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Reimportation of Prescription Drugs as Contributing Component to Patient Drug Adherence: A Qualitative-Grounded Theory Study

Jeffrey Tubbs
Walden University

Walden University

College of Health Sciences

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Jeffrey Tubbs

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Review Committee
Dr. John Oswald, Committee Chairperson, Health Services Faculty
Dr. Lee Bewley, Committee Member, Health Services Faculty
Dr. Loretta Cain, University Reviewer, Health Services Faculty

Chief Academic Officer
Eric Riedel, Ph.D.

Walden University
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Abstract

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Jeffrey Allen Tubbs

MD, Windsor University School of Medicine, 2013

MBA, University of Texas at Arlington, 2008

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Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

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Abstract

Pharmaceutical drugs are one of the most socially important heath care products. They are part of many individuals' everyday lives, from the eradicating of diseases at birth to treating patients at the end of life. However, for many patients access is prevented due to expensive cost. This study explored cost-related non-adherence (CRN) and researched if reimportation of pharmaceutical drugs from other countries could increase patient drug adherence. The perceptions of 10 patients and 10 providers in Maine were assessed. Maine is the only state that allowed its citizens to purchase prescription drugs from abroad. The research questions addressed (a) how reimportation drugs could contribute to drug adherence, (b) the perceptions of patients, and (c) the perceptions of key providers of reimportation. This study was guided by a theoretical framework utilizing Kurt Lewin's theory of organizational change. Participants answered 15 open-ended questions. The study utilized a qualitative grounded theory approach; data were analyzed inductively. The research demonstrated that patients and healthcare providers had positive perceptions for a reimportation policy. Future research of other regions for this topic should prevail. Member checking was used to validate the emerging theories of increased long term drug adherence incentivized by affordable drug cost, which contributes to perception of competence, better management of current disease, and decreased safety concerns. Positive social change implications can be achieved through savings to the health-care industry by creating a pathway to affordable drugs that will bring more drugs to market and create a competitive structure that can drive down pricing.

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Dedication

I dedicate this dissertation to: Edward Nathaniel Tubbs (Dad) (Deceased) and George “Pops” Jones Jr. (Grandfather) (Deceased), your presents are always felt. Also, to my beautiful, caring, and loving daughter “Asia Royal”; my love for you all is immeasurable. With every word that was written……. you were there.

Love You……..Siempre (Always)

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Table of Contents

List of Tables

List of Figures

Chapter 1: Introduction to the Study

Introduction

Per capita expenditures for prescribed drugs are much greater in the United States than other developed nations. The United States' population for cost related non-adherence (CRN) are doubled that of Canadian residents (Kennedy & Morgan, 2009). Kanavos, Ferrario, Vandoros, and Anderson (2013) found that brand drug prices increased from 5% to 198% in the United States within the past decade. According to a 2013 survey by Health Affairs, drug prices in the United States are so high that more than 50 million American patients (21%) are currently skipping doses or never getting the prescription filled (Cohen,Whitney, Kirzinger and Gindi 2013). Patients often skip doses in an attempt to save money; however, this tactic is most likely to increase personal healthcare costs (Cohen, et al, 2013).

Stuart (2014) suggested that increased pharmaceutical spending is partially due to the rapid uptake of newer and more expensive drugs in comparison to other nations. For example, Celebrex (a nonsteroidal anti-inflammatory drug used for the treatment of pain or inflammation) has an average cost of $225USD in the United States, which is twice as much as the cost in Britain ($112USD) and four-times as much as the cost in Canada ($51USD). Higher prices for mandated prescription drugs lead to prescriptions not being filled (Stuart 2014). Therefore, cost is a contributing factor to patients' non-adherence (Khatter & Dickens, 2006). In particular, retired, senior citizens may experience a lapse in Medicare insurance coverage and leave prescription drug request unfulfilled (Khatter & Dickens, 2006).

The purpose of this research was to analyze the perceptions of Maine citizens with chronic diseases and recurring prescription drug refills concerning reimportation of

pharmaceutical drugs. State legislation allowed low-cost drugs to be reimported. The overall effects of this policy were also analyzed. In this chapter, I discuss the background, problem statement, research questions, hypotheses, theoretical framework, nature of the study, definitions, assumptions, scope/delimitations, limitations, and significance of the study. More importantly, I discuss the implications for positive social change and how savings to the healthcare system and patients can ensue; while giving increase accessibility to much needed expensive medications. Social, health, and economic costs of chronic disease management are high and knowledge about potentially greater and cheaper access to prescription drugs can improve the overall health of the individual and community.

Background

According to the Alliance for Health Reform (2006) reimportation of prescription drugs has gained momentum in the political discourse. Having other incentives in place to help supplement expensive drugs (such as Medicaid Part D) is needed. Thus, other alternatives measures are required; reimportation of medication drugs could be one of those alternatives. Views on reimportation are polarized (safe for U.S. citizens or not safe for citizens) amongst those who support and oppose this measure with both sides attempting to justify their voices (Bhosle & Balkrishnan 2007). The Medicine Equity and Drug Safety Act of 2000 (MEDS Act) allowed certain institutions to reimport U.S. manufactured, and Food and Drug Administration (FDA) approved drugs, exported outside the United States back into the United States at a discounted price (Bhosle & Balkrishnan 2007). However, because of the lack of approved votes in Congress by the Department of Health and Human Services (HHS) the MEDS Act was terminated in December 2000 (Bhosle & Balkrishnan, 2007). The opposing concern for

reimportation is safety. According to former Secretary of Health and Human Services, Donna Shalala, prescription drugs that are made in the United States, shipped overseas, can safely be reimported (CDC.gov, Retrieved 2015). Former Secretary Donna Shalala stated that the FDA can monitor the safety of drugs coming back into the United States for $24 million more in the budget in order to increase inspection services (Kaiser Health, 2009).

Ho, Bryson, and Rumsfeld, (2009) stated as a result of high drug prices and the need for less expensive drugs there is a system within healthcare that contributes to patients nonadherence to drug medication. There are many studies exploring nonadherence. Many chronic diseases have been researched for patients' nonadherence levels (Brown & Bussell, 2011). Medication nonadherence has been a growing concern to healthcare providers and other stakeholders due to increased evidence that it is linked to adverse reactions and increased long-term healthcare costs (Ho et al, 2009).

Diabetes is a chronic disease that is prevalent throughout the nation and regionally in Maine. According to the Centers for Disease Control (CDC), (2014) undiagnosed and diagnosed diabetes in the United States totaled 29.1 million citizens or 9.3% of the population having diabetes. Diagnosed population consisted of 21.0 million people and undiagnosed consisted of 8.1 million people; also 27.8% of citizens with diabetes are not diagnosed. According to the official Maine website (Maine.gov),(2014) diabetes is one of four contributing diseases to the state's mortality rate. It is imperative to investigate options to decrease mortality rates and improve quality of life. Affordable medication from other markets would allow for exploration of patients' adherence levels. This research gave researchers, healthcare officials and others,

data (not seen in any other regions of the country) options, and corrective measures needed for patients' ability to maintain physician's guided drug regimen.

Problem Statement

A plethora of research literature exists on patients' medication non-adherence practices. There also exists literature on cost determinants of drugs and affordability. But literature gaps are present in terms of research providing data concerning reimportation of drugs as one corrective measure to patients' mandated drug regimen. This is in part because of the current policies and the federal government denial of reimportation drugs into the United States' markets. Therefore, research is needed to understand the impact of reimportation on non-adherence drug regimen. Accomplishments of this study can be obtained by studying the one state that has legislation in place. Healthcare officials, politicians and others are then allowed to evaluate the perceptions of Maine's population as they are free to reimport medication.

The research study explored the link between patient drug nonadherence and reimportation of drugs. Utilization of a qualitative approach allowed for the experiences, opinions, and feelings of the informants to form a hypothesis. Increasing supply and opening the market to other countries will bring more prescriptions to market. Purchase of prescriptions drugs at a lower cost from a different market through reimportation will render immediate savings that may contribute to increased drug adherence.

According to Kennedy, Coyne, Joseph and Sclar (2004) a small but increasing population of United States' citizens are unable to purchase medications that are prescribed to them. Cost-related nonadherence is similar to other health care access issues; it is not evenly distributed among the population. Senior citizens on fixed incomes often make the decision to

purchase food or purchase their monthly prescription drugs (Carrns, 2012); as a result, drugs are not taken or prescriptions are not filled at all. Chronic illnesses continue to get worse, and higher healthcare treatment cost ensues. The change in locations of drug purchases significantly decreases the cost. Citizens given the opportunity to save a tremendous amount of money on prescription drugs could experience enhanced long-term healthcare benefits due to their ability to purchase and comply. Cleemput and Kesteloot (2002) stated that it is an important factor of impediment to the effects of health interventions; gaps exist between efficacy and effectiveness due to non-compliances. Research is needed to explore if reimportation of medication drugs and the effects of reimportation have an effect on patients' adherence. It may contribute to decreasing long-term healthcare cost and improve the disease state of patients.

The purpose of this proposed research was to explore one component of patient non-adherence of prescription drugs (CRA) and investigate if reimportation policies will enhance drug adherence among the Americans with chronic diseases. The study looked at non-adherence due to CRA that causes patients to skip dosages or not fill the prescription at all. Newly implemented policies in the state of Maine have adopted reimportation drug laws for its citizens. The study assessed the perception of this population in relationship to the newly implemented reimportation law in the state of Maine.

Purpose of Study

The purpose of the study was to determine the perceptions and explore the influences of drug reimportation policy on chronic disease patients in the state of Maine. This new legislation was selected for its uniqueness within the United States. The research attempted to further demonstrate optional corrective measures for patients' medication regimen and interpret the

perceptions of the participants from the data collected. It is the desire of this research to contribute data on a national scale that could be replicated in other states.

Research Questions

Research questions were formulated to correspond to interview questions in order to capture patients' and provider's perception of this process. The questionnaires/interviews were designed to address the following research questions:

RQ1: How does a reimportation prescription drug policy contribute to patients' drug adherence?

RQ2: What perceptions do patients have about reimportation drugs as related to a chronic disease?

RQ3: What are the perceptions of key providers (physicians, physician assistants & nurse practitioners) regarding the impact of reimportation drug laws on patient medication adherents?

Theoretical Framework

The U.S. government has many layers of political management thereby creating a complex bureaucratic process. This can lead to frustration from the general population and the willingness for change is diminished. There is a need for new and better legislation from political officials and for better internal processes. Kurt Lewin's (1947) theory of organizational change proposes a thought process that could be utilized. Kurt Lewin's previous works consisted of studies within leadership and various effects of leadership (Burnes, 2004). Morrison (2014) noted that Lewin focused his attention on group based decision-making, developing the force field theory, unfreeze, change and refreeze change management models with action research, and

the group approach to training dynamics. With a focus on three distinct stages of change management: (a) unfreezing, (b) change (transition), and (c) refreezing he suggested unfreezing is the method that involves locating a process to make possible for people to relinquish counterproductive old habits and patterns.

Unfreezing is needed to overcome the levels of resistance and group conformity that allows for moving to a new stage or changing movement. Secondly, change/transition is needed to have change in thoughts, feelings, behaviors, or all three that results in liberation, and increase productivity. Lastly, refreezing is putting into place the newly accepted changes into a new accepted habit; it now becomes standard operating procedure (Morrison, 2014). It is possible to revert to the old habits without this implementation. Adaptation and implementation of new policies is built upon this framework. Organizations, leaders, and others must acknowledge a new mindset which is imperative to employ new national legislation related to prescription drugs. Many processes and strategies could increase the chance of health policies and programs to be adopted and enforced within formal institutions (Kritsonis, 2005).

Nature of Study

I explored the perception of individuals residing in Maine in order to determine if the reimportation policies have any effect(s) on patients' perceptions of medication adherence. In my research I used semi-structured questionnaires/interviews to produce data on a sample participant pool diagnosed with a chronic disease.

As a joint venture, physicians and patients must communicate concerns of the drug regimen, therefore, it is necessary to query healthcare providers on their assessment, perceptions

and experiences with their patients. Patients and providers are able to provide new insight on the effects of the reimportation policy.

Definition of Terms

Reimportation: The importation of goods into a country which had previously been exported from that country (http://www.merriam-webster.com, Retrieved, 2014).

Adherence: the obedience of the patient to the medical advice (http://www.merriam-webster.com, Retrieved, 2014).

Non-adherence: a lack of adherence (http://www.merriam-webster.com, Retrieved, 2014).

Federalism: a system of government suggesting sovereignty is constitutionally divided between a central governing body and constituent political sub-units (states or provinces) (http://www.merriam-webster.com, Retrieved, 2014).

Proclivity: often choosing or do something regularly; an inclination or predisposition toward a particular thing (http://www.merriam-webster.com, Retrieved, 2014).

Chronic Disease: along lasting condition that can be controlled but not cured (http://www.merriam-webster.com, Retrieved, 2014).

Drug Tiers: categories in which drugs are assigned to one of four or five category sections (copayment or coinsurance *tiers)*, based on medication usage, clinical effectiveness and cost (Blue Cross-Blue Shield [BCBS], Retrieved 2014).

Grounded Theory: consist of a theory that is inductively formulated from work gathered in the field from real world experiences, emerging from researcher's interviews and observations; often used in qualitative approach methodology (Patton, 2002).

Assumptions

Qualitative researchers assume deep understanding and rich description are indication of the methodology. This research study believes reality is looked upon as subjective and that environments of social realms are personal constructs generated by individualism and are not generalizable (Velez, Retrieved 2014). These thoughts are grounded in constructivism and not positivism. It is assumed not to be a generalizable reality that is quantifiable for larger populations. Qualitative researchers also believe that exploration is guided and developed by the values of the researcher along with the hypotheses, theories or the framework being utilized.

Context is crucial, and one can assume that without an exquisite comprehension of the contextual nature of an exploration project the investigative data cannot be categorized as generalizable (Sechrest & Sidani, 1995). Pluralistic, interpretive, and open-ended is the desire, along with contextualized perspectives (Creswell & Miller, 2000). The integrity of this research was built upon a platform of trustworthy responses from the informants; it was the assumption that participant's willingness to participate in this study will result in veracious responses.

Limitations

The study is limited to a population from only one state. The state of Maine is the least dense state in the Northeast region of the United States and ranks 2nd behind Vermont as having a population predominantly of Whites, 95% (Long, 2012). Therefore, the study does not represent other entities of race and demographic regions. With a focus on chronic disease patients, the study cannot theorize for the experiences of participants having various other acute diseases. Therefore, nonadherence and reimportation effects and perceptions of these diseases remain to be seen. Maine's new reimportation policy and implementation tenure are short (only 1

year) and perhaps not enough time has passed by to see the true effects of this legislation. It is possible that this research could yield additional and beneficial data by repeating the research study in 2-4 years into the future.

Significance of the Study

The research is timely since it allowed access to a population (Maine) that is first and only in the nation to adopt such reimportation drug policies. As of October 2013, Maine has a population of approximately 1.3 million citizens. This equates to approximately 41.3 citizens per square mile, making Maine the least dense state in Northeast region (Census.gov, Retrieved 2014). The majority of Maine's population (75%) dies from just a few chronic diseases: cancer, diabetes, chronic lung disease, and cardiovascular disease (CDC, 1994). These diseases also cause major disabilities. On a national scale, 1out 10 Americans suffers from these four chronic diseases (CDC, 1994). Research is needed to explore options to assist patients with chronic diseases in order to provide better living conditions now and long-term.

Significant knowledge could be gained from this population that can be replicated nationwide. This proposed study included data from a population on nonadherence of prescription drugs and the reimportation policy effects. The results of this study presented new data not seen by any other state because of null reimportation policies. The state of Maine is precedent in this manner and this research study has presented new data, new insight to drug reimportation. Also, allowing for continued dialog of the topic with the intent to generate discussion for the implementation of new healthcare policies.

Scope of Study/Delimitation

The research study was conducted with adult, chronic disease patients and providers with access to the new reimportation policy in Portland, Maine (patients) and state-wide (providers). Adults with an age range of 18 years old and older were solicited; conformation of age was achieved via demographic profiling within the research questionnaire apparatus. The research had a total of 20 participants: 10 patients and 10-providers. The adult participants were diagnosed with a chronic disease and have a continuous regimen of prescription drug refills. Healthcare providers such as physicians, nurse practitioners, and physician assistants were given questionnaires for their perceptions of this policy. The exclusionary and inclusionary decision process performed during the development of the study identified boundaries of the research topic. The initial delimiting step was choosing the research topic, implying that all other related research concerns have been rejected. Both genders men and women were considered and a diagnosed with a chronic disease was confirmed. The apparatus used to collect data was questionnaires/interviews; these questionnaires were used to make several distinctions. The geographical placement of the study is unique and can only be performed in one locale (Maine). Therefore, it was critical to visit Maine to capture vital information and observe non-verbal cues that cannot otherwise be observed.

