The University of Toledo The University of Toledo Digital Repository

Theses and Dissertations

2005

Anticholinergic medications used by older adults with memory problems

Rachel F. Kemper Medical College of Ohio

Follow this and additional works at: http://utdr.utoledo.edu/theses-dissertations

Recommended Citation

 $Kemper, Rachel F., "Anticholinergic medications used by older adults with memory problems" (2005). \textit{Theses and Dissertations}. 1441. \\ \text{http://utdr.utoledo.edu/theses-dissertations}/1441$

This Thesis is brought to you for free and open access by The University of Toledo Digital Repository. It has been accepted for inclusion in Theses and Dissertations by an authorized administrator of The University of Toledo Digital Repository. For more information, please see the repository's About page.



Graduate School

Knowledge Begins with Research

FINAL APPROVAL OF THESIS Master of Science in Nursing

Anticholinergic Medications Used by Older Adults with Memory Problems

Submitted by

Rachel F. Kemper

In partial fulfillment of the requirements for the degree of Master of Science in Nursing

Signature

Examination Committee

Date of Defense:

April 12, 2005

Linda Pierce, Ph.D., R.N. (Major Advisor)	Starce, Pho, R)
Barbara Hicks, M.S.N., R.N.	Darpasa Hucko MSN, RN
Victoria Steiner, Ph.D.	Ceclora Leiner Pho
Dean, School of Nursing Jeri Milstead, Ph.D., R.N., FAA	N Jan a Milsters, Ph.D., RV, FRAN
Dean of the Graduate School Keith K. Schlender, Ph.D.	Hert Schlen

Anticholinergic Medications

Used by Older Adults with Memory Problems

Rachel F. Kemper

Medical College of Ohio

2005

DEDICATION

I would like to dedicate this to God and my family for all of their love and support.

ACKNOWLEDGEMENTS

I would like to acknowledge the assistance and guidance of Barbara Hicks, M.S.N., R.N., Linda Pierce, Ph.D., R.N., and Victoria Steiner, Ph.D. throughout my research and in the composure of this thesis. I would also like to acknowledge the larger study "Office-Based Evaluation of Older Adults with Potentially Reversible Dementias" from which the research data for this study was taken. The principal investigator of the larger study was Dr. Cletus Iwuagwu with Dr. Victoria Steiner and Barb Hicks, M.S.N., R.N. as co-investigators. Funding for "Office-Based Evaluation of Older Adults with Potentially Reversible Dementias" was a Research and Educational Grant provided by the Center for Successful Aging at the Medical College of Ohio. Data for the larger study were collected from 3/1/04 to 2/28/05.

TABLE OF CONTENTS

	Page
DEDICATION	ii
ACKNOWLEDGEMENT	iii
TABLE OF CONTENTS	iv
LIST OF FIGURE AND TABLES	vi
CHAPTER I Introduction	1
Statement of the Problem	1
Theoretical Framework	3
Statement of the Purpose	4
Research Question	4
Definition of Terms	4
Significance	7
Assumptions	8
Limitations	8
Summary	9
CHAPTER II Review of Literature	10
Theoretical Framework	10
Literature Review	12
Summary	27
CHAPTER III Method	28
Design	28
Data Collection	28

LIST OF FIGURE AND TABLES

	Page
Figure 1 Conceptual Map Linking Orem's (2001) Concepts to the Study Variables	13
Table 1 Beers Updated Criteria for Potentially Inappropriate Medications fo	r Older
Adults	21
Table 2 Over-the-Counter Medications with Anticholinergic Side Effects	23
Table 3 Prescription Medications with Anticholinergic Side Effects	23
Table 4 Anticholinergic Drugs	31
Table 5 Drugs with Anticholinergic Side Effects	32
Table 6 Characteristics of the Sample: Continuous Variables	35
Table 7 Characteristics of the Sample: Categorical Variables and Conditioning	
Factors	36
Table 8 Drugs with Anticholinergic Side Effects Used by Older Adults within the S	Study at
Initial Visit	38

CHAPTER I

Introduction

This study examined the use of over-the-counter (OTC) and prescription medications that have anticholinergic side effects, by a sample of older adults with memory problems seen in an outpatient setting. The most common anticholinergic effects include: dry mouth, constipation, urinary retention, urinary hesitancy, headache, mental changes, and dizziness (Skidmore-Roth, 2003). Anticholinergic medications can also exacerbate pre-existing memory impairment, leading to increased memory deficits, confusion and disorientation, agitation, hallucinations, and delirium (Mintzer & Burns, 2000).

In this chapter, the statement of the problem, statement of the purpose, identification of the nursing theoretical framework, research question, definition of terms, significance to nursing, assumptions, and limitations of the study are identified. The terms within the research question are conceptually and operationally defined in the definition of terms section. A summary of the contents concludes this chapter.

Statement of the Problem

The natural aging process equates to an increased likelihood of illness and a gradual decline in physical condition. The combination of these factors leads to a disproportionate amount of OTC and prescription medications consumed by the elderly (Mintzer & Burns, 2000). The elderly currently represent less than one-fifth of the U.S. population, but they account for more than one-third of all prescription medications dispensed (Sloane, Zimmerman, Brown, Ives, & Walsh, 2002). In addition, it was estimated in 1992 that the elderly consume 40% of all OTC medications sold in the U.S.

(Coons, Johnson, & Chandler, 1992). Seven years later, Beyth and Shorr (1999) reported an increase in elderly consumption of OTC medications. They reported that the elderly consumed more than 50% of all OTC medications. Tracking OTC usage is complicated (Hughes, McElnay, & Fleming, 2001). Practitioners are dependent on the honesty and recall of clients to report accurate usage. Problems that older adults may have include inappropriate OTC drug use, drug-drug interactions leading to complications, and the possible risk of OTC usage masking and potentially delaying treatment of a serious medical condition (Bradley & Bond, 1995).

Anticholinergic medications, and medications that cause anticholinergic-like side effects (even though they are not classified as such), were chosen as a research topic because of their possible central nervous system (CNS) effects on cognition. Anticholinergic CNS side effects include sedation, decreased concentration, forgetfulness, confusion, and psychotic symptoms (Vangala & Tueth, 2003). These side effects can occur from a single medication or from an individual's total anticholinergic burden. The total anticholinergic burden of a person reflects the cumulative effects of all agents that they are currently consuming that produce anticholinergic effects (Miller, 2002). The higher a person's burden, the more likely they are to suffer from side effects and increased levels of complication. Roe, Anderson, and Spivack (2002) made note that special care should be exercised when prescribing medications for the elderly, especially those who already suffer dementia or memory loss problems. Increased sensitivity to adverse effects, potential difficulty with adhering to a regimen, and reduced ability to recognize and report adverse events make this group of elders a challenging population. It is important for prescribers to weigh the risks versus benefits of anticholinergic drug use

and to educate people on medications that may present complications and what types of complications to be aware of when taking these drugs.

Theoretical Framework

Orem's (2001) self-care deficit nursing theory is the theoretical framework for this study. Orem's main theory is structured on three underlying theories: 1) the theory of self-care, 2) the theory of self-care deficit, and 3) the theory of nursing systems. Orem described the theory as focusing on people in relations. Self-care focuses on the self, self-care deficit focuses on "you and me," and finally, nursing systems focus on people functioning within a community. All three portions of these structures were applied to this study, with a concentration on the first and second.

The theory of self-care is the "voluntary regulation of one's own human functioning and development that is necessary for individuals to maintain life, health, and well-being" (Orem, 1995, p. 95). People desire and take actions in order to maintain a certain quality of life. These actions are called self-care agency (Orem, 2001). Within the confines of this study, the investigator sought to know the number of older adults with memory problems that are consuming prescription and OTC medications with anticholinergic side effects, which may aggravate current memory problems. The person consuming these products is performing self-care agency. It is assumed that people are consuming these drugs in order to maintain their desired health state.

Within the theory of self-care deficit, Orem (2001) describes when an individual's balance of desired life, health, and well-being is disrupted. The person poses a need that they currently cannot meet for any number of reasons. The self-care deficit that this study

examined is the use of OTC and prescription medications with anticholinergic side effects within older adults with memory loss problems.

The final portion of Orem's (2001) theory of nursing systems described nursing care for the people when they are unable to meet all of their self-care needs and a deficit has occurred. Nurses care for the person, until the person returns to a normal state of health or learns to function within their new state. Because this study looked only at frequency and not an action or educational recommendation or tool, this theory was not directly applied. If a need is determined, this theory can be applied to future research in this area.

Statement of the Purpose

The purpose of this study is to examine the frequency of the use of OTC and prescription medications which can cause anticholinergic side effects in a sample of older adults presenting with memory problems in an outpatient setting.

Research Question

What is the frequency of the use of OTC and prescription drugs with anticholinergic side effects in a sample of older adults with memory problems in an outpatient setting?

