

2016

# Generic Drugs : Physician Prescribing Practices for Brand Name and Generic Medications

Tamuno Raymond George  
*Walden University*

Follow this and additional works at: <https://scholarworks.waldenu.edu/dissertations>

 Part of the [Medicine and Health Sciences Commons](#)

---

This Dissertation is brought to you for free and open access by the Walden Dissertations and Doctoral Studies Collection at ScholarWorks. It has been accepted for inclusion in Walden Dissertations and Doctoral Studies by an authorized administrator of ScholarWorks. For more information, please contact [ScholarWorks@waldenu.edu](mailto:ScholarWorks@waldenu.edu).

# Walden University

College of Health Sciences

This is to certify that the doctoral dissertation by

Tamuno George

has been found to be complete and satisfactory in all respects,

and that any and all revisions required by

the review committee have been made.

Review Committee

Dr. Amy Thompson, Committee Chairperson, Health Services Faculty

Dr. Amy L. Wilson, Committee Member, Health Services Faculty

Dr. Gudeta Fufaa, University Reviewer, Health Services Faculty

Chief Academic Officer

Eric Riedel, Ph.D.

Walden University

2016

Abstract

Generic Drugs: Physician Prescribing Practices for Brand-Name and Generic  
Medications

by

Tamuno Raymond George

MHSA, Strayer University, 2007

MBA, Strayer University, 2006

BSN, North Carolina Central University, 2005

Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Philosophy

Healthcare Administration

Walden University

August 2016

## Abstract

Brand-name drug costs continue to create a burden for many US seniors who receive care from healthcare institutions. Generic medication is as therapeutic as is brand-name drugs and, in most cases, costs far less. Despite this cost difference, physicians continue to prescribe brand-name drugs. The purpose of this cross-sectional study was to explore physicians' patterns of prescribing brand-name drugs over generic drugs. This study was guided by the medical home model, which was developed in 1967 by the American Academy of Pediatrics. The study incorporated a purposeful sampling approach with a sample size of 151 physicians. Multiple linear regression was used to examine the associations between cost of treatment using generic medications and determinants of physicians' pattern of prescribing brand-name medications over generic medications. There were no statistically significant associations between physician belief of cost using generic medications and determinants of physicians' pattern of prescribing brand-name medications over generic medications, suggesting that physicians' prescription patterns are not solely determined by cost of the drug to the patients. The positive social change implication of this study is in the awareness that it generates among physicians, with evidence to suggest the need for more education on the utility of generic drugs instead of brand-name medications.

Generic Drugs: Physician Prescribing Practices for Brand-Name and Generic  
Medications

by

Tamuno Raymond George

MHSA, Strayer University, 2007

MBA, Strayer University, 2006

BSN, North Carolina Central University, 2005

Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Philosophy

Healthcare Administration

Walden University

August 2016

## Acknowledgements

First of all, I would like to give thanks to my God, my Lord and savior, for without him this research work would not have been possible. I would also give thanks to my beloved mother who started this educational journey with me in Nigeria. My mother, the love of my life, could not live to see this day as she died in 2013 and was laid to rest in 2014. My sincere thanks goes to my beloved wife Gloria George, and my children, Joshua George, Grace George, Abigail George, Joseph George, and Benjamin George: They supported me throughout my academics and motivated me to complete this research. I would also like to express my whole-hearted gratitude to my committee chairperson, Dr. Amy Thompson, as well as Dr. Amy Wilson Sango, and my URR person, Dr. Gedete Fufaa for their unlimited guidance. Also, thank you to my classmates, and my friends whose constant and immense support has been a foundation of continuous inspiration and guidance.

## Table of Contents

List of Tables-----	vii
Table of Figures-----	viii
Chapter 1: Introduction to the Study.....	1
Introduction.....	1
Problem Statement.....	3
Significance.....	10
Purpose of the Study.....	12
Theoretical Framework.....	12
Research Question.....	14
Hypotheses.....	14
Nature of the Study.....	15
Study Limitations.....	15
Summary.....	15
Chapter 2: Literature Review.....	18
Introduction.....	18
Theoretical Framework.....	24
Cost of Chronic Conditions.....	26
Chronic Condition Treatments.....	30
Historical Perspective of Medicare and Medicaid.....	33
Medicaid.....	33
Medicare.....	35

Medicare is Different from Medicaid .....	37
Drug Approval Process .....	38
Brand-name versus generic drug .....	40
Cost difference between brand-name and generic drug.....	41
Prescription drug cost .....	42
Generic drugs are not different from brand-name drug.....	50
Generic drugs and cost savings.....	51
Summary .....	53
Chapter 3: Methodology .....	55
Design of the Research .....	55
Justification for the Selected Research Design.....	59
Ethical Considerations .....	59
Specific Ethical Issues in the Study .....	60
Confidentiality of the Data.....	61
Limitations of the Study.....	61
Inclusion and Exclusion Criteria.....	62
Sample Size and Process of Sampling .....	64
Process of Recruitment .....	65
Data Collection .....	66
Instruments Used .....	67
Analysis of the Data.....	69
Summary .....	70



Chapter 4: Analysis and Discussion .....	72
Introduction.....	72
Participant Demographic Characteristics.....	73
Analysis of the Questionnaire.....	75
Item number 1: Generic Drugs and Therapeutic Effect.....	75
Item Number 2: Side Effects – Generic Drugs and Branded Drugs .....	75
Item Number 3: Lack of Quality Check on Generic Drugs .....	76
Item Number 4: Low Cost Generic Drugs.....	77
Item Number 5: Popularity – Generic VS Branded Drugs .....	77
Item Number 6: Representatives - Generic VS Branded Drugs .....	78
Item Number 7: Prescription of Branded Drugs.....	79
Item Number 8: Quality - Generic VS Branded Drugs.....	79
Item Number 9: Safety - Generic VS Branded Drugs .....	80
Item Number 10: Inferiority - Generic Versus Branded Drugs .....	81
Item Number 11: Patent Expiry of Originator/Innovator .....	82
Item Number 12: Low Quality - Generic VS Branded Drugs .....	82
Item Number 13: Multinational Product VS Local Product.....	83
Item Number 14: Remembrance of Brand Name Medicine .....	84
Item Number 15: Affordability - Generic VS Branded Drugs .....	84
Item Number 16: Preferences of Patients .....	85

Item Number 17: FDA and Brand Medications.....	86
Item Number 18: Option to Choose for the Medications .....	86
Item Number 19: Quality of Expensive Medications .....	87
Descriptive Statistics.....	88
Correlation .....	89
Correlations with generic drugs are unable to produce therapeutic effects .....	90
Correlations with do patients prefer brand name drugs to generic drugs .....	91
Correlations with generic drugs cause more side-effects than brand name drugs .....	91
Correlations with generic drug have lower cost compared to brand drugs.....	91
Correlations with more generic prescribing can reduce cost of treatment.....	91
Regression Analysis.....	91
Linearity Test Summary .....	93
Summary.....	97
Chapter 5: Recommendations, Implications, and Conclusion .....	100
Key Recommendations .....	100
Stakeholders.....	100
Legal Framework .....	100
Healthcare Insurance Plans.....	100
Hospitals and Healthcare Professionals .....	101
Employers .....	101
Consumers/Patients.....	101

Study Implications .....	102
Study Limitations.....	102
Conclusion .....	103
References.....	106
Appendix: Instruments.....	118

## List of Tables

Table 1: Frequency and Percentages of Participant Demographic Characteristics .....	74
Table 2: Frequency and Percentages of Responses for Survey Question 1 .....	75
Table 3: Frequency and Percentages of Responses for Question 2 .....	76
Table 4: Frequency and Percentages of Responses for Question 3 .....	76
Table 5: Frequency and Percentages of Responses for Question 4 .....	77
Table 6: Frequency and Percentages of Responses for Question 5 .....	78
Table 7: Frequency and Percentages of Responses for Question 6 .....	78
Table 8: Frequency and Percentages of Responses for Question 7 .....	79
Table 9: Frequency and Percentages of Responses for Question 8 .....	80
Table 10: Frequency and Percentages of Responses for Question 9 .....	81
Table 11: Frequency and Percentages of Responses for Question 10 .....	81
Table 12: Frequency and Percentages of Responses for Question 11 .....	82
Table 13: Frequency and Percentages of Responses for Question 12 .....	83
Table 14: Frequency and Percentages of Responses for Question 13 .....	83
Table 15: Frequency and Percentages of Responses for Question 14 .....	84
Table 16: Frequency and Percentages of Responses for Question 15 .....	85
Table 17: Frequency and Percentages of Responses for Question 16 .....	85
Table 18: Frequency and Percentages of Responses for Question 17 .....	86
Table 19: Frequency and Percentages of Responses for Question 18 .....	87
Table 20: Frequency and Percentages of Responses for Question 19 .....	87
Table 21: Descriptive Statistics for Primary Survey Questions (N = 151 .....	89

Table 22: Pearson Correlations between the Variables (N = 151).....	90
Table 23: ANOVA for the Relationship between The Independent Variables and More of Generic Prescribing can Reduce Cost of Treatment (The Dependent Variable).....	92
Table 24: Regression Coefficients for the Relationship between The Independent Variables and More Generic Prescribing can Reduce Cost of Treatment (The Dependent Variable) .....	93
Table 25: Test of Linearity and Deviation from Linearity for PHYPRESCRIPTION * GENERICDRUG.....	94
Table 26: Test of Linearity and Deviation from Linearity for PHYPRESCRIPTION * BRANDEDDRUG.....	95
Table 27: Test of Linearity and Deviation from Linearity for PHYPRESCRIPTION * PERCEPTION .....	96
Table 28: Test of Linearity and Deviation from Linearity for PHYPRESCRIPTION * GENMEDICATION.....	97

## Table of Figures

Figure 1. Power analysis of the sample size by Creative Research Systems survey software (2012). .....	64
--	----

## Chapter 1: Introduction to the Study

### **Introduction**

The cost of prescription drugs is too high for many in the United States. Because of the high cost of prescription drugs, more people in the United States, including children, are going without needed medications. According to Felland and Reshovsky (2009), many people in the United States cannot fill their prescriptions due to the high cost, and less favorable prescription drug coverage may also contribute to the high rate of unfilled prescriptions. The most vulnerable individuals who continue to face these challenges are the elderly, those with low income, and individuals without insurance (Felland & Reshovsky, 2009). The cost of prescription drugs has become a policy issue for the Medicare and Medicaid programs. At the state level, the debate has been driven by increased Medicaid drug spending. Despite the issue of prescription drug cost, researchers have not examined why physicians will not prescribe generic prescription drugs when such equivalent generic brands exist.

The number of people in the United States under the age of 65 who were having problems filling their prescriptions due to the high cost of prescription drugs was steady in the early decade, but this trend changed. For example, the number of individuals younger than 65 years of age who cannot afford their medication due cost grew from 10.3% in 2003 to 13.9% in 2007 for all (Felland & Reshovsky, 2009). About 36 million people in the United States between the ages of 19 and 64 went without prescription drugs because of cost in 2007; this was an increase of 11.7 million compared to 2003, and unmet medication needs among working individuals rose from 13.8% to 17.8% between

2003 through 2007 (Felland & Reshovsky, 2009). Medication under-usage was also a common reported problem among the elderly with chronic health conditions such as asthma, heart failure, hypertension, high cholesterol, depression, and diabetes (Piette, Heister, & Wagner, 2004). Because children more likely to be in better health compared to their elderly counterparts, they require fewer medications and have less prescription access problems; however, unmet prescription medication needs grew between 2003 and 2007 from 3.1% to 5% (Felland & Reshovsky, 2009). It is possible that the increase in prescription drug nonaffordability was a result of higher prescription drug cost, increased use of brand-name drugs, and physicians not prescribing generic drugs. Furthermore, it could be a result of drug prices rising faster than individual earnings and the introduction of newer and more expensive medications in the marketplace.

The Medicare Modernization Act (MMA, 2003) is a voluntary program that helps pay for prescription drugs through a private plan that is approved by the federal government. According the Center for Medicare and Medicaid Services (CMC), there are about 49 million individuals who have access to Medicare drug benefit programs [CMS], 2011). Public programs such as Medicare and Medicaid play a role in helping individuals pay for their health care including prescription drugs, but continued increases in prescription drug costs may make the program nonviable. There is also public concern about the future of the prescription drug benefit program, particularly in light of the new healthcare policy passed into law by the Obama administration, according to the Congressional Budget Office [CBO], 2014). Seniors continue to be the largest users of prescription medication: Those over 50 years of age use 64% of prescription drugs.



Meanwhile, use of medications by people 19- to 25-years old went down. This change in per-capita prescription drug use could be a result of better disease management or a trend in self-rationing by patients, which could contribute negatively or positively to the future healthcare costs in the US, according to Management Information System [MIS] (2011).

### **Problem Statement**

Medication serves as a therapeutic intervention designed to manage both acute and chronic health conditions. People in the United States who suffer from multiple health conditions may depend on several medications to manage their health. Currently, Medicare and Medicaid provide healthcare benefit for seniors through paying for some of their healthcare costs including prescription drugs. However, out-of-pocket costs, higher costs of prescription drugs, and the recent Medicare and Medicaid benefit reduction may reduce the ability of seniors to meet this extra cost. Nursing homes may experience difficulties in providing adequate care for their residents (CMS, 2012). The Health System Change (HSC, 2003) revealed that many seniors in nursing homes take more than one prescription drug to manage their chronic health conditions. According to Klein, Turvey, and Wallace (2004), the elderly sometimes delay refilling their prescriptions due to high costs. Being unable to refill a prescription could result in the individual not following their medication regimen, which in turn can lead to further health problems and even hospitalizations.

Chronic health conditions such as diabetes, hypertension, high cholesterol levels, asthma, and depression require medications (Wood, 2012). According to Wood (2012), high admission rates have been reported because of medication noncompliance and, in up

to 33% to 69% of patients, the lack of medication compliance has resulted in up to 125,000 deaths per year in the United States . Cardiovascular disease is a chronic condition associated with hypertension. In 2001, some 89,000 deaths would have occurred among patients age 40 and older if blood pressure medications were not taken (Wood, 2012). Patients who are diabetic are less likely to die prematurely if they adhere to their medication regimen, and those who suffer from asthma are 11% less likely to visit the emergency room (ER) or be hospitalized (Wood, 2012).

The New England Healthcare Institute (NEHI, 2009) reported that medication noncompliance leads to a waste of dollars in the healthcare system. The NEHI further revealed that most people in the United States do not take their medication as prescribed; the resultant effect is an additional \$100 billion yearly hospitalization costs, and the barriers to medication compliance include the cost of prescription drugs (NEHI, 2009). There is a correlation between poor health outcomes and patients who do not take their medication as prescribed by their physicians. Among diabetic and heart-disease patients, those who do not take their medication as prescribed had a higher mortality rate, 12.1% versus 6.7% (NEHI, 2009). Additionally, among those who suffer from diabetes, hypertension, high cholesterol levels, and poor heart conditions, the rate of hospitalization is higher compared to those who take their medication as prescribed. In addition, because 75% of US healthcare costs are tied to chronic disease due to medication noncompliance, high prescription drug costs is a potential drawback to improving health outcomes.

Prescription drug spending continues to increase. In 2001, the cost of prescription drugs in United State was \$141 billion. Because seniors depend on Medicare prescription benefit programs to offset some of their prescription drug costs, containing drug costs could help to stabilize the Medicare program (Haas, Phillips, Gerstenberger, & Seger, 2005).

In 2007, yearly prescription drug costs in the United States reached \$286 billion (Paul et al., 2010). Generic drugs cost less when compared to brand-name drugs, so an increased use of generic drugs could result in healthcare savings and serve as a cost-cutting strategy for nursing homes suffering from Medicare and Medicaid cuts. Several expensive drugs will go off patent between 2010 and 2014. This will result in \$209 billion yearly sale. If this trend continues, brand-name drug sales will see a further reduction in yearly sales (Paul et al., 2010). Increasing or improving generic prescription rates and reducing the sale of brand-name drugs can reduce healthcare costs and prevent nursing homes from falling short in their revenues.

According to the Robert Wood Johnson Foundation (1996), chronic conditions are the major cause of death among people in the United States, and almost 100 million people in the United States suffer from some form of chronic health issue. It is projected that by 2040, an estimated 160 million people in the United States will have a chronic condition. The Robert Wood Johnson Foundation further revealed that the cost for caring for people in the United States with chronic condition was \$470 billion in 1995, and by the year 2040, that cost is estimated to be \$864 billion. According to Anderson (2004), in 2002, the United States 70% of all deaths were due to a chronic condition (i.e., heart

disease, cancers, stroke, diabetes, mental illness, Alzheimer's, kidney disease, and respiratory diseases). In addition, 90% of seniors in the United States suffer from one chronic disease, and 77% suffer from more than one chronic condition. According to Mendelson, Ramchand, Abramson, and Tumlinson (2002), in 2002, nursing homes residents received an average of 6.7 routine prescription drugs daily, with an additional 2.7 as-needed medications.

The cost of medications used to treat chronic conditions has social and economic implications. For example, in 2008 one in five hospital admissions was a result of diabetes, with total cost of \$83 billion. Hospital stays of individuals with diabetes are longer when compared to those without diabetes. Medicare covered 60% of the diabetes cost, private insurance covered 23%, and the rest was covered by private payments (Fraze, Jiang, & Burges, 2008).

Currently, state Medicaid programs provide healthcare services for people with low incomes, long-term care for the older population and for individuals with disabilities. As more chronic conditions become apparent, more people will need healthcare services, and more will qualify for Medicaid benefits. In the state of North Carolina, there has been an increase in the older population, with people having more chronic diseases. But with recent Medicare and Medicaid budget cuts, there is a need for new strategies in order for the state to improve the quality of healthcare services and decrease healthcare costs (Kaiser Health News [KHN], (2014)). Medicare and Medicaid provide benefits for seniors to pay for some of their healthcare costs, including prescription drugs. Any remaining balance is considered an out-of-pocket cost and is the responsibility of the recipient (CMS, 2012).

The HSC (2003) revealed that many seniors take more than one prescription drug to manage their chronic health conditions. The high costs of prescription drugs could eat deeply into their low incomes and may prevent them from paying their Medicare and Medicaid out-of-pocket costs including refilling their prescriptions (Strickland & Hanson, 1996). Nursing homes are revenue-driven organizations, and when residents run out of money, two things may happen: they may be asked to go home without completing their stay, or they may not have enough money to pay for their prescription drugs.

For example, paracetamol is a chemical ingredient found in brand-name painkillers, but it is also sold as a generic drug. The Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement does not prevent governments from requiring accurate labeling or allowing generic substitution. Competition between drug companies and generic producers has been more effective than negotiations with drug companies in reducing the cost of drugs. The price of an average generic drug is 75% less than a brand-name prescription drug (CBO, 2010).

The National Health Expenditure Accounts (NHEA) revealed that healthcare spending reached \$2.6 trillion in 2010. This is about \$8,402 per person, and it is 18% of the U.S. gross domestic product (CMS, 2012). The U.S government financed 29% of healthcare costs in 2010, an increase from 23% in 2007. The NHEA also reported that average yearly healthcare costs are expected to grow from 6.2% through 2018, a number that surpasses the anticipated overall economic growth for the period of 4.1%. By 2018, it is projected that national healthcare spending will reach \$4.4 trillion (CMS, 2012). At this

growth rate, in 15 years, healthcare costs will amount to 50% of U.S. GDP. The question becomes whether or not the U.S. economy is sustainable with this amount of expenditure.