Implications for Social Change

Pharmaceutical drugs are the most socially important healthcare product, having influences in every healthcare facet. As of 2012, the United States had 312 million citizens (Census.gov, 2014). Most individuals will be affected by pharmaceutical drugs at some point in their lives. From time of birth and throughout life, drugs play an important role for good health

and enhancement of quality of life. Childhood immunizations have eradicated many previously life-threatening diseases, and individuals continue to use drugs throughout their lives. The entire population is affected directly and indirectly. Cost-related nonadherence is a significant factor for continued health problems and rising healthcare costs. Consumers of any product or service will typically make the most economic, cost saving decision before making a purchase; drug purchases are no different. Keeping reimportation in the forefront can allow for many officials, various healthcare departments to unite and figure out a logistical process for ensuring safety and quality. Reimportation drugs can surmount to a healthier population while contributing to a significant savings to the healthcare system.

This research study addressed real-world applications within the healthcare arena. It contributes to strategies that can be implemented to enhance patient adherence of their drug medication regimen. As seen in the state of Maine, this research desired to foster new dialog that contributes to national policy change. With current national policies and the continuous high cost of drugs, there exists a social problem that has been greatly overlooked. The action of reimportation (as a contributing remedy to increasing adherence) will significantly contribute to positive social change to a population which relies on these drugs but have limited access due to the significant high cost. Reimportation policies can have a significant impact on healthcare prescription savings with long-term health care savings, due to drug adherence. This increase adherence can decrease chronic diseases from getting to a worsen state, that requires additional medical treatments and cost.

Summary

Due to the social economics, cultural and the structure platform of the pharmaceutical industry (its ability to control pricing) the United States' healthcare system has created and sustained cost-related nonadherence that has contributed to an increasingly worsen state for chronic disease patients. Their inability to afford much-needed drugs has forced patients to not adhere to physician's orders for medication regimen. Unfortunately, the outcome results in higher medical costs, decrease quality of life and an issue that is perpetuated without any resolve. Senior citizens are affected more due to their social economic status and insufficient medical insurance coverage. The general population will (in time) demand safe, affordable drugs whilst current policies are deficient in delivering the demands of a nation. Organizational change is needed to create and sustain safe new policies while changing the mindset of political officials and healthcare officials granting patients safe and cost saving drugs which may contribute to their ability to become increasingly adherent.

The literature review in Chapter 2 presents details of factors contributing to drug nonadherence, cost comparisons, contrasting information on the European pharmaceutical system and reimportation concerns and details. In Chapter 3, I described detail of the design for the research study using qualitative grounded theory methodology. Chapter 4 outlines the results of the data collected from participants in Maine. I presented the results of memoing, opinions, feelings, and perceptions of the informants. In Chapter 5, I presented and explained the findings of the research.

Chapter 2: Literature Review

Introduction

Several studies have been performed in relationship to patients' non-compliance of their prescription drugs regimen. Also, existing is a plethora of data (pros/cons) for reimportation of prescription drugs. Current federal laws of the United States will not allow any state to reimport prescription drugs; therefore, research has been quite limited. But the situation is changing, a new ruling (first of its kind) in the state of Maine allows direct purchases of mail-order drugs from foreign pharmacies (Levitz & Martin, 2013). The new policy took effect in October 2013. Literature gaps are present regarding research concerning reimportation of drugs as one corrective component to patients' mandated drug regimen. This research explored this topic and provided research data to the study.

Research is needed to understand and explore the impact of pharmaceutical reimportation drugs in relation to patients' non-adherence conduct; accomplished by studying the one and only state that has legislation in place. Maine's population is free to reimport pharmaceutical medications and does not have to participate in any clandestine activities or be in fear of punitive repercussions. Thus, there exists a completely different mindset among this population (that is not found in other locales) that could render valuable information on the topic.

The purpose of this study was to research the perceptions of drug reimportation policy on chronic disease patients in the state of Maine and the influences of said policy as it relates to drug adherence. The study further explored optional corrective measures for patients' medication regimen and interpreted the perceptions of the participants from the data collected.

This chapter discussed the demographics of Maine's population, local and national diabetes prevalence, and reimportation current stance. Additional discussion consisted of adherence measurements, and a specific population who is having difficulties filling prescriptions. Medicare Part D along, with a preventive healthcare model is discussed. Further discussion of drug cost determinants, long-term health costs, and a brief overview of the pharmaceutical industry while addressing some political voices, FDA rulings and gaps within the literature.

Literature Review Proper

Non-adherence is a topic of heavy discussion within the healthcare arena. It is a key issue concerning the plight of patient care. Patients often state more prescription use (adherence) to their physician than what actually occurs (Karmel, 2005). In a compliance study performed by Dr. Michael Kass (published in 1986) he discovered a large discrepancy between self-reported adherence 100% and the true value of 76% (Karmel, 2005); and the problem still persists today. Most patients blame the increased cost of drug as the problem for their non-adherence; this is known as cost-related non-adherence (CRA).

Some reports for reimported drugs thus far are indicating significant savings to the citizens of Maine. For example, utilizing a Canadian broker (CanaRX) the city of Portland, Maine pays approximately $200.00 for a 3 month supply (with no co-pay) of Nexium; Nexium is a heartburn medication regulating at a 40 mg dose per tablet. The same exact Nexium medication through Aetna Insurance Inc. (USA) is at $620.00 and has a co-pay of $156.00 (Levitz & Martin, 2013); that is a savings of $576.00 to the patient and the healthcare system. Many other

medications fall under similar savings, therefore, the overall cost savings to the healthcare system would be enormous.

Karmel (2005) looked at a meta-analysis of 569 studies that observed prescriptions of non-psychiatric physicians, this study had a 25 % non-adherence rate; the study also revealed a 30% non-adherence rate for silent conditions such as diabetes and pulmonary diseases that demanded long-term and complex drug regimens. This research study focused on the chronic disease patients for Maine's population and their nonadherence conduct. Early reports from Maine are already indicating cost savings. A spokesman for a private firm in Maine has stated that access to international pharmacies has reduced its annual health-care spending cost up to $600,000 (Levitz, 2013).

Because of the esoteric nature of Maine's policy and its genesis stage, I explored various factors that would yield information on the pharmaceutical industry, the political arena, and culture and socioeconomics aspect of reimportation. The literature mining also explored long-term cost saving, the federal law stance and briefly contrasted foreign pharmaceutical markets to the United States markets.

Literature Search Strategies

A search of several electronic databases with respect to patient drug non-adherence, and drug reimportation included Google Scholar, Proquest Health and Medical Complete, Proquest Central, EBSCO, ERIC, Medline, Government websites (FDA, CDC and others) various university school libraries and the reference section of reviewed articles; all terms were entered into each database. Keywords and phrases used within each database included; *patient drug compliance, patient drug non-compliance, patient drug adherence, patient drug non-adherence,*

reimportation bill, Maine reimportation law, and chronic disease; Canadian exports of drugs, drug tiers, pharmaceutical intellectual property, preventive healthcare, European pharmaceutical markets, generic drugs, reimportation safety, grounded theory and FDA reimportation.

Basic economics can justify decreased pricing of products and services when consumers are given a choice, and competitive markets are applied. Applying this theory to the pharmaceutical system and making a connection that increases patient drug adherence has yet to be seen. And, this is not surprising because the (United States) has not allowed legal reimportation of any pharmaceutical drugs thereby studies of reimportation drugs and patients' adherence are void and null. Literature of variables, reimportation and adherence, is not supported within the literature review. Thus, it is imperative to capture data and study this new policy and learn of the affects it is having on a given population.

Gaps in Literature

Research literature exist on patient drug adherence and non-adherence; there also exist literature on cost of drugs and the affordability (or the lack thereof) but there are literature gaps concerning research that provide a link to reimportation of drugs as a corrective measure for patients' non-adherence. Literature gaps are to be expected due to the current policies and the denial of reimportation drugs into the United States. It is imperative to explore the only state that has policies in place for reimportation of pharmaceutical drugs.

Asking if and how reimportation affects patients' adherence is completely valid, it has yet to be determined. The literature is void to null on the affects (if any) that these variables have to each other. It is the hope of this research that federal enforcements (FDA & others), lawsuits and

any other antagonistic efforts do not interfere with reimportation efforts and that this topic can be transitioned to other states. The tempestuous discussions of reimportation should keep the topic in the forefront of political officials and the general public.

Pharmaceutical drugs (without a doubt) are the most socially required healthcare products. The integral role affects every facet of healthcare and the quality of life for patients; this is evident from the many diseases that have been eradicated by drugs that previously killed many individuals worldwide (NAPSRx, 2013). Cleemput and Kesteloot (2002) stated that non-adherence is an important factor of impediment to the effects of health interventions; gaps exist between efficacy and effectiveness due to non-adherence.

This qualitative study explored the perception and mindset of individuals who were once clandestine in their efforts to acquire inexpensive drugs from foreign markets and what affects are being displayed with this new found freedom. Therefore, many gaps exist and much knowledge awaits future researchers who take on the pharmaceutical industry and challenge them to provide more affordable drugs and keep in mind the financial distresses that many social, and economic hardship patients have.

Theoretical Foundation

This exploration is built upon Lewin's (1947) theory of organizational change. It proposes a thought process that could be utilized for federalism change. Kurt Lewin (1890-1947, social psychologist) whose work involved studies of leadership and their effects that focused on three distinct stages of change management: (a) unfreezing, (b) change (transition) and (c) refreezing he suggested unfreezing is the method that involves locating a process to make possible for people to relinquish old habits and patterns that proved counterproductive.

Levels of resistance and group conformity must be unfrozen in order to allow forward progression to a new stage; thereby incorporating change (transition) in thoughts, feelings, behaviors, or all three that result in liberation and increase productivity. Lastly, refreezing puts into place the newly accepted change into a new accepted habit. It now becomes standard operating procedure (Morrison, 2014). It is easy to revert to the old habits without this implementation of refreezing. Adaptation and implementation of new policies is built upon this framework. Organizations, leaders, and others must acknowledge a new mindset which is imperative to employ new national legislation related to prescription drugs. Many processes and strategies could increase the chance of health policies and programs to be adopted and enforced within formal institutions (Kritsonis, 2005).

Demographics-Maine

As of 2013, Maine had a population of approximately 1.3 million citizens; this equates to approximately 41.3 citizens per square mile, making Maine the least population-dense state in Northeast region (Census.gov, 2014). Maine's age-distribution is somewhat out of balance stated Professor Colgan an instructor at the University of Southern Maine's Muskie School of Public Service (Colgan, 2014); the oldest national status shows a median age of 43.5 y/o according to 2012 U.S Census Bureau; this is an indication that half of Maine's population is older than 43.5 y/o and half is younger.

Maine trails only the state of Vermont in having the lowest percentage of citizens under the age of 18. The Census department estimates that Maine has approximately 411,540 citizens between ages of 45 and 65 while another 301,124 citizens are between 20 and 39 years of age

(Census.gov, 2014). In 2011 and 2012 for the first time in 70 years, more people died in Maine than were conceived according to Maine's Office of Vital Records (Maine.gov, 2014).

High Disease Prevalence

Seventy five percent of Maine's population dies from four chronic diseases: chronic lung disease, cardiovascular disease, diabetes, and cancer (CDC.gov, 1994). Maine's chronic disease prevalence is in alignment with national levels. According to the CDC, as of 2012, approximately 50% of adults (117 million people) have one or more chronic disease(s) health conditions. Over a fourth of adults have two or more chronic health conditions. Seven of 10 reasons of death in 2010 were related to chronic diseases. Heart diseases and cancer combined accounted for nearly 48% (half) of all deaths (CDC.gov/chronic diseases, 2014) and diabetes is the primary cause of kidney failure that often leads to death. In addition to killing 75% of Maine's citizens, these diseases also cause major disabilities. This is comparable to the national scale; for 1out of 10 Americans. These four chronic diseases contribute to limitations of daily activities (CDC.gov, 1994). Therefore, it is significant to research options that can alter the plight of patients' living conditions now and long-term.

Diabetes Maine

Although the research consisted of patients with various chronic diseases, diabetic patients display high numbers of non-adherence in the United States and regionally in the state of Maine. Prevalence of pre-diabetes has remained steady yet diabetes among the population of Maine has steadily increased over the years staying in line with increase rates of the United States (Maine.gov, 2014). Utilizing data from the Maine Behavioral Risk Factor Surveillance

System (BRFSS) data is collected from random adults with chronic related diseases and injury; each year over 6,500 Maine adults participate in this survey (CDC.gov, 1997).

Pre-diabetes among males and females are very similar for survey years 2008 to 2010 (Maine.gov, 2014). According to state records, 7.4% of its population has diabetes; this ranking is 20th of 51(among other states); that equates to 6.6 adults out of every 100 adults having diabetes. Furthermore, for every 100,000 citizens there were 27 deaths related to diabetes in 2002 (CDC.gov, 2014).

Diabetes Type II

WHO (2003) suggested poor adherence to the regimen for diabetes resulting in avoidable pain and suffering for patients that translates to excess healthcare cost. In a World Health Organization study in Europe, only 28% of patients treated for type 2 diabetes achieved good controlled glucose levels (WHO.gov, 2003). The study stated that the control of diabetes requires more than consumption of medicine, suggesting that change of diet, monitoring of blood levels and eye examinations are required. In contrast, the study noted that in the United States<2% of adults with diabetes performed the full level of care as reported by the American Diabetes Association; among one of the reasons for this was economic costs (WHO.org, 2014).

United States Reimportation Bill (2000)

Competing proposals to aid Medicare beneficiaries pay for medicine (Dewar, 2002) is an ongoing discussion. The process of allowing drugs produced in the United States, to be shipped out of the country and returning to its origin (reimportation) remains elusive in today's healthcare system. Current legislation remains inactive and necessitates certification from the

Health and Human Services Secretary (HHS). Until such processes, the United States will be devoid of cost benefits and savings to the healthcare system from a national reimportation policy.

Federal Drug Administration/Federal Ruling

Several safety concerns are noted within the import revision of the Federal Food, Drug, and Cosmetic Act (FFDCA) that vigorously limit types of drugs that can be imported into the United States. Several concerns from the FDA exist; for example it is unclear whether overseas pharmacies exporting prescription drugs would follow the United States' federal laws that protect privacy. Under any proposed mandate, states have no mechanism in place to ensure foreign pharmacy compliances, thus physicians, pharmacists, and patients are unable to judge properly whether products are safe and effective (FDA, 2014).

The FDA is also concerned with labeling of products and a lack of logistical recall procedures in place; there are no practices to ensure that only FDA approved products are shipped. Several other concerns are listed, and discussions for each can be quite overwhelming yet many believe that now is the time to take a closer look at reimportation.

United States Pharmaceutical Industry/Intellectual Property

Arfwedson (2014) suggested that reimportation is the protocol whereby drugs are protected by intellectual property rights (IPR); for example patents, copyright or trademark) and these drugs are placed into market circulation and then reimported to another market (without authorization of owner). The argument extends to both sides of the aisles with some stating that the reimportation undermines intellectual property that decreases re-investment opportunities; while others state the decreasing cost of reimportation drugs benefits their citizens. Intellectual

property rights (IPR) (although limited) are conveyed by the state for certain ideas, expressions-products of intellect.

Because IPR is conveyed by state mandates, their existence has limited barriers that are bound by a geographic barrier. But many states implement "principle of national exhaustion" that states IPR holder's rights are extinct upon first sale within national borders. In contrast, international exhaustion terminates rights upon first sale anywhere and reimportation may not be excluded (Arfwedson, 2014). Exhaustion policies vary in many ways and within different countries.

In the United States, the first sale mantra applies when purchased outside a vertical distribution chain (Thomas, 2007). Reimportation of pharmaceutical drugs are admissible, in order to block and trademark owner needs to show that imports are not identical in quality to the original products. Currently, there is no legally binding global consensus pertaining to exhaustion of intellectual properties. The closest concept we have to a global agreement is the Trade-Related Aspects of Intellectual Property Rights (TRIPS) that is govern by the World Trade Organization; TRIPS provides very limited intellectual rights standards therefore limited protection (WHO.org, 2014).

Pharmaceutical Lobbyist-Opposition

With such large profits, it is no surprise to see drug companies in opposition for new policies that would infringe upon their closed markets. Hess (2002) indicated that The Pharmaceutical Research and Manufacturer of America (PHrMA) has voiced its opposition to reimportation. He (Hess, 2002) also stated that the drug industry has spent well over $40 million to dispute new legislations that could promote reimportation. Senator DeLauro (D-Conn) stated

that current policies allows drug manufacturers a way around the processes that undermines the entire system (Hess, 2002) due in part to having a strong representation (lobbyist group) assembled in Washington D.C.