Definition of Terms

Terms central to the study are outlined below. Each term has been described using both a conceptual and operational perspective. A conceptual definition describes each term within the context of Orem's (2001) self-care deficit nursing theory. An operational definition is derived from a set of procedures or progressive acts that a researcher performs in order to measure or explain a variable (Burns & Grove, 2001). The

definitions are intended to enable the reader to more fully understand the specifications of the study.

Frequency

Conceptual. Frequency is conceptually defined in this study as the number of self-care agents (Orem, 2001) that are using OTC and prescription drugs with anticholinergic side effects in order to correct a health deviation self-care deficit and maintain self-care agency and a balanced state of health (Burns & Grove, 2001).

Operational. Frequency is operationally defined in this study as the number of older adults within the sample that include in their list of current medications, one or more OTC or prescription drugs that can cause anticholinergic side effects, during their initial assessment interview at an outpatient clinic (Burns & Grove, 2001).

Over-the-Counter Drugs with Anticholinergic Side Effects

Conceptual. Over-the-counter drugs with anticholinergic side effects are conceptually defined in this study as a self-care demand in response to a health deviation self-care deficit (Orem, 2001). The action of choosing, purchasing, and consuming an OTC drug with anticholinergic side effects is done by an individual in order to meet a perceived need.

Operational. Over-the-counter drugs with anticholinergic side effects are operationally defined in this study as drugs that can be purchased without a prescription (Venes, & Thomas, 2001) and that can cause specific undesired side effects including: constipation, hyperthermia, mydriasis, tachycardia, dry mouth, urinary retention, mental changes, and hot, dry, flushed skin (Miller, 2002).

Conceptual. Prescription drugs with anticholinergic side effects are conceptually defined in this study as a self-care demand in response to a health deviation self-care deficit (Orem, 2001). The client must have previously received a medical prescription for the medication and then chose to act by filling and consuming the drug with anticholinergic side effects in order to meet a perceived need.

Operational. Prescription drugs with anticholinergic side effects are operationally defined in this study as drugs that can only be obtained with a prescription and that can cause specific undesired side effects including: constipation, hyperthermia, mydriasis, tachycardia, dry mouth, urinary retention, mental changes, and hot, dry, flushed skin (Miller, 2002).

Older Adults

Conceptual. Older adults or elderly are terms that are used interchangeably within this study. Conceptually, they can be defined as the self-care agents, aiding in their own care (Orem, 2001).

Operationally. The term older adults in this study can be operationally defined as people age 50 years or older (American Association of Retired Persons Online, 2005) who act on their own behalf in meeting their self-care needs.

Memory Problems

Conceptual. Memory problems are conceptually defined in this study as a deficit within the universal self-care requisite of normalcy (Orem, 2001). The memory problems affect the person as a whole and increase the possibility of complications stemming from

usage of OTC or prescription drugs with anticholinergic side effects (Mintzer & Burns, 2000).

Operational. Memory problems are operationally defined in this study as changes, declines, or impairments in cognitive functioning. Cognitive functioning encompasses the processes by which an individual perceives, registers, stores, retrieves, and uses information (Foreman, Fletcher, Mion, & Simon, 1996).

Outpatient Setting

Conceptual. Outpatient setting is conceptually defined in this study as a basic conditioning factor. The setting is an influence on the person. In this setting, the person is responsible for more of his/her own self-care agency, because outpatient care is less controlled than an inpatient care setting (Orem, 2001).

Operational. Outpatient setting is operationally defined in this study as a clinical setting in which the person receives medical care from licensed medical professionals, but does not remain in this setting overnight (Venes & Thomas, 2001).

Significance

Older adults represent a vulnerable portion of the population. As age increases, the likelihood of suffering from dementia increases. Kawas and Katzman (1999) reported that 15% of people age 65 years will suffer dementia and this statistic increases to approximately 40% of those 85 years of age and older (Mintzer & Burns, 2000). Use of OTC and prescription drugs that have anticholinergic side effects can initiate or exacerbate memory problems. Tune (2001) noted that drugs causing anticholinergic effects, even mild effects, are a significant cause of memory problems in older adults. Treatment should, therefore, be aimed at removing, reducing, or limiting use of such

medications in this population. Removal of such problematic OTC and prescription drugs is a fundamental way to lessen mental decline.

Assumptions

An assumption is information that is believed to be true. This study was based on the following assumptions, which have been conceptualized within Orem's (2001) self-care deficit nursing theory: 1) these individuals have at least one or more self-care deficits for which they are taking prescription or OTC medications; 2) all older adults have the self-care deficit within the universal self-care requisite of normalcy of memory loss problems prior to their initial clinic visit; and 3) some percentage of these individuals were using an OTC or prescription medication in response to a health deviation self-care deficit that can produce undesired, anticholinergic side effects.

Limitations

A limitation is a possible restriction or drawback to the study. The following limitations were acknowledged in the study within Orem's (2001) self-care deficit nursing theory:

- 1) This study used information from each older adult client extracted from his/her initial interview at the clinic. Information utilized included basic conditioning factors and self-care deficits. The clients may report additional basic conditioning factors and self-care deficits at a later appointment and these data were lost to this study, as they were not collected.
- 2) The clients were all from the same general geographic area. They may have very similar basic conditioning factors which may result in the subjects not

- being representative of the general population's basic conditioning factors; making the two groups incomparable.
- 3) The clients have all experienced the self-care deficit of memory loss; they may not remember what OTC or prescription medications they are using in order to correct their perceived health deviation self-care deficits.

Summary

In Chapter I, the problem upon which this study is based was defined. Chapter I contained a description of the study's problem statement, theoretical framework, statement of the purpose, research question, definition of terms, significance, assumptions, and limitations.

Although research has been done related to the elders' use of OTC and prescription medications and to the known cognitive side effects caused by anticholinergic medications (and those medications that cause anticholinergic effects), little research has combined these two areas. Self-medication using OTC drugs is becoming an increasingly important area of study within healthcare (Hughes, et al., 2001). Health professionals need to take steps to 1) recognize associated risks of consuming drugs with anticholinergic side effects; 2) assess usage by persons; and finally, 3) to educate people on such risks. The aim of this study was to assess the frequency of use of OTC and prescription medications in a sample of older adults with memory problems.

CHAPTER II

Review of Literature

In the beginning of this chapter, a discussion of the application of Orem's (2001) conceptual framework for the study is discussed. The conceptual map that contains the variables for this study within Orem's theoretical concepts follows the discussion. The second portion of the chapter contains the review of research and literature pertaining to the use of medications by the elderly and the implications of using medications with anticholinergic side effects. This section concludes with a summary.

Theoretical Framework

Orem's (2001) self-care deficit nursing theory provides the nursing theoretical framework for this study. Underlying Orem's theory are three interrelated theories: the theory of self-care, the theory of self-care deficit, and the theory of nursing systems. Self-care is the assumption that people maintain life, health, and well-being through a series of specific self-care actions. Self-care can be thought of as the maintenance of homoeostasis. Self-care deficits occur when homeostasis is interrupted and a person is no longer able to meet their needs. An older adult who chooses, is able to purchase, and then proceeds to use an OTC medication is performing self-care. They are attempting to remedy a current health deviation self-care deficit. Likewise, individuals who choose to go to a practitioner who prescribes a drug for them is also performing self-care. The person is choosing to go to the practitioner and, additionally, choosing to fill and take the prescription as recommended by the practitioner; these choices are the person's self-care in order to correct a health deviation self-care deficit. People desire a level of health from which they perceive themselves as having deviated from, resulting in their current state

and health deviation self-care deficit. These individuals are performing self-care in order to return to health or homeostasis and correct their perceived health deviation.

Finally, nursing systems describe the role of the nurse as she/he compensates or does for the person what they are not currently able to do for themselves. The role of the nurse is to educate the person about medications with possible anticholinergic side effects, the interaction of multiple medications, and then to care for the person if a problem/complication does arise. This final portion of Orem's (2001) nursing theory, the theory of nursing systems, is not directly applicable to this study.

Fundamental to Orem's (2001) self-care deficit nursing theory are several concepts including basic conditioning factors (BCF), self-care requisites, self-care demands, self-care agency, and the continual movement toward health and well-being. Basic conditioning factors are anything that affect or influence a person. Orem's BCF that were examined in this study include: age, gender, ethnicity, marital status, and living arrangement. All or any combination of these BCF influence a person's knowledge, ability and desire to self-medicate. Self-care requisites are needs that are universal to humans similar to the final concept of maintenance of health and well-being. Self-care demands are the therapeutic actions taken in order to meet self-care requisites. Self-care demands on a person is the need to take the medication. Self-care agency is the ability of a person to perform self-care demands in order to attain self-care requisites. If the person is able to decide which medications will be safest and most effective, are these medications available to the person and can they afford the optimal choice? These are all self-care agency issues. The final concept is health and well-being in which Orem (1995) defined as "a state characterized by soundness or wholeness of developed human

structures and of bodily and mental functioning" (p. 101). Health or wholeness is what the person is attempting to attain by taking the drugs with anticholinergic side effects.