Prescription drugs are dispensed in hospitals, including long-term care facilities, for the management of chronic diseases. Based on increasing healthcare costs, the use of cheaper generic prescription drugs will hold down the growth of healthcare costs nationally and across institutional settings such as hospitals and long-term care facilities. The use of generic drugs saved the U.S. healthcare system about \$1.07 trillion from 2002 through 2011, with \$192.8 billion in savings in 2011 alone (CMS, 2012). Knowing that the U.S. government's share of healthcare spending will soon reach 30% and as the oldest Baby Boomers become eligible for government-sponsored programs such as Medicare, the increased use of generic prescription drugs is critical ensuring Medicare and Medicaid sustainability (CBO, 2010).

Researchers have identified cost-saving approaches from various studies, estimates that result because of the use of generic drug, and generic and therapeutic substitutions. Other scholars have examined savings to the U.S. healthcare system and savings from program implementations (CBO, 2010; Haas et al., 2005; Scott & O'Donnell, 2007). The Generic Pharmaceutical Association (GPhA) estimated the amount paid on generic drugs and brand-name drugs for the year 1999 through 2010 and found that generic substitution saved the U.S. healthcare system about \$1 trillion. In 2010 alone generic substitutions saved the U.S. healthcare system more than \$157 billion (GPhA, 2011). The CBO (2010) examined savings that resulted because of the use of

generic drugs in the Medicare Part D prescription drug program and found that it resulted in a cost saving of \$33 billion in 2007.

The CBO (2010) evaluated additional savings from generic and therapeutic substitutions and found that an increase in generic substitutions at the rate of 100% would have resulted in cost savings at about \$900 billion and an additional cost savings of \$4 billion in therapeutic substitutions in 2007. Scott and O'Donnell (2007) analyzed cost savings through program implementation in a managed-care organization in the form of physician participation in 2005 and 2006 and found that after program costs, the organization saved \$397,486 in 2005 and \$453,545 in 2006. Dobscha, Winterbottom, and Snodgrass (2007) conducted a study for the Department of Veterans Affairs (VA) hospital and found potential savings through program implementation of promoting the use of generic antidepressants over brand-name medications. From March of 2002 through August, the policy resulted in a net saving of \$2.5 billion (Dobscha et al., 2007).

Two scholars used data regarding claims from 45 private health insurance organizations from 2003 through 2007 to compare the cost of health care in individuals using selective serotonin reuptake inhibitors (SSRI) when therapeutic substitution occurs midtreatment. Wu et al. (2011) found that patients who switched from brand-name drugs to generic drugs had higher rates of hospitalization due to switching in midtreatment. The switch also result in healthcare cost savings of \$881 dollars (Wu et al., 2011). Viahiotis, Devine, Eicholz, and Kautzner (2011) used claim data from 2005 to 2007 and compared healthcare costs of using brand-name drugs versus generic drugs in midtreatment for 6 months. The conclusion was that the cost of generic antidepressant

SSRIs was significantly lower when compared to brand-name medications (the average was \$3,660 and \$4,587, respectively) (Viahiotis et al., 2011).

### **Significance**

Concerns have been raised about the rise in prescription drug spending, the cost of diabetes, and Medicare and Medicaid expenditures. These factors influence Medicare and Medicaid spending with respect to hospital and nursing home funding. Nursing home expenditures are a financial burden for those who receive treatment, and particularly for those who are not covered by Medicare and Medicaid. The CBO (2010) reported that in 2007, dispensing generic drugs rather than brand-name drugs reduced prescription drug costs by \$33 billion. The American Diabetes Association (ADA, 2013) revealed that in 2012, the total estimated cost of diagnosed diabetes was \$245 billion, including \$176 billion in direct medical costs and losses to productivity of \$69 billion. In patients with a chronic medical condition such as Type 2 diabetes, intensive blood glucose control with prescription drugs may decrease the progression of microvascular disease and prevent heart attacks. However, the cost of prescription drugs may inhibit this treatment (ADA, 2013).

Generic prescription drugs are therapeutic and serve the same purpose as brand-name drugs, but they are less expensive when compared to brand-name drugs. The United States Food and Drug Administration examines generic drug formulation and if it finds them to be suitable, will approve them as therapeutically equivalent to brand-name drugs in terms of safety, strength, and quality (as cited in Haas et al., 2005). Substituting generic drugs for more expensive brand-name prescription drugs will provide savings for



the drug-consuming population (Haas et al., 2005). Due to the rising cost of healthcare stemming in part from the cost of prescription drugs and the cost of managing chronic health conditions, healthcare policy makers can no longer ignore...Many depend on Medicare and Medicaid for healthcare services, and sustaining these social programs is critical in addressing healthcare costs. The increased use of generic prescription drugs through physician automation generic prescription is critical to ensuring Medicare and Medicaid sustainability.

The results of this study can lead to positive significant social change by providing patient education on potential savings from generic medication and by providing information on how generic drugs are cheaper and are therapeutically equivalent as brand-name drugs. The time required for generic entry into the U.S. market is too long. This has a significant negative implications on pharmaceutical expenditure. The knowledge gained from this study can be used to reverse this trend. The use of generic drugs is a policy option that will allow for access to affordable drugs. The knowledge gained from this study can also be used to address negative perceptions of generic drugs. If patients have a positive perception of generic drugs, they may be prompted to use more generic drugs or to ask their physicians to prescribe generic drugs, making it easier for them to afford to pay for their medication. Through generic substitution savings, more money will be available to increase the primary prevention aspects of care. Finally, this study will provide policy makers with relevant information that will aid in their decision-making process. Because Medicare and Medicaid cuts are a

challenge to seniors, the information gained from this study can serve as a strategic tool in the area of generic cost savings.

### **Purpose of the Study**

This study used a quantitative research approach. The purpose of this study was to address the behavior of primary care physicians regarding the prescribing of generic and brand-name drugs for the treatment of chronic conditions in the state of North Carolina. Although government programs such as Medicare and Medicaid provide health benefits to millions of people in the United States, including prescription drug benefits, recent cuts in these programs and the cost of prescription drugs continue to impact beneficiaries of these programs, including those in North Carolina (KHN, 2014).

### **Theoretical Framework**

The theoretical framework of this study was based on the medical home model concept that was presented in 1967 by the American Academy of Pediatrics. The medical home model is characterized by the availability of a personal physician for every family/patient. The delivery of first-contact care is ensured by the physician in this model. Understanding of the needs of the family/patient and facilitation of comanagement that is planned throughout the individual's lifespan is also made certain by the physician. The physician must have the capacity and resources to fulfill the needs of the family/patient (Health Policy Brief, 2010).

The basis of this model resides in the delivery of patient-centered care that involves a team-based approach for facilitating a complete range of healthcare services. This includes the provision of care to all age groups and at all the stages of chronic care,

acute care, mental and behavioral health care, end-of-life care, and preventive services. It also involves the coordination and integration of care that is not delivered by the Patient-Centered Medical Home Model (PCMH) across the multifaceted healthcare system and patient community. The emphasis of this model is on the reduction of the costs of care by improving access to vigorous primary care. The medical home model presents a way to improve health care in the United States through the transformation of the process of organization and delivery of primary care, according to Consumer Assessment of Healthcare Providers and System (CAHPS, 2011). This framework is of value for the provision of care by primary care physicians practicing in Raleigh, North Carolina. It forms the basis for the prescription of appropriate drugs that can be more affordable in order to ensure that the population is receiving adequate care in accordance with the guidelines of the medical home model concept.

This theoretical framework was selected because it provides an approach towards integrative health care that, in this model, is based on one main point of access. Most of the healthcare systems in the United States are using this model of health care for providing services to patients. Data can be retrieved through this model regarding the prescribing practices of primary care physicians in the state of North Carolina. Several scholars have used this model (Henderson, Princell, & Martin, 2012; Jaudes et al., 2011). Lee et al. (2011) used this model to determine the possibility of eliminating disparities in health care that are encountered by minorities in accessing healthcare services. Windel, Anderko, and Konetzka (2011) claimed that this model can be employed for shared decision making that can be useful in supporting the choices of patients regarding the

prescription of drugs. Shared decision making ability permits the patient to be involved in selecting the most appropriate type of drug that is best from all aspects. This model can also curb the cost of health care through the use of medicines that are preventative and cost effective (Marshall et al., 2011). Therefore, this model was used as a theoretical framework in this study because it can facilitate the use of generic medicines.

The medical home model can also be applicable to the healthcare needs of seniors residing in nursing homes. Just as geography, transportation, and financial barriers impact children, these barriers also affect seniors in nursing homes across the United States. The model is designed so that patients, including seniors in nursing homes, get care when and where they need it (National Committee for Quality Assurance [NCQA], 2011). Using the medical home model provides a template for providing care for seniors residing in nursing homes in North Carolina.

### **Research Question**

This study included the following research question:

1. What factors influence physicians' patterns of prescription of brand-name medications over generic medications?

### **Hypotheses**

$H_1$ : Brand popularity and its therapeutic effect do not influence prescribing behavior of brand-name medications over generic medications.

$H_0$ : Brand popularity and its therapeutic effect do influence prescribing behavior of brand-name medications over generic medications.

### **Nature of the Study**

This study was quantitative in nature. I examined the behavior of physicians regarding the prescribing of generic and brand-name drugs for the treatment of chronic conditions in North Carolina.

### **Study Limitations**

There were several limitations associated with this study. First, I was required to conduct the surveys in a predetermined period of time. Second, the sample of the study included only the population of North Carolina. Therefore, the results of this research were representative of only a specific region and might not be applicable to the entire population of the United States. The sample size of the study was also a limitation because it was too small to represent the practices of all the general practitioners regarding the prescription of generic and brand-name drugs. Another limitation of this research was the method of data collection in that an online survey was used. This method did not produce a large enough sample size. This can cause difficulties in the statistical analysis of the data. Quantitative studies using a statistical analysis method require a large sample size to provide valid results. Based on this fact, there will be a need for further research with a larger sample size to ensure the development of valid results.

### **Summary**

The cost of prescription drugs poses a challenge for millions of people in the United States, and also presents a cost-control challenge for private and public health organizations. Because of the high cost of prescription medications, more people in the

United States are going without prescribed drugs. According to Felland and Reshovsky (2009), one in seven individuals under the age of 65 in the US was not able to fill their prescription drug as a result of cost. The high cost of medication and less favorable prescription drug programs may contribute to the high rate of unfilled prescriptions. The elderly are the most vulnerable individuals who continue to face these challenges because most of them lack insurance and are on low or fixed incomes (Felland & Reshovsky, 2009). Several researchers (CBO, 2010; Haas et al., 2005; Scott & O'Donnell, 2007) indicated that generic drugs are therapeutic and cost far less when compared brand-name drugs, and significant cost savings can result with increased use of generic medications.

Reports also indicate that the elderly delay refilling their prescriptions due to cost. The elderly saw their prescription drug cost jump from \$28.50 in 1992 to \$42.30 in 2000 while the number of prescriptions written is steadily increasing (Korn, Reichert, Simon, & Halm, 2003). The impact of not being able to refill prescription drugs as a result of cost could lead to non-medication compliant. Medication noncompliance has been shown to result in repeat hospital visits. In 2001, the cost of prescription drugs in the United States was \$141 billion. Since seniors depend on social programs such as the Medicare prescription benefit to offset some of their prescription drug costs, containing drug spending costs could stabilize the Medicare program. There is a need for educating patients, healthcare professionals, policy makers, and physicians to make them more aware that greater prescription of generic drugs can save money. Chapter 2 will focus on the literature review, a brief history of Medicare and Medicaid, brand-name drugs versus generics, and cost differences.



## Chapter 2: Literature Review

### **Introduction**

The rise in prescription drug costs, particularly for brand-name prescription drugs, is concerning to many people in the United States, including private and public health institutions. This cost is a central policy issue for the Medicare and Medicaid programs. At the state level, the debate has been driven by increases in Medicaid drug spending. Despite the continued rise in prescription drug costs, little research has been conducted concerning why physicians will not automatically prescribe generic drugs considering the relative low cost of generic medication as compared to brand-name prescription drugs. State awareness of prescription drug spending in nursing homes has also increased as budget challenges force Medicaid cost-containment strategies. At the same time, the elderly population is increasing in the United States, and this growing population has chronic health conditions. Most of this older population depends on nursing homes for their healthcare needs (Mendelson et al., 2002). In 1997, for example, there were about 1.6 million residents in 17,000 nursing homes across the United States (author, year). This number will continue to increase as a result of the growing older population (Mendelson et al., 2002). In 2002, nursing home residents received an average of 6.7 routine prescription drugs daily, with an additional 2.7 as-needed medications. The number of medications prescribed in nursing homes increased by 14% in 2000.

The aging of the Baby Boomer generation is predicted to increase the percentage of people over the age of 75, a cohort that was 5.8% of the population in 1997 and is expected to account for 9.4% in 2025. Also, advances in medical technology will allow



more people to live longer (sometimes with less social support) and there are presently not enough nursing homes to care for the elderly population. According to NCCPPR (2013), the elder population in the state of North Carolina will double in 2030, increasing from 1.1 million to 2.2 million. The Medicaid program will take up more portions of the state budget. Currently, the state Medicaid program provides healthcare services for people with low income, long-term care for the older population, and care for individuals with disabilities. As this growth continues, the state will need spend more on nursing-home services because more people will qualify for Medicaid benefits. Is the state of North Carolina ready for this population growth, particularly with recent Medicare and Medicaid budget cuts? Or are there strategies the state can employ to improve the quality of healthcare services and decrease or at least control healthcare spending?

Other components that affect the Medicare and Medicaid budgets include the cost for managing chronic diseases such as diabetes, cardiovascular disease, cancer, and asthma. For example, according to the CDC (2011), 23 million children and adults in the United States—about 8% of the population—suffer from diabetes. About 25% of the U.S. population age 60 and older have diabetes, and it is estimated that by the year 2050, 48 million U.S. residents will be diagnosed with diabetes (CDC, 20011). About 107 million people in the United States suffer from some form of chronic illness, and seven of 10 people die from chronic disease every year. Heart disease, cancer, and stroke constitute the major share of these conditions, contributing to about 50% of all deaths each year (CDC, 2011). The cost of one chronic disease, diabetes, as reported by the ADA (2013), was \$245 billion in 2012, including \$176 billion in direct medical costs, and losses in

productivity amounting to \$69 billion. The components that make up those diabetes medical expenditures include hospital in-patient care, which is 43% of total medical care; prescription drug to manage diabetes, which is 18%; and diabetic agents and other medical supplies, which account for 12%. Physician office visits are 9% and nursing homes/ residential facility stays are 8% (ADA, 2013). An increased understanding the economic consequences of diabetes and its determinants could help policy makers at both the state and federal levels to find ways to reduce healthcare spending. Heart disease, cancer, asthma, diabetes, and hypertension are among the five most costly chronic conditions in the United States. They cost the country about \$347 billion in 2010, which is about 30% of total healthcare costs (CDC, 2011). The number of individuals diagnosed with Alzheimer's in the United States is increasing. It is reported that by 2050, the number of Alzheimer's cases will reach 16 million (CDC, 2011). This trend will impact Medicare spending; in fact, in 2005 Medicare paid \$9 billion for individuals diagnosed with Alzheimer's; by 2015, it was expected to reach \$189 billion (CDC, 2011).

The CDC (2011) reported that it costs the United States approximately \$74 billion to care for a cancer patient (a treatment with Avastin costs more than \$90,000 for a 1.5 month period), and Medicare paid \$7.3 billion on in-patient cancer care (CDC, 2011). Because chronic diseases account for much Medicare spending, any increase in the number of chronic conditions will impact the Medicare budget. Medications can help manage acute and chronic health conditions, and many older adults depend on several medications to help them manage health effectively. The current Medicare and Medicaid programs provide benefits for seniors, including those in nursing homes, to pay for some

portion of their healthcare costs including prescription drugs. The remaining balance is considered out-of-pocket cost and is the responsibility of the recipient (CMS, 2012). The HSC (2003) revealed that many seniors in nursing homes are on low and/or fixed incomes and take more than one prescription drug to manage their chronic health conditions. Considering the high costs of prescription drugs, those with fixed and low incomes may find it difficult to pay for their Medicare and Medicaid out-of-pocket costs, including refilling their prescriptions (Strickland & Hanson, 1996). Medication is an essential aspect of managing chronic diseases, particularly for the elderly. Because social programs such as Medicare do not cover all aspects of prescription drugs, the elderly have difficulty affording drugs (Reed, Hargraves, & Cassil, 2003).

Prescription drug costs are a burden for African Americans, as researchers have found that among African Americans age 65 and older, those using Medicare find it difficult to fill their prescriptions (Reed et al., 2003). The increase in chronic conditions, low income, and a lack of supplementary insurance explain the prescription access gap that exists between older African American and their European American counterparts (Reed et al., 2003). According to Reed et al. (2003), chronic conditions such as heart disease, high blood pressure, and diabetes are common among older African Americans, and they require prescription drug management. Additionally, complications that can result from diabetes such as renal failure, blindness, and gangrene because of lack of medication compliance can be avoided through proper prescription drug regimens (Reed et al., 2003).

According to Klein et al. (2004), the elderly sometimes delay refilling their prescriptions due to high costs. Not taking medication as prescribed can have health consequences; it could lead to a further decline in health, result in repeated visits to the hospital, and may increase the number of days that the patient must stay in a nursing home. Besides the cost impact on individuals, prescription drug costs also impact other segments of society. In 2001, the cost of prescription drugs in the United States was \$141 billion. Because seniors depend on Medicare prescription benefit programs to offset some of their prescription drug costs, containing drug costs could stabilize overall Medicare program costs (Haas et al., 2005). Generic prescription drugs are considered therapeutic, serve the same purposes as brand-name drugs, and are less expensive when compared to brand-name drugs. The United States Food and Drug Administration examines generic drug formulations and, if it finds them suitable, approves them as therapeutically equivalent to brand-name drugs in terms of safety, strength, and quality (Haas et al., 2005). According to Haas et al. (2005), substituting generic drugs for the more expensive brand-name prescription drugs would provide savings for the drug-consuming population.

Medicare and Medicaid are two social programs designed to provide medical support for many Americans, including the elderly. The demand for these programs will continue to increase because as the population grows, the increase in chronic conditions grows as well. As this trend continues, the nation and the individual states will continue to be challenged to find new ways to minimize costs while at the same time delivering quality of care. Promoting a comprehensive Medicare prescription drug benefit plan that

incorporates automatic physician prescription of generic drugs will close the access prescription drug gap that exists between elderly American Blacks and their White counterparts, and it will further more create savings for nursing homes including those in North Carolina.

In preparing this literature search, sources such as MEDLINE, CINAHH, Walden Library, Book, and CDC, ADA, FDA websites, including some nonpeer-reviewed articles were used to maximize search effectiveness while minimizing extraneous results. The following words were used in retrieving the relevant documents: Full text, HTML, Boolean methods, PROQUEST, EBSCO, and SAGE Full-Text.

Articles that meet the following criteria were utilized for the literature review: (a) the study has bearing on the current research been undertaken, (b) full-text copy that includes a detailed description of the study including study design and methodology, and (c) the publication or article is written in English. The information obtained from the articles, books, and web sources are addressed and summarized in the following sections within Chapter 2 of the Literature review. In the first two sections, chronic health conditions including diabetes and conditions that require treatment with medications are presented. Diabetes is included in the discussion because it is considered a chronic health condition, and many seniors who are residents of nursing homes including those in North Carolina suffer from diabetes. In the third section, a historical perspective of the Medicare and Medicaid system is presented, and in the fourth section, the drug approval process, the costs of brand-name prescription drugs and generic drugs are presented. And in the fifth section, brand-name prescription drug and generic prescription drug

affordability, costs to organizations and costs to individuals are presented. The sixth section includes a chapter summary.