Reimportation National Stance-In Favor

Reimportation of prescription drugs continues to gain national support at various political levels; a system called reimportation due to many products origins and is produced in one locale (country), shipped to another locale (outside the country) and is then returned to original locale where it is sold at a discounted price. Broader reimportation legislation was addressed yet one caveat to this legislation (within the body of the policy) was that it must be certified by a sitting Human Health Secretary (HHS). Former Human Health Secretary Donna Shalala did not certify it therefore (reimportation policies) never took effect (Lueck, 2002); there exist an inactive, non-enforceable law on the books as it relates to reimportation. Many Americans fail to realize that such a bill exist and was (also) signed by former President George Bush but again certification from then Secretary of Health and Human Services Tommy Thompson eluded the process and the non-certified process has repeated up to current day thus, no national reimportation policy.

Arias (2003) stated that Canadian processes for labeling, distribution and handling prescription drugs are safe and also stated that in many instances the process was even safer than the United States. Outspoken leaders from both sides of the aisle agree that safety must come first. Arias (2003) noted that the cost comparison of drugs between Canada and the United States are quite substantial. Several leading companies in the private sector are advocates for such measures, for example, The America Association of Retired Persons (AARP) has long favored

reimportation as they showed support for a bipartisan bill introduced by Senators Snowe (R-ME) and Senator Stabenow (D-MI) (Moscovitch, 2011).

One of the largest pharmaceutical retail distributors (CVS) has also indicated support for reimportation. CVS (based in Rhode Island) operates over 4,100 pharmacies nationwide; they were the first major drug store chains to support drug reimportation (Ryan, 2004). High ranking officials in many states also have stated their support for this matter and some 20 state attorneys' general in various regions has indicated high support for drug reimportation. Other supported documentation has been established by Representative Ron Paul, his bill indicates a possible savings of nearly $20 billion from the Congressional Budget Office with the implementation of drug reimportation (Congress.gov, 2014).

DeAgostino (2004) stated that a reimportation bill would pose no safety risk and that the reimportation in Europe is very common and safe; facts indicate that reimportation of drugs has been done for over 20 years in Europe. The United States' healthcare system has made attempts to soften the high price of medication but to no avail. Democrat Kernan and Republican Daniels support drug reimportation if the government is unable or unwilling to curb high prices.

Because of high prices, many cities throughout the nation are considering looking to Canada for prescription drugs. Boston Mayor Thomas Menino announced a pilot program that will lower cost of over 7,100 employees and retirees of the state (Austin American-Statesman, 2003). The state of Minnesota is setting up a website while West Virginia and Illinois look to reach out to Canadian brokers as well.

Reimportation National Stance-Against

There is no shortage of contrasting voices on reimportation, many officials have a common say in the matter and safety is the main concern. Former Department Health and Human Services Secretary Tommy Thompson stated that he could not vouch for the safety of drug imports and felt that any savings would be limited (Dalmia, 2003). Further discussion suggests that removing protection barriers for drugs could invite U.S. patients to counterfeit, dangerous medicines, and adulterated drug products (PR Newswire, 2000). For every region of political representation there are those who oppose reimportation; many political officials echoing the voices of the people in their political regions.

Safety concerns continue to block efforts to streamline drug reimportation programs Arias, (2004). Officials agree that safety must come first when purchasing prescription drugs. Speaking to the U.S. Newswire Dr. Matthews stated reimportation is a safety issue but also suggested that it is a job issue as well. Local communities across America would suffer due to the outsourcing effects reimportation has on local economies.

Reimportation-Maine's Stance

Under Maine's Labor, Commerce, Research and Economic Development distributed by direction of the Secretary of the Senate the state of Maine Senate 126th Legislature First Regular Session implemented "An Act To Facilitate the Personal Importations of Prescription Drugs from International Mail Order Prescription Pharmacies" (Maine.gov, 2014); in short, this is Maine's, reimportation policy. The first in the nation to allow its citizens to import prescription drugs from foreign markets.

Many are inclined to assume that the drugs are coming in from Canada (solely) but this legislature allows for imports from Northern Ireland, United Kingdom of Great Britain, New Zealand , and The Commonwealth of Australia that meet that country's regulatory and statutory requirements (Maine.gov, 2014). Maine has stepped into the forefront as it battles the increase cost of prescription medications. Along with this new policy other programs have been implemented to aid the cause. "Health Maine Prescriptions" utilizes the purchasing power of Medicaid to give up to 25% discount to lower income individuals (Toner, 2002); Maine is ground zero but this is a national issue. Surprisingly there are advocates on both sides of the aisle. Pugh (2004) stated Republicans find the idea appealing, and the number is growing who support reimportation.

Patient Non-Adherence

Basskin (1998) suggested one should consider asking several questions to get to the root of the cause of non-adherence. For example, is the reason for nonadherence preventable or avoidable? Does improving compliance improve outcomes? To what degree does a specific intervention improve adherence and is the intervention cost effective? Patients have an ongoing responsibility to seek help and to confide with their physician/providers to help quail this problem.

The additional consequences of nonadherence with prescription drugs are documented by many studies. Frost & Sullivan (2006) has indicated that in the United States patients' compliance with long term pharmaceuticals medication has an average of only 50 percent; estimation of nonadherence to pharmaceutical medication causes nearly 125,000 deaths per year. Also, according to Frost & Sullivan (2006), approximately 10% of hospital admissions and an

estimated 23% of patients in a nursing-home are due to drug nonadherence. Some one-third of all drug prescriptions are never filled, and more than (50%) of prescriptions that are filled are incorrectly administered.

The results of poor adherence are seen as the burden of chronic illnesses increases worldwide. The outcome of poor adherence to long-term treatments results in poor health outcomes while increasing the cost. Improving adherence also enhances the safety of the consumer. Effectiveness of adherence could possibly have increase implications health-conditions of the population than any other medical treatment; as a nation, health systems must step up to the occasion (WHO.org, 2003).

Compliance vs. Adherence

The new preferred term is *adherence* although often interchangeable with compliance a more definitive reference has been established for the terms. Compliance (original term) implied that patients following doctors orders. Adherence (appearing later in literature) refers to active patient participation and a doctor-patient partnership (Karmel, 2005) - this term allows for patients to assume more responsibility for their care.

Adherence Measurements

Throughout many years non-adherence of 25% or greater have been monitored and measured through patient self-reporting, reports of prescription refilling, electronic monitoring, and with open-ended questions to patients (hoping for truthful responses). The World Health Organization (WHO, 2003) suggested one measurement approach is to ask providers on adherence behaviors, but there seems to be a tendency to overestimate their adherence. Simply counting remaining tablets can be performed at the clinic however inaccurate counting is very

common. The WHO states that there are no definitive ways to assess specific behaviors that are reliable to predict adherence.

Patients Who Fill and Not Filling Prescriptions

Several studies suggest that senior citizens are having the most trouble with adherence of their medication regimen. A study performed by Shah, Desai, Gajjar and Shah (2013) of 200 geriatric patients (of various outpatient departments) suggested lower socioeconomic status, complex drug regimens along with the duration of the treatment significantly contribute to senior citizen's nonadherence conduct. The research also stated the lack of education is a huge contribution factor; a United Kingdom study also reflected the importance of education intervention. Nordqvist (2011) noted an increase in drug cost has taken place along with a population increasing in age that has lead to significant financial burden to those needing medication.

Combined with high employment and increase insurance payouts by employees, coupled with many non-insurers many Americans under the age of 65 find themselves in the same predicament.

Medicare Part D

The Medicare Prescription Drug Improvement and Modernization Act 2003 (MMA) represented a greater expansion of benefits to over 42 million senior citizens. Activated in 2006, the program gave access to prescription drug benefit (Part D). The program gave rise for the need of improved drug coverage and opportunities to mitigate increase drug costs.

Five key elements for Medicare were realized in recent years, information obtained from a 2003 national survey conducted by Saran, Neuman, Schoen, Kitchman, Wilson, Cooper,

Chang, and Rogers resulted in the importance of prescription medicine in the healthcare system of the United States and the effects it has on elderly citizens. Secondly, the United States has over 40 percent of low-income citizens who lack insurance in several states. Third, Medicaid has had a positive role and moving patients over to the new Part D plans is essential; forth we see that not all plans are equal and that variances exists from state to state that requires extensive education, outreach and enrollment strategies (Saran et al., 2003).

Finally, the increased rates of nonadherence to prescription medications due to costs and other factors indicates that the new Part D plan may be of benefit in this matter in limited form but other nonadherence factors may need to be addressed via doctor/patient interactions and on a larger scale within the healthcare system (Saran et al., 2003). In a Consumer Report's survey (2012), 62% (<65 y/o) declined medical test due to cost, 45% skipped filling a prescription due to high cost, 63% put off doctor's appointments and 51% skipped a medical procedure; over 81% of the individuals said they had done at least one of these steps due to financial burdens (Morran, 2012). One finding from the survey was that many consumers did not confide with professionals who could aid them. For example, the physician could have provided sample medication or offered coupon incentives from the drug manufacturer. Medicare is the largest purchaser of drugs in the world's largest market. By law, Medicare is prohibited to locate better prices. Getting Medicare to seek more affordable pricing would save the federal government $137 billion over a ten year period, according to the Congressional Budget office (journalinquirer.com, 2013).

Preventive Healthcare

Public health and preventive medicine is guided by preventing diseases, promoting health, and managing the health of the community and populations. Health officials combine

public health skills, population, and knowledge of primary, secondary, and tertiary prevention-oriented clinical practices in various settings (theabpm.org, 2014). Increase patient drug adherence can provide a better outcome that can better reduce the chronic aspect of a disease; decreasing the more serious characteristics of long-term diseases; thus, overall healthcare savings would be seen having a better outcome for the patient (theabpm.org, 2014).

Another factor is patient/provider partnership-the extent in that patients and providers agree, adherence requires the patient to believe there is a beneficial component to taking medication; there cannot be any barriers and open communication is important, this comes only with time (AmericanCollegeofPrevention.org, 2014).

Pharmaceutical Drug Cost Determinants

Determinants of drug cost from originator branded drugs across various regulatory setting and health care systems differ in many ways. For example, release date of the drug can play a significant role in pricing along with patent status and marketing techniques (Kanavos, Vandoros, 2011). Distribution margins for generics and new medication hitting the market contribute to price formation throughout the country as well.

Kanavos, Vandoros (2011) stated exchange rates of countries and the volatility of the market can make a grave difference on pricing. But in the United States one must not forget about taxes and logistical factors that inflate pricing. Prices of branded medication do not necessarily decrease because of exhausted patents and the release of generic drugs.

Reasons for High Cost

Many reasons can account for high drug cost in the United States; it is heavily documented that the pharmaceutical industry is allowed to set their prices (no government price

regulations). Zall (2001) noted Pharmaceutical companies intend to recover their entire costs and produce a profit. In order to recoup all the costs associated with research and development along with marketing, pharmaceutical companies will charge what the market can bear; that market is the consumers they serve. For example, mass advertising is fairly new, the process seems to be designed to appeal directly to consumers. The nation's pharmaceutical companies spent $1.3 billion in previous years and recouped the cost in sales (Lancaster New Era, 1999). The Lancaster Business Group on Health stated that increases in insurance premium along with increase co-pays contribute to this issue as well; most companies saw a 12-20 percent increase that will continue to rise.

Swatz (1995) stated that the very high cost of research and development that exceeds $350 million per drug is why companies insist on 20 years patent protection, this helps drug companies to hold on to the drug and recoup costs. Kana, Ferrario, Vandoros & Anderson (2013) suggested that US per capita pharmaceutical spending has a rapid uptake of newer and pricier drugs in the United States in comparison to other countries. Simply put other countries require drug companies to provide strict evidence of the value of the new drug, the United States does not. Paul, Chandra & Lambrinos (2006) suggested that insurance has made drugs more affordable thus, increased the consumption and cost of pharmaceutical drugs.

Long-term Healthcare Cost

Lueck (2002) wrote that Americans could have saved $38 billion in 2001 if Americans were allowed to make prescription drug purchases from Canada. Quon, Firszt, & Eisenberg (2005) performed a comparison of 44 brand drugs to the Canadian markets and concluded that Americans can save a mean of 24% if drugs were purchased from Canadian internet pharmacies;

stating that brand drugs are substantially less expensive. Savings is a two-fold concept in that direct purchases contribute significantly to healthcare savings and the affordability would lead to an adherence factor that would increase better living conditions and decrease the chance of diseases elevating to a worst state.

If one was to consider nonadherence alone, Frost & Sullivan (2006) suggested that nonadherence contributes to $100 billion (direct cost) to the United States' health care system. Indirectly costs exceed $1.5 billion yearly due to the lost of patients' earnings and unrecoverable productivity ($50 billion). The nature of this issue has prompted the National Council on Patient Information and Education (NCPIE) to term nonadherence as "America's other drug problem".

Adherence Comparison; Canada vs. USA

Although the emphasis is on drug prices in the United States, we see problems in other nations having similar healthcare issues to tackle. In the United States and Canada patients having trouble funding their medication drugs are more likely not to adhere thus, risking increase illnesses and death while increasing healthcare cost (Kennedy & Morgan, 2006).

Kennedy & Morgan, (2006) indicated in a joint Canada and United States survey (2002-2003) by the Statistics Canada (Ottawa, Ontario, Canada) and The U.S. National Center for Health Statistics (Hyattsville, Maryland) consisting of 3,505 citizens in Canada and 5,183 in the United States reported that residents of Canada are less likely to report cost-associated nonadherence (5.1% vs. 9.9; $P< 0.001$). The report goes on to say that Americans having no insurance (28.2%) and Americans & Canadians with no prescription coverage (16.2%) were more likely to report cost-related nonadherence. The conclusion of the survey stated the general r

cost-associated nonadherence is greatly higher in the USA (even with the availability of health insurance and pharmaceutical coverage (Kennedy, Morgan, 2006).

Drug Tiers

Regardless of the paying entity such as private insurance company, Medicare, Tricare, Medicaid and other programs they all maintain a list of pharmaceutical drugs that they will pay out known as formulary. Formularies are comprised of prescription drugs, generic drugs, and often times over-the-counter medication (OTC) that were prescribed. It (formulary) is structured in such that they vary in co-payments. Torrey (2014) gave a summation of Tiers 1, 2, 3 & 4:

Tier 1 or (I): Drugs are limited to generic brands- they are the lowest price drugs. Many lower prices branded drugs fall into this tier. Tier I drugs co-pays range from $10 to $25.

Tier 2 or (II): This tier usually consists of branded name drugs and/or more expensive generics. Tier II drugs have value co-pay, ranging from$15 to $50.

Tier 3 or (III): For more expensive brand name drugs, (most often not the first choice for your insurance company because of increase cost) they are also known as non-preferred. Tier III drugs cost are more than the lower tiers, having a range of $25 to $75 co-pay.

Tier 4 or (IV): Known as specialty drugs: newly approved pharmaceutical drugs, and are so expensive that insurance companies will discourage patients from obtaining these prescriptions drug. Tier IV is a newer designation, initiated in 2009; tier IV designation seems to categorize all other expensive drugs. Co-pays are assigned a percentage and not a dollar amount.

Motheral & Fairman (2001) suggested that the three-tier drug co-pays can control cost without confirmation of changes in other regions of medical resources.

Generic Drug Benefits

Many costs saving measures have been attempted to ease the cost of drugs. Physicians often give out sample drugs to individuals who are having trouble paying for their prescriptions. Pharmaceutical companies have initiated programs to assist consumers who by high cost are burden. The government has even stepped in to promote generic drug production while decreasing the time to get generic drugs to market.

The Hatch-Waxman Act also known as the Drug Price Competition and Patent Term Restoration Act of 1984 is the most enhance drug-related legislation linked to the pharmaceutical and healthcare industries since the early 1960's. This act made it faster and easier to bring generic prescription drugs to market by mandating the FDA to only look at bioavailability studies in order to approve the drug known as the Abbreviated New Drug Application (ANDA). ANDA allows a 30-month cooling off period for challenges of patent infringements (NAPSRx, 2013). This measure helped encouraged the increase of generic drugs over branded drugs, faster development, along with quicker delivery to consumers.

Dr. Emanuel (2012) stated that the cost savings can be achieved by substitution (using) generic drugs. During the years of 2004 to 2009, the use of generic drugs for branded drugs increased to 75% from previously 57%. In 2010, the United States spent an estimated $262 billion of prescription drugs equating to approximately 10% of total healthcare expense $2.6 trillion (WHO.org, 2014).