Central to Orem's (2001) three interrelated theories of nursing is the concept of self-care. People elicit self-care when they purchase and make the decision to take OTC medications. When complications occur, a health-deviation self-care deficit results (Orem). Health-deviation self-care requisites are needs that occur because of changes in health and include the following possible actions: seeking and securing appropriate medical assistance, effectively carrying out medically prescribed measures, and modifying an individual's self-concept and accepting oneself as being in a different state of health requiring specific forms of health care (Orem). This investigator has developed a conceptual map (Figure 1) embracing Orem's theory of self-care deficit and depicting how the research question is explained within its confines. This schematic drawing demonstrates that both self-care deficits and BCFs have a direct affect on OTC and prescription use by an older adult, possibly leading to undesired side effects.

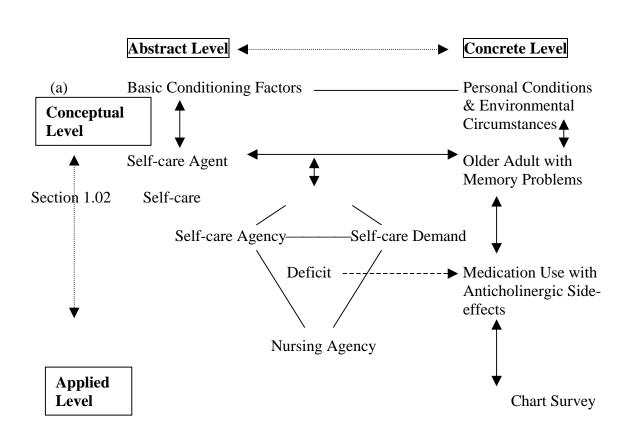
Literature Review

Few professional research journal articles were found that discussed the prevalence of anticholinergic drug use in an elderly population with memory-loss problems. Therefore, additional articles were chosen that highlighted: 1) dementia and the prevalence of dementia in older adults; 2) the frequency of OTC and prescription medication use in older adults; 3) problems associated with OTC and prescription use in older adults; 4) anticholinergics and other medications that produce anticholinergic-like effects; and finally, 5) problems in educating medical personal and clients about

medications. It is important to note that the literature utilized for this review was drawn from various fields in health care.

Figure 1

Conceptual Map Linking Orem's (2001) Concepts to the Study Variables



This review is limited to materials published within the last 15 years. Key search terms included: *anticholinergic, Beers criteria, dementia, elderly, older adults, over-the-counter, OTC, prescription, drugs* and *medication*. Articles were drawn from the CINAHL and MedLINE databases. The literature was critically reviewed using criteria from Burns and Grove (2001), which emphasizes the need for clarity, purpose,

summarization of current knowledge, collection, analysis, and interpretation. The greater part of the literature reviewed was derived from professional nursing and pharmacological journals. No nursing literature was found that specifically discussed the frequency of anticholinergic drug use in older adults, but by expanding the literature reviewed, articles were found in pharmacological and gerintological journals. Nursing research that was applicable to portions of the topic is discussed.

Dementia and the Prevalence of Dementia in Older Adults

Dementia refers to a variety of signs and symptoms that stem from changes in brain function (Porth, 2002). Various symptoms may include: 1) repeating questions or phrases, 2) becoming lost in familiar places, 3) being unable to follow directions, and 4) disorientation concerning time, familiar people, and places. Dementia can be both irreversible and reversible depending upon the cause of the cognitive decline.

Alzheimer's disease and multi-infarct dementia are permanent conditions and cause irreversible dementia. Reversible dementia maybe the result of high fever, dehydration, vitamin deficiency and poor nutrition, the effects of medications, problems with the thyroid gland, or a minor head injury.

Dementia is a common and debilitating disorder among older adults. It is a growing health concern because of the worldwide adding phenomenon (Fratiglioni, deRonchi, & Aguero Torres, 1999). Fratiglioni, et al., (1999) examined 15 prevalence studies from within 10 years prior and estimated that 0.3 to 1.0 per 100 persons between 60 and 65 years have some form of dementia. This number increases dramatically as the population's age increases. Prevalence among individuals age 95 years and older was estimated to increase to 42.3 to 68.3 per 100 people. In the U.S. it is estimated that 5-10%

of the adults populations age 65 years and older is affected by dementia and incidence doubles every 5 years after age 65 (Costa, Williams, & Somerfield, 1996).

Affecting a significant number of both the worldwide and U.S. populations, dementia requires continued clinical attention and study.

The Frequency of OTC and Prescription Use in Older Adults

Society's continually growing understanding and knowledge of health and disease and its efforts to achieve longevity are resulting in an ever increasing elderly population (Giron, et al., 1999). In order to fully understand the frequency of drug usage in this population, patterns in both prescription and nonprescription drugs were examined. As part of a 7 year study in Sweden, drug use patterns in a very elderly population (mean age >85 years) were examined (Giron, et al.). The study highlighted that as the population aged, drug usage also increased. The number of regularly used drugs rose from 3.4 to 4.6 during the study. Giron and associates concluded by recognizing that because of this population's increase in drug usage, there is likely an increase in unwanted adverse drug reactions and interactions.

Drug use in the elderly has been extensively investigated because of the population's widespread medication consumption. The elderly currently represent less than one-fifth of the U.S. population, but they account for more than one-third of all prescription medications dispensed (Sloane, et al., 2002). Previously, it was estimated that the elderly consumed 40% of all OTC medications sold in the U.S. (Coons, et al., 1992). Seven years later, Beyth & Shorr (1999) reported an increase in this figure. They stated that the elderly consumed more than 50% of OTC medications. Barat, Andreasen, and Damsgaard (2000) reported that 87% of the people studied received prescription

drugs and 72% used over-the-counter drugs. In the same study, Barat, et al. also stated that drug use in both the general population and particularly in the elderly has increased dramatically over the last decades. In another study, Hanlon, Fillenbaum, Ruby, Gray, and Bohannon (2001) compared six documented studies of various U.S. populations and geographic areas. They found that 31-96% of the populations examined indicated the use of OTC medications. Hanlon et al. also determined that OTC usage was correlated with gender, females used more than males, and with heritage, whites used the most OTC medications. Hispanics were found to use the least.

While Hanlon et al. (2001) confirmed the trend of polypharmacy in the elderly, Pitkala, Strandberg, and Tilvis (2001) expanded on this topic by posing the question "Is it possible to reduce polypharmacy in the elderly?" Over a 2 month period, the number of doses of prescribed medications taken per day in an elderly experiemental group was reduced by nurses and medical staff, but the number of drugs taken per day did not decrease, because the experimental group (of their own choice and abilities) increased their usage of OTC drugs. Twelve months later the group was re-polled and almost all had returned to or increased the number of medications they were consuming. Polypharmacy is a problem and medical professionals need to recognize its prevalence and dangers.

Problems Associated with OTC and Prescription Medication Use in Older Adults

Older adults are more at risk for experiencing drug problems than the younger population for several reasons. Ryan (1998) cited the following reasons: 1) the physiological aging process and its effects on the body's absorption, distribution, metabolism, and excretion; 2) older adult's narrower therapeutic window or small range

between the dosage level for benefits and adverse side effects of the drug; 3) health problems requiring drug treatments that are prevalent in the elderly because of the body's natural decline in function; and 4) the natural increase in problems and prescribed medications causing an increase in the incidence of medication errors because of complicated regimens and daily multi-dosing. Finally, this population is more at risk for problems because of cognitive decline; medications may not be taken, because they are forgotten (Ryan).

Research studies concentrating on problems associated with OTC medications are not as prevalent as prescription usage. Over the counter drug use is more difficult to track than prescription drug use because prescriptions require medical authority and documentation (Hughes, et al., 2001). Presumably, this is why more studies have focused on the use of prescription drugs. In studies on OTC medications, people are usually questioned as to the type and frequency of OTC usage. Researchers must assume that people are 1) being truthful, and 2) not forgetting any medications.

Older adults have also demonstrated drug problems related to inappropriate drug use of both prescription and OTC medications (Hanlon, Linblad, Hajjar, & MaCarthy, 2003). Inappropriate use of medications can mask signs and symptoms of medical problems and potentially delay treatment of a medical condition (Bradley & Bonds, 1995). Often inappropriate drug use occurs because people take OTC medications, most of which are meant for short term-use, for long periods in order to control chronic problems. The last and perhaps most obvious inappropriate use is taking the drug, knowingly, for a reason other than for what the drug is meant (Hughes, et al.). Any one or a combination of these inappropriate uses can cause an unwanted, unhealthy result.