### **Theoretical Framework**

The theoretical framework of this study will be based on the medical home model concept presented in 1967 by the American Academy of Pediatrics. The medical home model is characterized by the availability of a personal physician for every family/patient. The delivery of first-contact care is ensured by the physician in this model. Understanding of the needs of the family/patient and facilitation of co-management that is planned throughout the lifespan is also made certain by the physician. The physician must have the capacity and resources to fulfill the needs of the family/patient (Health Policy Brief, 2010).

The basis of this model rests on the delivery of patient-centered care that involves a team-based approach for facilitating a complete range of healthcare services. This includes the provision of care to all the age groups and at all stages including chronic care, acute care, mental and behavioral healthcare, end-of-life care, and preventive services. It also involves the coordination and integration of the care that is not delivered by the PCMH across entire fundamentals of the multifaceted healthcare system and patient community. The emphasis of this model is on the reduction of the cost of care by improving access to vigorous primary care. A promising way is represented by the medical home model for improving healthcare in America through the transformation of the process of organization and delivery of primary care (CAHPS, 2011). The medical home model is important because it provides guidance for physicians following the

medical home model. Within this model, the primary care physician would be able to provide treatment while bearing the mind the affordability of the prescribed drug for the family/patient.

This theoretical framework has been selected because an approach is provided towards integrative healthcare by this model that is based on one main point of access. Most of the healthcare systems in the US are utilizing this model of healthcare for providing services to patients. An enormous amount of data can be retrieved through this model regarding the prescribing practices of primary care physicians in the state of North Carolina in Raleigh, and thus provide a better opportunity towards initiation of change in the practices of primary care physicians pertaining to their prescription practices. There are several studies that have utilized this model (Henderson et al., 2012; Jaudes et al., 2011). Lee et al. (2011) utilized this model to determine the possibility of elimination of disparities in healthcare that are encountered by the minorities in accessing the healthcare services. Windel et al. (2011) described the benefits of this model as it can be employed for shared decision making that can be useful for supporting the choices of patients in the prescription of drugs. Shared decision making permits the patients to be involved in selecting the most appropriate type of drug that is best for them from all aspects. This model can also help to curb the costs of healthcare through the utilization of medicines that are better preventatives and are more cost effective (Marshall et al, 2011). Therefore, this model has been utilized as a theoretical framework of this study because it can facilitate the utilization of generic medicines.

### **Cost of Chronic Conditions**

A chronic condition is a repeating health consequence that affects individual daily life, and it may last for several years (Anderson & Horvath, 2004). There is currently no cure for many chronic health conditions, but they can be managed adequately with medication. Chronic conditions are costly and tend to afflict the elderly population. It is estimated that more than 70 million Americans age 50 and older suffer from one type of chronic health condition, diabetes is one of them. According to the Robert Wood Johnson Foundation (1996), chronic conditions are a leading cause of death, and almost 100 million Americans suffer from some form of chronic health issue. The projection is that by 2040 an estimated 160 million Americans will have a chronic condition of one sort or another. According to Anderson (2004), in 2002 in America 70% of all deaths in 2002 were attributed to a chronic condition such as heart disease, 90% of seniors in America suffer from one form of chronic health condition, and 77% suffer from more than one chronic condition.

Long-term care includes nursing home facilities. Nursing homes provide care to an increasing number of U.S. elderly persons who suffer from several chronic health condition including diabetes. A study conducted by Resnick, Heineman, Stone, and Shorr (2004) collected data on 11,939 from nursing home residents aged between 65 years representing 1.32 million individuals. In their study they found that in 2004, 24.6% of all nursing home admissions were suffering from diabetes at the time of admission. Also, those admitted with diabetic complications tended to be admitted from acute-care hospitalizations (42.5% of such admissions, compared to only 35.5% for other non-



diabetic patients), and those admitted with diabetic complications typically had longer stays in the facility than non-diabetic patients.

A similar study conducted by Johnson, Brosseau, Soul, and Kolberg (2008) made the following observation about chronic diseases such as Type 2 diabetes: it affects 190 million people globally, and it is reported that this number is expected to increase to 300 million by 2025. Their study further revealed that patients residing in long-term care facilities often suffer from more than one chronic disease, with 25% suffering from diabetes, 80% suffering from cardiovascular disease, 56% suffering from hypertension, and a total of 69% of patients suffering from more than one chronic condition. The cost of managing chronic diseases has been a major concern for healthcare professionals because patients who suffer from multiple chronic diseases take more than one medication to manage their chronic conditions, and the high cost of prescription drugs is an issue.

According to the American Diabetes Association (ADA, 2007), in 2007 there were 17.5 million people with diagnosed diabetes with an estimated cost of \$174 billion in direct medical costs and indirect costs through lost productivity. A second study conducted by the ADA in 2013 that used a prevalence-based approach reported that the economic burden due to diabetes in the US in 2012 was \$245 billion—a 41% increase compared to the previous study. The components that make up those diabetes medical expenditures include hospital in-patient care (43% of total medical care), prescription drugs to manage complications associated with one of the chronic condition, diabetes was

18%, antidiabetic agents and other medical supplies account for 12%. Physician office visits 9%, and finally nursing homes/ residential facility stays 8% (ADA, 2013).

Murray and Callahan (2003) concluded in their study that American adults age 50 and above suffer from multiple chronic diseases and require more than one medication to manage their chronic condition. A research study conducted by DeVol and Beddroussian (2007) for the Milken Institute revealed that in 2003 treatment cost for seven chronic diseases totaled \$277.7 billion. Treatment costs were highest for heart disease, at \$64.7 billion; for five leading cancer treatments, the combined cost was at \$48.1 billion; mental health disorders reached a total treatment cost of \$45.00 billion; pulmonary conditions cost \$45.2 billion; hypertension came in at \$32.5 billion; diabetes was at \$27.1 billion, and stroke accounted for \$13.6 billion.

Klonoff (2008) reported that the cost of prescription drugs is on the rise, particularly for diabetes medications. His study revealed that as of 2007, treatment of diabetes become the leading source of increased spending on prescription drugs. The CDC (2009) revealed that approximately \$7,900 was spent in 2009 to manage chronic conditions, this will translate into \$3 out of every \$4 spent on the nation's healthcare. The agency further revealed that it cost \$432 billion per year to treat heart disease and stroke, while lung disease cost \$ 154 billion per year, and Alzheimer's disease cost \$148 billion per year. The long-term effects of chronic diseases add to suffering and chronic pain, and unfortunately many Americans in this situation continue to face rising healthcare costs while in many cases access to care is limited. The financial burden on individual, families and on society as a result of chronic disease can no longer be tolerated.

There are several components that contribute to healthcare cost. These include the high cost of prescription drugs and the cost it takes to manage chronic diseases such as diabetes. The Robert Wood Johnson Foundation (1996) found that the cost of caring for Americans with chronic conditions was \$470 billion in 1995, and by the year 2040 that cost is estimated to reach \$864 billion.

The share of Medicare beneficiaries with more than one chronic condition increased from 30% in 1987 to 50% in 2002 (Thorpe & Howard, 2006). Chronic condition management varies by treatment, its cost is a burden to society, and it affects public programs such as Medicare and Medicaid. Holahan, Schoen, and McMorrow (2011) reported that it cost the U.S. public health programs about \$635 billion in 2010 to manage chronic illness: This is about 30% of total U.S. healthcare spending, and nearly half of that \$635 billion—an estimated \$304.5 billion—was spent on beneficiaries of Medicare and Medicaid.

The ADA's 2007 report also revealed that a total of 168 million inpatient hospital days in the U.S. was attributed to one chronic condition alone, diabetes and an estimated one-third of all nursing days stay was attributed to diabetes. Increased understanding of the economic consequences of diabetes and its major determinants will help policy makers at both the federal and state levels to formulate policies that will address the prevalence of diabetes and its associated economic burden. Since most hospitals, nursing homes, and the elderly depend on Medicare and Medicaid program payments and benefits, current reductions in Medicare and Medicaid payments mean that proper management of diabetes in the hospital and nursing home settings may be in jeopardy.

Heart disease, cancer, asthma, diabetes, and hypertension are among the five leading most costly chronic conditions in the US. Together, these cost the country about \$347 billion in 2010, or about 30% of total healthcare spending (CDC, 2011). The number of individuals diagnosed with Alzheimer's in the US is increasing, and it is predicted that by 2050 the number of Alzheimer's cases will reach 16 million (CDC, 2011). This trend will greatly impact Medicare spending. In fact, in 2005 Medicare paid \$9 billion for care of individuals diagnosed with Alzheimer's; by 2015 it will reach \$189 billion (CMS, 2005).

### **Chronic Condition Treatments**

Prescription drug cost is a major concern to so many Americans and it plays a major role in managing ill health. According to Reed et al. (2003), chronic conditions such as heart disease, high blood pressure, and diabetes that are very common among older Black Americans can be managed effectively with prescription drugs. Additionally, complications that can result from diabetes such as renal failure, blindness, and gangrene can be avoided by following a proper prescription drug regimen (Reed et al., 2003).

Besides prescription drug costs, there are other components that impact healthcare costs. These include chronic conditions such as cardiovascular diseases, cancer, and diabetes. State government also feels the cost of ill health as a result of chronic conditions, and without some form of an aggressive intervention these rising cost trends will continue. The issue of pharmaceuticals can play a major role. According to the Agency for Healthcare Research and Quality (ahrq, 2005), in the US the prevalence of

diabetes continues to rise, it disproportionately affects the elderly, and it is higher among racial and ethnic minorities. Type 2 diabetes can be managed effectively with diet and oral diabetes medications. Data from a randomized controlled trial demonstrated that the risk of retinopathy can be reduced by improving glycemic control in individuals suffering from Type 2 diabetes (ahrg, 2005).

The two types of drugs use in treating Type 2 diabetes in 1995 were sulfonylurea and insulin. However, there are many more new pharmacotherapy options available today. Currently in the US there are 11 classes of diabetes prescription drugs, including biguanides (i.e., metformin), thiazolidinediones, sulfonylureas, dipeptidyl peptidase-4 (DPP-4) inhibitors, meglitinides, glucagon-like peptide-1 (GLP-1) receptor agonists, amylin analogue, bromocriptine, alpha-glucosidase inhibitors, colesevalam (a bile-acid sequestrant), and insulin (ahrg, 2005). All of these drugs work differently, and it was reported that between 1999-2000, about 6% of Type 2 diabetic patients were taking only three classes of medication, as compared to 2005 - 2006 when 35% of such patients take two classes of antidiabetes medication and 14% take three or more classes (Ahrg, 2005).

American adults within the age of 50 years and above suffer from multiple chronic health conditions and require more than one medication to manage their chronic health condition (Murray & Callahan 2003). According to Murray and Callahan (2003), the use of medications including diabetes medications has several benefits: it improves quality of life, preserves cognition and physical functioning, reduces economic burden on society, and reduces the risk of additional comorbidity and eventual death.

Better management of diabetes that includes the use of diabetic agents is critical in reducing the economic burden presented by this disease; however, the cost of prescription drugs in its treatment is an issue. According to Klonoff (2008), in 2007 diabetes medication accounted for 7% of prescription drug spending. Medco in 2007 reported that diabetes medication is number one as a top therapeutic category contributing to increased drug spending in the US (Klonoff, 2008). Future diabetes drug cost trend will be affected by new approved drugs, and the predicted prevalence increase in diabetes will increase drug utilization and thus drug costs. Generic prescription drugs are effective in the management of chronic diseases including diabetes because they have almost the same components as the brand-name prescription drug and cost less (Klonoff, 2008).

Heart disease can cause death in men and women. Hypertension, high levels of cholesterol, obesity, and diabetes are known to be complications associated with heart disease. A daily dose of aspirin can prevent heart disease, and statin medications are known to lower cholesterol levels. Hypertension can be managed with a combination of drugs; they include angiotensin converting enzyme (ACE) inhibitors, water pills or diuretics, beta-blockers, and calcium channel blockers.

There are two class of chemotherapy drug for treating cancer; they include alkylating agents and antimetabolites. Chemotherapy drugs such as alkylating agents work by damaging the DNA of the target cells and thus preventing reproduction; they are used to treat leukemia, lymphoma, Hodgkin's disease, cancer of the breast, and lung cancer. Antimetabolites work differently. This class of drugs interferes with DNA and

RNA growth by the process of substitution. They are used to treat leukemia, cancer of the breast and ovarian cancer.

### **Historical Perspective of Medicare and Medicaid**

The Social Security Act of 1965, commonly referred to as Title XVIII, was implemented to provide health insurance benefits for the aged and the disabled persons. The Act was later amended in 1966 to provide coverage for persons age 65 and older through the Medicare payment system (Stephen & Torrens, 2002). Medicare is a federally sponsored program, while Medicaid is a partnership program between the Federal government and the states. Both programs provide meaningful support for and play a crucial role in the U.S. health delivery system. Hospitals and nursing-home residents who need special services with chronic health conditions depend on Medicare and Medicaid for insurance benefits. With increases in the U.S. elderly population as a result of the baby boomer generation, increases in chronic health conditions and recent reductions in both programs, those that depend on these programs may have to come-up with additional out-of-pocket fees to cover for needed medical services.

### **Medicaid**

After much debate from Congress, the legislation to establish Medicare and Medicaid program under Title XVIII and Title XIX was enacted into law in 1965 (Stephen & Torrens, 2002). Medicaid was established as a public response to the lack of medical care available under public assistance. Both programs were originally managed by the Department of Health, Education, and Welfare; in 2002, the duties of both

programs were transferred to the Center for Medicare and Medicaid Services (Stephen & Torrens, 2002).

Title XIX was established as the Medical Assistance program and it was later known as the Medicaid program which was expanded through the Kerr-Mills Medical Assistance program for the aged (Stephen & Torrens, 2002). Funding for Medicaid is supported by the federal government and administered by the states, eligibility for Medicaid is limited to low-income individuals and families. Title XIX of the Medicaid program mandates the states to provide the following basic health related services: hospital in-patient care, hospital outpatient services, nursing home care for those age 21 and older, diagnosis, laboratory, and X-ray services. Additional services under the program include a prescription drug benefit, and physician services.

Healthcare spending in the U.S. saw significant growth over last few decades. For example, in 1960 it was \$27.5 billion, and in 1993 it was \$912.6 billion with an average increases of 11.2% yearly (CMS, 2007). While healthcare spending saw a decline of a relatively small amount in the years 1993 to 1999, it picked up in the years between 1999 and 2002, rising 7.0% in 2000, 8.6% in 2001, and 9.1% in 2002. As a share of gross domestic product (GDP), healthcare spending in the US rose from 13.8% of GDP in 2000 to 16.0% in the year 2005. For the number of 297 million residing in the U.S, average healthcare expenditure in the year 2005 was \$6,697 per individual (CMS, 2007).

The largest share of healthcare spending for the US under the CMS comes from Medicare, Medicaid, and the State Children's Health Insurance Program (SCHIP). Altogether these cost the U.S government an estimated \$661 billion in 2005 (CMS,



2007). Since the implementation of Medicare and Medicaid programs, there have been many legislative initiatives and public outcries to make changes that will help the nation's aged, disabled, and disadvantaged.

### **Medicare**

Title XVIII was known as the Social Security Act of 1965, and it was designed as a health insurance program to help the aged and the disabled. This program is now called Medicare (Stephen & Torrens, 2002). First implemented in 1966, Medicare provides coverage for individuals age 65 and older, and in 1973 railroad retirees and individuals with end-stage renal diseases (ESRD) became eligible.

Medicare when it was first designed contained two components: A part known as the Hospital Insurance (H1), or part A; and the other part is called the Supplementary Medical Insurance (SMI), or part B. Part A provides for in-patient hospitalization, home health, skilled nursing facility care, and hospice care. Part B, the Supplementary Medical Insurance component, covers physician services, home health care, outpatient hospitalization, and other services. Part B eligible patients pay a premium (Stephen & Torrens, 2002). There is a third component to the Medicare program—Part C, the Medicare Advantage program. This program was established under the Medicare +Choice program by the Balanced Act of 1997. This program later became the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) that was enacted into law during the Bush Administration.

Since 2006, the MMA program provides prescription drug insurance coverage at a subsidized rate to eligible persons, and also gives individuals the freedom to participate in

private health insurance plans. Since July 1, 1996, those enrolled in the Medicare program total 19 million that number grow to over 44 million in 2007 for both Part A and Part B Medicare programs, and about 8 million for the Medicare Advantage plan. In the year 2006, Part A Medicare program provided hospital care for about 43 million persons, 36 million aged and 7 million disabled persons, and total Part A benefit cost was \$189.0 (CMS, 2007). Medicare Part A provides the following services: in-patient hospitalization, coverage under this part includes cost of semi-private rooms, meals, regular nursing services, operating room services, prescription drugs, laboratory tests, psychiatric consultations, long-term care when it is medically needed, in-patient rehabilitation, and X-ray services. Deductibles and copayments are required under the Part A Medicare program. Additional services under part A include skilled nursing facility services. Under this part, care is given only if it is within 30 days of a hospitalization and required for 3 days or more. Coverage is the same as defined under in-patient hospitalization, the number of days under this part is limited to 21-100 days, and copayment is required. Part A does not pay for skilled nursing services if patients do not fall under skilled services and skilled rehabilitation. Hospice and home health agency are covered under Part A Medicare. Part B Medicare Services provides some limited services and supplies, including diagnosis, laboratory and X-ray services ,home healthcare not covered by Part A, preventive and screening services, physical and occupational services, speech pathology services, radiation therapy, dialysis services, and transplant services. Also included are rural health clinic services and ambulance services. For persons enrolled in

Part A and Part B Medicare programs, the new Part D Medicare program provides a prescription insurance benefit for most FDA-approved prescription drugs.

### **Medicare is Different from Medicaid**

Medicare and Medicaid are both under federal funding. Medicare is an insurance program that is sponsored in part by the federal government and through premiums paid by those who are enrolled in the program. The Medicare program is run by the Department of Health and Human Services through contracted fiscal intermediaries called the Center for Medicare and Medicaid Services (CMS, 2012). Because Medicare is a national program, coverage from state to state does not vary. Also, as an entitlement program, every American that meets the age and disability requirements qualifies.

Medicaid on the other hand is designed as a means-tested program: certain criteria must be met before eligibility, such as household income, resources, and asset level (CMS, 2012).

Medicaid is a joint partnership between the federal government and the states, with 57% of program funding coming from the federal government, and 43% from the states. Because Medicaid is an entitlement program, states cannot limit the number of persons who are covered so long as those individuals meet established guidelines for coverage. According to CMS (2012), North Carolina has about 1.8 million individuals enrolled in the Medicaid program. This represents 19.5% of the total North Carolina population. Reports from the state of North Carolina revealed it cost the state about \$6,424 for each single enrollee. With increased enrollment in the future for 766,200 individuals, total costs could run to \$4.9 billion. Recent cuts to Medicare and Medicaid

benefits may prevent these two key public programs from meeting their obligations, so some cost containment strategies is necessary for the state of North Carolina.