Contrasting Markets Using the European Pharmaceutical Industry

For every aspect of this issue (reimportation) the United States should look beyond its borders and be willing to adopt portions of legislation (from other nations) that

eliminate unproductive outcomes and promote better quality of life; this is in alignment with the theoretical framework of Lewin's organizations change theory that this research has adopted. Contrasting this market is important for United States' officials to see that an existing reimportation model does exist. The European program also reassures the public that no pandemic or epidemic is occurring as it relates to reimportation of drugs (known as parallel imports in Europe) lending a sense of security and safety to the masses.

It is significant to note the tremendous savings has been afforded to the European healthcare system. Replication of this process is possible in the United States with slight modifications that suites the demographics population and the U.S. healthcare structure. In other words, there is no need to develop a process from infantile stages when a fairly workable model exists. It is important to observe the components of their (Europe's) structure, pricing policies, and price control strategies.

In the past two decades or so expenditures on pharmaceutical drugs and other healthcare costs have increased faster than gross national product of all European nations (Ganslandt & Maskus 2004). European policies are multidimensional and accounts for issues of public expenditure, public health, and pharmaceutical incentives. Consumption patterns and various pricing levels determine the total expenditure that varies across the various European nations.

Ganslandt & Maskus (2004), stated pricing policies are generated by product price control, reference pricing and profit controls. Product pricing control is use in determining the prices of medication. The vast difference was the introduction of Single European Pharmaceutical Market that implemented parallel imports (Ganslandt & Maskus 2004). Similar to the U.S. market several practices have been put into place to control cost of patients' expense.

The uses of generic drugs are encouraged, also providing a listing of drugs that are reimbursable (positive list) or a negative list (one that does not reimburse) including the co-payments of each drug.

Due to the Single European Market structure it is not surprising to know that countries reimport drugs from each other all the time. Using data from a Sweden research, prices from parallel imports decreased in comparison to other drugs over the time period of 1994-1999 suggesting parallel imports (reimportation) decreasing manufactured cost by 12-19% indicating a saving can be passed on to patients (Journal of Health Economics, 2004).

Political Aspect-Congress

Klein (2014) suggested that many people feel the Affordable Care Act (Obamacare) may hold the pharmaceutical industry more in line, give the government some leverage of drug pricing, and allow for reimportation of drugs from Canada. Congress has spoken out on many occasions; with rhetoric from both aisles the 113th Congress talked about Medicare cuts. They suggested that billions of dollars could be saved over the next decade if new policies were implemented. They suggested putting Medicare drug out for bidding, allowing reimportation of safe drugs and banning "pay for delay" of generic drugs.

The Preserve Access to Affordable Generics Act of 2013-2014 would end brand name pharmaceutical companies from keeping equivalent generic brands off the market pay for delay. Yates (2013) suggested reintroduction of Senate Bill-319 (S-319 of the 112th Congress); sponsored by Senator Snowe (Republican-Maine).The bill will revise provisions governing the reimportation of prescription drugs (Congress.gov, 2014). Several senators from northern states are pushing for new policies; the lawmaker's bill gives permission for U.S. pharmacies and

wholesalers to resell and buy medication from Canada. Proximity to Canada seems to be one indicator for these northern states pushing for new legislation.

Federalism

Implementation of such federal policies will require dialog from both state and federal officials. Federalism in the United States evolves relationships between state and federal governments of the United States; the American government has evolved from a dual federalism system to one of associative federalism (Cornelllaw.edu, 2014). This arrangement has various agents, departments, and trustees of the people constituted with various levels of power. It is a political concept that has a group of members bounded together by a covenant. The term is frequently referred to as a level of sovereignty.

In order to improve the plight of patients and improve patient adherence no one single component will do. When coupled with other programs and policies, reimportation could aid the situation and allow researchers, physician (and others) to address patient adherence. But first, there must be a new order of federalism (a system of government in which the same territory is controlled by two levels of government Cornelllaw.edu, 2014) that will conform to both state and federal levels of government that will give more sovereignty without repercussions. This increase power of freedom would allow state levels to take the bold, rogue steps to improve healthcare accessibility to drugs as seen in Maine.

Better quality of life has always been the agenda and consideration in pharmaceutical development. It is quite difficult to see the effects if patients are non-adherent. Dr. Kweder (retired deputy director of the FDA) stated medication can't work unless it is taken (FDA.gov, 2014). The largest world markets of pharmaceuticals (United States, Western Europe, Japan-

respectfully) all suffer from a market-place that lacks standardization; this fact contributes to the complexity of the pharmaceutical enterprise.

As the leader of the world in many aspects, the United States should take the lead at standardization, development and affordability; thereby new policies are needed. Converting to a pharmaceutical structure seen in Europe may have many benefits; the parallel import reimportation structure has worked for over two decades.

Summary

Literature on non-compliance of patients having various chronic diseases has revealed that the cost is a common theme. Although other factors come to light, several research studies and surveys have concluded that the cost related non-adherence is a major concern.

The literature review also demonstrated that many voices exist on the topic of reimportation of pharmaceutical drugs. Research variables "reimportation" and "patient adherence" is null within the literature review. Because of the opportunity occurring in Maine, these variables can now be addressed. An important component to this exploration while underlining a fluid, adaptive approach is the theoretical framework. Lewin's (1947) theory of organizational change is a solid approach to what is needed for reimportation adaptation. A smooth, transient mindset change can be achieved with Lewin's organizational change; with emphasis on unfreezing, change, and the freezing approach. This approach allows for releasing insufficient processes, making a change to a more sufficient process (or policies) and then locking those new changes into place.

Millions of low-income individuals and senior citizens (with fixed income) cannot afford the high price of their drugs as evidenced by a 2013 Commonwealth Fund study that stated 50

million Americans did not fill a prescription due to high costs in 2012 (Hamburg, 2014). Thus, patient non-adherence will continue until a series of resolutions are identified and executed.

Contributing to this research was a qualitative, grounded theory approach. This methodology aimed to get a better understanding through field experiences, truthful data collection, along with accurate conversation feedback (validation-member checking process). It strived to comprehend how the informants derive meaning from their experiences, and how these experiences influence their behavior (Creswell, 2007). Chapter 3 outlined how this research was conducted and described in depth the qualitative methodology used to conduct this research.

Chapter 3: Methodology

Introduction

After a review of the literature this study focused on two variables: reimportation of pharmaceutical drugs and cost-related non-adherence (CRA). Several factors contribute to non-adherence of patients' drug regimen, but cost is relevant to many senior citizens and individuals with chronic diseases. Briesacher, Soumerai &Gurwitz (2007) suggested that many links exist between prescription drug nonadherence because of the high cost and social economics, but due to depression and other diseases. The literature is null as it relates to reimportation of drugs and increasing patients' adherence for patients with a chronic disease. Kurlander, Kerr, Krein, Heisler & Piette (2009) stated that patients who do not comply with their medications for chronic pain seem to stem from pressures of their economic status, where other patients who selectively reduce their regimens are driven by their own perceptions, personal beliefs, and moods.

A better understanding of reimportation and adherence is required to improve the plight of patients with chronic diseases. Therefore, it is important to obtain data from a population (within the United States) who can legally obtain prescription drugs without clandestine efforts. Qualitative method and grounded theory were selected for this research in order to determine the effectiveness of the reimportation policy. The chapter described the rationale for utilizing grounded theory, qualitative paradigms, complete description of the design, the sample demographics (population), descriptive of the data collection methods, grounded theory protocol and ethical consideration for participant's protection.

Research Design and Rationale

Reimportation drugs are developed, produced and bottled in the same exact facilities as domestic drugs, with the exact same labeling. Many people find it quite difficult that the Food and Drug Administration (FDA) cannot create logistic safeguards to ensure that this process could be undertaken in the United States. Dayen (2009) suspects a more sinister reason as he suggested that any reimportation implementation would void the pharmaceutical industry's backroom deal with Senate Finance Committee Chair (Max Baucus) and the White House, which limited the drug industry's exposure to "losses". This deal was set at $80 billion dollars over a ten-year lifespan. Therefore, we have cost-related nonadherence due to the pharmaceutical industry's proclivity towards profits.

I selected the grounded theory approach to determine the effectiveness of the reimportation policy within the study population (Maine) and to gain knowledge of the perception of this policy on said population. The grounded theory design and qualitative method are appropriate as suggested by its paradigm of advocacy and participatory characteristics. Creswell (2008) suggested that this worldview "needs to be intertwined with politics and a political agenda" (p.9) thereby having an action agenda for reform.

Role of the Researcher

Rudestam & Newton (2001) noted that data gathered from qualitative research is compiled from various tools: questionnaires, interviews, personal knowledge, audio recordings and documents of previous scholars. Researchers then proceed to review the data obtained from these many sources; throughout the process categories (primary) and additional categories are

generated, and the creation of theories are introduced. Creswell (2007) states that assumptions, worldviews, bias about the study and the participant pool should be established initially.

Creswell (2008) noted that qualitative researchers play the primary role as a tool in data collection they embark personal values, biases and assumptions prior to the study. In this research project, data was recorded from open-ended and close-ended interviews and questionnaires with participants. This form of recording was provided via electronic digital recording and note taking. I developed and designed the questionnaire/interview questions to address the following research questions:

RQ1: How does a reimportation of prescription drug policy contribute to patients' drug adherence?

RQ2: What perceptions do patients have about reimportation drugs as related to a chronic disease?

RQ3: What are the perceptions of key providers (physicians, physician assistants & nurse practitioners) regarding the impact of reimportation drug laws on patient medication adherents?

Pilot Study

A feasibility study (pilot study) was performed to determine the appropriateness of the interview questions in order to yield a refinement component for better understanding and foster responses that are necessary to answer the research questions. This study took place one day prior to the actual research start date. The participants in this study yielded data that was not utilized in the data analysis process. Conducting this feasibility study does not necessarily guarantee success within this exploration, but could increase the likelihood of success. It is the

desire of this feasibility study to fulfill a series of important functions that can yield valuable insight for the primary exploration.

Bias Interpretations

Bias in qualitative research is a problematic concept, because qualitative researchers are part of the process, and researchers vary in style and approach. The human element has been stated to be the greatest weakness and the greatest strength of a qualitative method. Qualitative research mandates explicit acknowledgement of bias, in contrast quantitative attempts to eliminate bias completely. This research has bias components as well and must be declared. This declaration is noted due to the confinement of all the fieldwork to one geographic location, suggesting that other major markets are not represented. The uniqueness of this study requires a sampling population of one locale (the state of Maine). This state is the only locale that can provide the participant pool needed to execute said study because of new state policies for reimportation. All participants were pooled from this region.

The research also notes bias within the educational and socioeconomic realm. The study does not make any assertions of patients' level of education on reimportation, pharmaceutical drugs, and non-adherence levels. Thus, higher educated participants with knowledge of reimportation, the pharmaceutical industry, and patients' non-adherence could be excluded from the study. Also, since a major component of the research is related to cost-related issues, one can assume that socioeconomic factors play a significant role of the participants. Therefore, the more affluent population may not be represented adequately in this study; income levels of these participants are not a delimitation factor to this research.

Ethical Considerations

The research project has conformed to all mandated requirements of Walden University and Walden Institutional Review Board (IRB). I (as a researcher) "respected the rights, values, needs, and desires of the informants" (Creswell, 2008, p.198). Articulation of the identity of the study, the role of the research, and risks (if any) was given to all informants. Informants were informed that all data collected will be kept in confidence and that they would not be identified by first or last name. The informants were informed that their responses will only be seen and reviewed by the researcher.

Informants were briefed on the importance of their rights to refuse to participate and that they are under no distress or pressure to participate. Articulation to participants (patients) stated that a small monetary (gift card) was being offered for their participation efforts by the researcher. No incentives were negotiated with any institution. It was articulated that participating in this research is strictly volunteer. Written permission from informants to proceed with the study was received and documented. For those who choose to participate, they were told at any time they could exit the project and it was solely their right to do so without any repercussions. For any individuals (on site) who volunteered and assist in any manner, it was articulated that protecting the informant's data is of priority in this research study and a sign confidentiality agreement was required. For any follow-up concerns (i.e. validation, credibility) informants were handed a participation identification number in such that their questionnaire and interview responses will match the informant.

Sample and Setting

Sampling (in general) is a complex topic. Determining the appropriate number of subject is one complexing aspect of sampling. Creswell (2007) states that an adequate number range for a qualitative method consists of 10-30 informants; cost and time are important factors when considering sample size. The sample size in this research (20 participants) is needed to develop a well-saturated theory and is suitable for smaller participant pools (Charmaz, 2006). The theoretical saturation consist of qualitative data analysis that have continued sampling and analyzing of data to the point that no new data is identified and other concepts in the theory are well identified and developed (Morse, 2007). Concepts and linkages have formed a theory and verification (member checking) have been performed. This inductive analytical approach concludes that no aspects of the theory remain hypothetical. Morse (2007) goes on to state that all conceptual boundaries are marked. Allied concepts have surfaced, documented, and delineated. Theoretical saturation is the belief of theoretical sensitivity; this assumption of theoretical sensitivity is that data analysis is driven by the data collected.

The research atmosphere and settings are important components as they set the tone of the research. For example, this research conducted research interviews on location in the state of Maine; the logic behind this was that (participants) would feel the research is for official business and provides a sense of comfort.

Informants were selected based on their ability to contribute to this research while seeking a threshold of saturation (Creswell, 2007). This research reached out to a sector within the state of Maine that uses reimportation drugs and who are familiar with this policy. This study attempted to use the various sectors of the city of Portland, Maine for patients and the

entire state for providers. Healthcare providers were selected via social media and they provided their inputs. Patients were selected based on their interest from a poster. Also, patients were approached and solicited (fact-to-face) for their help to this research.

When utilizing these providers it was the desire to encompass certain characteristics of the providers. Since the interview questions have been designed specifically for the providers and patients, it was important to have a manageable working relationship with the patients (from the view point of the providers). Although the providers make up 50% of the participant pool they have access (and will give their perceptions) to several patients; thereby rendering valuable information (indirectly) about patients' plight. In order for them to share this information, they should process the ability to listen well resulting in a nonjudgmental approach. Strong doctor-patient relationship was needed for the sake of trust, respect and partnerships are a desired trait as well. These characteristic components can influence the analytical process.

Patients and providers were called upon via email, social media and telephone conversations before traveling to various site locations in Maine. Once these individuals were identified it was necessary to invite them to the research study. Providers responded 100% via email and social media. I formulated an email containing the research information and attached a consent form and questionnaire and sent out to providers who met the criteria. The identity of the study along with their rights was also articulated. Those accepting this opportunity signed and returned the consent forms. Charmaz (2006) suggested that the focus of the research is the ultimate driver of the project design, and the size of sample population. It is suggested that a smaller studies with modest claims can achieve saturation sooner verses a study that is focused on the process that spans disciplines.

Methodology

A qualitative research study using grounded theory as the design was selected for this project due to (a) literature review yielded deficits in data for reimportation and the effects on patients' adherence, and (b) grounded theory affords researchers the opportunity to compile a theory (Creswell, 2008). In contrast to quantitative who employ experimental/quasi-experimental design that often controls the outcome of the research while restricting the focus of attention (Rudestam & Newton, 2001). Patton (2002) suggested that quantitative methods have the possibility of not capturing the total dynamics of the responses from the participants or how the project affects the participants. According to Buckley & Waring (2009), researchers benefit from the qualitative approach because it allows nuances of languages and behaviors to be detected that can contribute to a qualitative approach often select nonrandom sampling that yields inferences from the research as it relates to the whole population (Creswell, 2008). This research study benefited from the use of convenience sampling, making a qualitative approach more appropriate. (Rudestam & Newton, 2001) stated that there is no national standard approach within social sciences "although a common understanding that chosen methods of inquiry must rest on rational justification" (p.23). Patton (2002) observed that qualitative methods (grounded theory) often produce significant details about smaller number of participants therefore, I rejected ethnographic method because it required a large culture group setting that requires researchers interpretations.

Case study was not a proper fit due to the limited number of participant's need to describe their experiences at a specific time (Creswell, 2008) and because of the individual responses desired. I looked at the perceptions of this population with efforts concentrated on

several participants at various junctures thus the narrative approach was not selected due to the writing experiences of a single individual and the creation of a narrative story line that described those events. The various past experiences and different backgrounds that are sought in this study requires an individuality approach; the interpretations of the phenomenological approach would not be appropriate as "shared beliefs" (Creswell, 2008) of the participants is the focus-therefore rejected.