Another complication related to misuse stemmed from the varying methods that people used in order to remember to take their drugs. Methods used include: 1) memory, 2) scheduling, 3) medication devices (such as pill boxes), and 4) associating medication consumption with regular daily "cues" (Hughes, et al., 2001; Cramer, 1998). Most reported that they used "memory" in order to know when to take their medications and an average of over 40% reported an incident of having forgotten to take a medication (Hughes, et al., 2001). Cramer (1998) determined that no single method was optimal for use in all patients. Methods for remembering to take medications should be individualized in order to meet the needs of each consumer. People may prefer a specific method or a combination of methods in order to accurately consume their medication regime (Cramer).

One of the possible unhealthy results of consuming incorrect or multiple prescription and/or OTC medications can be drug-drug interactions. According to Lehne (2004), consequences of drug-drug interactions include 1) intensification of effects, 2) reduction of effects, or 3) production of a new (not previously seen) response. These complications can result in desired, healthy effects or undesired, unhealthy effects and without the supervision and guidance of a practitioner, pharmacist or other health care provider, the person is not likely to understand all of the possible outcomes.

Reasons for inappropriate drug use can extend beyond possible mistakes or lack of education of consumers. Prescribers can also be the source of medication errors (Hanlon, Schamder, Ruby, & Weinberger, 2001). Hanlon et al. (2001) outlined three specific types of inappropriate or "suboptimal" prescribing: 1) overuse or polypharmacy, 2) inappropriate use, and 3) under use. Causes of suboptimal prescribing vary, but can

occur because consumer may seek care from multiple prescribers, if each prescriber does not take the time to assess what other prescribers are advising the consumer to take inappropriate medications may be prescribed; and/or prescribers may lack understanding of the effects of drugs that they are prescribing or of the reactions the different drug may have when combined (Hanlon, 2001). No matter the reason, prescribing errors pose increased health risks to consumers.

Various tools for decreasing inappropriate medication use have been developed. The Beers criteria is such a tool, specifically developed in order to decrease inappropriate drug use in older adults. Beers (1991) compiled a list of prescription and OTC medications that were determined to be inappropriate for use within this population. The Beers criteria are compiled of medications that were found to have consistent toxic effects and drug related problems leading to possible unhealthy medical and safety consequences for older adults. Additionally, these unhealthy consequences can lead to increased health care costs effecting overall health care economics (Fick, et al., 2003). In 1997, Beers published an updated version of inappropriate medications and in 2003 the list was again updated (Fick, et al.).

In the article, *Trends in the Prescription of Inappropriate Drugs for the Elderly Between 1995 and 1999* (Stuart, et al., 2003), authors outlined a study that researched whether the Beers criteria (1997) had decreased use of inappropriate drugs within the older adult population. Using the Beers criteria, the study compared inappropriate drug use in 1995 and in 1999, examining 7,628 community-dwelling elderly in 1995 and 8,902 community-dwelling elderly in 1999. A significant decline in inappropriate drug use was seen between 1995 and 1999, from 24.8% to 21.3%. However, an estimated 7 million

elderly patients still received drugs found on the Beers criteria in 1999, equating a continued need for increased interventions and improved prescribing practices within this population (Stuart, et al., 2003).

The most current Beers criteria (Fick, et al., 2003) lists 48 medications or medication classes that are inappropriate for older adults. A summary of the updated list can be found in Table 1. The listing of medications is very clinically friendly because of it brevity. The complete list includes 1) the medication or medication class, 2) a summary of concerns of use and 3) a severity rating for the medication: high or low (Fick, et al.). The Beers criteria (Fick, et al., 2003) were developed using the previous Beers criteria (1991, 1997), multiple questionnaires and the Delphi method (Fick, et al.). The Delphi method provides a means to reach consensus within a group of experts. The Beers criteria (1991, 1997, Fick, et al., 2003) have been widely utilized clinically and cited. The criteria are an important tool for medical professionals who work with older adults.

In 2000, Aparasu and Mort complied a comparison of eight prior relevant studies that utilized the Beers criteria within elderly populations. Aparasu and Mort found that between 1 in 4 and 1 in 7 elderly patients received an inappropriate medication as defined by the Beers criteria. The majority of the people who received an inappropriate medication received only one and that as the overall medication use increased, the likelihood of inappropriate medication use also increased. In ambulatory settings 7.9% of the elderly reportedly used inappropriate medications verses in a nursing home care setting, 40.3% of elderly were found to be consuming an inappropriate medication (Aparasu & Mort).

Table 1

Beers Updated Criteria for Potentially Inappropriate Medications for Older Adults

Drug / Drug Class	Severity Rating (High or Low)	Drug / Drug Class	Severity Rating (High or Low)
All barbiturates	High	Halzepam	High
(except Phenobarbital)	C		C
Alprazolam > 2mg	High	Hydroxyzine	High
Amiodarone	High	Hyoscyamine	High
Amitriptyline	High	Indomethacin	High
Amphetamines	High	Isoxsurpine	Low
Anorexic agents	High	Ketorolac	High
Belladonna alkaloids	High	Lorazepam > 3mg	High
Bisacodyl	High	Meperidine	High
Carisoprodol	High	Meprobamate	High
Cascara sagrada	High	Mesoridazine	High
Chlorazepate	High	Metaxalone	High
Chlordiazepoxide	High	Methocarbamol	High
Chlordiazepoxide-	High	Methyldopa	High
amitriptyline	111811	our, roopu	111611
Chlorpheniramine	High	Methyldopa-	High
	mgn	hydrochlorothiazide	mgn
Chlorpropamide	High	Methyltestosterone	High
Chlorzoxazone	High	Mineral oil	High
Cimetidine	Low	Naproxen	High
Clidinium-	High	Neoloid	High
chlordiazepoxide	High	recoloid	High
Clonidine	Low	Nitrofurantoi	High
Cyclandelate	Low	Orphenadrine	High
Cyclobenzaprine	High	Oxaprozin	High
Cyproheptadine	High	Oxaprozm Oxazepam > 60mg	High
Desiccated thyroid	High	Oxybutynin Oxybutynin	High
Dexchlorpheniramine	High	Pentazocine	High
Diazepam	High	Perphenazine-	High
Diazepani	High	amitriptyline	High
Dicyclomine	High	Piroxicam	High
Digoxin	Low	Promethazine	High
Diphenhydramine Diphenhydramine	High	Propanthline	High
	High		
Disopyamide		Propoxyphene	Low
Doxazosinn	Low	Quazepam	High
Doxepin Erast masylaids	High	Reserpine > 0.25mg	Low
Ergot mesyloids	Low	Short acting nifedipine	High
Estrogens only	Low	Short-acting	Low
Ethornio and	T c	dipyridamole	ŢŢ' . 1.
Ethacynic acid	Low	Temazepam > 15mg	High
Ferrous sulfate > 325mg	Low	Thioridazine	High
Fluoxetine	High	Ticlopidine	High
Flurazepam	High	Triazolam > .25mg	High
Guanadrel	High	Trimethobenzamide	High
Guanethidine	High	Tripelennamine	High

Using the Beers (1997) criteria in order to determine if a medication was inappropriate, researchers attempted to assess the relationship between inappropriate medication use in the elderly and health status outcomes (Fu, Liu, & Christensen, 2004). Two groups were established, Group 1 used one or more inappropriate medications and Group 2 participants did not. It was found that individuals using inappropriate medications to report poorer health status (Fu, et al.).

Anticholinergics and Other Medications that Produce Anticholinergic-like Effects

Anticholinergic is a drug classification. This class of drugs is used to treat a variety of medical problems. Some of the more common types of anticholinergic drugs include: tricyclic antidepressants, antipsychotics, antihistamines, cycloplegics, antispasmodics, antiparkinsomianagents, proprietary sleeping medications, belladonna alkaloids, and some toxic plants (Perry & Lund, 1996). Over-the-counter medications that have anticholinergic side effects are found in Table 2. Examples of anticholinergic medications that can be received with a prescription are listed in Table 3. The phrase anticholinergic side effects describes both OTC and prescription drugs that may or may not be classified as traditional anticholinergic drugs, but they poses similar side effects and need to be treated with the same precautions when taken. Precautions that consumers should use when consuming anticholinergic (and any) medications include: 1) know the side effects of the medications; 2) know if and when signs and symptoms begin to occur; and 3) report signs and symptoms to prescriber (Lehne, 2004).