Nursing homes play an important role in the delivery of healthcare services, particularly to the elderly who lack the ability to care for themselves. Most of this vulnerable population is on a low fixed income, suffers from multiple chronic conditions, and depends on Medicare and Medicaid to help pay for health services including prescription drugs. However, the cuts imposed by CMS in 2011 will significantly impede nursing home facilities from delivering quality care. Medicaid covers nursing home services, and Medicare through Part D provides for prescription drug benefits, but the reduction enacted by CMS will exacerbate existing Medicaid shortfalls. Medicare payments are important because they help nursing homes to cover cost of care for Medicaid-funded patients, thus helping nursing homes to remain viable. With the increases in chronic conditions for the elderly and the aging of in the baby boomer generation, the need for nursing homes will increase. Unless policy makers look for ways to address current Medicare and Medicaid cost-reduction issues, there will not be enough nursing home facilities available to accommodate the baby boomer generation.

### **Drug Approval Process**

The Food and Drug Administration (FDA) is an agency within the U.S. government that regulates the nation's food and drug supply. In 1938, Congress passed the Food, Drug, and Cosmetic Act as a result of 107 deaths from Elixir Sulfanilamide, a then-legal compound that contained diethylene glycol (Peters et al., 2009). The law that

was passed in 1938 gave the FDA the authority to require evidence of drug and food safety before allowing them to be sold to the consuming public.

It is worth recapping a brief timeline concerning the history of the generic drug approval process. In 1968, a Drug Efficacy Conference was convened through the National Academy of Science/National Research Council to oversee all drugs approved between 1938 and 1962 for drug safety. The agency gave drug companies a 2-year grace period to provide supportive evidence of drug effectiveness (Peters et al., 2009). In 1984, the Hatch-Waxman Act (Drug Price Competition and Patent Term Restoration Act) was passed by Congress. The act allowed the FDA to approve the manufacture of generic drugs without requiring repetition of the research conducted by the original innovator to prove drug safety and efficacy. The same act also allows for patent extensions and exclusivities to innovators' drug firms.

The goal of the Hatch-Waxman Act was to introduce generic medication that is equivalent to brand-name drugs, but costs far less when compared to brand-name drugs. Before being approved, new drugs must meet certain standards set forth by the FDA. The manufacturer must provide evidence after a rigorous process that the drug is safe and effective, and after the patents expire, other companies interested in manufacturing the generic form of the original drug can do so under the guidance of the FDA (Peters et al., 2009). For a generic medication to be considered a substitute for a brand-name drug, the FDA requires that certain applicable guidelines be met, including that the generic drug must have the same clinical effect and safety profile when given to patients under the conditions outlined on the label. The generic drug must also prove as safe and effective as

the brand-name drug, it must be pharmaceutically equivalent and bioequivalent, and it must be produced in accordance with current manufacturing best-practice regulations.

**Brand-name versus generic drug.** A brand-name drug by definition is a medication or medicine that is researched, developed, and marketed by a pharmaceutical company and sold under an exclusive patent-protected brand name. When the new medication is discovered, the company that first discovered the drug files for a patent. This process prevents other drug manufacturers from copying and selling the new drug (FDA, 2013). A drug has two names: the generic drug name is the common scientific name; the other name is the brand name of the drug. This name makes the drug stand out in the marketplace. This is true for both prescription medications and over-counter medications. A commonplace example of this is the pain killer sold under the brand name of Tylenol: the generic name is acetaminophen.

The FDA approves the manufacture and distribution of a generic drug because it has the same active ingredients as its brand-name drug counterpart. Usually generic medication is available to the public when the patent expires (patents normally last for 20 years for most drugs). When the patent expires, the original drug developer may decide to make the generic form of the original medicine, or other drug manufacturers may decide to make the generic version of the original drug (FDA, 2013).

Generic medication has some similarities and differences when compared to brand-name medications. The FDA requires that to substitute generic drug for brand name drug, the generic version must contain the same active ingredients contained in the brand-name drug, it must have the same dosage strength, it must also have the same

dosage form (e.g., liquid or pill form), and finally the generic drug must deliver the same amount of drug to the bloodstream within the same time period (FDA, 2013). Federal law requires that generic drugs have different sizes, shapes, and color markings, may have different inactive ingredients. Generic medications are developed and manufactured by different drug manufacturing industries and cost far less when compared to brand-name drugs. It has been reported that generic drugs can cost between 20- and 80% less when compared to their brand-name counterparts (FDA, 2013).

**Cost difference between brand-name and generic drug.** It takes several years before new medications reach the consuming public. Research, clinical studies, advertising, and manufacture of a new medication is costly. Generic versions of the same drug do not have the development and research cost, and as a result generic medication cost less than brand-name medications (CBO, 2010). The issue of not prescribing generic medication automatically has been a concern for many, particularly with so much cost difference. Generic medications are barred under patent provisions for up to 20 years for most drugs (FDA, 2013).

Considering brand-name versus generic drugs is critical in managing the critically or chronic ill patient because the cost of prescription drugs is high, Medicare and Medicaid are having difficulty meeting their obligations because of skyrocketing healthcare costs, and many in society cannot afford prescription drugs. Educating the public as to the benefits of generic drugs and encouraging prescribing physicians to consider generic drugs is critical in creating a better quality healthcare system.

**Prescription drug cost.** The cost of prescription drugs has been a major concern for many, but especially so for the elderly, healthcare organizations, and policy makers. For example, the overall cost of prescription drugs in the US reached \$307 billion in 2010, according to the CBO, an increase of \$135 billion since the year 2001. This expenditure comprised about 12% of all healthcare spending in the US. The rise in the cost of diabetes medication, the increase in chronic health conditions, the delays in issuing generic drugs due to patent laws, and the costs of brand-name medications are among some of the drivers of prescription drug cost.

Generic medication is available to the drug consuming public at the expiration of the original patent covering a brand-name drug. Yet, doctors do not prescribe generic drugs as often as they do brand-name medications. This may be because of lack of knowledge about generics, insufficient time to research the availability of newer generic drugs and what costs less, and the fact that physicians have different drug experiences and belief systems concerning drug efficacy. Medical insurance dictates and personnel preferences also play key roles.

A generic drug is a pharmaceutical product intended to be interchangeable with a brand-name product that is manufactured without a license from the drug's originating company and marketed after the expiry date of the drug's patent or other exclusive rights. Generic drugs are marketed under a non-proprietary or approved name rather than a proprietary brand name. Generic drugs are usually as effective as, but much cheaper than, brand-name drugs. For example, paracetamol is a chemical ingredient found in brand-name painkillers, but is also sold as a generic drug. Because of their low price, generic



drugs are often the only prescription drug that the non-wealthy can access. The Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement does not prevent governments from requiring accurate labeling or allowing generic substitution. It is argued that competition between drug companies and generic producers has been more effective than negotiations with drug companies in reducing the cost of drugs. The price of the average generic drug is 75% cheaper than the retail price of the equivalent brand-name prescription drug (CBO, 2010).

The cost of prescription drugs totaled \$100 billion in 1999, and it is considered the fastest growing part of personal health expenditure, the most affected is the 13 million US population that are under Medicare benefit who do not have insurance medication after hospitalization (Korn et al., 2003). The elderly have also seen cost of prescription drug jump, going from \$28.50 in 1992 to \$42.30 in 2000 and is still increasing as a result of the cost of prescription drugs and the number of prescriptions being written (Korn et al., 2003). Haas et al. (2005) reported that in 2001 the national expenditure for prescription drugs was \$141 billion. Another study conducted by Holahan and Cohen (2006) revealed that spending on prescription drugs is among the fastest growing public programs in recent years, and recent trends have seen an average growth of 16% in Medicaid spending between 2000 and 2004. This growth put state Medicaid program prescription cost at \$30 billion per year. Holahan and Cohen's 2006 study also found that in 1990, Medicaid expenditures were 7%, but it has risen to more than 14% in recent years.

Prescription drug costs impact every segment of society. For example Gellad, Huskamp, Phillips, and Haas (2012) reported that the out-of-pocket cost of prescription drugs is a serious concern for racial and ethnic minorities, as well as for the near poor, including seniors with chronic conditions. On January 1, 2006, the Medicare Prescription drug benefit (Part D) became law. The intention of the program was to expand drug benefit coverage for the elderly population, including those in nursing homes with chronic conditions.

Reports from the National Health Expenditure Accounts (NHEA) revealed that healthcare spending reached \$2.6 trillion in 2010. This is about \$8,402 per person, and represents about 18% of the U.S. GDP, (CMS, 2012). The U.S. government financed 29% of healthcare costs in 2010, (an increase from 23% in 2007), and state and local government paid another 16%. Further analysis from NHEA report indicates that average yearly healthcare cost is expected to grow by 6.2% through 2018, a number that surpasses the anticipated overall economic growth of 4.1 for the same period, and by 2018 it is reported that national healthcare spending will reach \$4.4 trillion (CMS, 2012). At this growth rate, in 15 years healthcare cost will amount to 50% of U.S. GDP. The question becomes whether or not the U.S. economy is sustainable with this level of expenditure.

Prescription drugs are often dispensed in hospitals and long-term care facilities for the management of chronic diseases. It is reported that the price of the average generic drug is 75% less than the retail price an equivalent brand-name prescription drug (CBO, 2010).

There are several drivers that contribute to the nation healthcare cost, the driver's includes chronic health condition such as diabetes, the growing elderly population, and prescription drug cost. It is reported that prescription drug spending in the U.S reached \$307 billion in 2010, this is an increased from \$135 billion in 2001, this figure comprises of all healthcare spending of 12% (IMS Health, 2011). In the early 2000s, cost of drug was among the fastest growing driver of healthcare spending but this spending declined as a result of greater generic medication availability and the expiration of patents. Generic drug is therapeutic and serve the same purpose as brand name drug and cost less when compared to brand name drug (CBO, 2010).

Several studies conducted on generic prescription drugs have shown conclusively that the use of cheaper generics are a critical part of what will hold down the growth of healthcare cost both nationally and across institutional settings such as hospitals and long-term care facilities. Studies also show that the use of generic drugs saved the U.S. healthcare system about \$1.07 trillion from 2002 through 2011, with \$192.8 billion in savings in 2011 alone (CMS, 2012). Knowing that the U.S. government share of healthcare spending will soon reach 30%, and as the oldest baby boomers become eligible for government-sponsored program such as Medicare, increased use of generic prescription drugs is critical in bending the curve of Medicare and Medicaid sustainability.

This literature review identified cost-saving approaches from various studies. Some researchers looked at estimates that result because of the use of generic drug, others looked at generic substitution, while still others focused on both generic and

therapeutic substitutions. Additionally, other studies examined savings for the U.S. healthcare system, and savings from program implementations (CBO, 2010; Haas et al., 2005; Scott & O'Donnell, 2007).

Multiple studies conducted for the Generic Pharmaceutical Association (GPhA) showed analytic estimates of the amount spent on generic drugs and brand-name drugs for the years 1999 through 2010. The report found that generic substitution saved the U.S. healthcare system about \$1 trillion during that period, and that in 2010 alone generic substitution saved the U.S. healthcare system more than \$157 billion (GPhA, 2011). The Congressional Budget Office (CBO) in 2010 examined savings that resulted because of the use of generic drugs in the Medicare Part D prescription drug program. Based on claims data, the CBO found that substituting generic drugs for brand-name drugs resulted in a cost saving of \$33 billion in 2007 (CBO, 2010).

The CBO study further evaluated the additional savings from generic and therapeutic substitution, and found that an increase in generic substitution rate of 100% would have resulted in cost savings \$900 billion for generic use and additional cost savings of \$4 billion for therapeutic substitutions in 2007 (CBO, 2010). Another study analyzed cost savings through program implementation in a managed-care organization in the form of physician participation in 2005 and 2006 of those that did not participate, the study found that after program cost the organization saved \$397,486 in 2005 and \$453,545 in 2006 (Scott & O'Donnell, 2007). Yet another study used Department of Veterans Affairs (VA) data to examine policy implementation in a VA hospital to promote the use of a generic antidepressant over the brand-name drug. The researchers

found that from March of 2002 through August, the policy resulted in a savings of \$2.5 billion (Dobscha et al., 2007).

Two particular studies used claims data from 45 private health insurance organization plans from 2003 through 2007 to compare the cost of health care in individuals using SSRIs when mid-treatment occur in therapeutic substitution. The study found that patients who switched from brand-name drugs to generic drugs had higher hospitalization because of switching from brand name drug to generic drug in midtreatment, the switched also result in generic use of healthcare cost of \$881 dollars (Wu et al., 2011). A similar study conducted by Viahiotis et al. (2011) reached a different conclusion: their study used claim data from 2005 to 2007 and compared the healthcare costs of using brand-name drug versus generic drugs in mid-treatment for 6 months. Their conclusion was that the cost of generic antidepressant SSRIs was significantly lower when compared to brand-name medications—the average costs were \$3,660 and \$4,587 respectively.

The projected cost of the Medicare Part D prescription drug program is estimated to reach \$700 billion for 2006 through 2015. Despite the promise of extended coverage, the very nature of the program may require additional out-of-pocket payments from those that the program is supposed to help, particularly with respect to the gap in coverage known as “the doughnut hole” (Gellad et al., 2012). Gellad et al. (2012) examined data from 1996 through 2000 from the Medical Expenditure Panel Survey Household Component (MEPS-HC), and concluded that the prescription drug Part D program as designed did not provide all drug coverage for racial and ethnic minorities or the near

poor, including seniors with chronic conditions. The rise of prescription drug costs is a central policy issue for both Medicare and Medicaid programs. The incidence of chronic health conditions is on the rise, the elderly population is growing, and prescription drug costs are also high. According to the U.S. Census Bureau (2002), the baby boomer generation age over 75 populations will increase from 5.8% in 1997 to 9.4% in 2025. It is also reported by the same agency that because of advances in medical science, those with chronic conditions are living longer; however, there will be a lack of social support including adequate appropriate housing. Thus, increasing the number of nursing home facilities is critical.

Currently, many states are concerned about the increase in prescription drug costs in nursing homes because of aggressive cuts to state Medicaid programs. Second, newer drugs have been developed to help the management of many chronic conditions, but these newer drugs are expensive. Finally, nurses and other health professionals are concerned about the increased use of pharmaceuticals in nursing homes. According to Mendelson et al. (2002), an individual in a nursing homes receives an average of 6.7 routine medications per day, with an additional 2.7 as needed medication per day. Nursing homes are financed by three payment systems: Medicare, Medicaid, and private sources (this includes personal funds and long-term care insurance).

Recent cuts in two major social programs will impact the way nursing homes are financed. For example, the prescription drug benefit under Medicare Part D is designed to help with the costs, but the structural design of the program can require additional out-of-pocket payment for those it is designed for (Hass et al., 2012). Gu, Zeng, Patel, and

Tripoli (2010) in their retrospective study of Medicare Part D of 12,881 diabetes patients age 65 concluded that the coverage gap—the so-called “donut hole” in Medicare Part D—had a negative impact on diabetes medication adherence. A similar study conducted by Piette et al. (2004) concerning out-of-pocket costs of diabetes reported that out-of-pocket cost is a significant burden to many older adults with diabetes. Their study further revealed that diabetes patients in that study under-use their medication because of out-of-pocket cost. Several studies revealed that lack of medication compliance may lead to further declines in health, poor quality of care, and for diabetes patient glycemic control is almost impossible without adherence to their drug regimen.

One of the contributing factors of healthcare cost is medication noncompliance. Piette et al. (2004) reported that older adults who suffer from diabetes do not adhere to their medication regimen due to out-of-pocket cost, and lack of medication adherence may lead to noncompliance. A study conducted by Mahoney, Ansell, Fleming, and Butterworth (2008) concluded that medication noncompliance results in 125,000 annual deaths, and accounts for 10- to 25% of all hospital and nursing home admissions. Klein et al. (2004) conducted a cross-sectional study of a national sample of 6,535 elderly people, and concluded that the elderly delay refilling their prescription drugs as a result of high prescription drug cost. Felland and Reschovsky (2009) found that drug affordability continued to be a major concern, not only within the adult U.S. population but also among children, and some working-class Americans cannot afford their prescription drugs due to cost. That study also found that in 2007, one in seven Americans under the age of 65 did not fill their prescription (by comparison, in 2003 that figure was one in

10). Their study also revealed that the most vulnerable are those with low incomes, the uninsured, and the individuals suffering from chronic conditions.

**Generic drugs are not different from brand-name drug.** The cost of prescription drugs has been a major concern for many, including the elderly, healthcare organizations, and policy makers. For example, the total cost of prescription drugs in the U.S. reached \$307 billion in 2010, according to the CBO, an increase of \$135 billion since the year 2001. It has been reported that generic medications are equivalent to brand-name drugs in terms of efficacy, and generic drugs cost far less. Generic medication usually becomes available to the public upon the expiration of the brand-name drug's patent (FDA, 2013). In 1984 the Hatch-Waxman Act (Drug Price Competition and Patent Term Restoration Act) was passed by Congress. The Act allows the FDA to approve the manufacture of a generic drug without requiring repetition of the research conducted by the original drug innovator to prove drug safety and efficacy. The same act also allows for patent extensions and exclusivities to innovator drug firms. The goal of the Hatch-Waxman Act was to introduce generic medication that is equivalent to brand-name drugs but costs far less when compared to the brand-name drug.

The bioequivalence of generic drugs to brand-name drugs has been documented in several articles. For example, a study conducted by Peters et al. (2009) revealed that generic drugs are safe, effective, and affordable when compared to brand-name drugs. Another study conducted by Kesselheim et al. (2010) consisted of a systematic review and meta-analysis of seizure outcomes following the use of generic versus brand-name antiepileptic drugs. The researchers found no difference in the use of generic drugs versus



brand-name drugs. Kesselheim et al. (2008) conducted a meta analysis to compare generic and brand-name medications for patients suffering from cardiovascular disease. This study concludes that the brand-name drug was not superior to the generic medication in treating cardiovascular disease. The FDA requires that a generic drug be a copy of a brand-name drug because it has the same dosage, safety, and strength, quality, and performance. The FDA also requires that the only allowable differences between generic drugs and their brand-name counterparts are shape, scoring, release method, packaging, colors, flavors, and preservatives (FDA, 2013).

**Generic drugs and cost savings.** The Restoration Act of 1984 was enacted to regulate generic drugs, and the addition of the Hatch-Waxman Act was to strike a balance between drug innovation and cost-saving generic drug development through proper drug approval process. The FDA requires that for a generic drug to be pharmaceutically equivalent to a brand -name drug, it must have the same active ingredient. Several studies have revealed that generic medication is identical to the brand-name drug counterpart (Kesselheim et al., 2010; Peters et al., 2009).

The prevalence of chronic conditions such as diabetes is on the rise, and so is the cost of prescription drugs. For example, the cost of prescription drugs totaled \$100 billion in 1999, and it is considered the fastest growing part of personal health expenditures. Those most affected include the 13 million Americans who are receive Medicare benefits who do not have insurance medication after hospitalization (Korn et al., 2003). According to the American Diabetes Association (ADA, 2007), in 2007 there were 17.5 million people with diagnosed diabetes with an estimated cost of \$174 billion in medical

expenses and lost productivity. A similar study conducted by the ADA in 2013 that used a prevalence-based approach reported that the economic burden for diagnosed diabetes in the US in 2012 was \$245 billion. This is a 41% increase compared to their previous study. Proper glycemic control is critical in the management of Type 2 diabetes. Currently there are several medications on the market to accomplish this objective; however, prescription drug prices continue to increase. Diabetes is common in nursing home facilities and among the elderly population, but recent cuts in Medicare and Medicaid benefits mean that some elderly patients have not been able to afford their prescription drug because of cost. This may negatively impact effective diabetes management.