Qualitative approach was designed and developed in 1967 by researchers B. Glaser and A. Strauss (sociologist) who beliefs consist that theories should be "grounded" and have a genesis in the field. This method required a theory of interactions, and actions based on data collected from the participants (Creswell, 2007). They also stated a revision to constructivist grounded theory in which individuals construct both the phenomenon and the research process through actions. More recent theorist advocated constructivist grounded theory thereby introducing another perspective onto grounded theory procedures. Patton (2002) noted that a constructivist looks at how variables are grounded, given meaning and how it plays out in participant lives. Constructivist grounded theory gained support with its introduction by K. Charmaz in (2006); yet other viewpoints were supported by A. Clark (2005). She (Clark) relied on postmodern perspectives such as the political nature of research and the interpretation (Creswell, 2007).

Grounded theory has several defining features that may be incorporated into a research project; the researcher must focus on processes that have guided steps overtime thus, grounded theory has movement. Researchers also seek (in the end) to conclude with a theory that may come in many forms. But, in simple terms it (theory) defines the understanding of the data that

was collected. Memoing is integrated as it allows researchers to write down ideas as the data is collected and analyzed; this form of data collection is often in the form of interviewing, questionnaires, focus groups and recorded memos (Patton, 2002). Lastly, data analysis is performed to developed categories that aid the theory process while detailing additional categories in which incorporates inductive style approach (Creswell, 2007). Using inductive approach for analysis (a) processes raw textual data into a succinct summary format; (b) develops clear and concise conceptual links between the evaluation and the summation drawn that is concluded from the raw data; (c) develops a structure of the underlying framework of experiences (Thomas, 2006).

Research Design

According to Denzin and Lincoln (1994), a qualitative study needs the interpretation of a phenomenon within their natural habitats in order to make sense of the meanings informants bring to the research. Qualitative research involves memoing, collecting information, sorting, note taking, and data collection and coding about personal experiences of the informants; this is acquired by interviews, interactions, historical, and visual text which are pivotal moments that have a meaningful component in people's lives.

Patton (2002) defined qualitative research as making an attempt to comprehend various interactions in a situation. While purpose of comprehending is not to predict what may or may not occur, yet rather to make every attempt to comprehend in depth the components of a situation and the meaning that participants contribute during that moment. Qualitative research is the most flexible techniques, it uses a variety of methods and structures that are accepted throughout the research arena; from individual case study to very in depth interviews, these types of studies

demand carefully constructed and planned designs. No standard structures have been adopted; interviews, case studies, and survey designs are the most often used methods.

According to Rudestam & Newton (2001), qualitative design has 10 considerations that researchers should realize; (a) the focus of the inquiry, (b) determine the worldview (paradigm) to focus, (c) determine the fit of paradigm to the substantive theory, (d) one must decide on where and from all data will be collected, (e) is there a need for additional phases of the inquiry, (f) what instrument(s) will be used, (g) data collection and recording codes, (h) data analysis process, (i) planning the logistics, and finally (j) plan for the validity process.

Several advantages are seen with qualitative techniques. Qualitative is quite useful when subjects are too complex, and no simple yes or no hypothesis can be discerned. They (qualitative) designs are easier to plan and execute. Many feel they are useful when financial decisions have to be considered. Within a broader view qualitative designs often succeed in generating useful information in contrast to quantitative; it (quantitative) can generate an unproved hypothesis resulting in valuable time and resources being wasted (Shuttleworth, 2008). There exist smaller sample groups with qualitative because it is not necessary to rely upon sample sizes with qualitative.

Qualitative is not perfect; researchers must realize at very early stages that a lot of careful thought planning is required (Shuttleworth, 2008). One disadvantage of qualitative is that data cannot be statically (mathematically) analyzed in the same comprehensive manner as quantitative; thereby only a general pattern is seen. Qualitative is design for various interpretations due to the open, opinion and judgmental components and duplications are more difficult due to the uniqueness of the design.

Data Collection

All informants were coded with a participation identification number. Demographic profile obtained consisted of: age, race, gender, smoking status, and chronic diseases. All information from patients was collected at the study site in Maine with the exception of one patient. The identity of the study was articulated, and the rights of the patients and providers were given. For example, participation in the research is strictly voluntary and early withdrawal is an option to the participants. All questions at this juncture were addressed. Moving forward, individual interviews were performed. I utilized random sampling; this method increased the credibility of this study. I located healthcare providers in the state of Maine that met the criteria of the research. Providers were located via "Linkedin.com" a profession social media website. The site allowed for identification of occupation, location, and other pertinent information that was needed for selection. Upon reaching out to these professions and befriending them, I was able to send them (directly via their personal email address) a detailed email explaining the research. I also, attached the consent form and the questionnaire to the email. This method allowed for the research to reach various healthcare professionals throughout the entire state of Maine thus, a better representation of healthcare professions were obtained. Those who elected to participate signed and returned the consent form and questionnaire.

The individual interviews for patients were selected instead of a case study (group) because I wanted individuality. For example, I did not desire a response from PT3 to be based on what he or she heard from PT7. Interviews consisted of open and close-ended questions developed by the researcher; as suggested by Creswell (2008) a central question and sub-questions was established. I initially engaged in dialog (ice breakers) in order to get the patients

comfortable with me in their environment. I welcomed all questions related to the research and my credentials. Engagement was be brief not to intrude on normal behavior patterns which could cause a decrease in honesty (Creswell, 2007).

According to Birks, Chapman, & Francis (2008) memoing allows researcher to make conceptual leaps of the raw data to those abstractions that gives explanation of the research within the context that is examined; therefore memoing is applicable to this research project. Electronic recordings of each interview was performed this aided the transcribing process. This research project benefited from face to face (FtF) interviews for several reasons. According to Opdenakker (2006) the interviewer and interviewee can directly have a reaction to what the other does or says. One advantage of this synchronous communication is that answers are more spontaneous from the interviewee. FtF can also aid this research due to social cues that are given off by the interviewee. This method yields the interviewer additional information that can be added to the study (Opdenakker, 2006). A combination of questions being read aloud and informant's responses will comprise the interview process.

Upon completion of the interview process, analyzing and transcribing commenced. This process was performed manually in order to formulate codes, categories, themes, and sub-themes.

Issues of Trustworthiness

Validity of this project will proceed with member checking by sharing the transcripts with the informants. Goldblatt, Karnieli-Miller & Neumann (2011) noted that sharing research findings from a qualitative method with participants, member-checking is perceived as a process

formulated to increase research credibility and informant's involvement. Throughout this process and post interview, informants were given the opportunity to clarify any inaccurate information.

Data Analysis

Data from this research was coded manually and allowed the data to be converted into themes (Creswell, 2007). The research consisted of interview questions consisting of close-ended and open-ended format. Close-ended question consisted of age, gender, race, chronic disease status. These questions contributed to the demographic profile of informants. Also, close-ended questions within the interview questionnaire were formulated. These questions gave substantial support to the overall research project, whilst supporting the research questions. Open-ended questions allowed informants to explore and elaborate on their experiences pre-policy era and post policy era, in the hopes they will convey true personal perceptions, experiences and opinions. According to Throne (2000) data allows qualitative study to stand out with a category of principles, assumptions, values concerning truth, and real life; in contrast, quantitative research that uses the scientific methods to understand reality.

Data retrieved from this research project involved voice responses, informant's reactions, tonations (voice projections) and developed ques to identify and capture non-verbal reactions. All interviews were held individuality. This design allowed the researcher to capture true responses from the informant and decrease the "copy cat" response heard from other informants (often) seen in group or case settings. Retrieved data was safeguarded according to Walden University (IRB) guidelines. Information was (and is) stored on my personal computer, personal cloud (virtual) account (which is password protected) and is safeguarded for future use for a number of years that is applicable to Walden University (IRB) policies.

Creswell (2007) suggested that field notes, interviews be situated in some type of order for the purpose of analyzing. The purpose for this process is to develop core variables to aid the relationship amongst codes and concepts, generate themes and subthemes that will be used to generate a hypothesis. Coding was in three stages; open coding, axial coding and selective coding. Each coding has specific features; categories are formed with open coding, assembly of data in new ways is seen with axial coding, and linking the categories is seen for selective (Creswell, 2007). Persistence, an innovative data-gathering approach, and inquiring mind, can navigate a researcher into undiscovered worlds and provide rich data. The research made every attempt to do this. I validated this research with member checking via repeating informant's statements back to them and allowing for any further corrections and clarifications in order to verify the accuracy. To further validate, I used opposing views and contrasting viewpoints to the themes that manifested.

Several interview questions have been developed and designed to address the three research questions:

RQ1: Does a reimportation prescription drug policy contribute to patient drug adherence?

RQ2: What perceptions do patients have about reimportation drugs as related to a chronic disease (diabetes)?

RQ3: What are the perceptions of key providers (physicians, physician assistants & nurse practitioners) regarding the impact of reimportation drug laws on patient medication adherents?

Two sets of questions were developed and designed in response to the research questions. The first set is designed for the patients (informants) referred to as "Informant Questions" (I.Q.). The next set is designed for the providers (physicians, nurse practitioners, and physician's assistants) referred to as "Providers Questions" (Pro-Q): see appendix.

- The following (I.Q.) were used for research question-1 (RQ1); 1, 2, 3, 4, 5 (see Appendix I).
- The following (I.Q.) were used for research question-2 (RQ2); 6, 7, 8, 9, 10 (see Appendix I).
- The following (I.Q.) were used for research question-3 (RQ3); N/A (see Appendix I).
- The following (PR-Q) were used for research question-1 (RQ1); N/A(see Appendix P).
- The following (PR-Q) were used for research question-2 (RQ2); N/A (see Appendix P).
- The following (PR-Q) were used for research question-3 (RQ3); 1, 2, 3, 4, 5 (see Appendix P).

At the conclusion of this research process, I disclosed data analysis to all appropriate parties and deliver hard copies including a copy to Walden University for publication into ProQuest Dissertations or any other forum within the university.

Summary

This chapter briefly discussed and outlined the design (grounded theory) and the methodology (qualitative) use for this research project. This approach and design method was chosen because of deficiencies in the literature review material and because of the flexibility it provides to informants for their opinions and feelings. Data collection was performed via questionnaires, and interviews. All questions posed to the participants consisted of open and close-ended questions; validation for accuracy was performed by member checking.

Chapter 4 will consist of the research findings, the process in which these findings were acquired

and to analyze data that was discovered from the perspective of the informants in relationship to their questionnaires and interview questions.

Chapter 4: Results

Introduction

The purpose of this research was to investigate one component of patients' non-adherence of prescription drugs cost- related non-adherence (CRA) and research if reimportation of said drugs will have an effect on prescription drug adherence among the American population who have a chronic disease. Two theories were used to navigate this study; a grounded theory approach and Kurt Lewin's organizational change theory. Three research questions were devised from the theories:

RQ1: How does a reimportation prescription drug policy contribute to patients' drug adherence?

RQ2: What perceptions do patients have about reimportation drugs as related to a chronic disease?

RQ3: What are the perceptions of key providers (physicians, nurse practitioners, physician assistants) regarding the impact of reimportation drug laws on patients' medication adherence?

To address these questions, 10 health care providers, and 10 patients were invited to participate in the research. Health care providers who prescribe drugs in the state of Maine consist of physicians, nurse practitioners and physician assistants; these 3 professions made up the health care providers for this research. Patients consisted of individuals who have a chronic disease that warrant refill of prescribing medications. Participants (patients) in the study were diagnosed with several diseases such as diabetes, cancer, thyroid disease, hypertension, high cholesterol and attention deficit disorder. They are currently taking medication for their

conditions. In this chapter, the procedures utilized to ensure quality of the data will be discussed. The population sample of study and methods used to analyze the data will also be discussed. In chapter five, the research findings will be summarized.

Demographics

Upon receiving institutional review board approval from Walden University (Walden University Institutional Review Board (IRB) approval number # 04-22-15-0289886; I contacted several physicians, nurse practitioners, and physician's assistants in the state of Maine. I also reached out to patients via the public forums (social media-Linkedin.com) and from face-to-face encounters upon arrival in Portland, Maine.

All participants were of adult age and met the criteria for the research that included: diagnosed with a chronic disease, monthly medication use, a citizen of the state of Maine, and knowledge of acquiring drugs from non-United States markets. The research yielded a majority of Caucasian ethnicity but also included other ethnicities; a right mixture of males and females were also involved.

Protection of Participants

As the researcher, I approached this exploration with the responsibility of protecting the rights of all participants. This research had a focus to abide by the Health Insurance Portability and Accountability Act (HIPAA) thereby, maintaining complete confidentiality of all data that was collected. The names of all participants were not disclosed. The only identifiers utilized were the conversion of names to patient and provider numbers (for example: PT1, PT2, PT 3… and PR1, PR2, PR3-for providers).

This research consisted of two sets of population sampling (patients and health care providers). Several challenges awaited this process (in relation) to recruitment of candidates from a great distance. I had no previous contact information on participants therefore, I had to develop methods of communication and be creative in locating this specific population sample. I decided to recruit providers first because of the strenuous work schedule I needed ample time to reach them and to acquire their participation; I turned to social media in this effort.

I crafted a brief, detailed statement explaining the research and attached the consent form and questionnaire to an email. This email was sent to several health care professionals in the entire state of Maine. I befriended several individuals on social media website"LinkedIn.com". The social media site provided detail information of individuals that allowed for selections that met the research criteria. For example one is able to see occupation, location, email address, and other pertinent details that allow for selection. After their acceptance, I then sent the email containing consent form and questionnaire. This method of recruitment allowed for multiple providers from various regions of Maine to participate, thereby lending an accurate representation of the health care population within this state. All patients' data collection was performed face-to-face in Portland, Maine. One exception was PT1 who submitted her answers via email. All informants participating in this research agreed to the terms of the research by signing the consent form and returning it with a completed questionnaire. Data collection from participants (both patients and providers) was in the form of email submission, phone interview, and face-to-face interaction.

Researcher as Instrument

Researchers in qualitative methodology research are the primary instrument of the study (Hatch, 2002). To maintain complete neutrality and increase credibility of the study, I scrutinize my attitude and biases initially prior to the study. I also realized that different people have different perspectives, and I must adapt to the participant on an individual basis. This adjustment was needed to maintain consistency within the questioning and follow up process (member checking). I anticipated various responses, gestures and behaviors and accepted answers as they were (with further clarification when needed). I expected to succeed in collecting the data within a particular timeline. And found that the citizens in Maine that I encountered (generally speaking) were very welcoming and eager to help in the name of research.

Data Collection

The research study consisted of 20 participants n=10 (patients), n=10 (providers). Patients answered a 10 question interview/questionnaire survey and providers answered a 5 question interview/questionnaire over a 12-week period. Data collection took place from April 23, 2015, to June 21, 2015. Providers' data collection commenced initially because of the various time constraints health care professionals have. I wanted to allow additional time for them (if needed) and be flexible to their schedule. Thus, sending the questionnaire via email was the most appropriate way that allowed for them to answer at their convenience while agreeing to a deadline. Extended time was given to obtain the 10 participants that were needed. Patients' answers were obtained in Portland, Maine after articulation of the research and receiving signed consent agreements from all participants. Patients' interview took approximately 10-12 minutes to complete, and additional time for follow-up questioning was needed to clarify answers and to perform member checking.

Interviews/Questionnaires

I developed 15 interview questions to address and answer three research questions. Ten questions focused on patients' perceptions, and the remaining five were for the perceptions of the health care providers. Interview questions PT1, PT2, PT3, PT4, and PT5 were formulated to answer Research Question 1: How does a reimportation prescription drug policy contribute to patients' drug adherence? I utilized interview questions PT6, PT7, PT8, PT9, and PT10 to answer Research Question 2: What perceptions do patients have about reimportation drugs as related to a chronic disease? These two research questions had a focus on patients' perceptions. I used interview questions PR1, PR2, PR3, PR4, and PR5 to address Research question 3: What are the perceptions of key providers (physicians, nurse practitioners, and physician's assistants) regarding the impact of re- importation drug laws on patients' medication adherence? Transcription of data was completed after leaving the Portland, Maine research site. All questions were developed as open-ended questions to foster more detailed answers from the participants.

Providers' questions being sent out via e-mail (electronic mail) address afforded the opportunity for participants to take their time and address the questions without any external factors. Thereby, they were able to perform a self-member checking before submitting their responses to me. But upon receiving answers, I thanked the participants for their help. During this line of communication, I asked if any information should be added or changed (member checking). One exception ensued with PT1 who submitted her answers via email. PT1 was afforded the same self-member checking as the providers and a follow-up email to her was sent for member checking as well. Upon receiving the answer, I found no ambiguity; all the answers

were clear and well understood. Although questions were open- ended and remained unchanged post-pilot study some responses were short and required further probing to understand further what the participant was attempting to say. The interview schedules for both providers and patients are listed in Tables 1 and 2. Provider's schedules were developed based on the receipt of the answers via e-mail. Assignment of identifiers numbers were randomly given (immediately) upon receipt of answers. Patients' identifiers were given immediately following their interview; PT1 was the only patient to respond via e-mail on May 22, 2015; all other patient surveys were performed face-to-face.