Table 2

Over-the-Counter Medications with Anticholinergic Side Effects

Benadryl Allergy Diphenhydramine		
Chlor-Trimeton 12-Hour Allergy Chlorpheniramine		
Dimetapp Allergy Bropheniramine		
Tavist-1 Antihistamine Clemastine		
Choricidin HBP Cold and Flu Chlorpheniramine, Acetaminophen		
Choricidin Night Time Liquid Brompheniramine, Acetaminophen		
Actified Pseudoephedrine, Triprolidine		
Benadryl Allergy/Congestion Pseudoephedrine, Diphedhydramine		
Towers, 2001		

Table 3

Prescription Medications with Anticholinergic Side Effects

Analgesics	Codeine	Antispasmodics	Dicyclomine		
	Oxycodone		Hyoscyamine		
			Oxybutynin		
Anti-allergy	Diphenhydramine	Anti-vertigo	Meclizine		
	Fexofenadine	agent			
	Hydroxyaine				
	Loratadine				
Antidepressants	Amitriptyline	Bronchodilator	Theophylline anhydrous		
	Doxepin				
Antihypertensives	Captopril	Corticosteroid	Prednisolone		
	Furosemide				
	Nifedipine				
Anti-parkinson	Benztropine	H2 Blockers	Cimetidine		
agents	Trihexyphenidyl		Ranitidine		
Antipsychotics	Haloperidol	Other	Digoxin		
	Thioridazine	Cardiovasculars	Dipyridamole		
	Trifluoperazine		Isosorbide dinitrate		
			Warfarin		
Vangala, & Tueth, 2003					

Anticholinergics can cause a variety of side effects which include constipation, hyperthermia, mydriasis, tachycardia, dry mouth, urinary retention, mental changes, and hot, dry, flushed skin (Miller, 2002). Monitoring usage of these medications in the elderly is of greater importance than in the general population because of their effects on the central nervous system (CNS) and these effects on the CNS can lead to inaccurate diagnoses. The elderly population is already at a greater risk for suffering memory loss and other various mental disorders.

Specific mental changes caused by anticholinergics may include sedation, decreased concentration, forgetfulness, confusion, and psychotic symptoms (Vangala & Tueth, 2003). These side effects can occur from a single medication or from what health care providers have termed the "total anticholinergic burden." The total anticholinergic burden of a person reflects the cumulative effects of all agents that they are currently consuming that produce anticholinergic effects (Miller, 2002). The higher a person's burden, the more likely they are to suffer from side effects and at higher levels of complication.

Anticholinergics cause a direct threat to a person's optimal cognitive function, which can result in a variety of problems. Possible complications include inaccurate psychiatric diagnoses resulting from anticholinergic caused cognitive changes, such as diagnoses that include depression, dementia, mania, and schizophrenic exacerbation (Vangala & Tueth, 2003). Anticholinergic side effects can also complicate existing memory problems (Tune, 2001). In addition to memory problems, these cognitive changes can result in physical harm to the person. Aizenberg, Sigler, Weizman, and Barak (2002) correlated total anticholinergic burden with an increased risk in falls for

people. Because of these possible cognitive effects, anticholinergics can be dangerous for use by older adults.

As previously discussed, the Beers criteria (Fick, et al., 2003) is frequently utilized in order to determine if a medication is inappropriate for use in the elderly population. The Beers criteria classifies several anticholinergic medications as inappropriate. Various anticholinergic medications have been found to be frequently misused and prescribed. Howard, Dolovich, Kaczorowski, Sellors & Sellors (2004), researchers who utilized the Beers criteria (1997), found oxybutynin (e.g., Ditropan), an anticholinergic, to be a highly consumed inappropriate medication. Within their random sample of 48 elders, 3.7% were taking oxybutynin. Oxybutynin is given for the treatment of bladder incontinence, which is a common condition among older adults.

Medication Education Problems Encountered When Educating Medical Staff and Clients

Practitioners and other health care providers should take steps to both monitor and decrease or discontinue the use (if possible) of anticholinergic medications and drugs that result in similar side effects. Roe, Anderson, and Spivack (2002) made note that special care should be exercised when prescribing medications for the elderly, especially those who already suffer dementia, because of this group's increased sensitivity to adverse effects, potential difficulty with adhering to a regimen, and reduced ability to recognize and report adverse events. Special care should be taken to educate this population and their primary care givers about the risks of medication consumption and the importance of following a regular medication regiment. Esposito (1995) found that elderly clients who were given a specific medication schedule by healthcare providers demonstrated the highest medication compliance.

Through use of the Beers criteria (Fick, et al., 2003) by healthcare professional and prescribers, and education of clients, prescribers, nurses and caretakers concerning the side effects of anticholinergic use, the number of inappropriate drugs consumed by older adults can be decreased (Stuart, 2003). In order to meet the educational needs of clients, it is important for nurses, practitioners and other medical staff to have a complete understanding of drug administration, patient assessment, prescribing, and patient medication education needs and tools (King, 2004). King found that nurses demonstrated a limited understanding of pharmacology and dissatisfaction with previous teaching they had received concerning pharmacology; both factors leading to anxiety when providing client medication teaching. In order to improve the medication education among nurses, Manias and Bullock (2002) proposed that nursing curriculum should include pharmacology taught as a separate class, as well as an integrated component. Proper educational initiatives in pharmacology can improve client medication management (Manias & Bullock). Nurses will be better equipped to educate clients (and other healthcare professionals) if they themselves are knowledgeable.

In general, the elderly population suffers a greater risk of side effects because of decreased body metabolism of medications, as previously discussed. It is important for prescribers to weigh the risk-benefit ratio of anticholinergic drug use carefully. Through thorough nursing assessment, client and family teaching, and by increasing the awareness of other professionals about the problems of misuse and undesired side effects that anticholinergic OTC and prescription medications can cause, use of these drugs can be decreased from use in the elderly population.

Summary

This review of literature has provided a broad look at the problems that OTC and prescription medications with anticholinergic effects can cause in the elderly population. Specifically discussed was the elder's use of pharmaceutical interventions and in particular, medications which cause anticholinergic side effects. Problems that can arise from this population's unsupervised use of OTC medications also were addressed. A brief discussion on what anticholinergic side effects are and how they can impair a person's CNS and affect cognition concluded the review.

It was determined through this review that there was need for further research and inquiry into this topic because the problems that can result from anticholinergic effects can lead to serious cognitive repercussions that are correctable. This is an area where nursing could have a profound and highly beneficial impact. Nurses that are, themselves, educated concerning anticholinergic dangers can educate client about these dangers and, in turn, help to decrease anticholinergic use (both prescription and OTC). Discovering the percent of anticholinergic medication use in older adults with memory problems, it is hoped, will demonstrate the need for continued research and educational efforts on this topic.

Orem's (2001) self-care deficit nursing theory was discussed as the theoretical framework for this research. The self-care agent was identified to be the person taking OTC and/or prescription medications causing anticholinergic effects, specifically memory impairment.

CHAPTER III

Method

The purpose of this study was to examine the frequency of OTC and prescription medications with anticholinergic side effects used in a sample of older adults with memory problems who were seen in an outpatient setting. A description of the research design, subjects and setting, methods for data collection, steps that were taken in order to insure protection of human subjects, and the method of data analysis are included in this chapter.

Design

The design of this study is a secondary data analysis. The data examined in this study was previously collected for a larger study, "Office-Based Evaluation of Older Adults with Potentially Reversible Dementias." The principal investigator was Dr. Cletus Iwuagwu and the co-investigators were Dr. Victoria Steiner and Barb Hicks, M.S.N., R.N. Funding for the study was a Research and Educational Grant provided by the Center for Successful Aging at the Medical College of Ohio. Data for the study were collected from 3/1/04 to 2/28/05.

Data Collection

Setting and Sample

The charts of 193 subjects, referred to an outpatient geriatric center in northwest Ohio for consultation, memory evaluation, or comprehensive geriatric assessment, and who demonstrated signs and symptoms of memory impairment, were reviewed. The sample size was determined to be adequate based on the Central Limit Theorem sampling rule of 30 subjects per variable. The Central Limit Theorem affirms that a population's

mean for a single variable can be generated from a sample of 30 or more subjects (Norwood, 2000). This study examined 193 subjects and a single variable.

Protection of Human Rights

Approval for the retrospective chart review was obtained from the Institutional Review Board (IRB) for Protection of Human Subjects at a medical college prior to reviewing the data. This study was part of a larger study occurring at the college and permission was received via an amendment to the original IRB application (see Appendix A). In order to protect the confidentiality of the clients whose charts were used, their names were excluded from the database. The clients were identified in the database by numbers assigned to them. No clients could be identified by the information provided to this investigator. The data is currently being stored at the geriatric outpatient clinic. Access to the collected data is limited to the investigators, researchers, and clinicians in the geriatric center.

Data Collection

Data for this study were extracted from the database of information collected from the medical records of older adults evaluated for memory problems in the geriatric clinic between October 1999 and April 2004.