The use of generic drugs as a cost-saving alternative to brand-name drugs has been supported by several research articles. Shank, Choudhry, Liberman, and Brennan (2011) conducted a study to compare the importance of controlling blood pressure in non-diabetic patients. Their study concluded that previous studies found that the use of brand-name drugs cost an estimated \$52,983 per quality-adjusted year life, but their study found that by using generic drug the cost was \$7,753 per quality-adjusted year life. According to Haas et al. (2005), substituting generic drugs for the more expensive brand-name prescription drug will provide savings for the drug consuming population. Peters et al. (2009) revealed that generic drug is safe, effective, and affordable when compared to brand-name drugs. Fischer and Avorn (2003) conducted a study to analyze state-by-state Medicaid prescription drug spending in 2000. They concluded that in 2000, Medicaid payments to the states was more \$20.9 billion, and of this total \$4.3 billion was for brand-

name and generic medications. Their study further revealed that they identified a potential savings of \$229 million from the use of generic prescription drug.

A report from the Congressional Budget Office revealed that in 2007 total expenditures for the Medicare Part D prescription drug benefit was \$1 billion, and total payment for pharmacies and other plans was \$60 billion. Using Part D prescription drug data, the Congressional Budget Office (CBO, 2010) reported that dispensing generic drugs rather than brand-name reduced prescription drug cost by \$33 billion in 2007, and that total payment to plans and pharmacies would have been \$95 billion without generic substitution.

### **Summary**

The literature reviewed thus far revealed several relevant issues. For instance, the literature revealed that there are several drivers that increase healthcare cost, these drivers include the high cost of brand-name prescription drugs, the prevalence of diabetes and other chronic health conditions, and an increasing older population as a result of the aging of the baby boomer generation. For example, according to the American Diabetes Association (ADA, 2007) in 2007 there were 17.5 million people with diagnosed diabetes with an estimated price tag of \$174 billion in medical costs and lost productivity. The prevalence of chronic conditions such as diabetes is on the rise, and so is the cost of prescription drugs. For example, the cost of prescription drugs total \$100 billion in 1999, and it is considered the fastest growing part of personal health expenditure. The population most affected is the 13 million Americans who receive Medicare benefits but who do not have insurance for medications after a hospitalization (Korn et al., 2003). The

cost of prescription drugs in the US reached \$307 billion in 2010, according to a CBO report—an increase of \$135 billion since the year 2001.

The cost of prescription drugs to the Medicaid program is \$30 billion per year, and in 1990 Medicaid expenditures were 7%, but has climbed over 14% in recent years. With this amount of healthcare cost, Medicare and Medicaid will have trouble meeting their obligations to the state nursing home healthcare delivery system. If the cost of prescription drugs is among the contributing factors to rising healthcare cost that is impacting public programs such as Medicare and Medicaid, and generic drugs are therapeutically equivalent to brand-name drugs, why are physicians not automatically prescribing generic drugs? Chapter 3 of this study will focus on methodology, and the following areas will be discussed: research design, justification for the design, ethical issues, data collection method, inclusion and exclusion criteria, instruments used, and data analysis method.

### Chapter 3: Methodology

The purpose of this study was to address the behavior of primary care physicians regarding the prescribing of generic and brand-name drugs for the treatment of chronic conditions in the state of North Carolina. The focus of this chapter is on the description of the research methodology that was employed for conducting this research. The ethical considerations and the limitations posed by the selected research design are described. Inclusion and exclusion criteria and the process of recruitment of participants are discussed. The process of data collection and the tools used in the collection of data are also presented with the justifications for their selection. The method used for the analysis of data is discussed, including a discussion of the validity and reliability of the research.

#### **Design of the Research**

The design of the research provides the process through which a study is performed. Therefore, it is imperative to select a design that facilitates the accomplishment of the objectives of the research. A quantitative design is represented in numbers and statistical methods. Its measurements are numerically based, while its findings are used to test a causal hypothesis. This research design is used when the aim of the researcher is to perform a large-scale study that involves a baseline survey or an assessment of the needs of individuals. This research design does not require the participation of the researcher and is autonomous because it can be replicated by any person and the results would be the same as that of the primary researcher (Friedhoff et al., 2013). Every research design has some advantages and disadvantages, and the selected research design also has some disadvantages. There are several advantages of

quantitative research design, including the fact that it can be used for the collection of large quantities of data. The results of this design are typically quantifiable because they are considered objective. Thus, the data are believed to be quantifiable and they can be generalized to a population that is larger. It enables the observation of changes over a long period and aids in the development of quantitative indicators (Creswell, 2014). It facilitates the provision of distinct, quantitative measures that can be used for proposals and grants.

There are numerous disadvantages of a quantitative research design, including the calculation of its results through software used for data analysis (such as SPSS, Access, or Excel); quantitative data software might not be accessible in many countries. This research design is time consuming because the process is lengthy and it involves the entering, cleaning, and analysis of the data by the researcher. The duration of this process is prolonged with a larger sample size because a large sample size includes more data that requires more time for analysis and interpretation of the results. Furthermore, a large sample size also requires more time for the collection of data.

Therefore, a quantitative research design was used for performing this study, as it addressed the objectives of the research. A cross-sectional survey design was employed because it involved the use and analysis of the data that are presented in numerical form through the employment of statistical techniques. There are several questions that are posed by quantitative research, including when, how much, what, how, who, how many, and where. The quantitative research method produces data that are statistically reliable (Creswell, 2014). This enables the researcher to develop an understanding of the

perceptions of people regarding an issue and their practice of a specific thing. The format of quantitative data is typically in numerical form such as ranges, ratios, and averages (ACAPS, 2012).

A qualitative design was not selected due to the constraints posed by the length and nature of the study. Use of this design would not have offered the integrity provided by the unspecified phenomenon through a quantitative approach.

The cross-sectional research design is a type of descriptive design that involves the collection of data at a specific point in time from a representative population. These designs provide information regarding the entire population or subsets of a population that has been selected for the research. These are descriptive studies that can be used to describe the prevalence of an attitude in the selected group of population (Schmidt, 2008). This design is used to determine the impact of one variable on other variables. Thus, this design is used to analyze the strengths, degree, direction, and magnitude of associations. This design enables the emergence of hypotheses that can be further tested through experimental and quasi-experimental design. Less cost is involved in this research design, and there is a reduced possibility of bias. The information provided through this research design is comprehensive, and it describes the variables and the pattern of their distribution. This design predicts the association of variables. This design does not necessitate waiting for observed outcomes of the research. However, there is a possibility of selection bias in this research design because the sample is selected from a targeted group of a population which is predefined (Sousa, Driessnack, & Mendes, 2007). The aim of cross-sectional surveys is the determination of frequency of a characteristic in

a population that has been defined. This attribute is present in the population at a particular point in time. Contact is made with the participants at a fixed point in this type of research design to collect relevant information. Classification of the participants is then performed on the basis of this information to identify them as possessing or lacking that attribute. In some cases, an attempt of cross-sectional is beyond the limits of provision of information on the frequency of the characteristic of interest in the population of study through collection of information on both the characteristic of interest and latent risk factors. These surveys are also used to assess the attitudes, practices, beliefs, and knowledge of a population in association with events pertaining to health. The findings of these surveys provide an indication of the extent of a problem in a specific population at a particular period in time. The design of apt public health measures can also be performed through this research design (Merrill, 2013).

There are two methods of data collection: primary and secondary. Primary data provides access to primary resources, while secondary data offer information that has been provided by previous research. Secondary data excludes the possibility of obtaining the results that are delivered by the first-hand sources. Primary data is useful because it allows the researcher to collect the information directly from the participants. This ensures that the data is presented by the actual subject and not an interpretation of the results of the original data provided by the participants to another researcher (Little, 2013).

Considering the significance of primary data, I selected this source of data. There are numerous methods that can be used for the collection of primary data, and those methods



vary according to the design of the research. This study was performed through a quantitative design, and data collection was conducted by a primary data collection method.

### **Justification for the Selected Research Design**

This study determined the behavior of primary care physicians regarding the prescribing of generic and brand-name drugs for the treatment of chronic conditions in the state of North Carolina. The design for this research was a cross-sectional design. This design was chosen because it addressed the research question of the study regarding the influence of brand-name drugs, the therapeutic effects of brand-name medicine, and their popularity on physicians' patterns of prescription of brand-name medications over generic medications considering the relative low cost of generic drugs. Through the use of a cross-sectional research design, it became possible to predict the factors that are responsible for impacting the attitudes of general physicians to prescribe either brand-name or generic medicine. It facilitated the evaluation of the impact of these factors over a specific time period on the behavior of general physicians.

### **Ethical Considerations**

It is important to consider ethics prior to the commencement of a study. Ethical considerations are a significant aspect of research throughout a study (Burns & Grove, 2011). The ethics of a study are referred to as the tentative, reasonable, and moral aspects of employment of data provided by other researchers in a manner that does not escort its manipulation. This phenomenon is associated with the characteristics of conscientious research that focuses on the strength of attentiveness and legitimate consequence that

must be agreed upon by the researcher when performing a study. Because a quantitative design was employed in this study, there were numerous ethical considerations involved that needed to be addressed before the commencement of the research.

### **Specific Ethical Issues in the Study**

An ethical approval was obtained from the Institutional Review Board to allow the researcher to perform this study. Utilization of the information regarding the practices of general physicians might be considered sensitive because it may enable the prediction of the practices of GPs and the influence on the behavior of patients regarding the use of drugs. It is important to ensure the confidentiality of the participants so that their identities can be concealed. Therefore, the participants will be asked to accept the terms and conditions of the survey that will be mentioned on the online survey site. The demographic data provided by the participants will be kept strictly confidential. The results of this research will demonstrate the attitudes of GPs regarding the prescription of drugs, so there is a chance of professional threats being posed to the GPs participating in the research. Additionally, HIPAA issues are also involved in this research because there are restrictions imposed by HIPAA related to the access to patient information. This can serve as a barrier in obtaining the information from primary care physicians regarding their habits in prescription either the brand-name or generic drugs. Therefore, participants will sign an informed consent document to allow sharing the healthcare information for this study (Jacobs, 2010).

**Confidentiality of the Data**

It will be guaranteed that the information obtained in this research is not utilized for any purposes other than for this specific study. The data obtained from this research will be kept confidential and protected by keeping all the data in a personal password-protected laptop to ensure that only the researcher has the access to data. Following the completion of research, all the data will be destroyed to minimize the risk of disclosure of any confidential data.

**Limitations of the Study**

There are several limitations in this study. The first limitation of this study is the limited availability of time for conducting the research as the researcher will be required to conduct the surveys in a predetermined period of time. Second, the sample of the study will rely only on the population of North Carolina. Therefore, the results of this research will be representative of only a specific region and so might not be applicable to the entire population of the world. Thus, this study will not be able to address and determine the factors responsible for the behavior of physicians regarding the prescription of brand-name drugs over generic medicines at a global level. The sample size of the study will be a limitation since it is too small to represent the habits of all general practitioners regarding the prescription of generic and brand-name drugs.

Another prominent limitation of this research comes from its methods of data collection. As mentioned above, the survey will be performed online through an online survey site. This can cause difficulties in the analysis of the data, as it will be performed statistically and it is a prerequisite of the statistical analysis method that the sample size

should be large enough to provide valid results. Based on this fact, there will be a need for further research with a larger sample size to ensure the delivery of valid results.

### **Inclusion and Exclusion Criteria**

The inclusion criteria of a study ensures that those participants are recruited that are the target population. In the present research the target population is physicians in North Carolina mostly because it was convenient for the researcher to contact and conduct survey in this specific region. Other regions were not selected for conducting the survey because the researcher was interested in determining the prescribing practices of general physicians in this area. The parameters of the inclusion and exclusion criteria of the primary and secondary research are different. These variations are based on the fact that secondary research includes the information that is not provided directly by the participants; rather, it is representative of the data provided by the primary data of other studies. Therefore, the inclusion criteria of this study include the characteristics of primary research method that is based on the recruitment of target population of the research.

The participants of this study will be included based on their relevance to the target population of the research (i.e., they must be practicing primary care physicians in North Carolina because the object is to determine the prescribing practices of these physicians). The researcher will ensure that all the participants prescribe both kinds of drugs (generic and brand-name) so that it becomes possible to determine the factors that are involved in the practicing attitudes of primary care physicians. Both male and female physicians will be included in the study to determine the perceptions and behaviors of

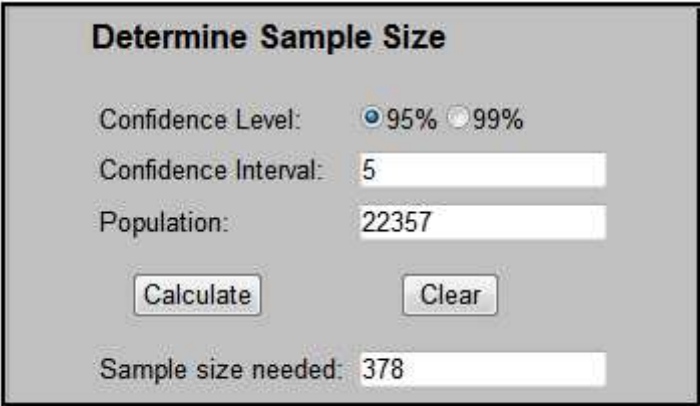
both the genders regarding the prescription of brand-name and generic medications. This provides an opportunity to view the differences in the prescribing practices of both genders. This enables the collection of cumulative data. Participants would be required to have a clinical practicing experience of at least one year.

The research question that guides this study is, “what factors influence a physician’s pattern of prescription of brand-name medications over generic medications?” The hypotheses is *H<sub>0</sub>*: brand popularity and its therapeutic effect do influence prescribing behavior of brand-name medications over generic medications, and *H<sub>1</sub>*: brand popularity and its therapeutic effect do not influence prescribing behavior of brand-name medications over generic medications.

Data analysis is a vital component of quantitative research. The frequently used method for analysis of quantitative data is through statistical analysis. There are various factors that determine the manner in which the analysis of data is performed. These factors include number of variables that are being examined, the extent of measurement of those variables, the utilization of the data for the purpose of inferential or descriptive functionality, and ethical responsibilities. As a result, descriptive statistics, correlational analysis, and multiple linear regression analysis were utilized for this study using SPSS version 23.0. Prescribing generic drugs more frequently can reduce the cost of treatment (the dependent variable), while independent variables are therapeutic effects, side effects, lack of quality control, and the low cost of generic drugs.

### Sample Size and Process of Sampling

The sample size of a study is a major consideration because it is the primary source of data. Therefore, it is essential to ensure that the size of the sample is adequate to provide results that are valid and representative of the views and observations of the participants. It is difficult to predetermine the size of the sample because the survey will be performed online through an online site that allows only small samples. Therefore, the power analysis was applied by getting the list of all practicing physicians in North Carolina from the state Board of Examiner's Registry. Creative Research Systems survey software was used for calculating the sample size. It provided a total population of 22,357 physicians practicing in North Carolina, and with a confidence interval of 5, the sample size required for this study was calculated to be approximately 378 participants. A logistic regression analysis test of the collected data was performed.



**Determine Sample Size**

Confidence Level:  95%  99%

Confidence Interval:

Population:

Sample size needed:

*Figure 1. Power analysis of the sample size by Creative Research Systems survey software (2012).*

There are several strategies that can be used for selecting an appropriate and adequate sample. Types of sampling methods include non-probability and probability

sampling. The nonprobability sampling method includes purposive sampling, convenience sampling, and snowball sampling, while the probability sampling method includes random sampling, stratified, and cluster sampling (Rubin & Babbie, 2009).

The sampling method used in this study is a purposive sampling method. This is based on the fact that the aim of this study is to determine the factors that affect the prescribing attitudes of the physicians regarding brand-name and generic drugs. The target population of this study is primary care physicians; hence, the researcher will ensure that a sampling method is used that assures a valid sample of the target study group. Based on these facts, a purposive sampling method was employed to make certain that the sample contains only the physicians that are practicing medicine in North Carolina.

### **Process of Recruitment**

The recruitment process of this study was performed by getting a list of all the practicing physicians in North Carolina from the state registry. Obtaining this list allowed gathering of the contact details of all those physicians. All the primary care physicians were then contacted via telephone and asked to participate in the survey. Contacts were made in alphabetical order and all the physicians were called, thus ensuring that they are practicing medicine in North Carolina. Physicians were provided brief information about the research and if a physician did not show interest in participating, then next physician was contacted until a sample of 378 general physicians was recruited. Therefore, the sampling of this study was performed through purposive sampling and all the primary care physicians practicing in North Carolina were given the chance to participate in this

study. Physicians were guided to the online survey site where the research was being conducted. Participants were provided with all necessary information regarding this research to make them aware of the purpose and aim of this study. Recruitment was based on the desire of participants to take part in the study. All participants willing to participate were provided a link to the online survey site and further information about the duration of the survey.

### **Data Collection**

Data collection in this study was performed through primary methods. Although there are several methods of data collection in quantitative primary research, surveys are the most common and popular method for the collection of data. This is particularly important when information has to be gathered from large groups and it is vital to obtain standardization. There are several ways in which a survey can be constructed. Despite the manner in which a survey is constructed, two components are always present: questions and responses (Fowler, 2009). There has been a change in the process of surveys from the days of paper and pencil. Exploration of the various emerging technologies is being performed by various evaluators in the healthcare field in order to employ these new technologies in the process of research that has led to the use of online surveys for the collection of data (Fielding et al., 2008).

There are numerous factors that determine the selection of an appropriate survey method. These factors include availability of resources, complexity of the questions, and the schedule of the project. There are several factors that make web-based surveys attractive. Firstly, they allow direct input of the collected data into a database, thus



reducing the time and procedures involved in the collection of data and its analysis.

Secondly, through systematic checks, it becomes possible to block out the responses that are out of range (Chaudhuri & Stenger, 2010).

This research requires the collection of descriptive data, and surveys allow this with ease. Limitations of time and resource availability are the constraints of this study that can be overcome by the employment of an online survey. Therefore, an online survey method was used in this research. It has been predicted that this method will involve some issues regarding the quality of data. It will be difficult to determine the actual identity of a respondent. Furthermore, it will also be difficult to determine the precision of the survey responses. A 40% response rate will be ensured through notifications to the participants sent prior to the initiation of the survey. Evidence suggests that online surveys usually receive higher response rates in comparison to the traditional methods (Burton, Civitano, & Steiner-Grossman, 2012). However, considering the possibility of lower response rates, participants were prompted by sending online flyers to motivate them to participate in the research. Reminders were also sent to the participants to improve the response rates (Nair, 2013).