Table 1- *Schedule of Interviews/Questionnaires Surveys (Providers)*

Date	Providers (PR)
5/1/2015	7
5/2/2015	10
5/2/2015	8
5/3/2015	3
5/4/2015	2
5/7/2015	6
5/7/2015	1
5/10/2015	9
5/11/2015	4, 5

Table 2 -*Schedule of Interviews/Questionnaires Surveys (Patients)*

Date	Patients (PT)
5/22/2015	1
6/17/2015	2
6/17/2015	3
6/17/2015	4
6/17/2015	5
6/17/2015	6
6/17/2015	7
6/17/2015	8
6/17/2015	9
6/17/2015	10

(Patients 2-10 interviews commenced throughout the entire day on 6/17/2015)

Data Analysis

This research performed an inductive data analysis of collected raw data that consisted of transcription, coding the data, placing data into categories and reducing data to themes and sub-themes. The purpose of this is to condense textual data, establish clear links among research objectives and to summarize findings (Thomas, 2006). I utilized constant comparisons, sought concepts, themes and experiences of the raw data using open and selective coding (Charmaz, 1990). I manually coded the data to develop themes by extensive comparison of the data. I looked for patterns, similarities, and contrasting answers that would address the three research

questions. Selective coding was used to establish a core variable. Codes were then transferred to themes and sub-themes that I found to be more salient.

Axial coding aided this process and allowed for an open coding category to generate a "core phenomenon" (Creswell, 2007, p. 66). And it allowed for the data to create categories around this phenomenon (Creswell, 2007). I addressed and answered three research questions in this exploration developing semi-structured open-ended questionnaires/interviews of participants; these relationships of the results that emerged from data collected will be discussed in subsections that will follow.

Interviews/Questionnaires

Ten providers responded to five questions, and 10 patients responded to 10 questions. The collection of data consisted of electronic mail responses, phone interviews and face-to-face interviewing. I coded all data with open- ended coding by segmenting all interview questions that addressed and answered each corresponding research question. Table 3 indicates succinct answers to the interview questions and shows the corresponding research questions for patients; Table 4 displays the answers and corresponding research questions for the providers.

Table 3. *Summary of Patients' Responses to Interview Questions*

Interview Questions	Themes	No.#	Research Question Answered
1. What concerns (if any) do you have or have had about medication drug purchase from Non-USA markets such as Canada?	No concerns	4	1
	Prefer U.S.A only	1	
	Not same meds as U.S.A	1	
	Drug Abuse Concern	1	
	Counterfiet	2	
	Cutting Corners	1	
2. What concerns do you have if you are unable to take your medication(s)?	Death	3	1
	Worsening of current condition	4	
	Side effects	1	
	Cost	1	
	Family not able to get meds	1	
3. Are you experiencing cost savings or expect cost savings (from overseas purchases) of your drug medication purchases (please explain why or why not)?	Expect Savings	4	1
	No	6	
4. Can you describe the impact of you taking medication (as prescribed) if cost was not a factor?	Best Thing	1	1
	Would be great	1	
	"Be able to take meds"	3	
	No impact	1	
	Feel better	1	
	Improve condition	1	
	A good thing	1	
5. Please explain if cost has or has not afected our ability to follow your drug regimen?	Has not	5	1
	N/A	1	
	Yes	4	
6. do you feel the drugs from these pharmacies (overseas) are safe, if so, why and what concern(s) do you currently have (if any)?	Safe	4	2
	N/A	2	
	No	2	
	Not sure	1	
	Possibly	1	
	Yes/no (50/50)	1	
7. How do you percieve (concerns, understanding) the overseas drugs in relationship to local drugs for the long term healthcare?	Affordable	1	2
	Same as U.S.A	1	
	N/A	3	
	Increase research needed	1	
	Less Expensive	1	
	U.S.A. meds only	1	
8. Chronic diseases are long term decision process; describe your preparation for this as it relates to your medication choices?	Hoping for cure	1	2
	Consult Physician	1	
	No preparation	3	
	Would use cheaper market	3	
	U.S.A. meds only	2	
9. Are you given optional advice to seek more affordable medication from your phycisian (provider), if sowhat options were suggested?	No advice given	6	2
	"Yes"- Generic Drugs	4	
10. How has re-importation (being able to purchases from Canada) policy help you manage your disease?	N/A	8	2
	Peace of Mind	1	
	Good Option	1	

Table 4. *Summary of Providers' Responses to Interview Questions*

Interview Questions	Themes	No.#	Research Question Answered
1. Describe how this policy (can) improve patient's adherence levels?	Affordable	5	3
	Cheaper	2	
	Less Expensive	2	
	Much likely to take	1	
	They will use it	1	
	Canadian Market helps to stay on meds	1	
	Will take medication	1	
	Can't afford meds otherwise	1	
	Helps many of my patients	1	
2. How often do you consult patients about adherence of drug regimen and what do you focus on?	Always	1	3
	Each Visit	4	
	Every Visit	4	
	Focus on:		
	Adherence	7	3
	Side effects	3	
	Safety	2	
	Dose Verification	1	
	Education of drug(s)	1	
	Cost	1	
3. How does (in your opinion) this policy affect patient's adherence levels? - or - is it too soon to tell?	More likely to adhere	1	3
	Helpful	1	
	Too soon to to tell	2	
	Will have an affect	1	
	Makes a big difference	1	
	No direct impact	1	
4. Describe any improvement with your patients' adherence since this policy has been in place?	Don't know of any	1	3
	Have not notice	2	
	Can't say	3	
	None	1	
5. Describe in your opinion the pros/cons of this policy long term?	Pros:		
	Lower Cost	1	3
	Helpful because of cost	3	
	Reasonable cost	1	
	Need similar pricing in U.S.A.	1	
	Safety	4	
	Cons:		
	Legality & Extra effort	1	3
	Not same accountability	1	
	No policy is gonna matter	2	
	Lack of effort to control	1	
	big pharma	2	
	Qualiy Assurance		

Research Question 1

Interview Questions PT1, PT2, PT3, PT4, and PT5 answered Research Question 1: Does reimportation prescription drug policies contribute to patients' drug adherence? Overall, the answers to questions IQ1, IQ2, IQ 3, IQ4, and IQ5 demonstrated a positive perception for reimportation policies and a positive contribution to medication adherence. In response to IQ1 (40%) of the 10 participants felt drugs from the Canadian market are safe; while (30%) have some reservation about drugs from non-United States markets. PT7 stated "I am concerned about the ingredients in the medication" and PT10 had concerns about expired drugs and counterfeit drugs. PT3 stated: "United States drugs only" was her preference and PT5 had concerns of drug abuse from these markets. When I further probed about his drug abuse statement he stated that the "cheap cost" could cause the abuse.

IQ2: What concerns do you have if you are unable to take your medication? Seven (70%) of the 10 participants are concerned about their current medical condition worsening when they are unable to take their medication with 30% fearing death. PT1 was also concerned with being placed in a nursing home. Only 10% of the patients are concerned on how to obtain and pay for the medication. PT4 is concerned with side effects.

IQ3 answers demonstrated that 40% were experiencing savings or expected to save money with the reimportation policy in place. PT2, PT4, PT8 stated "no cost savings at this time" because of current medication insurance that only utilizes the United States pharmacies. The stated these insurance companies "pays all cost" or (as stated) by PT2 "I have a very low co-pay." In response to IQ4, eight of the participants stated a positive response to "if cost were not a factor". PT1 stated: "would be a great thing." PT2, PT6 and PT8 stated "would be able to take

prescription." "Would feel better" was the response from PT4; while PT9 responded "best thing!" "Devastating if cost was a factor" responded PT10. Only PT3 stated there would be "no impact". PT5 responded: "this could be a double edge sword", after follow-up questioning he states it could be "good and bad".

In response to IQ5: Please explain if cost has or has not affected your ability to follow your drug regimen? Cost is affecting or has affected patients' ability to obtain and take their medication; 40% of the patients stated this. PT9 stated that cost has affected her because she "lives pay check to pay check". Insulin cost is unaffordable for PT5 she responded "I can't afford my insulin without the reimportation policy." PT2 responded "that paying anything for medication out of pocket is a concern." Forty percent of other patients say cost is not a factor because of current insurance from job or state. PT6 (a cancer patient) gets all her medications from Canada and stated "cost is not a factor because of the Canadian market." Past cost was an issue for PT8 but not anymore because as he stated "it is not a problem now since I cross the border."

Research Question 2

Interview Questions (PT6, PT7, PT8, PT9, and PT10 answered Research Question 2: What perceptions do patients have about reimportation drugs as related to a chronic disease? IQ6 had a response of 50% that are favorable towards safety of Canadian pharmacies. PT1 stated "safe because of Canada's reputation"." PT7 and PT8 responded with "possibly" and "not sure" respectively. PT4 and PT10 stated "not safe" because of "incorrect chemical compounds" and "no" because "I just don't know the pharmacy."

IQ7 had a 50% positive perception of the reimportation policy and obtaining drugs from Canada in comparison to the United States markets. The understanding of the reimportation policy varies. All patients were aware of the ability to use the Canadian market. I interpreted the Canadian market and the United States market to be on an uneven playing field. PT1, PT2, PT3, PT5, and PT8 responded favorably. PT1 responded: reimportation that allows for Canadian drugs are "safe and affordable" in comparison to the United States local markets. PT2 believes "drugs are the same" as the United States drugs. Although it takes a little longer to receive, it is a "good once I receive them" stated PT5. Twenty percent stated unfavorable answers; PT10 understanding of non-United States markets is that all drugs come from undeveloped nations and that "Americans should stay away from them". PT6 is a cancer patient who consumes a $2000.00 drug every month (if purchased in the United States) for her cancer treatment. But she gets her medication from Canada (every month) for only $30.00 co-pay. Thus, her understanding is that "doctors and officials are not helping citizens, and those costs are controlled by the government".

In response to IQ8: patients' preparation for future use of the policy and the Canadian market indicated 40% will consider using the Canadian market to obtain medication; to allow for adherence of their regimen. PT1 responded "will use Canada drugs." PT4 and PT9 stated "would consider cheaper market". PT3, PT5, and PT8 indicated no preparation for long term use as it relates to their medication. PT7 and PT10 preparation is to "use United States drugs only". PT2 states she will continue ongoing consultation with her physician to see what is best for her.

IQ9 indicated (60%) of patients are not consulted by their health care providers on affordable drugs and how these affordable can increase adherence. PT3, PT6, PT7, and PT9 were

the only patients who stated they are consulted on affordable drugs. Generic drugs were the affordable medication options given to PT3 and PT7 by providers. Consultation for using reimportation drugs from non-United States markets were not mentioned by any provider. In response to IQ10 concluded with nine patients 90% indicating that purchases from international markets are not applicable in relationship to the total management of their current disease. After follow-up questioning, the majority of answers demonstrated that there is no way to link exclusively the international markets solely to disease management. Their drug purchases are inter-mixed with drug purchases from the United States. One exception to this is PT6. Recall, PT6 gets her $2000.00 medication from Canada for $30.00 co-pay thereby, management of her disease is greatly increased and the reimportation policy has helped.

Research Question 3

Interview Questions (PR1, PR2, PR3, PR4, and PR5) addressed and answered Research Question 3: What are the perceptions of key providers (physicians, nurse practitioners, and physician assistants) regarding the impact of re- importation drug laws on patient medication adherence? The overall answers for all interview questions from the providers demonstrated a positive/good optional program. Providers responded (100%) favorable that the policy can improve patients' adherence. PR1 and PR5 responded "cheaper drugs, they will take" PR3 responded "the Canadian market helps to stay on meds." "Much likely to stay on prescription" stated PR4. Access to affordable drugs helps many of my patients" stated PR6. PR9 responded:"patients will stop taking medication if cannot afford". "More likely to obtain if cost is less as in Canada" stated PR10.

IQ2 answers indicated that (100%) of the providers feel discussing medication adherence is important at every visit. Words such as “always”, “each visit”, every visit” and “during regular visits” were used. The majority of focus (70% of providers) stated that during consultation, the focus was on taking the medication and if not taking, then why? PR2 states that education about the medication was a main focus in consultation about adherence. Other answers were “dose verification”, “safety”, and “side effects” were topics of conversations when speaking about adherence.

IQ3 responses demonstrated a positive response from 80% of the providers stating that the policy will have a positive effect on adherence levels. PR4 and PR9 were the only participants to state that “it is too soon to tell” of any effects from the policy.

Providers stated words such as “ helpful”, “affordable”, “makes a big difference”, “will have an effect” and “would provide a good option”, and “affordable drugs a big help”. PR1 stated “that a policy is not going to change people mindset they will continue to cross the border here in Maine for medication it was going on before the policy and will continue.”

Provider’s ability to monitor patients’ health solely based on where drugs are purchase is a difficult task. Thereby, 80% of the providers stated that they don’t know of any direct link to adherence of the policy at this time. Answers such as “can’t say” and “have not noticed any major changes” were given. Provider’s response to IQ5 exhibited favorable perception to the benefits of the reimportation policy. They (providers) stated “ cheaper”, “reputable”, “reasonable cost”, “medication for less”, “helpful because of cost”, and “competitive “. PR7 was the only provider to state “not sure yet.” IQ5 elicited some concerns from providers as they stated “the legality and extra effort is needed” also “quality assurance and safety could be an

issue" stated PR4, PR8 and PR9. PR2 stated that the "lack of effort to big Pharma to make meds affordable is not there."

Themes

Diagrams to demonstrate and organize the relationship of concepts, themes and categories are important (Corbin & Strauss, 2008). Constructing theories though concepts can be generated in many different ways; the relationships are based on the data obtain and is grounded in the data (Corbin& Strauss, 2008). Therefore, I developed three diagrams to demonstrate the relationship between dominant themes and subthemes that were influence from constant comparing and analyzing the raw data. Figure-1 corresponds with themes related to the providers; Figure-2 corresponds with themes related to patients' responses and Figure-3 is corresponding to common themes seen from both providers and patients.