Data were collected from clients who visited the geriatric center. The clients were asked to give an initial health history. Information was provided by the clients and family members and/or caregivers. Demographic information used from the database included: age, gender, ethnicity, marital status, and living arrangement. The clients and/or their families were asked to identify all the medications they were currently taking, both prescribed and over-the-counter. Memory loss or impaired cognitive functioning was

examined and confirmed in clients using Folstein's Mini Mental State Examination (MMSE) (Varcarolis, 2002). This test is an 11-question measure that tests five areas of cognitive function including: orientation, registration, attention and calculation, recall, and language. The maximum test score is 30. The MMSE is scored as follows: 0-9 is severe impairment; 10-21 is moderate impairment; 22-28 is mild impairment; and 26-30 is mild cognitive impairment (Reuben, et al., 2003). The MMSE is a valid and extensively utilized tool to determine impairment, both in clinical practice and research. Korner, Lauritzen, & Bech (1996) found the MMSE validity to have a high statistical significance, scoring between .95 and .98.

This study examined the medications the older adult was taking prior to possible changes made at the geriatric outpatient clinic. A list complied by Mintzer and Burn (2000) of anticholinergic drugs and drugs with anticholinergic side effects was used in order to identify drugs posing an anticholinergic danger to the person. The specific medications can be found in Table 4, anticholinergic drugs, and Table 5, drugs with anticholinergic side effects. The medications are categorized by drug classification (or drug class). A drug class refers to a term under which numerous drugs may fall; these drugs are grouped together according to various criteria including chemical structure or pharmacological action. Drugs grouped together because they share a similar pharmacological action is the most common method for grouping (Lehne, 2004). Within Table 4 and Table 5 the desired clinical effects of each group of medications is also highlighted. Medications are listed by their generic names. Medications have a generic name and a trade name. A generic name is a name given to the drug by the United States Adopted Names Council (Lehne, 2004). A drug may have only one generic name. A

trade name is usually assigned to the drug by the company that produces it and multiple companies may produce the same drug, so multiple trade names may exist for the same drug. In order to simplify information on the chart the drugs are listed by only their generic names.

Table 4

Anticholinergic Drugs

Anticholinergic Drugs			
Drug Class	Desired Clinical Effects	Drug	
Antiemetics/Anti-vertigo	Prevention and/or treat of nausea, vomiting, dizziness, and vertigo.	Hyoscine Cyclizine Dimenhydrinate Meclozine Trimethobenzamide Promethazine Prochlorperazine	
Antiparkinson	Reduction of stiffness, tremors, spasms, and poor muscle control associated with Parkinson's disease.	Benztropine Biperiden Procyclidine Trihexyphenidyl Ethopropazine	
Antispasmodics (gastrointestinal)	Relief from spasms of the gastrointestinal tract (stomach and intestines) and the biliary tract. This is helpful in controlling conditions such as colitis, diverticulitis, infant colic, renal and biliary colic, peptic ulcer, irritable bowel syndrome, splenic flexure syndrome, and pancreatitis.	Belladonna alkaoids Clidinium bromide Dicycloverine Hyoscyamine Methscopolamine bromide Propantheline	
Antispasmodics (genitourinary)	Relief from spasms of the bladder. This is helpful in controlling conditions such as spastic bladder.	Oxybutynin Flavoxate Dicyclomine	
Anti-migraine drugs	Reduction of brain activity and the nervous system, causing relaxation and relief of migraine or from developing migraine.	Belladonna alkaloids	
Brochodilators	Inhalation is used to prevent bronchospasm. By preventing narrowing of the airways, air flow to the lungs is increased.	Atropine solution Ipratropium	
Pre-anaesthetics	Reduction of body secretions and reduction of muscle tension (muscle relaxor).	Hyescine Atropine	
Mydriatics/cyctoplegics	Causes the muscles in your eye to become relaxed. This widens your pupil. It is used to dilate (widen) your pupil for diagnostic procedures.	Atropine solution Cyclopentolate Homatropine Tropicamide	
Adopted from Mintzer, & Burns, 2000; Lehne, R., 2004			

Table 5

Drugs with Anticholinergic Side Effects

Drugs with Anticholinergic Side Effects			
Drug Class	Desired Clinical Effects	Drug	
Antiarryhthmics	Affects the way your heart beats and is used to treat seriously irregular heartbeat patterns.	Disopyramide Procainamide Quinidine	
Antidiarrheals	Relief from spasms of the gastrointestinal tract and decrease of body secretions, resulting in a reduction in liquid in stools and muscle cramping associated with diarrhea.	Diphenoxylate/atropine Tincture of belladonna	
Antihistamines	Blocks the effects of the naturally occurring chemical histamine in your body, treating sneezing, runny nose, itching watery eyes, hives, rashes, itching, and other symptoms of allergies and the common cold. Also causes relaxation and drowsiness, can be used as sleep aid.	Diphenhydramine Chlorpheniramine Clemastine Dexchlorpheniramine Hydroxyzine Mepyramine Promethazine	
Skeletal muscle relaxants	Relaxes muscles by blocking nerve impulses (or pain sensations) that are sent to your brain. Can be used, along with rest and physical therapy, to treat injuries and other painful muscular conditions.	Cyclobenzapine Orphenadrine	
Anti-ulcer drugs	Causes reduction of the secretions of certain organs in the body, aiding in controlling conditions such as peptic ulcers that involve excessive stomach acid production.	Propantheline	
Antidepressants	Affects chemicals in the brain that may become unbalanced and cause depression. Antidepressants are used to relieve symptoms of depression such as feelings of sadness, worthlessness, or guilt; loss of interest in daily activities; changes in appetite; tiredness; sleeping too much; insomnia; and thoughts of death or suicide.	Amitriptyline Imipramine Doxepin Trimipramine Nortriptyline Protriptyline Amoxapine Maprotiline Clomipramine	
Antipsychotics	Changes the actions of chemicals in the brain, resulting in the treat of symptoms of psychosis including hallucinations, delusions, and confusion.	Chlorpromazine Thioridazine Clozapine Fluphenazine Prochlorperazine Thiothixene	
Miscellaneous	Glutethimide is a sedative used to treat some sleep disorders. Pethidine is used to relieve moderate to severe pain, commonly associated with use during child birth and surgery.	Glutethimide Pethidine	
Herbal medicines	Henbane and deadly nightshade yield hyoscyamine and scopolamine which are used primarily as a sedative and to treat nausea and prevent motion sickness.	Henbane Deadly nightshade	

The Mintzer and Burns (2000) list was chosen as a guide because it was comprehensive, including prescription and OTC drugs. The medications on the list have significant anticholinergic activity or posses the ability to produce anticholinergic-like symptoms. The list of medications the clients were taking at the initial visit was analyzed by this investigator and the frequency of use of these drugs was extracted.

Assumptions

An assumption is information that is believed to be true. This study was based on the following assumptions: 1) clients and their families were honest when reporting both prescription and OTC medication usage at the outpatient clinic; 2) clients and their families were accurate when reporting both prescription and OTC medication usage at the outpatient clinic; 3) the clients have experienced memory loss problems prior to their initial clinic visit; and 4) some percentage of the sample used at least one prescription and/or OTC medication that can produce an undesired, anticholinergic side effects.

Limitations

The following limitations were acknowledged: 1) information for each client was extracted only once from their initial interview at the clinic; the client may report usage at a later appointment; 2) the clients are all from the same general geographic area; they may not be representative of the general population; and 3) the clients have all experienced memory loss problems; they may not remember what medications they are using.

Data Analysis

The information extracted from the client's charts was put into an Excel spreadsheet for data management and data analysis purposes. To characterize the sample

studied and the frequency of anticholinergic drug use, means, and percentages were calculated.

Summary

This study identified the frequency of drugs producing anticholinergic side effects taken by a sample of older adults that may be exacerbating cognitive impairment. The study design, sample and setting, instruments utilized, and data collection were described in this chapter. Protection of human subjects and the plan for data analysis also were explained.

CHAPTER IV

Results

This chapter includes a description of the sample, with a table outlining the clients' characteristics. Also included is a discussion of the sample's basic conditioning factors. Concluding the chapter is a description and table of the findings and answers to the research question.

Description of Sample

This study was composed of 193 subjects. All subjects were older adults experiencing memory loss problems that had visited the same outpatient clinic specializing in cognitive problems in northwest Ohio, between October 1999 and April 2004.

Basic Conditioning Factors

The sample contained a variety of basic conditioning factors, as posed within Orem's self-care deficit nursing theory. The subjects were primarily female (64%); 36% were male. The majority of the subjects, both male and female, were of white ethnicity and in their late 70s, widowed and lived in a single family home. On average, subjects demonstrated moderate impairment within the context of the MMSE (Reuben, et al., 2003). See Table 6 and Table 7 for a report of the subjects' characteristics and BCF's.

