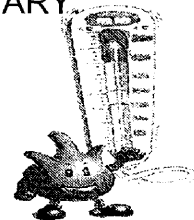
Flyer



What socio-demographic and other important variables affects medication non-compliance among hypertensive patients 50 years old and above ?



MARIA VICTORIA SMITH, A NURSE PRACTITIONER STUDENT FROM UNIVERSITY OF MICHIGAN-FLINT IS DOING A STUDY TO FIND OUT SOME OF THE REASONS THAT PREVENTS PATIENTS AGES 50 YEARS OLD AND ABOVE FROM TAKING THEIR BLOOD PRESSURE MEDICATIONS ON A REGULAR BASIS AS PRESCRIBED BY THEIR DOCTORS. WOULD YOU LIKE TO PARTICIPATE? TO FIND OUT MORE ABOUT THIS STUDY, PLEASE INFORM THE CLINIC SECRETARY



Appendix F

(Approval letter from Dr. Jose Lopez)

(Appendix F)

Approval letter from Dr. Jose Lopez

GENESEE FAMILY CARE, P.C
J. B. LOPEZ, M.D., PLC Ma. C. M. OCAMPO, MD

3020 S. Genesee Rd.
Burton, MI 48519
Tel. # (810) 715-3049 Fax # (810) 744-2850
24 Hour Answering Service

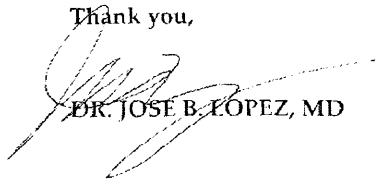
23 January 2006

To: The Institutional Review Board

I, Dr. Jose B. Lopez, having full authority in my practice, grant Maria Victoria L. Smith any kind of access for her research study entitled "Sociodemographic Factors and Other Important Variables of Medication Non-compliance among Hypertensive Patients 50 years old and above in a primary Out-patient Clinic in Flint, MI".

Maria Victoria L. Smith, who's an UM-NP graduate student can recruit subjects from my patients population voluntarily without my influence and use my office including utilization of my staff given that they volunteer to do so.

Thank you,



DR. JOSE B. LOPEZ, MD