### **Instruments Used**

Instruments used for the collection of data appropriate for gathering the data. There are several instruments that are employed in the data collection process in primary quantitative research. An online survey was used for the collection of data for this study, via the SurveyMonkey Web site. It is Web site that allows creation of online surveys on a wide range of subjects. The survey questionnaire was adapted from various previous

studies such as Omojasola et al. (2012), El-Dahiyat and Kayyali (2013), and Alghasham (2009). The questionnaire was based on both open-ended and closed-ended questions and on the nature of the question being asked. Demographic data were obtained through a demographic questionnaire that included name, age, and clinical practice experience of the participants. The questions used a Likert-type scale with five possible responses: *strongly agree*, *agree*, *disagree*, and *strongly disagree*, and *neutral*. The variables included: low-cost, popularity, therapeutic effect, effectiveness, quality, preference, and side effects. This type of questionnaire enabled me to gather the data regarding the behaviors and attitudes of the physicians regarding the prescribing of generic and brand-name drugs in their practices. The various factors that lead to this behavior were explored and determined in a descriptive and numerical form through the utilization of this kind of questionnaire. Thus, the researcher was able to statistically analyze the data in a concise manner. This questionnaire allowed collecting the data in a more descriptive form that facilitated the development of increased understanding of the topic. The questions in the questionnaire were based on the medical home model because they determined the association of the reduced cost of generic drugs to be related with the prescribing practices of the physicians. The concept of the medical home model is based on the availability and provision of medicine to all the patients depending on their needs and financial condition. The prescribing practices of primary care physicians related to the low cost of generic drugs can predict the application of the medical home model in the practices of those physicians. Thus, primary care physicians are expected to prescribe

generic drugs to patients with less financial resources, based on the demands of the patients themselves.

Validity is referred to as the accuracy or truthfulness of the measurement as intended. The study was performed over a short duration that facilitated the exclusion of the influence of history and maturation. The effect of experimental mortality was not a factor in this research as it was based on a survey instead of an experiment. The threat of testing and instrumentation was not an issue because the questionnaire was adapted from a previous study (Omojasola et al., 2012). Reliability is based on the consistency of the procedures involved in the research to deliver the results. It is also associated with the extent to which research findings can be repeated or reproduced under similar settings (Ayodele, 2010). Cronbach's alpha was utilized further for ensuring the reliability of the instrument by assuring that its value was .80. Furthermore, the collection of responses from all the respondents through the same questionnaire and the possibility of utilization of the questionnaire elsewhere ensure the repeatability of this study. Therefore, the findings of this research are both valid and reliable. The reliability score of the developed questionnaire was calculated with the help of SPSS and was found to be .89 for the 10-item measure. This helps determine that the samples selected were valid and the instrument is reliable.

### **Analysis of the Data**

Data analysis is a vital component of quantitative research. A frequently used method for analysis of quantitative data is statistical analysis. There are various factors that determine the manner in which the analysis of data is performed. These factors

include the quantity of variables that are being examined, the extent of measurement of the variables, the utilization of the data for the purpose of inferential or descriptive functionality, and ethical responsibilities.

The data from this study was analyzed statistically. SPSS version 23.0 was utilized for this purpose. Descriptive statistics of the responses collected from the participants were analyzed. This method determined the percentages and frequencies for the participants' demographic data and prescribing practices. Statistical tests applied included logistic regression analysis of the prescribing practices of participants. This test was based on the dependent and independent variables of the study.

### **Summary**

Data analysis is a vital component of quantitative research. A frequently used method for analysis of quantitative data is statistical analysis. There are various factors that determine the manner in which analysis of data is performed. These factors include quantity of variables that are being examined, the extent of measurement of variables, the utilization of the data for the purpose of inferential or descriptive functionality and ethical responsibilities. The data of this research was analyzed statistically. Chapter 4 of this study focuses on data analysis, participants' demographics, analysis of the survey responses, correlation, and regression analysis, including descriptive statistics.



## Chapter 4: Analysis and Discussion

### **Introduction**

The purpose of this research was to explore physicians' patterns of prescription of brand-name drugs over generic drugs. The research question for this study was the following: What factors influence physicians' pattern of prescription of brand-name medications and generic medications?

These perspectives included the responsibilities and attitudes of physicians in their prescription patterns. North Carolina is striving to supply premium healthcare services in a period of inadequate resources, which generated the need for increased use of generic medications because generic medication is lower in cost compared to branded drugs. Data were analyzed using SPSS version 23.

The intended sample size for this study was 378; however, the participants' response rate was 40% and only 151 participants completed the research study. To help increase the return rate so as to increase the small sample size, the following techniques were used: survey repetitions, changing email subject lines, pipping, and e-mail notifications. Participants were male and female. In this chapter, I describe the participants' demographics including age, gender, ethnicity, qualification, clinical practice, and clinical practice setting. This is followed by a presentation of the findings from the analysis of the questionnaire analysis, which included correlations and regression analysis.

### **Participant Demographic Characteristics**

Participants from varied demographic backgrounds completed the research study and their following characteristics are described: gender, age, education, race and ethnicity, clinical practice, and clinical practice setting. There were 151 participants. Age in years ranged from 20 to 47 with a mean age of 30.12 ( $SD = 6.25$ ). As seen in Table 1, 67 participants were female and 87 were male, and the proportions of male were higher than the female in this survey. According to the survey respondents, 51 respondents are postgraduate who practice medicines, and 100 respondents have MD degree in medicines. In the demographic data, there is one table that relate to clinical practice.

Fifty four respondents were primary physicians practices; while 97 were doing medical practice. With respect to clinical practice setting, the chart and table illustrate that clinical practice setting is based on office setting, as described by the 55 respondents. On the other hand, 33 respondents; stated that hospital setting is imperative, and 63 respondents reported that long term facility is their place of practice.

Table 1: *Frequency and Percentages of Participant Demographic Characteristics*

Demographic Characteristics	<i>n</i>	%
<b>Education Level</b>		
High School	0	3.1
Some College	0	9.2
College Graduate	0	33.8
Graduate School	0	50.8
Post Graduate	51	1.5
Master Degree in Medicine	100	1.5
Total	151	
<b>Race &amp; Ethnicity</b>		
African American	23	4.6
Asian/Pacific Islander	34	4.6
Hispanic	29	3.1
Caucasian	64	1.5
Other	1	1.5
Total	151	100.0
<b>Clinical Practice</b>		
Primary Physician	54	83.1
Medical practice	97	7.7
Total	151	100.0
<b>Clinical Practice Setting</b>		
Hospital setting	33	4.6
Long term facility	63	35.4
Office/clinical setting	55	60.0
Total	151	100.0



### Analysis of the Questionnaire

This section of the study focus on the outcome of the questionnaire that was returned from the survey participants

**Item number 1: Generic Drugs and Therapeutic Effect.** The focus of the first survey question questionnaire was on physician perception of generic drug ability to produce a therapeutic effect. As seen in Table 2, around 59% ( $n = 89$ ) of respondents strongly agreed that generic drugs are able to produce a therapeutic effect. On the other hand, 7.3% ( $n = 11$ ) strongly disagreed that generic drugs are able to produce therapeutic effect.

Table 2: *Frequency and Percentages of Responses for Survey Question 1*

Generic drugs are able to produce therapeutic effect.	<i>n</i>	%
Strongly Disagree	11	7.3
Disagree	13	8.6
Neutral	11	7.3
Agree	27	17.9
Strongly Agree	89	58.9
Total	151	100.0

**Item Number 2: Side Effects – Generic Drugs and Branded Drugs.** As seen in Table 3, about 60% ( $n = 91$ ) respondents strongly agree that generic drugs cause more side effects than branded drugs. On the other hand, only 6.6% ( $n = 10$ ) of respondents strongly disagreed that generic drugs cause side effects.

Table 3: *Frequency and Percentages of Responses for Question 2*

Generic drugs cause more side effects than brand drugs.	<i>n</i>	%
Strongly Disagree	10	6.6
Disagree	14	9.3
Neutral	13	8.6
Agree	23	15.2
Strongly Agree	91	60.3
Total	151	100

**Item Number 3: Lack of Quality Check on Generic Drugs.** About 24% ( $n = 36$ ) of respondents strongly agreed that there is lack of quality check on generic drugs (see Table 4). On the other hand, 10% ( $n = 15$ ) of respondents strongly disagreed that there is a lack of quality check on generic drugs.

Table 4: *Frequency and Percentages of Responses for Question 3*

There is a lack of quality check on generic drugs.	<i>n</i>	%
Strongly Disagree	15	10
Disagree	36	24
Neutral	17	11
Agree	47	31
Strongly Agree	36	24
Total	151	100

**Item Number 4: Low Cost Generic Drugs.** As seen in Table 5, 30% ( $n = 45$ ) of respondents strongly agreed that generic drugs have low cost when compared to branded drugs. On the other hand, 16% ( $n = 24$ ) of respondents strongly disagree that cost of generic drugs is lower than branded drugs.

Table 5: *Frequency and Percentages of Responses for Question 4*

Generic drugs have low-cost.	<i>n</i>	%
Strongly Disagree	24	16
Disagree	15	10
Neutral	4	3
Agree	63	42
Strongly Agree	45	30
Total	151	100

**Item Number 5: Popularity – Generic VS Branded Drugs.** According to Table 6, 23% ( $n = 35$ ) of respondents agreed that generic drugs are not as popular as branded drugs. On the other hand, 20% ( $n = 30$ ) of respondents disagree that generic drugs are not as popular as branded drugs.

Table 6: *Frequency and Percentages of Responses for Question 5*

Generic drugs are not as popular as brand drugs.	<i>n</i>	%
Strongly Disagree	20	13
Disagree	30	20
Neutral	28	19
Agree	38	25
Strongly Agree	35	23
Total	151	100

**Item Number 6: Representatives - Generic VS Branded Drugs.** As seen in Table 7, 14% ( $n = 21$ ) of respondents strongly agree that representatives of branded drugs are more convincing than the representatives of generic drugs. Conversely, 17% ( $n = 25$ ) of respondents disagree that representatives of branded drugs are more convincing than the representatives of generic drugs.

Table 7: *Frequency and Percentages of Responses for Question 6*

Representatives of brand drugs are more convincing than representatives of generic drugs.	<i>n</i>	%
Strongly Disagree	25	17
Disagree	36	24
Neutral	20	13

Agree	49	32
Strongly Agree	21	14
Total	151	100

**Item Number 7: Prescription of Branded Drugs.** The focus of this part of the research questionnaire is on patients preferences with respect to branded drugs. As seen in Table 8, 17% ( $n = 26$ ) of respondents strongly disagreed that patients do not prefer to be prescribed a branded drugs. On the other hand, 35% ( $n = 53$ ) respondents strongly agreed that patients prefer to be prescribed a branded drug.

Table 8: *Frequency and Percentages of Responses for Question 7*

Patients prefer to be prescribed a brand drug.	<i>n</i>	%
Strongly Disagree	26	17
Disagree	28	19
Neutral	5	3
Agree	39	26
Strongly Agree	53	35
Total	151	100

**Item Number 8: Quality - Generic VS Branded Drugs.** 16 % ( $n = 24$ ) respondents strongly disagreed that generic drugs are not equal in quality as brand drugs (see Table 9). Conversely, 28% ( $n = 42$ ) of respondents strongly agreed that generic drugs are equal in quality as brand drugs.

Table 9: *Frequency and Percentages of Responses for Question 8*

Generic drugs are equal in quality as brand name prescription drugs.	<i>n</i>	%
Strongly Disagree	24	16
Disagree	19	13
Neutral	23	15
Agree	43	28
Strongly Agree	42	28
Total	151	100

**Item Number 9: Safety - Generic VS Branded Drugs.** With respect to safety of generic drugs, 36% ( $n = 55$ ) of the respondents strongly agreed that generic drugs are safer than branded drugs, (see Table 10). On the other hand, 14% ( $n = 21$ ) of the respondents strongly disagreed that generic drugs are safer than branded drugs.

Table 10: *Frequency and Percentages of Responses for Question 9*

Generic drugs are as safe as brand name prescription drugs.	<i>n</i>	%
Strongly Disagree	21	14
Disagree	28	19
Neutral	4	3
Agree	43	28
Strongly Agree	55	36
Total	151	100

**Item Number 10: Inferiority - Generic Versus Branded Drugs.** About 28% ( $n = 43$ ) respondents strongly agree that generic drugs are inferior in quality than branded drug (see Table 11). On the other hand, 23% ( $n = 35$ ) of respondents strongly disagree that generic drugs are inferior to branded drugs.

Table 11: *Frequency and Percentages of Responses for Question 10*

Generic drugs are inferior to brand name prescription drugs.	<i>n</i>	%
Strongly Disagree	35	23
Disagree	24	16
Neutral	10	7
Agree	39	26
Strongly Agree	43	28

Total	151	100
-------	-----	-----

---

**Item Number 11: Patent Expiry of Originator/Innovator.** According to 24% ( $n = 35$ ) of the respondents, generic drugs are not manufactured after the patent expiry of originator or innovator (see Table 12). Conversely, 33% ( $n = 50$ ) of the respondents strongly agreed that generic drugs are manufactured after the patent expiry of originator or innovator.

Table 12: *Frequency and Percentages of Responses for Question 11*

Generic medicines are manufactured after the patent expiry of originator/innovator.	<i>n</i>	%
Strongly Disagree	19	13
Disagree	16	11
Neutral	23	15
Agree	43	28
Strongly Agree	50	33
Total	151	100

---

**Item Number 12: Low Quality - Generic VS Branded Drugs.** 21 % ( $n = 32$ ) of respondents strongly disagree that generic drugs are of low quality than branded drugs (see Table 13). Conversely, 29% ( $n = 44$ ) respondents strongly agree that generic drugs are of low quality than branded drugs.



Table 13: *Frequency and Percentages of Responses for Question 12*

Generic medicines are of low quality than brand name medicines.	<i>n</i>	%
Strongly Disagree	32	21
Disagree	18	12
Neutral	14	9
Agree	43	28
Strongly Agree	44	29
Total	151	100

**Item Number 13: Multinational Product VS Local Product.** According to Table 14, 32% ( $n = 49$ ) of the respondents, multinational products are of better quality than local company's product. Conversely, 16% ( $n = 24$ ) of respondents strongly disagree that multinational products are of better quality than local company's product.

Table 14: *Frequency and Percentages of Responses for Question 13*

Multinational products are of better quality than local company products.	<i>n</i>	%
Strongly Disagree	24	16
Disagree	21	14
Neutral	14	9
Agree	43	28
Strongly Agree	49	32

Total	151	100
-------	-----	-----

---

**Item Number 14: Remembrance of Brand Name Medicine.** According to Table 15, 12% ( $n = 18$ ) of respondents strongly disagree that it is not easier to remember the name of branded drugs; while, 30% ( $n = 45$ ) of respondents strongly agreed that it is easier to remember the name of branded drugs.

Table 15: *Frequency and Percentages of Responses for Question 14*

It is easier to remember a brand name medicine.	<i>n</i>	%
Strongly Disagree	18	12
Disagree	24	16
Neutral	20	13
Agree	44	29
Strongly Agree	45	30
Total	151	100

---

**Item Number 15: Affordability - Generic VS Branded Drugs.** From 151 respondents, 34% ( $n = 52$ ) of respondents strongly agree that generic drugs are more affordable as compare to branded drugs (see Table 16). On the other hand, 9% ( $n = 14$ ) of respondents strongly disagree that generic drugs are more affordable as compare to branded drugs.

Table 16: *Frequency and Percentages of Responses for Question 15*

Generic medicines are more affordable as compared to brand medications.	<i>n</i>	%
Strongly Disagree	14	9
Disagree	18	12
Neutral	24	16
Agree	43	28
Strongly Agree	52	34
Total	151	100

**Item Number 16: Preferences of Patients.** According to Table 17, 41% ( $n = 62$ ) of respondents strongly agreed that patients mostly prefer branded drugs; while only 9% ( $n = 14$ ) of respondents strongly disagreed that patient do prefer branded drugs

Table 17: *Frequency and Percentages of Responses for Question 16*

Patients prefer brand medications.	<i>n</i>	%
Strongly Disagree	14	9
Disagree	18	12
Neutral	14	9
Agree	43	28
Strongly Agree	62	41
Total	151	100

**Item Number 17: FDA and Brand Medications.** As seen in Table 18, 26% ( $n = 40$ ) of respondents strongly agreed that prescription of branded drugs is good for the health of patients as compare to generic drugs because they are approved by the FDA. Conversely, 16 % ( $n = 24$ ) of respondents strongly disagreed that prescribing brand drugs is good for the patient because they are approved by the FDA.

Table 18: *Frequency and Percentages of Responses for Question 17*

Prescribing brand medications feel safe because they are approved by the FDA.	<i>n</i>	%
Strongly Disagree	24	16
Disagree	28	19
Neutral	14	9
Agree	45	30
Strongly Agree	40	26
Total	151	100

**Item Number 18: Option to Choose for the Medications.** According to Table 19, 32% ( $n = 48$ ) of respondents, patients should be given the option to choose for the medication that is affordable to them. Conversely, 21 % ( $n = 32$ ) of respondents strongly disagree that patients should be given the option to choose for the medication that is affordable to them.

Table 19: *Frequency and Percentages of Responses for Question 18*

Patients should be given the option to choose for the medication that is affordable to them.	<i>n</i>	%
Strongly Disagree	32	21
Disagree	24	16
Neutral	10	7
Agree	37	25
Strongly Agree	48	32
Total	151	100

**Item Number 19: Quality of Expensive Medications.** According to Table 20, 33% ( $n = 50$ ) of respondents, expensive medications are considered to be better and more effective by the patient. Conversely, 12% of respondents state that expensive medications are not considered to be better and more effective by the patient.

Table 20: *Frequency and Percentages of Responses for Question 19*

Expensive medications are considered better and more effective by the patients.	<i>n</i>	%
Strongly Disagree	18	12
Disagree	16	11
Neutral	24	16
Agree	43	28
Strongly Agree	50	33

Total	151	100
-------	-----	-----

---

The following six questions and their relationships were further explored using descriptive statistics, correlational analysis and multiple linear regression: (a) generic drug are unable to produce therapeutic effects, (b) do patient prefer brand name drug to generic drugs, (c) generic drug cause more side-effects than brand name drugs, (d) generic drug have lower cost compare to brand drugs, and (e) more of generic prescribing can reduce cost of treatment.

### **Descriptive Statistics**

The descriptive statistics for these variables appear in Table 21. Responses for generic drugs are unable to produce therapeutic effects ranged from 1 (strongly disagree) to 5 (strongly agree) with a mean of 4.12 ( $SD = 1.28$ ). This indicates that, on average, participants agreed that generic drugs are unable to produce therapeutic effects.

Responses for do patients prefer brand name drugs to generic drugs ranged from 1 (strongly disagree) to 5 (strongly agree) with a mean of 4.13 ( $SD = 1.28$ ). This indicates that, on average, participants agreed that patients prefer brand name drugs to generic drugs. Responses for generic drugs cause more side-effects than brand name drugs ranged from 1 (strongly disagree) to 5 (strongly agree) with a mean of 3.61 ( $SD = 1.52$ ). This indicates that, on average, participants were neutral or agreed that generic drugs cause more side-effects than brand name drugs. Responses for generic drugs have lower cost compare to brand drugs ranged from 1 (strongly disagree) to 5 (strongly agree) with a mean of 4.32 ( $SD = 1.26$ ). This indicates that, on average, participants agreed that

generic drugs have lower cost compare to brand drugs. Finally, responses for more generic prescribing can reduce cost of treatment ranged from 1 (strongly disagree) to 5 (strongly agree) with a mean of 4.32. On average, participants agreed that more generic prescribing can reduce cost of treatment.