Table 6

Characteristics of the Sample: Continuous Variables (n=193)

Variable	Range	Mean	
Age	51-96	78.4	
Mini Mental Status	0-30	20.5	
Evaluation			

Table 7 ${\it Characteristics of the Sample: Categorical Variables and Conditioning Factors (n=193) }$

Variable		Frequency	Percentage
Gender			
	Male	70	36%
	Female	123	64%
	Total	193	100%
Ethnicity			
	American Indian	0	0%
	Asian	3	1%
	Black	19	10%
	Hispanic	2	1%
	White	169	88%
	Total	193	100%
Martial Status			
	Married	77	40%
	Widowed	90	46%
	Divorced	14	7%
	(includes 2 that are separated)		
	Single/Never married	9	5%
	Unknown	3	2%
	Total	193	100%
Living Arrange	ment		
	Single family home	143	74%
	Apartment	22	11%
	Assisted living/Group home	22	11%
	Nursing home	3	2%
	Unknown	3	2%
	Total	193	100%

Findings

After analyzing the data from the chart review, it was found that 20 subjects were consuming at least one or more medications with anticholinergic side effects at the time of their first visit to the clinic. This equates to 10.3% of the 193 subjects studied. Twentyone medications with anticholinergic side effects were being taken by the 20 subjects. One subject was taking two medications with anticholinergic side effects. Subjects were consuming medications with anticholinergic side effects that were available both with a prescription and over-the-counter. Twelve of the 21 medications being consumed were available only by prescription. Nine of the 21 medications were available both over-thecounter or with a prescription. Oxybutynin (e.g., Ditropan), which is used to control bladder spasms and reduce urinary frequency and incontinence, was the most frequently taken medication available only with a prescription; 3 of the 20 subjects (1.5%) were taking it. Diphenhydramine (e.g., Tylenol PM) was the most frequently consumed medication available both over-the-counter or with a prescription. Nine of the 20 subjects (4.9%) were consuming a type of diphenhydramine, which is often used as a sleep aid. Table 8 lists the various medications with anticholinergic side effects consumed by the subjects. The medications are categorized 1) within their drug class, 2) by their generic name, and 3) by the trade name that was listed in the subject's chart. Frequencies are given for the drug classes and generic names. A confidence interval gives an estimated range of values which is likely to include an unknown population parameter, the estimated range of 7% to 14% was calculated from a given set of sample data.

According to the frequencies provided in Table 8, antihistamines were the most often consumed drug class. Of the patients using medications with anticholinergic side

effects, 52.4% were taking an antihistamine. Within this class, 42.9% of the subjects were consuming diphenhydramine, the most frequently consumed drug. Various diphenhydramine trade names were being used by subjects and are listed on Table 8. Diphenhydramine is frequently used as a sleep aid and is available both over-the-counter or with a prescription.

Table 8

Drugs with Anticholinergic Side Effects Used by Older Adults Within the Study at Initial

Visit (n=20)

Drug Class	Generic Name	Trade Name	No. of Drugs	Percentage
Antidepressants			3	14.3%
	Amoxapine	Amoxapine	1	4.8%
	Maprotiline	Ludiomil	1	4.8%
	Nortriptyline	Nortriptyline	1	4.8%
Antihistamines			11	52.4%
	Diphenhydramine	Benadryl		42.9%
		Excedrin PM	9	
		Sure Sleep		
		Tylenol PM		
	Hydroxyine	Hydroxyine	2	9.5%
		Vistaril	2	
Antispasmodics			5	23.8%
	Hydroamine	Levbid	2	9.5%
		NuLev	2	
	Oxybutynin	Ditropan	3	14.3%
Brochodilators			2	9.5%
	Ipratropium	Combivent	2	9.5%

Not all of the drug classes that were examined had drugs in them that were being used by the subjects. Seventeen drug classes were examined (see Table 4 and Table 5), but only four were being used. These drug classes included: antidepressants, antihistamines, antispasmodics, and brochodilators.

Summary

A description of the sample according to the basic conditioning factors of age, sex, marriage status, ethnicity, and type of housing was presented in this chapter. This study hypothesized that an unknown percentage of subjects who visited the memory loss clinic would report use of medications with anticholinergic side effects at their initial visit. After analyzing the chart review data, 10.3% of the 193 subjects were found to be consuming one or more medications with anticholinergic side effects. These findings revealed that drugs with anticholinergic side effects are continuing to be consumed by older adults.

CHAPTER V

Discussion

This chapter contains a discussion of the study's findings and conclusions.

Orem's (2001) self-care deficit nursing theory applied to the study's findings is also included. Study limitations are identified. The study's implications for nursing practice and education are discussed. Recommendations for further research conclude the chapter.

Findings

Frequency of Use of Drugs with Anticholinergic Side Effects

The research question, "What is the frequency of the use of OTC and prescription drugs with anticholinergic side effects in a sample of older adults with memory problems seen in an outpatient setting?" was answered in this study. It was found that within the sample of 193 subjects, 21 medications with anticholinergic side effects (both prescribed and OTC) were being consumed by 20 subjects. One subject was consuming two drugs with anticholinergic side effects; all other subjects were consuming only one drug with anticholinergic side effects.

Use of drugs with anticholinergic side effects appears to be continually declining. In 1983, Blazer, Federspiel, Ray, and Schaffner reported that within one year, 23% of older adults living within the community had consumed a drug with anticholinergic side effects. Following the introduction of the Beers criteria (1991, 1997) of inappropriate drugs, Stuart et al. (2003) reported a drop in the use of medications included within the Beers criteria; use decreased from 24.8% in 1995 to 21.3% in 1999. In 2000, Aparasu and Mort reviewed four preveious studies that had utilized the Beers criteria in order to discover frequencies of inappropriate drug use. The review revealed some consistent

patterns across healthcare settings and Aparasu and Mort estimated that, in ambulatory settings, the prevalence of inappropriately used medications was 7.9%. The results of this study demonstrated a slight increase when compared to the Aparasu and Mort (2000) article; 10.3% of the population was found to be using a drug with anticholinergic side effects. However, this study's results continue to demonstrate a decline when compared to the percentages reported in studies conducted throughout the 1990s.

The declining use of inappropriate medications is both encouraging and discouraging. It is encouraging to know that use is declining, and therefore, a smaller percentage of older adults are being exposed to the dangerous side effects that these medications can cause. It is also beneficial to know that tools such as the Mintzer and Burns (2000) list medications with anticholinergic side effects and the Beers criteria (1991, 1997, Fick, et al., 2003) of inappropriate medications for older adults have been effective (Stuart, et al., 2003). However, the rate of decline is discouraging. The use of inappropriate medications has been the focus of research for over 20 years (Blazer, et al., 1983). There needs to be a continued emphasis on education in order to end use of inappropriate medications.

Use of Prescription Drugs with Anticholinergic Side Effects

Twelve of the medications with anticholinergic side effects that were used within the sample group were available only with a prescription and therefore, it is assumed, were prescribed to the older adult by a medical prescriber. Oxybutynin (e.g., Ditropan) was the most frequently used drug available only with prescription. Ditropan is used to decrease bladder spasms, urinary frequency, and incontinence. It was taken by 3 older

adults. As previously discussed in the literature review, Howard et al. (2004) also found Dipropan to be frequently consumed within the elderly population. Howard et al. found 3.7% of 889 older adults to be consuming Ditropan.

Use of OTC Drugs with Anticholinergic Side Effects

Nine subjects were taking drugs with anticholinergic side effects available OTC or with a prescription. The most frequently used medication available OTC was diphenhydramine (e.g., Tylenol PM); 9 subjects were found to be using it. Tylenol PM is a nighttime sleep aid and diphenhydramine is one of its ingredients. Tylenol PM is made of acetaminophen and diphenhydramine HCl (Drug Information Online, 2005).

Diphenhydramine is included on the Mintzer and Burns (2000) list of anticholinergic drugs (Table 4 and Table 5) and on the Beers updated criteria (Fick, et al., 2003), (Table 1). Other drugs available OTC being consumed by older adults in this study included: Excedrin PM, Benadryl and Sleep Sure. Each of these medications also contains diphenhydramine (Lehne, 2004; Drug Information Online, 2005). According to Fick et al. (2003) diphenhydramine poses a high risk to older adults; it may cause confusion and sedation and should be avoided.

Use of Drugs with Anticholinergic Side Effects in a Drug Class

Medications in the antihistamines drug class were the most frequently consumed drugs with anticholinergic side effects among the subjects. Approximately 52% of the older adults consuming a drug with anticholinergic side effects were consuming an antihistamine. Antihistamines are available both OTC and with a prescription. Two types of antihistamines were reported: diphenhydramine (e.g., Tylenol PM) and hydroxyine (e.g., Vistaril). As previously reported by Barat et al. (2000), 72% of the elderly consume

OTC medications and Beyth and Shorr (1999) reported that older adults consume over 50% of all OTC medications sold. Knowing the high level of OTC use among elderly, it is not surprising to discover that medications with anticholinergic side effects available OTC are the most frequently consumed. It does, however, highlight that education of this population concerning the dangers of these medications that are available OTC could be beneficial. Consumer education will be further discussed later in this chapter.