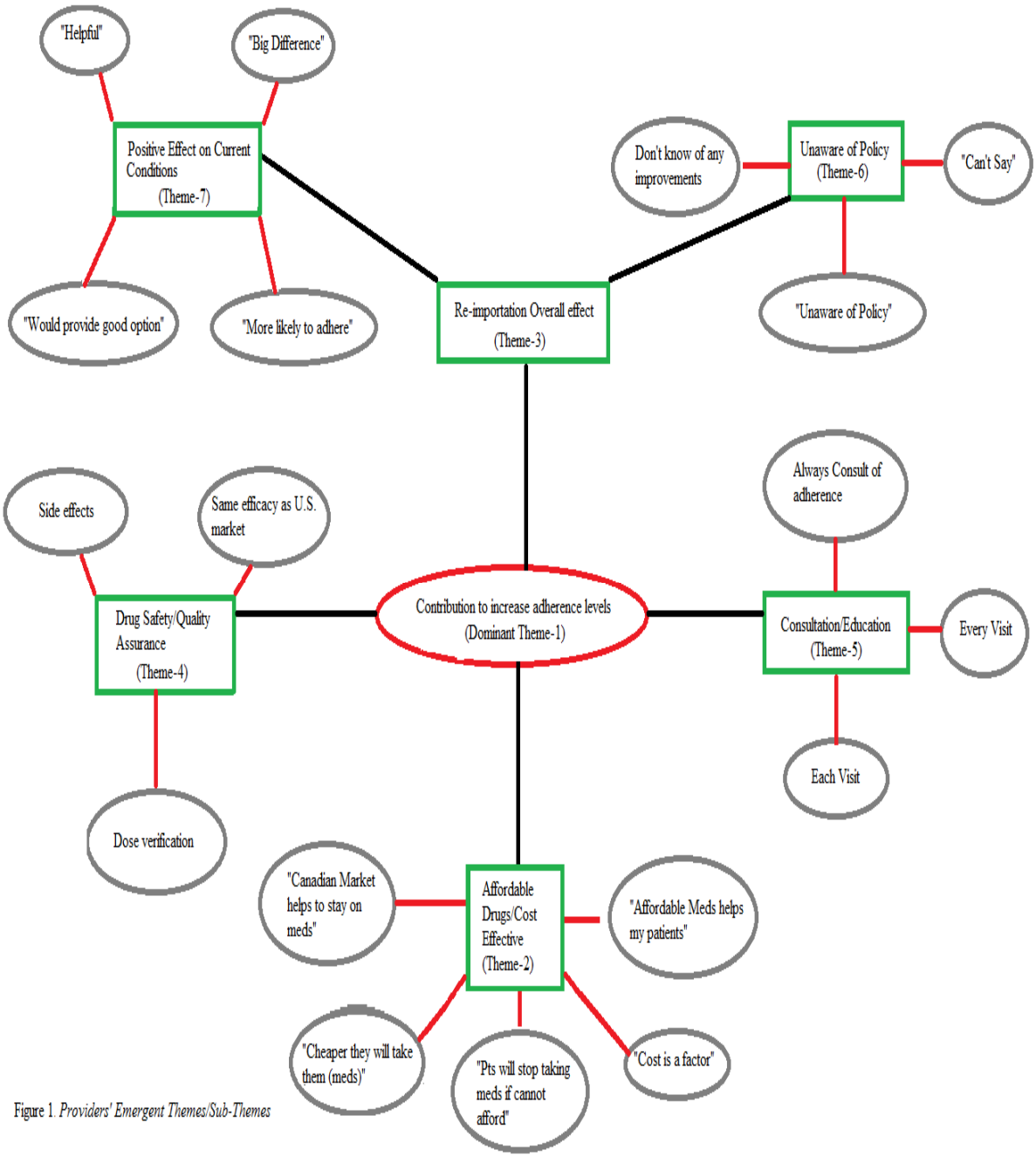

Figure 1. *Providers' Emergent Themes/Sub-Themes*

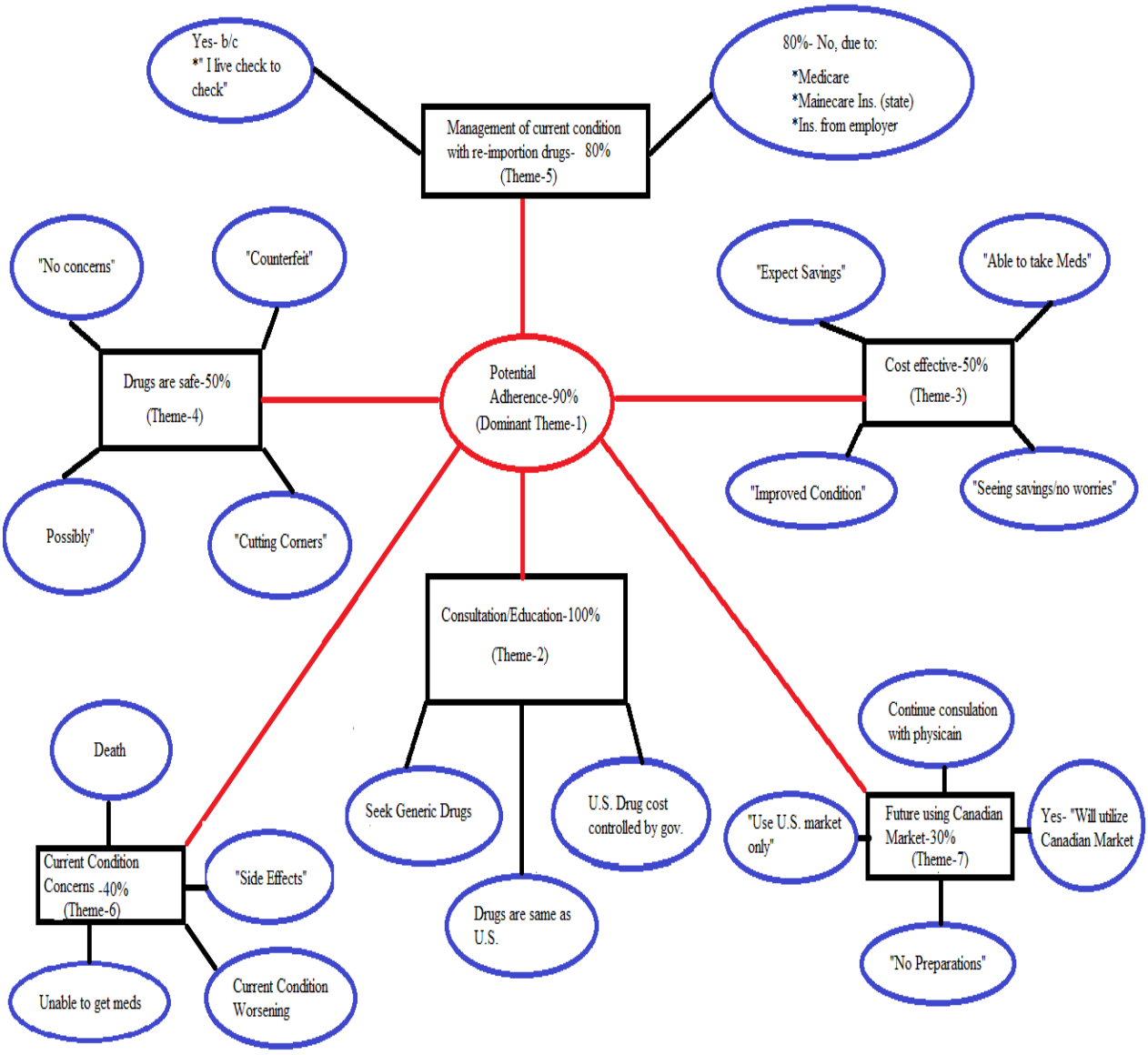

Figure 2- *Patients' Emergent Themes/Sub-Themes*

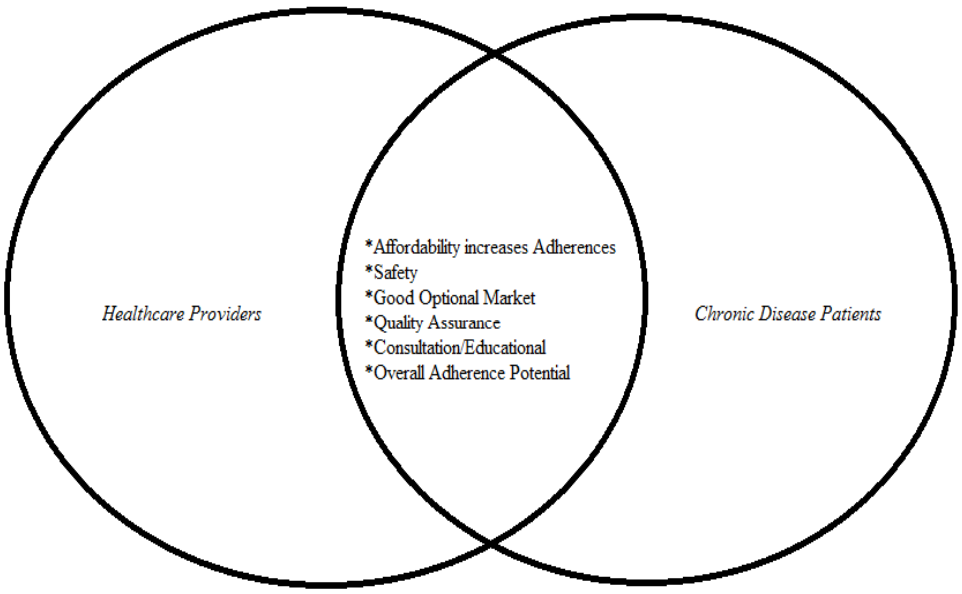

Figure 3.- *Common Themes among Providers & Patients*

Providers' Theme 1: Dominant Theme

Contribution to increase adherence level: Providers demonstrated overall that a reimportation policy contributes now and can contribute in the future to adherence levels positively. This theme emerged from IQ1, IQ3, and IQ5. In answer to IQ1, what asked: Describe how this policy can improve patients' adherence? Seven providers (70%) stated adherence will increase because "patients are able to obtain and take medication" and "Canadian market helps". Other statements followed such as "cost is a factor, more likely to take them" and "will take advantage of affordable drugs." My interpretation is that affordability is the incentivized driving force.

Providers' Theme 2

Affordable drugs/cost effective: Providers indicated that cost is a factor and a major cause why patient will seek these drugs and thus take them. This emergent theme comes from IQ1, IQ5. Providers responded to IQ1 with "cheaper", "less expensive"; IQ5 answers elicited "lower cost" and "reasonable cost".

Providers' Theme 3

Reimportation Overall effect: IQ3 and IQ5 demonstrated an overall positive response. IQ3 asked how this policy affects patients' adherence; five providers responded favorably stating "more likely to adhere" and "a good option." IQ5 demonstrated favorable answers; when asking providers to describe the pros and cons of this policy long term, three providers stated "helpful because of cost" and "safe"; other answers were "competitive because of lower cost".

Providers' Theme 4

Drug Safety/Quality Assurance: Forty percent of the providers demonstrated a positive safety response as emerging from IQ5. Responses included "reputable" and "no concern for safety coming from Canada."

Providers' Theme 5

Consultation/Education: This theme emerged from IQ2. All providers stated that consultation and education of drugs were very important; and the importance of adherence is discussed at "every visit", "each visit" and "always" stated providers.

Providers' Theme 6

Unaware of policy: This theme emerged from IQ4 as two providers were unaware of the policy but have patients that cross the border to secure drugs. PR1 stated that "no policy matters, they will still get meds with or without a policy from Canada." These two providers' answers stood out because it indicates that 20% of the providers are unaware of a policy that can help their patients. My interpretation is that increase communication and education are mandated.

Provider's Theme 7

Positive effects on current condition: Providers indicated that IQ3 answers to current conditions were helping with the use of the Canadian market. PR4 stated "yes and a few people outside my area are getting meds from Canada." PR3 responded "we need similar pricing here in the United States", makes a "big difference" stated PR2. Other favorable responses were "would provide an option" and "patients are finding alternative therapies in Canadian pharmacies."

Patients' Theme 1: Dominant Theme

Potential Adherence: Patients demonstrated a positive perception for reimportation of current and future adherence. This theme emerges from IQ1, IQ3, IQ4, IQ6, and IQ8. In response to IQ1 and IQ6: What concerns (if any) do you have or have had about medication drug purchases from non-United States markets: forty percent of participants stated no concerns and feel drugs are safe and 20% stated "possibly". Four patients say they are saving money and expect to save money (in response to IQ3). In response to IQ4, 90% stated adherence would increase if cost were not a factor. IQ8 answers yielded a 30% positive response for future use of Canadian markets, 30% stated they have no idea about what to do for future preparations. And 20% responded they will stay exclusively with United States pharmacies.

Patients' Theme 2

Consultation/Education: This theme stemmed from IQ6, IQ7, and IQ9.This theme emerged from answers and follow-up questioning from participants. My follow-up questioning leads me to intrepid that patients do not completely understand reimportation protocol. These drugs are manufactured in the United States and shipped out to other nations and then returns to the United States. In response to IQ6: Do you feel drugs are safe? Twenty percent stated "no" and 20% stated "possibly" or "50/50 chance they are." But 40% responded favorable to safe drugs from Canadian pharmacies. IQ7 answers yielded several variances to the question of how do you perceive the overseas drugs in relationship to local drugs? PT3 and PT4 responded "none", PT1and PT8 stated affordable and "cheaper". Other answers included PT2 respond that he understands "drugs are the same as United States" and 20% of patients (PT7 and PT10) responded that they will use only United States drugs. I interpreted additional education on the

topic could renderer increase favorable answers. In response to IQ9: Eighty percent of patients stated that they are not given information to seek more affordable medication from their health care provider. My interpretation is that additional education to providers is also needed for them

Patients' Theme 3

Cost Effective: Several patients stated that cost is a driving force for taking their medication now and the future. This theme emerged from IQ3, IQ5, IQ7, and IQ8. The answers for IQ3 are you experiencing cost savings or expect to save money: demonstrated that 40% of patients are saving or expect to save because of the reimportation policy. Six patients gave various reasons why they are not saving on Canadian drugs mainly stating that current employment insurance or Medicare is covering all prescription cost. Patients in IQ5 demonstrated that 40% of patients stated cost has a direct link in their ability to follow medication regimen. Fifty percent of patients stated no direct effect of management of their disease because of reimportation drugs; there is no exclusivity on Canadian market and drug purchases for current disease consist of United States' pharmacies as well. Thirty percent of patients stated "affordability" and "less expensive" answers when contrasting the United States' pharmacy markets. Other patients' answers suggested "additional research is needed" and "only United States medication" was preferred by one patient. In response to IQ8: Forty percent of patients stated that cost will be a factor in the future for adherence to drug regimen, and they will consider the Canadian market.

Patients' Theme 4

Drugs are safe: This theme emerged from IQ1, and IQ6. In response to IQ1, What concerns do you have about medication drugs purchased from non-United States markets? Four

patients stated they had no concerns, and with one patient stated “drug abuse”; while another patient is concerned with “counterfeit drugs” and “cutting corners.” IQ6 asked: do you feel drugs are safe from these pharmacies (overseas) if so why and what concerns do you have (if any)? Forty percent stated “yes” two other patients responded “possibly” and one patient stated “not sure.”

Patients’ Theme 5

Reimportation policy helps to manage current condition: This theme emerged from IQ10 that asked: How has reimportation policy help you to manage your disease? Only one patient (PT6, who exclusively gets her meds from Canada) responded positively on this question. One other patient stated “this is a good option”. The remaining patients 80% stated that there is no link to the policy and management of their current disease. Upon follow-up with these patients the majority responded that there is no way to exclusively (directly) connect the policy and Canadian drugs (to their management) when they also get medications from the United States.

Patients’ Theme 6

Current Condition Concerns: This theme emerged from IQ2 that asked what concerns you have if you are unable to take your medication. All patients (100%) stated that their inability to take medication is a big concern and will seek alternative therapies to get their medicine. Three patients stated “death” as a concern, and seven patients are concerned with current condition worsening.

Patients’ Theme 7

Future use of Canadian Market: This theme was created from IQ8. Four patients 40% are prepared to use the Canadian as a primary and supplement market for their future needs; they

stated cost as the reason. Three patients (30%) have no idea about their plans for future use and two patients 20% will continue to stay with the United States markets only.

Discrepant Case

Researchers should make every effort to locate discrepant cases (Merriam, 2002). This research study invited 20 participants (10 providers, and 10 patients). PT3 did not completely align with answers from other participants. This participant's initial answers were short and only stated his "allegiance" to American products. Many of his answers were "United States only!" for questions that did not warrant such answers. Further probing and questioning of this participant yielded a minimum additional clarification and understanding (but not much).

Conclusion

The findings in this research emanated from responses to interview questions observed for a 12-week period. Ten health care providers and 10 patients were invited to participate in this research that explored the perceptions of providers and patients in relationship to medication adherence levels and reimportation of prescription drugs. The answers from this three month long study demonstrated that health care providers and patients in the state of Maine have a positive perception of reimportation, and that said policy can contribute to increasing drug adherence that is incentivized by affordability.

Although additional education and discussions are needed, participants' answers reflected a favorable perception on the subject. At this juncture the playing field is not even when contrasting medication drugs from the international market and the United States markets. Media attention, advertisements and further understanding of reimportation must become more

equivalent for reimportation drugs, until then, it is my conjecture that favorable responses are not maximized.

This chapter outlined the population that took part in this exploration, how participants were protected, the role of the researcher, and the procedures utilized to ensure the quality of raw data collected. Also detailed was how data was collected, and methods used to analyze the data. Chapter five will summarize the finding of this study. I will discuss the relationship of the findings to the theoretical framework, a make inference to conclusions, briefly discuss implications for positive social change, and suggest recommendations for future research on this topic.

Chapter 5: Summary, Conclusion, and Recommendations

Introduction

The need for supplemental, affordable medication programs, and policies has been a growing topic within the health care arena. Patients' adherence levels of many chronic diseases continue to plague the medical field with growing distinction, soaring monetary costs, and illnesses. Health care officials for many years have debated the effectiveness and safety of reimportation drugs. This study went into the field to see what patients and health care providers have experienced; and to capture their thoughts, opinions, comments, experiences and listen to their voices. Providers who prescribe these medications have a role and voice in this matter as well. I wanted to see what these providers who are on the "front line" every day have to say concerning adherence levels and reimportation drugs. They are helping to change the plight of their patients through consultation and prescription drugs and any improvement to the health care system can aid this process.

It is very important to identify the components that can aid patients in the development of good, effective and solid policies. I expected only veracious answers from each participant and did not form any opinion prior to engaging in the research. My total commitment was to allow the results to yield a conclusion. Participants approached me and the study in a welcoming manner. The people of Maine displayed a level of sincerity to this topic by responding positively to me and the study. Interpretation of findings for the study, the conclusion, implication for positive social change, and further recommendations for this study ensues within this chapter.