Table 21: *Descriptive Statistics for Primary Survey Questions (N = 151)*

Survey Item	Min	Max	<i>M</i>	<i>SD</i>
Generic drugs are unable to produce therapeutic effects	1.0	5.0	4.12	1.28
Do patients prefer brand name drugs to generic drugs	1.0	5.0	4.13	1.28
Generic drugs cause more side-effects than brand name drugs	1.0	5.0	3.61	1.52
Generic drugs have lower cost compared to brand drugs	1.0	5.0	4.32	1.26
More generic prescribing can reduce cost of treatment	1.0	5.0	3.06	1.45

### **Correlation**

Pearson correlations were used to assess the bivariate relationships between the five primary variables: (a) generic drugs are unable to produce therapeutic effects, (b) do patient prefer brand name drugs to generic drugs, (c) generic drugs cause more side-effects than brand name drugs, (d) generic drugs have lower cost compared to brand drugs, and (e) more generic prescribing can reduce cost of treatment. It is important to note that correlations are used to examine the relationship between only two variables at a time. Table 22 shows correlations between the variables of interest.

Table 22: *Pearson Correlations between the Variables (N = 151)*

Survey item		1	2	3	4	5
1. Generic drug are unable to produce therapeutic effects	<i>r</i>	1				
2. Do patients prefer brand name drug to generic drugs	<i>r</i>	.07	1			
	<i>p</i>	.36				
3. Generic drugs cause more side-effects than brand name drugs	<i>r</i>	.18*	-.07	1		
	<i>p</i>	.02	.37			
4. Generic drugs have lower cost compared to brand drugs	<i>r</i>	.02	-.07	-.07	1	
	<i>p</i>	.73	.35	.35		
5. More generic prescribing can reduce cost of treatment	<i>r</i>	-.01	.03	-.06	.07	1
	<i>p</i>	.85	.64	.43	.33	

*Note.* \* indicates  $p < .05$ .

**Correlations with generic drugs are unable to produce therapeutic effects.** As seen in Table 22, there was a small, positive, statistically significant correlation between generic drugs are unable to produce therapeutic effects and generic drugs cause more side-effects than brand name drugs ( $r = .18, p = .02$ ). This indicates that as agreement that generic drugs are unable to produce therapeutic effects increases, agreement that generic drugs cause more side-effects than brand name drugs also increases. Generic



drugs are unable to produce therapeutic effects was not significantly correlated with any of the other variables.

**Correlations with do patients prefer brand name drugs to generic drugs.** As seen in Table 22, there were no statistically significant correlations between do patients prefer brand name drug to generic drugs and the other four variables.

**Correlations with generic drugs cause more side-effects than brand name drugs.** As previously noted, there was a small, positive, statistically significant correlation between generic drugs cause more side-effects than brand name drugs and generic drugs are unable to produce therapeutic effects ( $r = .18, p = .02$ ). There were no other statistically significant correlations between generic drugs cause more side-effects than brand name drugs and the remaining three variables (see Table 22).

**Correlations with generic drug have lower cost compared to brand drugs.** As seen in Table 22, there were no statistically significant correlations between generic drugs have lower cost compared to brand drugs and the other four variables.

**Correlations with more generic prescribing can reduce cost of treatment.** As seen in Table 22, there were no statistically significant correlations between more generic prescribing can reduce cost of treatment and the other four variables.

### **Regression Analysis**

A simultaneous multiple linear regression analysis was used to explore the relationship between (a) generic drug are unable to produce therapeutic effects, (b) do patients prefer brand name drug to generic drugs, (c) generic drugs cause more side-effects than brand name drugs, (d) generic drugs have lower cost compare to brand drugs

(the independent variable) and (e) more generic prescribing can reduce cost of treatment (the dependent variable).

As seen in Table 23, the model was not statistically significant ( $F(4, 146) = 0.41$ ,  $p = .79$ ) and accounted for only 1.1% of the variance in perceptions that more generic prescribing can reduce cost of treatment.

Table 23: *ANOVA for the Relationship between The Independent Variables and More of Generic Prescribing can Reduce Cost of Treatment (The Dependent Variable)*

		Sum of				
	Model	Squares	<i>df</i>	Mean Square	<i>F</i>	<i>p</i>
1	Regression	3.55	4	0.88	0.41	.79
	Residual	313.78	146	2.14		
	Total	317.33	150			

The Tolerance, and the Variance Inflation Factor were examined. Per Cohen, Aiken, and West (2004), the results indicated that multicollinearity was not an issue given that Tolerance values were above .10 and VIF values were less than 10. Given the lack of a statistically significant regression model, the regression coefficients in Table 24 were not interpreted. The null hypothesis that there will not be a statistically significant predictive relationship between (a) generic drug are unable to produce therapeutic effects, (b) do patients prefer brand name drug to generic drugs, (c) generic drugs cause more side-effects than brand name drugs, (d) generic drugs have lower cost compare to brand

drugs (the independent variable) and (e) more generic prescribing can reduce cost of treatment (the dependent variable) was accepted.

Table 24: *Regression Coefficients for the Relationship between The Independent Variables and More Generic Prescribing can Reduce Cost of Treatment (The Dependent Variable)*

Model	<i>B</i>	Std. Error	$\beta$	<i>t</i>	<i>p</i>	Tol.	VIF
Generic drugs are unable to produce therapeutic effects	-.01	.09	-.01	-.12	.90	.95	1.04
Do patients prefer brand name drugs to generic drugs	.04	.09	.04	.49	.62	.97	1.02
Generic drugs cause more side-effects than brand name drugs	-.05	.08	-.05	-.62	.53	.94	1.05
Generic drugs have lower cost compared to brand drugs	.09	.09	.07	.94	.34	.98	1.01

### Linearity Test Summary

Based on Table 25, the Deviation from Linearity value of 1.198 was not statistically significant ( $p > .05$ ). Thus, there is a linear relationship between the variables GENERICDRUG and PHYPRESCRIPTION.

Table 25: *Test of Linearity and Deviation from Linearity for PHYPRESCRIPTION \***GENERICDRUG*

			Sum of				
			Squares	<i>df</i>	Mean Square	<i>F</i>	Sig.
More generic prescribing can reduce cost of treatment *	Between Groups	(Combined)	7.696	4	1.924	.907	.462
		Linearity	.073	1	.073	.034	.853
		Deviation from Linearity	7.623	3	2.541	1.198	.313
Generic drugs are unable to produce therapeutic effects	Within Groups		309.641	146	2.121		
	Total		317.338	150			

Based on Table 26, the Deviation from Linearity value of 0.592 was not statistically significant ( $p > .05$ ). Thus, there is a linear relationship between the variables BRANDEDDRUG and PHYPRESCRIPTION.

Table 26: *Test of Linearity and Deviation from Linearity for PHYPRESCRIPTION \* BRANDEDDRUG*

			Sum of		Mean		
			Squares	<i>df</i>	Square	<i>F</i>	Sig.
More generic	Between	(Combined)	4.266	4	1.066	.497	.738
prescribing can	Groups	Linearity	.461	1	.461	.215	.644
reduce cost of		Deviation					
treatment * Do		from Linearity	3.805	3	1.268	.592	.622
patients prefer	Within Groups		313.072	146	2.144		
brand name	Total						
drugs to			317.338	150			
generic drugs							

Based on Table 27, the Deviation from Linearity value of 1.587 was not statistically significant ( $p > .05$ ). Thus, there is a linear relationship between the variables PERCEPTION and PHYPRESCRIPTION.

Table 27: *Test of Linearity and Deviation from Linearity for PHYPRESCRIPTION \**

*PERCEPTION*

			Sum of		Mean		
			Squares	<i>df</i>	Square	<i>F</i>	Sig.
More generic	Between	(Combined)	11.263	4	2.816	1.343	.257
prescribing can	Groups	Linearity	1.280	1	1.280	.611	.436
reduce cost of		Deviation					
treatment *		from Linearity	9.983	3	3.328	1.587	.195
Generic drugs	Within Groups		306.075	146	2.096		
cause more	Total						
side-effects							
than brand			317.338	150			
name drugs							

Based on Table 28, the Deviation from Linearity value of 0.320 was not statistically significant ( $p > .05$ ). Thus, there is a linear relationship between the variables GENMEDICATION and PHYPRESCRIPTION.

Table 28: *Test of Linearity and Deviation from Linearity for PHYPRESCRIPTION \* GENMEDICATION*

			Sum of		Mean		
			Squares	<i>df</i>	Square	<i>F</i>	Sig.
More generic prescribing can reduce cost of treatment *	Between	(Combined)	4.025	4	1.006	.469	.759
	Groups	Linearity	1.963	1	1.963	.915	.340
		Deviation from Linearity	2.062	3	.687	.320	.811
Generic drugs have lower cost compared to brand drugs	Within Groups		313.313	146	2.146		
	Total		317.338	150			

In Tables 25 through 28, a summary of linearity test was conducted to check for model violation, the analysis shows that there was no violation as such the model use is appropriate for this study.

### Summary

The focus of the study was to determine the primary care physicians' perspectives about the recommendation of generic medicines to their patients. These perspectives

included the responsibilities and attitudes of physicians who prescribe medications to their patients. The state of North Carolina is striving to supply premium healthcare services in a period of inadequate resources. This generated the need for increased use of generic medication due to its lower cost when compared to branded drugs. This chapter included a descriptive analysis of 19 survey questions and the examination of the bivariate and multivariate relationship between five key variables. All data were analyzed in SPSS version 23.

Bivariate analysis using Pearson correlation showed that there was a small, positive, statistically significant correlation between “generic drugs are unable to produce therapeutic effects” and “generic drugs cause more side-effects than brand-name drugs” ( $r = .18, p = .02$ ). As agreement that generic drugs are unable to produce therapeutic effects increases, agreement that generic drugs cause more side-effects than brand-name drugs also increases. There were no other statistically significant correlations between (a) generic drugs are unable to produce therapeutic effects, (b) do patients prefer brand-name drugs to generic drugs, (c) generic drugs cause more side-effects than brand-name drugs, (d) generic drugs have lower cost compared to brand-name drugs, and (e) more generic prescribing can reduce the cost of treatment.

Multivariate analysis using multiple linear regression showed that there was not a statistically significant predictive relationship between (a) generic drugs are unable to produce therapeutic effects, (b) do patients prefer brand-name drug to generic drugs, (c) generic drugs cause more side-effects than brand-name drugs, (d) generic drugs have lower cost compared to brand-name drugs (the independent variable) and (e) more



generic prescribing can reduce the cost of treatment (the dependent variable). As such, the null hypothesis was accepted.

## Chapter 5: Recommendations, Implications, and Conclusion

This chapter provides discussions on recommendations, study implications, study limitations, and conclusions of the study.

### **Key Recommendations**

#### **Stakeholders**

Although current picture of the U.S. health-insurance market is uncertain, enrollment can be anticipated in terms of demographics so there is a need for insurance providers, policy makers, and other healthcare providers to look for innovative ways to bring down the cost of prescription drugs.

#### **Legal Framework**

The state is responsible for creating reliable distribution channels that can provide easy access to the insurance market. This can be accomplished through necessary legislative, regulatory, and business policies, and it must comply with both state and federal regulations. Consumers of insurance should be thoroughly informed about services available, and must be taught in language that they understand. Finally, federal agencies should monitor premium trends of insurance firms

#### **Healthcare Insurance Plans**

Commercial insurance plans should be prepared by marketing experts with the help of innovative tools so that cost can be decreased and consumers have more choices for selecting different providers. These innovative tools should include social media sites, mobile applications, and print media for interacting with the consumers. Strategies should be developed for attracting new consumers through value-added services and products

like alternative medicines. Finally, better commercial insurance plans should include reduced operational costs and increased consumer baselines.

### **Hospitals and Healthcare Professionals**

Providers must manage the demands and visit resources, encourage hospitals to provide quality healthcare at less cost through coordination. Organizational structure and revenue analysis should be done for checking the accountability of the operations such as collections and facilities provision records. Providers should obtain the maximum possible information about the consumer to avoid potential bad debts, and patient networking should be present in the insurance market

### **Employers**

Employers should consider the incorporation of healthcare insurance as a value-added package for their employees, should analyze the availability of better tools that provide better potential outcomes, and provide flexibility to employees for choosing a healthcare plan of their own choice. Finally, IT companies should obtain accurate data for enrollment and determine ways for enhancing trends.

### **Consumers/Patients**

Consumers must participate in insurance retailing by selecting the insurance plan of their own choice through a better decision-making process. This can ultimately transfer the pressure to the insurance sector for providing potential benefits within the lowest-cost method of operations. The design of insurance plans should consider the risk and tolerance factor for the consumer.

### **Study Implications**

The positive social change implication of the results of this study is such that it would help to appropriately and optimally utilize resources by educating patients and healthcare services providers in regard to the use of generic drugs so as to minimize cost without compromising efficacy, and informing policy makers regarding the same.

### **Study Limitations**

There are several limitations associated with this study. First, there was not enough time for conducting the research as I was required to conduct the surveys in a predetermined period of time. Second, the sample of the study only included the population of North Carolina. Therefore, the results of this research will be representative of only a specific region and might not be applicable to the entire population of the United States. Sample size of the study is also a limitation because it is too small to present the practices of all the general practitioners regarding the prescription of generic and brand-name drugs. Another important limitation of this research was the method of data collection. An online survey approach was used, and this method may not produce a large enough sample size. This can cause difficulties in the analysis of the data, if such analysis is performed statistically. Quantitative studies using the statistical analysis method require a large sample size to provide valid results. Based on this fact, there will be a need for further research with a larger sample size to ensure the delivery of valid results.

## **Conclusion**

I concluded that in the absence of national health insurance, people are dependent only on self-sponsored insurance and pay their expenses out of pocket. The cost is increasing without making changes in the effectiveness of medication whether generic or brand-name drug. Thus, it forces the healthcare professionals to exclude the insurance benefits from the patients. The number of uninsured patients is still high and may increase due to the high level of premium contributions. Due to increased healthcare costs, the future growth of the sector is subjected to potential threats. Based on such consequences, most healthcare professionals suggest generic medicines to their patients because these drugs are cost effective.

Increased premium contributions force enrollees to switch from one plan to another. Thus, controlling sharp swings in premiums is necessary. A law such as the “America’s Healthy Futures Act of 2009,” although it includes insurance standards, does not support a public healthcare plan. Furthermore, the inadequate knowledge, along with the attitudes and perceptions of primary care physicians are minimizing the outcomes that confuse the patients about their medication choices; for instance, generic over brand-name drugs.

The standard criteria for medical interventions include assessment, classification, planning, and education. The assessment for determining the usage can be done by various methods by evaluating through discussion, physical evaluation, reviewing of medication, and psychosocial as well as environmental analyses. The medication assessment is essential for determining the effective ways of management of certain

illnesses such as pain management in older patients. For instance, it can be done by using an acronym such as “OPQRSTU” in which the letter “O” stands for Onset: it defines the beginning time of pain. “P” stands for Provoking: what factors make pain conditions better or worse. “Q” represents Quality: the feeling when the pain is occurring. “R” is for Region/Radiation, and defines the exact location of pain. “S” indicates Severity, and it defines the extent of the pain. “T” stands for Treatment, which establishes which medications are currently being used, what is their effectiveness, are there any side effects, and an examination of past medications records. The letter “U” denotes Understanding the factors that are responsible for the pain and how the pain affects the patient and family. “V” is for Values, and it defines the program in order to manage the pain by considering all factors and this aspect involves a physical assessment.

The healthcare system of the United States is established on the idea that healthy lives leads to healthy people. This is the overall strategy of the government and there is an increasing shifting of strategies because the US is facing the key challenges of non-communicable diseases, while sexually transmitted diseases are becoming more common and a large portion of the population engages in alcohol consumption and smoking. Furthermore, the mental health issue among young people and confusing conclusions given by the doctor also create issues that sometimes results the patient’s death or loss of function. Another bitter fact is the inequalities among poor and rich in terms of medical treatments since 85% of the population uses public healthcare facilities, which are less effective when the disease in question is a major threat to the life of the patient. This is

the dilemma and it could not be solved easily just by giving health education to the people of US (Petersen et al., 2005).

Teaching people in the US to appreciate the benefits that technology can bring for their health is portrayed as advantageous, even although it may not prevent issues about restrictions on the make use of ICT as “e-health” can enhance medical facilities. Health is a major concern for the US government and broad planning gives a structure for the improvement of the national healthcare system. The scheme gives the chance to collectively bring the resources of the country, intercontinental expansion, commerce and savings policies that influence the national healthcare administrative system. The conclusion should be a scheme that is challenging and attainable, that will get better wellbeing and welfare in the United States, and permit the government to report facts about healthcare system (Lehrman, 2005).

The government of US should be clear about the mandate of the World Health Organization (WHO) and other multinational agencies that can promote and encourage healthcare systems effectively. The inputs of the domestic government and agencies should be also countable in order to consider human rights with respect to promoting healthcare facilities. Moreover, this should also include protection of a safe water supply with adequate sanitary conditions in communities as well as at work places in order to achieve good physical health. Moreover, mental health can be beneficial for the progress of society as a whole and the population of a country (WHO, 2014).

### References

- ACAPS (2012) Qualitative and quantitative research techniques for humanitarian needs assessment. *An Introductory Brief*. Retrieved from [http://reliefweb.int/sites/reliefweb.int/files/resources/qualitative\\_and\\_quantitative\\_research\\_techniques.pdf](http://reliefweb.int/sites/reliefweb.int/files/resources/qualitative_and_quantitative_research_techniques.pdf)
- AHRQ. (2005). Oral diabetes medications for adults with Type 2 diabetes. An update executive summary. Retrieved from [www.effectivehealthcare.ahrq.gov/reports/final.cfm](http://www.effectivehealthcare.ahrq.gov/reports/final.cfm)
- American Diabetes Association. (2012). Economic costs of diabetes in the U.S. in 2012. *Diabetes Care* 2013, 36, 1,033-1,044,
- Anderson, G. (2004). The growing burden of chronic diseases in America. *Public Health Reports*, 119.
- Anderson, G., & Horvath, J. (2004). The growing burden of chronic disease in America. *Public Health Reports*, 119, 263-70.



- Ayodele, O. (2010). Validity and Reliability Issues in Educational Research. *Journal of Educational and Social Research*, 2(2), 1-10 Retrieved from [http://www.mcser.org/images/stories/JESRJOURNAL/Jesr\\_May\\_2012/oluwatayo\\_james\\_ayodele.pdf](http://www.mcser.org/images/stories/JESRJOURNAL/Jesr_May_2012/oluwatayo_james_ayodele.pdf)
- Barbour, R. (2010). *Introducing qualitative research. A student guide to the craft of doing qualitative research*. Retrieved from <http://www.amazon.co.uk/Introducing-Qualitative-Research-Students-Guide/dp/1412912660>
- Berwick, D. (2009). What patient-centered should mean: confessions of an extremist. [Electronic version]. *Health Affairs*, 4(28), 555-556.
- Burns, N. &, Grove, S. K. (2011). *Understanding nursing research: Building evidence based practice* (5<sup>th</sup> ed.). TX: Elsevier. Retrieved from <http://www.amazon.com/Understanding-Nursing-Research-Building-Evidence-Based/dp/1437707505>
- Burton, W., A. Civitano, and P. Steiner-Grossman. (2012). Online versus paper evaluations: differences in both quantitative and qualitative data. *Journal of Computing in Higher Education*, 24(1), 58-69. Retrieved from <http://link.springer.com/article/10.1007%2Fs12528-012-9053-3#page-1> o
- CAHPS<sup>®</sup> (2011). About the CAHPS<sup>®</sup> Patient-Centered Medical Home (PCMH) Item Set. CAHPS<sup>®</sup> Clinician & Group Surveys and Instructions. Pp. 1-9. Retrieved from: [https://cahps.ahrq.gov/Surveys-Guidance/docs/1314\\_about\\_pcmh.pdf](https://cahps.ahrq.gov/Surveys-Guidance/docs/1314_about_pcmh.pdf)
- Center for Disease Control (CDC). (2005). Aging trends (2005). Department of Health and Human Services.

Center for Disease Control and Prevention. Chronic disease overview. Cost of chronic disease. Center for Disease Control and Prevention. Retrieved from <http://www.cdc.gov/nccdphp/overview.htm>

Center for Drug Evaluation and Research, Drug applications: Abbreviated new drug application (ANDA) process for generic drugs. U.S food and drug administration. Retrieved from <http://www.fda.gov/cder/regulatory/applications/ANDA.htm> on

Center for Medicare and Medicaid Services, based on total population estimate of 9.2 million North Carolinians. Retrieved from <http://www.cms.gov/ResearchGeninfo/>

Center for Medicare and Medicaid Services. National Health Care Expenditures Projections: 2004-2014. Retrieved from <http://www.cms.hhs.gov/NationalHealthExpendData/downloads/nheprojectiopns2004-2014pdf>

Centers for Disease Control and Prevention. (CDC, 2008). *National Diabetes fact sheet. General information and National Estimates on diabetes in the United States-2007*. Retrieved from the U.S Department of Health and Human Services (USDHHS).

Chaudhuri, A., Stenger, H. (2010). *Survey sampling: Theory and methods* (2<sup>nd</sup> ed.). CRC Press. Retrieved from <http://www.amazon.com/Survey-Sampling-Statistics-Textbooks-Monographs/dp/0824757548>

Congressional Budget Office (CBO). (2010). *Effects of Using generic Drugs on Medicare's Prescription Drug Spending* (Washington, DC: September 2010).

- Cohen, J., Cohen, P., West, S. G., & Aiken, L. S. (2003). *Applied multiple regression/correlation analysis for the behavioral sciences* (3rd ed.). Hillsdale: Erlbaum.
- Cost effectiveness and strategic planning (WHO-CHOICE). (2014). AFR D: Cost effectiveness results for malaria. Geneva: World Health Organization; 2014. Available from [http://www.who.int/choice/results/mal\\_afrd/en/](http://www.who.int/choice/results/mal_afrd/en/)
- Creswell, J. (2014). *Research design: Qualitative, quantitative, and mixed methods approaches*. SAGE. Retrieved from <http://www.amazon.com/Research-Design-Qualitative-Quantitative-Approaches/dp/1452226105>
- Creswell, J. W. (2009). *Research design: Qualitative, quantitative, and mixed models* [Kindle Edition].
- De DeVol, R., & Bedroussian, A. (2007). *An unhealthy America: The economic burden of chronic disease charting a new course to save lives and increase productivity and economic growth*. Retrieved from <http://www.milkeninstitute.org/healthreform/pdf/AnUnhealthyAmericaExecSummary.pdf>
- Dobscha, S. K., Winterbottom, L. M., & Snodgrass, L. S. (2007). Reducing drug costs at a Veteran affairs hospital by increasing market-share of generic fluoxetine. *Community Mental Health Journal*, 43(1), 75-84.
- Felland, L. E., & Reschovsky, J. D. (2009). *More nonelderly Americans face problems affording prescription drugs. Health system change tracking report*.

- Fielding, N., Lee R., Blank, G. (2008). *The SAGE handbook of online research methods*. SAGE. Retrieved from <http://www.amazon.com/SAGE-Handbook-Online-Research-Methods/dp/1412922933>
- Fowler, F. (2009). *Survey research methods*. SAGE. Retrieved from: <http://www.amazon.com/Survey-Research-Methods-Applied-Social/dp/1412958415>
- Friedhoff, S., Verl, C., Pietsch, C., Meyer, C., Vompras, J., & Liebig, S. (2013). Replicability and comprehensibility of social research and its technical implementation. *RatSWD Working Paper Series*, 1-27. Retrieved from [http://ratswd.de/dl/RatSWD\\_WP\\_219.pdf](http://ratswd.de/dl/RatSWD_WP_219.pdf)
- Gellad, W, F., Huskamp, H, A., Phillips, K, A., & Haas, J, S. (2006). How the new Medicare drug benefit could affect vulnerable populations. *Health Affairs*, 25(1), 248-255.
- Generic and Brand Name Drugs: Understanding the Basics. Retrieved from [www.fda.gov/cder/orgdconsumerinfo/generics/q&a.htm](http://www.fda.gov/cder/orgdconsumerinfo/generics/q&a.htm)
- Gu, Q., Zeng, F., Patel, B., & Tripoli, L, C. (2008). Part D coverage gap and adherence to diabetes medications. *AMJ Managed Care*, 16(12), 911-918.
- Haas, J. S., Phillips, K. A., Gerstenberger, E. P., & Seger, A. C. (2005). Potential savings from substituting generic drugs for brand name drugs: Medical Expenditure Panel Survey, 1997-2000. *Annals of Internal Medicine*, 11(142), 891-897. Retrieved from <https://annals.org/article.aspx?articleid=718428>

- Hancock, B., Ockleford, E., & Windridge, K. (2009). An introduction to qualitative research. *The NIHR RDS EM / YH, 2007*, 4-37. Retrieved from [http://www.rds-yh.nihr.ac.uk/wp-content/uploads/2013/05/5\\_Introduction-to-qualitative-research-2009.pdf](http://www.rds-yh.nihr.ac.uk/wp-content/uploads/2013/05/5_Introduction-to-qualitative-research-2009.pdf)
- Hart, M. (2010). Indigenous worldviews, knowledge, and Research: The development of an indigenous research paradigm. *Journal of Indigenous Voices in Social Work*, 1(1), 1-16 Retrieved from [http://scholarspace.manoa.hawaii.edu/bitstream/handle/10125/15117/v1i1\\_04hart.pdf?sequence=1](http://scholarspace.manoa.hawaii.edu/bitstream/handle/10125/15117/v1i1_04hart.pdf?sequence=1)
- Health Policy Brief. (2010). Patient-Centered Medical Homes. A new way to deliver primary care may be more affordable and improve quality. But how widely adopted will the model be? *Health Affairs*, 1-6. Retrieved from [http://healthaffairs.org/healthpolicybriefs/brief\\_pdfs/healthpolicybrief\\_25.pdf](http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_25.pdf)
- Henderson, S., Princell, C. O., & Martin, S. D. (2012) The patient-centered medical home: this primary care model offers RNs new practice—and reimbursement—opportunities. *Am J Nurs*, 112(12), 54-59. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/23190675>
- Holahan, J., & Cohen, M. (2006). Understanding the recent growth changes in Medicaid spending and enrollment growth between 2000-2004, Issue paper, The Kaiser commission on Medicaid and the uninsured, May.
- Holahan, J., Schoen, C., & McMorrow, S. (2011). The potential savings from enhanced chronic care management policies. Retrieved from [www.healthpolicycenter.org](http://www.healthpolicycenter.org)

<http://www.nccppr.org/drupal/content/insightarticle/272/medicaid-and-north-carolinas-aging-population>

IMS Institute for Healthcare Informatics. (2010). The use of medicines in the United States; Review of 2010 (Parsippany, N.J.,: April 2011).

Jacobs, M. (2010). Institutional review boards and independent ethics committees. In M. J. McGraw, A. N. George, & S. P. Shearn (Eds.), *Principles of good clinical practice*. Pharmaceutical Press. Retrieved from [http://www.pharmpress.com/files/docs/principles\\_clinpract\\_sample.pdf](http://www.pharmpress.com/files/docs/principles_clinpract_sample.pdf)

Jaudes, K. P., Champagne, V., Harden, A., Masterson, J., & Bilaver, L. A. (2011). Expanded medical home model works for children in foster care. *Child Welfare, 91*(1), 9-33. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/22894013>

Johnson, E. L., Brosseau, J. D., Soule, M., & Kolberg, J. (2008). Treatments of diabetes in long-term care facilities a primary care approach. *Clinical Diabetes, 26*(4), 152-156

Jolley, J. (2011). *Introducing research and evidence-based practice for nurses*. Harlow: Pearson, Retrieved from <http://www.amazon.co.uk/Introducing-Research-Evidence-Based-Practice-Nurses/dp/0273719165>

Jolley, J. (2011). *Introducing research and evidence-based practice for nurses*. Harlow: Pearson. Retrieved from <http://www.amazon.co.uk/Introducing-Research-Evidence-Based-Practice-Nurses/dp/0273719165>

- Kesselheim, A. S., Misono, A. S., Lee, J. L., Stedman, M. R., Brookhart, M. A., Choudhry, N. K., & Shrank, W. H. (2008). Clinical equivalence of generic and brand-name drugs used in cardiovascular disease: A Systemic Review and Meta-analysis. *JAMA*, *300*(21), 2514-2526.
- Kesselheim, A. S., Stedman, M. R., Bubrick, E. J., Gagne, J. J., Misono, A. S., Lee, J. L., Brookhart, M. A., Avorn, J., & Shrank, W. H. (2010). Seizure outcomes following use of generic vs. brand-name antiepileptic drugs: A systemic review and meta-analysis. *Drugs*, *70*(5), 605-621.
- Klein, W., Turvey, C., & Wallace, R. (2004). Elders who delay medication because of cost: Health insurance, demographic, health, and financial correlates. *The Gerontologist*, *44*(6), 779-787. Retrieved from <http://webmedia.unmc.edu/alliedhealth/nichols/Medicare%20and%20Care.pdf>
- Klonoff, D. C. (2008). Spending for diabetes drugs is increasing in the United States. *Journal of Diabetes Science and Technology*, *2*(4), 543-545.
- Kushner, C. (2010). Medicaid and North Carolina's aging population. Retrieved from
- Lee, K., Palacio, C., Alexandraki, I., Stewart, E., & Mooradian, A. D. (2011). Increasing access to health care providers through medical home model may abolish racial disparity in diabetes care: evidence from a cross-sectional study. *Journal of the National Medical Association*, *103*(3), 250-256. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/21671528>
- Little, T. (2013). *The Oxford Handbook of Quantitative Methods, Volume 1: Foundations* (Oxford Library of Psychology), Oxford University Press, p. 1-759.

Retrieved from: <http://www.amazon.com/Oxford-Handbook-Quantitative-Methods-Volume/dp/0199934878> on 28<sup>th</sup> April, 2014

Lehrman, S. (2005). Need to cross language barrier highlighted by contest. *Quill*, 93(4), 11-44.

New Report: Individual Health Insurance Market Failing Consumers, data retrieved from, <http://www.commonwealthfund.org/News/News-Releases/2009/Jul/New-Report-Individual-Health-Insurance-Market-Failing-Consumers.aspx>

Mahoney, J. J., Ansell, B. J., Fleming, W. K., & Butterworth, S. W. (2008). The unhidden cost of noncompliance. *JMCP*, 14(6), 1-29.

Marshall, R. C., Doperak, M., Milner, M., Motsinger, C., Newton, T., Padden, M., ... & Mun, S. K. (2011). Patient-centered medical home: An emerging primary care model and the military health system. *Military Medicine*, 176(11), 1253-1259.  
Retrieved from: <http://www.ncbi.nlm.nih.gov/pubmed/22165652>

Medicaid and the Uninsured: Retrieved from <http://www.kff.org>

Medicare and Medicaid Fact Sheet: Retrieved from <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareMedicaidStatSupp/2012.html>

Mendelson, D., Ramchand, R., Abramson, R., Tumlinson, A. (2002). *Prescription drugs in nursing homes: Managing costs and quality in a complex environment*. NHPF Issue Brief No. 784, 1-18

Murray, M. D., Callahan, C. M. (2003). Improving medication use for the older adults: An integrated research agenda. *Ann Intern Med*, 139, 425-429.



National Diabetes Fact Sheet, 2011: Retrieved from

<http://www.cdc.gov/diabetes/pubs/references11.htm>

Omojasola, A., Hernandez, M., Sansgiry, S., & Jones, L. (2012). Perception of generic prescription drugs and utilization of generic drug discount programs. *Ethnicity & disease, 22*(4), 479. Retrieved from

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3522080/>

Parkinson, G., & Drislane, R. (2011). *Qualitative research*. In Online dictionary of the social sciences. Retrieved from <http://bitbucket.icaap.org/dict.pl>

Peters, J. R., Hixon, D. R., Conner, D. P., Davit, B. M., Catterson, D. M., & Parise, C. M. (2009). Generic drugs –safe, effective, and affordable. *Dermatology Therapy, 22*, 229-240.

Petersen, P. E., Bourgeois, D., Ogawa, H., Estupinan-Day, S., & Ndiaye, C. (2005). The global burden of oral diseases and risks to oral health. *Bulletin of the World Health Organization, 83*(9), 661-669.

Piette, J. D., Heisler, M., & Wagner, T. H. (2004). Problem paying out-of-pocket medication costs among older adults with diabetes. *Diabetes Care, 27*(2), 384-391.

Reed, M., Hargraves, & Cassil, A. (2003). *Unequal access: African- American Medicare beneficiaries and the prescription drug gap*, Issue Brief No 64, Center for Studying Health System Change, Washington, D.C.

Resnick, H. E., Heineman, J., Stone, B., & Shorr, R. (2008). Diabetes in U.S. nursing homes, 2004. *Diabetes Care, 31*(2), 287-288.

Rubin, A., & Babbie, E. (2009). *Research methods for social work*. Cengage Learning.

Retrieved from <http://www.amazon.com/Research-Methods-Social-Workers-7th/dp/0205820115>

SAVINGS An Economic Analysis of Generic Drug Usage in the U.S., GPhA, September 2011, page 1.

Schmidt, C. O., & Kohlmann, T. (2008). When to use the odds ratio or the relative risk?. *International Journal of Public Health*, 53(3), 165–167. Retrieved from [http://www.broadinstitute.org/~eliana/Papers/when\\_to\\_use\\_odds\\_ratio\\_relative\\_riskfulltext.pdf](http://www.broadinstitute.org/~eliana/Papers/when_to_use_odds_ratio_relative_riskfulltext.pdf)

Scott, A. B., Culley, E. J., & O'Donnel, J. (2007). Effects of a physician office generic drug sampling system on generic dispensing ratio and drug costs in a large managed care organization. *Journal of Managed Care Pharmacy*, 13(5), 412-419.

Shank, W. H., Choudhry, N. K., Liberman, J. N., & Brennan, T. A. (2011). The use of generic drugs in prevention of chronic disease is far more cost-effective than though, and may save money. *Health Reference Affairs*, 7, (2011), 1352-1357.

Sid Nair, C. (2013). The effect of email notification on web-based questionnaire responses. *Journal For Quality & Participation*, 35(4), 19-23. Retrieved from: <http://connection.ebscohost.com/c/articles/92897665/effect-email-notification-web-based-questionnaire-responses>

Sousa, V. D., Driessnack, M., & Mendes, I. A. C. (2007). An overview of research designs relevant to nursing: Part 1: quantitative research designs. *Revista latino-*

*americana de enfermagem*, 15(3), 502-507. Retrieved from:

<http://www.scielo.br/pdf/rlae/v15n3/v15n3a22.pdf>

The Robert Wood Johnson Foundation (1996). *Chronic care in America: A 21<sup>st</sup> century challenge*. Princeton, NJ.

Thinking outside the pillbox: A system-wide approach to improving patient medication adherence for chronic disease. A NEHI Research Brief-August 2009

Thorpe, K. E., & Howard, D. H. (2006). The rise in spending among medicare beneficiaries: The role of chronic disease prevalence and change in treatment intensity. *Health Affairs*, 25(5), 378-388.

U.S. Census Bureau. "Aging in the America into the XX1 Century" wallchart, U.S. Department of Commerce <http://www.census.gov/ipc/www/aginam.html>

Viahiotis, A., Devine, S, T., Eicholz, J., & Kautzner, A. (2011). Discontinuation rates and health care costs in adult patients starting generic versus brand SSRI or snri Antidepressants in commercial health plans. *Journal of Managed Care Pharmacy*, 17(2), 123-132.

Windel, L., Anderko, L., & Konetzka, T. (2011). Transforming primary care: improving on the medical home model. *Journal of Interprofessional Care*, 25(4), 305-307. Retrieved from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3130999/>

Wu, E, Q., Yu, A, P., Lauzon, V., Ramakrishan, K., Marynchenko, M., Ben-Hamadi, R., Blum, S., & Erder, M, H. (2011). Economic impact of therapeutic substitution of a brand selective serotonin reuptake inhibitor with an alternative generic selective

serotonin reuptake inhibitor in patients with major depressive disorder *The Annals of Pharmacotherapy*, 45, 441-451.

Congressional Budget Office, Updated estimates of the effects of the insurance coverage provisions of the Affordable Care Act.

[http://www.cbo.gov/sites/default/files/cbofiles/attachments/45231-ACA\\_Estimates.pdf](http://www.cbo.gov/sites/default/files/cbofiles/attachments/45231-ACA_Estimates.pdf).

North Carolina's \$10B Medicaid Challenge: Pay for Other States or Take Federal Money?

From

<http://kaiserhealthnews.org/news/north-carolinas-10b-medicaid-challenge-pay-for-other-states-or-take-federal-money/>

Cost effectiveness and strategic planning (WHO-CHOICE). AFR D: cost effectiveness results for malaria. Geneva: World Health Organization; 2014. Available from: [http://www.who.int/choice/results/mal\\_afrd/en/](http://www.who.int/choice/results/mal_afrd/en/)

New Report: Individual Health Insurance Market Failing Consumers, data retrieved from, <http://www.commonwealthfund.org/News/News-Releases/2009/Jul/New-Report-Individual-Health-Insurance-Market-Failing-Consumers.aspx>

## **Appendix: Instruments**

INSTRUCTIONS:

Please read and answer all questions.

## Survey Questionnaire

### Part A: Perceptions about Generic and Brand name Drugs

Please place an "X" in the box to your right to the following comments below:

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
Generic drugs are unable to produce therapeutic effect?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Generic drugs cause more side effects than Brand drugs:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
There is a lack of quality check on generic drugs:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Generic drugs have low-cost:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Generic drugs are not as popular as brand drugs:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Representatives of brand drugs are more convincing than representatives of generic drugs:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Patients prefer to be prescribed a brand drug:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Generic drugs are equal in quality as brand name prescription drugs:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Generic drugs are as safe as brand name prescription drugs:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Generic drugs are as effective as brand name prescription drugs:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Generic drugs are inferior to brand name prescription drugs:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Generic medicines are manufactured after the patent expiry of originator/innovator:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Generic medicines are of low quality than brand name medicines:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Multinational products are of better quality than local company products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please place an "X" in the box to your right to the following comments below:

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
It is easier to remember a brand name medicine:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Knowledge about cost of medications is low among prescribers:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Generic medicines are more affordable as compared to brand medications:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Medical representativeness influences prescribing practices:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Patients prefer brand medications:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Generic drugs generally produce the indented therapeutic effects:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Prescribing brand medications feel safe because they are approved by the FDA:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Generic drug prescribing can reduce the cost of treatment:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Patients should be asked about their preference prior to prescription of medication:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Patients should be given the option to choose for the medication that is affordable to them:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Generic medicines should only be prescribed on the request of patients:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Patients prefer brand medications:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Expensive medications are considered better and more effective by the patients:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### Part B: Demographics, Physicians

<b>Demographics</b>
---------------------

Name:

Gender:

Age:

Race & Ethnicity:

Level of Education:

Clinical Practice:

Clinical Practice Setting:

**Thank you for your time in completing this survey**