Interpretation of Findings

I conducted the study in the state of Maine where citizens are allowed to purchase prescription medication from non-United States pharmacies. In Maine, the reimportation market is better known as the Canadian market. Although the reimportation policy allows for purchases from United Kingdom, New Zealand, and Australia, Mainers (people from Maine) can relate to only the Canadian market; this was a realization from the pilot study.

The design of the study was qualitative with a grounded theory approach. The purpose of the study was to see if reimportation policies have an effect on patients' adherence levels. Three research questions were developed to 15 interview questions to gain insight of health care provider's and patients' perceptions. The research questions were answered by analyzes of participant's answers to open-ended interview questions within a natural setting. Ten patients and 10 providers responded to 10 questions and five questions, respectively. Data collection for this study used member checking to add credibility to the research.

Limitations of the Study

Within every endeavor there exist shortcomings; within this study one limitation is the fact that only one state has a reimportation law. Also, the majority of Maine's population is Caucasian descent. These factors limit the research as other ethnicities are not fully represented. Although this research did have two minority patients participate, the overall make-up of the sampling pool was voided of minorities.

Interviews

Research Question 1**:** How does a reimportation prescription drug policy contribute to patients' drug adherence?

Patients' answers demonstrated a positive outcome to this question. In response to IQ4: Can you describe the impact of your taking your medication (as prescribe) if cost were not a factor? Patients stated that reimportation of drugs had contributed to obtaining medication and taking them. The words used by the various participants included "much likely to stay on meds," Canadian market helps to stay on meds," "if cheaper, able to take meds", "affordable medication a big help"; along with "helpful", "will have an effect", and "more likely to adhere." PT5 responded to IQ5 that asked: please explain if cost has or has not affected your ability to follow your drug regimen? His response was "yes otherwise I cannot afford my insulin." The responses to the interview questions demonstrated an overall positive perception to reimportation policies and increases drug adherence. Many patients (40%) demonstrated no concerns about medication coming from the Canadian market. Additionally (40%) of patients are very concern if they are unable to take their medication and fear worsening of their current disease stating that affordable medication can resolve this issue.

Research Question 2**:** What perceptions do patients have about reimportation drugs as related to a chronic disease?

Another focus of the study was to explore the perceptions of patients about reimportation policies and adherence levels. Participants (overall) demonstrated a clear perception of this topic with favorable an answer. Patients' answers consisted of "safe", "affordable", "drugs are the same as the United States". Patients indicated they would use the Canadian markets for future

medication needs to remain adherence. A two patients indicated "not sure", or "possibly" to IQ6 that asked: do you feel the drugs from these pharmacies (Canada) are safe? Based on answers from IQ7, I interpret that they do not have a full understanding of the non- United States markets pharmacies and the reimportation protocol. Other responses were "should stay away from it", from PT10 response and "better if local markets are used" as stated PT7. The answers to the interview questions revealed that all patients experienced elevated levels of perception of reimportation policies and drug adherence.

Research Question 3: What are the perceptions of key providers (physicians, nurse practitioners, and physician assistants) regarding the impact of re- importation drug laws on patients' medication adherence?

Providers in the state of Maine who prescribe medication were invited to participate in this study. The answers indicated a positive, clear perception. Most of the providers indicated that affordability is the incentive that would have patients adhering to their medication. For example, words such as "cheaper," cost is a factor," and "less expensive" were used. IQ3 (PR): How does this policy affect patients' adherence levels? Seven out of 10 providers responded positively to increase adherence to this policy. Providers responded well to safety and quality assurance. PR5 responded that this policy "provides a good option." Providers also agree that future use of reimportation will enhance the adherence levels of their patients; words such as "increase access to drugs for less, will increase adherence." I encouraged all participants to speak freely and to give their true feelings and experiences.

Responses to the three research questions confirm the theoretical framework on which this study is based; Kurt Lewin's organization change theory; unfreeze, change, and refreeze

(Lewin, 1947). Although originally presented many years ago, it is still relevant today. The theory's first model (unfreeze); involves getting to a level of understanding that change is needed and preparing to move away from status quo. The second model (change or transition); defines the journey of movement that is made to changes. And finally refreeze; this is about getting to a stability point once the changes have been made. The changes are understood and accepted by all thereby, becomes the new norm (Lewin, 1947). The themes that resulted from participant's answers are outlined below:

Research Question 1: Does reimportation prescription drug policies contribute to patient drug adherence?

Themes:

- Patients felt adherences were contributed due to the affordability and the reimportation policies.
- Patients are experiencing cost savings.
- Patients thought the impact of reimportation policy was a good thing.
- Patients felt that not being able to take meds would worsen current state and would look to non- United States markets to obtain.

Research Question 2: What perceptions do patients have about reimportation drugs as related to a chronic disease?

Themes:

- Patients felt cost had affected their ability to follow drug regimen.
- Patients felt (overall) that drugs are safe from non-United States markets.
- Patients have a good understanding of drugs from Canada in contrast to the United States.

- Patients stated that they would utilize the reimportation policy in the future.
- Patients felt that consultation and education about affordable drugs were not given by providers.
- Patients stated that no direct impact on disease management on reimportation policy.

Research Question 3: What are the perceptions of key providers (physicians, nurse practitioners, and physician assistants) regarding the impact of reimportation drug laws on patients' medication adherence?

Themes:

- Providers stated drugs were affordable and this equates to adherence.
- Providers stated adherence consultation is given each visit.
- Providers can't state any direct improvement due to policy.
- Providers (overall) stated the safety of drugs was not a concern from Canada.

This research demonstrates that non-adherence and cost are problems (unfreezing). Attention is needed to address the problem (change/transition), and new policies are needed to be implemented (refreezing). This organization theory applies to the entire nation and new policies (reimportation) should be considered on a national scale.

Recommendations for Further Study

This research utilized a convenience sampling of 20 participants all over the age of 18 years old. Similar and different studies should be conducted among a larger population. Studies can look at specific chronic diseases or continue to focus on multiple chronic diseases as it relates to adherence levels and reimportation of prescription drugs.

I conducted the study over 12-weeks. I recommend that multiple longitudinal studies could benefit this research and is recommended to understand further if longer studies (with a significant amount of participants) would change the outcome of perceptions. Continued focus studies of medication adherence levels should carry on along with specific studies of reimportation concerns. Larger populations within and outside the state of Maine would benefit future research on this topic. Several states are considering a new order of federalism (system of government in which the same territory is controlled by two levels of government, Cornelllaw.edu, 2014) and implementing their reimportation policies; the majorities of these states are in the same region as Maine and have a close proximity to Canada. Once implemented, studies in these states can possibly contribute to the subject matter.

I also recommend the continued education of reimportation policies protocol to the citizens for whom it is intended for. Officials should continue to education health care officials to this subject matter in both rural and non-rural areas; all health care providers should know that such affordable markets are available for their patients.

Recommendations for Action

Political and health care officials who take on the authoritarian role within the health care arena have the responsibility to implement policies that can benefit the general population. These individual (officials) should consider the findings of this research when engaging new policies related to this topic.

Because many individuals have a chronic need for affordable drugs program, planners should be willing to break new ground and go against traditional methods and policies seen in the past. Many of these methods are not sufficient and require additional support and funding.

This study demonstrates that providers and patients see a benefit in reimportation policies and indicates an increase in patients' medication adherence with the aid of reimportation policies; this could contribute to the change of plight for many Americans desperately seeking help. The finding within this research should be considered.

The monetary value (savings) that this policy can have on a national scale is tremendous thereby, the components of this exploration should be included when discussions are underway. According to Brown and Bussell (2011), patients with chronic diseases, account for approximately 50% of non-adherence. This level of adherence leads to increase morbidity and death. And has an estimated $100 billion per year in costs; reimportation policies can reduce this cost significantly.

Implications for Positive Social Change

According to a study by Medco Health Solution data in 2008, it indicated that 51% of (Americans) children and adults were taking one or more prescribed medication drugs for a chronic condition. This indicated an increase from 50% from 2004-2007 and 47 percent in 2001. Medco examined prescribe medication records from 2001 to 2007 from a registry sample of 2.5 million customers (children to the elderly) in their database. Chronic medication consumption concerned areas were seen in all demographic groups. Two-thirds of women 20 years and older; one in four children and teenagers, 52% of adult men, and three out of four people 65 years or older. Among senior citizens, 28 % of women and 22% of men take five or more prescribe drugs regularly (Medco.com, Retrieve 2015).

This research can contribute to an entire nation. Prescription medications are the most significant health care product to society. Everyone at some point will be affected by

prescription drugs. And with increase life longevity many individuals will have a need to be medicated at some point. Continued discussions of reimportation and adherence levels should be taken very seriously. A dual process is being undertaken. First, patients are more likely to take medication if cost is not a factor, and second, in doing so, a significant saving to patients and the (health care) insurance industry ensues.

PT6 of this research is a good indication that this research is needed and that reimportation policies are contributing to increasing adherence thus, saving lives. Recall, PT6 must have a $2000.00 cancer drug every month (that she only pays $30.00 in Canada). And without the reimportation policy this much-needed drug would not be available. Likely, without the medication it would contribute to a worse state, leading to death. This research and other research on this topic are for all the PT6 in the nation who need a voice. The economic savings to health care insurance companies along with savings to patients could yield additional funding that can be repurposed to other health care issues such as research on various diseases.

Researcher's Personal Reflections

I commenced my study in Public Health Policy because of several reasons. I often have seen family members and friends suffer from not having the resources to purchase drugs monthly. They often had to make the tough choice of paying for prescription medications or pay other monthly bills. In medical school, I was so often saddened to see prescriptions written for patients who later will return 6 weeks later for a follow-up appointment, only to indicate that the prescription was never filled. Many times the patients would pull out the now faded, wrinkle prescription and say "I can't afford it doc". We (as health care providers) often give out samples

to aid this process but only so much can be done; other programs are needed to supplement the efforts of prescription adherence.

This research demonstrates that reimportation legislation should be highly considered. I feel that maximum benefits of a reimportation law will be seen with the extremely costly drugs. The average patient may not see elite benefits with some existing drugs that are cheaper (as in generic) and that are readily available anywhere in the United States. But that is not to say that a reimportation law may not help the mass, I believe it will. So much research on this matter is needed and the discussion should (in my opinion) remain in the forefront of health care officials and lawmakers throughout the nation. Reimportation policies cannot be a "savior" for all drugs and, for this reason, the research recognizes that reimportation does have some shortcomings.

Conclusion

The literature review of the research has disclosed inadequate research data for reimportation policies and the impact on patients' drug adherence. The literature review also voids the voices of providers and patients in this regard. Rhetoric from politicians and pharmaceutical companies display a proclivity for profits and not the voice of the people. There exist gaps in the literature to address reimportation and any contributions to drug adherence in the United States.

Although supplemental programs such as Medicare exists, and there is assistance from pharmaceutical companies to help patients (such as sample medications), this does not suffice to address adequately the problem. No one "fix" will aid patients in this endeavor; it will take the continued efforts of many organizations and officials to passionately help resolve this issue.

Reimportation can be one of many tools used to combat the problem of non-adherence, and should seriously be considered on a national scale.

Events in recent months in the state of Maine (I feel) substantiated the need for this research and further research on this topic is required. In February 2015, United States District Judge Nancy Torresen struck down the Maine Pharmacy Act that allowed Maine residents to purchase lower-cost prescription drugs from Canada, the United Kingdom, New Zealand, and Australia via a broker. According to the judge's 19-page ruling, the Food and Drug Administration (FDA) has jurisdiction over the importation of all medications (Silverman, 2015). Thus, at this juncture, of this study there exists no one state that has a reimportation law. But as stated by one of the providers (PR1)of this study "patients will continue to get medication from Canada with or without a policy." Advocates for reimportation are in discussion to see if an appeal is in order.

This study has reflected that providers and patients see reimportation as a tool that can contribute to higher levels of medication adherence. This research is not suggesting that reimportation policies completely replace existing programs that are in place. But, considerations for reimportation to be reinstated in Maine and to be a top consideration for all other patients (throughout this country) who voices have gone unheard. It is the duty of a nation to adhere to policies that change the plight of suffering patients and be united as one.

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Appendix A

Demographic Profile

In addition to interview questions, the following questions were asked of all participants in relation to their demographic profiling:

- Gender?
- Race?
- Age (range)?
- Smoking?
- Chronic Disease(s)?

Appendix B

Flyer-Information Poster

Dear Prospective Research Participant,

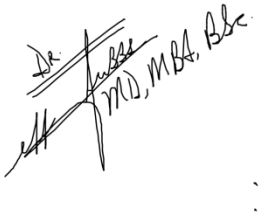
I am Jeffrey Tubbs; a PhD candidate in Health Services at Walden University, conducting a research study related to one component of patient non-adherence of prescription drugs and I am investigating if reimportation of prescription drugs has an effect on patients' drug adherence levels among participants who have a chronic disease.

I am seeking participants to interview (face-to face) who speak English fluently and have a chronic disease that requires monthly renewal prescription refills (on-going refills). Participants of the age of 18 years old and older are welcomed. Previously purchases of prescription medication from outside the United States (such as Canada) are desired. The interview time span may last between 10-15 minutes. At any time during the interview, the research participant may withdraw if he or she feels uncomfortable with the content of the interview protocol.

This research is not affiliate with this medical institution; your participation or non-participation will not have any effect on the treatment you receive or the relationship you have with staff members.

If you are interested please contact me via the below listed information. This research will make every effort to conform to Health Insurance Portability and Accountability Act (HIPAA) in that all information will be kept confidential and secure.

Sincerely,



Jeffrey Tubbs, MD, MBA, BSc.
PhD Health Services Candidate

Appendix C

The following research questions (RQ1) corresponds to the following stated interview questions:

RQ1: How does a reimportation of prescription drug policy contribute to patients' drug adherence?

Interview Questions

1. What concerns (if any) do you have or have had about the overseas drugs?
2. What concerns do you have if you are unable to take your medication(s)?
3. Are you experiencing cost savings (from overseas purchases) of your drug medication purchases (please explain why or why not)?
4. Can you describe the impact of you taking your medication (as prescribed) if cost was not a factor?
5. Please explain if cost has or has not affected your ability to follow your drug regimen?

The following research questions (RQ2) corresponds to the following-stated interview questions:

RQ2: What perceptions do patients have about reimportation drugs as related to a chronic disease?

Interview Questions

6. Do you feel the drugs from these pharmacies (overseas) are safe if so, why and what concerns do you currently have (if any)?
7. How do you perceive the overseas drugs in relationship to local drugs for long term health?
8. Chronic diseases are long term decision process; describe your preparation for this as it relates to your medication drug choices?

9. Are you given optional advice to seek more affordable medication from your physician, if so what options were suggested?
10. How has the reimportation policy help you manage your disease?

Appendix D

Providers Questions (PR-Q)

The following research question (RQ3) corresponds to the fore-stated interview questions:

RQ3: What are the perceptions of key providers (physicians, physician assistants & nurse practitioners) regarding the impact of reimportation drug laws on patient medication adherents?

Interview Questions

1. Describe how this policy (can) improve patients' adherence?
2. How often do you consult patients about adherence of drug prescriptions?
3. How does this policy affect patient adherence levels or is it too soon to tell?
4. Describe any improvements with your patients' adherence since this policy has been in place?
5. Describe in your opinion the pros/cons of this policy long term?

Appendix E

PhD Candidate: Jeffrey Tubbs, MD, MBA

Letter of Cooperation

(1.) Community Research Partner: (Research Site): _____

_____

(2).Authorization from (Contact Information) Name:

_____

Date:

Researcher: Jeffrey Tubbs, MD, MBA (College of Health Sciences)

Based on my review of your research proposal, I give permission for you to conduct the study entitled "Public Policy De Facto, New Order of Federalism: Re-importation of Prescription Drugs, a Major Factor to Patient Drug Adherence" (3.)within_____. As part of this study, I authorize you to conduct a full interview session with participant(s) and myself. Individuals' participation will be voluntary and at their own discretion.

We understand that our organization's responsibilities include: a small room that the partner will provide. This (institution/individual) reserves the right to withdraw from the study at any time if our circumstances change.

I confirm that I am authorized to approve research in this setting and that this plan complies with the organization's policies. Recruitment of participates (patients and physicians) are granted and they have the right to deny any participation of the research process.

I understand that the data collected will remain entirely confidential and may not be provided to anyone outside of the student's supervising faculty/staff without permission from the Walden University IRB. This research under-taking has been approved by Walden University Institutional Review Board (IRB) approval number # 04-22-15-0289886 (expiration date: Apr. 21, 2016).

Sincerely,

(4).Authorization Official (signature) _____

----Hand signature---- or -------

--------The use of your email can be used to sign this document electronically--------