Application to Nursing Theory

Orem's (2001) self-care deficit nursing theory provided the theoretical outline for the study. Subjects in the study chose to consume (self-care agency) drugs with anticholinergic side effects in order to meet a perceived need (self-care demand). This study found 20 subjects consuming drugs with anticholinergic side effects that are available either 1) only with a prescription or 2) OTC or with a prescription. These facts suggest that knowledge of the dangers of use of drugs with anticholinergic side effects may be lacking. However, because this study did not examine reasons for anticholinergic medication consumption, it is unknown if the 20 subjects who consumed medications with anticholinergic side effects had received teaching concerning the dangers of the medications. It is also unknown if the subjects understood the possible implications of taking these medications and chose to consume them anyway. Because drugs with anticholinergic side effects available only with a prescription were being consumed, it may be appropriate to educate medical personal on the dangers of these medications. Additionally, because drugs with anticholinergic side effects that are available over-thecounter were being consumed, education of this population focused on the dangers of

these drugs is needed. Educational needs may also extend beyond the dangers of medication consumption. It may be beneficial to provide information to both consumers and healthcare providers on non-pharmacological means for treatment of the medical problems that older adults are using these drugs with anticholinergic side effects to correct.

Limitations

Limitations for application of this study to the general population were as follows:

1) the homogeneity of the sample, and 2) all subjects were able to seek medical care for a perceived memory loss problem (financial and supportive means possibly not found throughout the general population).

Implications

The purpose of this study was to discover the frequency of use of drugs with anticholinergic side effects in a sampling of older adults being seen at an outpatient clinic for memory loss problems. Within the study sample, 10.3% of the subjects were found to be consuming a medication with anticholinergic side effects. The frequencies of consumption of medications available only with prescription, or OTC and with a prescription was very similar; 5.6% of the medications were available only with a prescription and 5.1% were available OTC or with a prescription.

Aparasu and Mort (2000) expressed that research concerning inappropriate prescribing or use trends is valuable because it can be instrumental in developing specific interventions to influence future prescribing practices. As previously discussed research has demonstrated a continuing decline in the use of inappropriate medications among older adults. Aparasu and Mort (2000), found that in an ambulatory setting, the

prevalence of inappropriately used medications was 7.9%. The percentage of clients using medications with anticholinergic side effects within the confines of this study was 10.3%, slightly more than Aparasu and Mort's findings. This study's findings demonstrate a need for further research. Questions that should be answered include: 1) is this 10.3% applicable to the general population, 2) what steps should be taken in order to continue the decrease in use among older adults in outpatient settings, and 3) what are the reasons that older adults are continuing to consume medications with anticholinergic side effects?

This study demonstrates the need for continued and perhaps increased teaching concerning the use of medications with anticholinergic side effects within an older adult population. Medication education has become increasingly important in the nursing role. Numerous nursing tasks require varying degrees of medication knowledge. Nurses must understand drug administration, how to provide patient drug education, and drug side effects, interactions, and concerns (King, 2004). The nursing field needs to educate 1) nurses, 2) clients/family and 3) other medical staff concerning anticholinergic implications. Most importantly, though, nurses must insure that they have a clear understanding, in order to provide a complete understanding to others.

Self-care Deficit Nursing Theory

Orem (2001) described a need for nursing if a self-care deficit exists. Subjects with memory loss problems who are consuming medications with anticholinergic side effects are demonstrating a need for nursing care. This study has identified consumption of drugs with anticholinergic side effects within an older adult population with memory loss problems as a self-care deficit. By consuming these medications, they are potentially

causing dangerous cognitive changes or exacerbating current memory impairment.

An educative nursing system is needed in order to educate clients, caregivers, and other medical staff about these complications. Educative nursing systems could also offer knowledge concerning alternative or non-pharmacological solutions in order to remedy the medical conditions that the older adults are attempting to correct with the use of drugs with anticholinergic side effects. When this deficit is corrected using an educative nursing system, the nurse (or other medical professional) has enabled the client to again provide themselves the healthful self-care agency. Nurses must be able to assess and fulfill the needs of their clients through the safest and most effective means, in order to help people maintain their desired level of health and well-being.

Nursing Education

Implications from this study for education focus on the education of nurses concerning anticholinergic side effects and the risks associated when taken by a person with memory loss problems. Aparasu and Mort (2000) encouraged the application of Beers (Fick, et al., 2003) updated criteria of inappropriate medications for use within elderly populations. The criteria is easily accessible and widely cited. Education using the Beers criteria, and specifically highlighting anticholinergics could begin in nursing undergraduate curriculums (perhaps pharmacological classes) and continue in advanced degree programs with more in-depth overviews, concentrating more on the varying medications undesired effects and the medications' severity ratings (Beers, 1997). Nurses must know what types of medications clients are taking. A complete medication assessment of clients should be conducted regularly. The assessment should include questions about the types of prescription, OTC and herbal or "home remedies" consumed.

Questions about how often a drug is taken and in what quantity are also needed.

Nurses should be able to explain the risks associated with these medications to a variety of audiences: clients, caregivers and other medical professionals. Nurse practitioners with the ability to prescribe should know not to prescribe medications with anticholinergic side effects to older adults and to questions these clients about all types of medications consumed.

Client Education

Clients and/or caregivers need to be thoroughly assessed by medical staff for 1) anticholinergic use (because these medications are available both by prescription and OTC), and 2) understanding of anticholinergic side effects and risks. Thorough medication assessment should occur during the person/medical professional interview when the medications consumed are discussed. It is important for medical professionals to question people about all drugs taken and not just those prescribed by a professional. People experiencing memory loss problems and their caregivers should be made aware of OTC medications with anticholinergic side effects, so as to avoid them. Educational brochures or easily accessible websites with lists of such OTC drugs may be helpful resources in an outpatient setting for distribution to clients and caregivers. Such information enables clients to be more knowledgeable and self-sufficient.

Recommendations for Future Nursing Research

Future research related to this topic could explore any of the following questions. First, what is the prevalence of anticholinergic used within an older adult population? Is the percentage continuing to decline? Second, do clients, caregivers or prescribers know the possible dangers of consumption of medications with anticholinergic side effects?

(Are they choosing to take them knowingly?) If knowledge of these dangers was found to be lacking, it would be appropriate to suggest that educational efforts be made. Third, are prescribers being adequately educated concerning the dangers of medications with anticholinergic side effects within the older adult population? Fourth, what are prescribers, nurses and/or pharmacologists currently doing to educate clients consuming these drugs about their side effects? Finally, what is the best means by which to inform clients and caregivers about the danger of use of medications with anticholinergic side effects?

Summary

This chapter included a discussion of the research findings and conclusions. The limitations of the study were identified. Implications for nursing practice and education were discussed. The study findings were outlined within Orem's self-care deficit nursing theory and recommendations for further nursing research were made.

REFERENCES

- American Association of Retired Persons [AARP] Online. (2005). *Membership Qualifications*. Retrieved April, 2005, from http://www.aarp.org/membership
- Aizenberg, D., Sigler, M., Weizman, A., & Barak, Y. (2002). Anticholinergic burden and the risk of falls among elderly psychiatric inpatients: a 4-year case-control study.

 *International Psychogeriatrics, 14 (3), 307-310.
- Aparasu, R., & Mort, J. (2000). Inappropriate prescribing for the elderly: Beers criteriabased review. *The Annals of Pharmacotherapy*, *34*, 338-345.
- Barat, I., Andreasen, F., & Damsgaard, E. (2000). The consumption of drugs by 75-year-old individuals living in their own homes. *European Journal of Clinical Pharmacology*, 56, 501-509.
- Beers, M. (1991). Explicit criteria for determining potentially inappropriate medication use by the elderly. *Achieves of Internal Medicine*, *151*, 1531-1536.
- Beers, M. (1997). Explicit criteria for determining potentially inappropriate medication use by the elderly. An update. *Achieves of Internal Medicine*, *157*, 1531-1536.
- Beyth, R., & Shorr, R. (1999). Epidemiology of adverse drug reactions in the elderly by drug class. *Drugs & Aging, 14* (3), 231-239.
- Blazer, D., Federspiel, C., Ray, W., & Schaffner, W. (1983). The risk of anticholinergic toxicity in the elderly: a study of prescribing practices in two populations. *Journal of Gerontology*, 38 (31), 31-35.
- Bradley, C., & Bond, C. (1995). Increasing the number of drugs available over the counter: Arguments for and against. *British Journal of General Practice*, 45, 693-701.

- Burns, N., & Grove, S. (2001). *The practice of nursing research: Conduct, critique,* & utilization. (4th ed.). Philadelphia: W.B. Saunders Company.
- Coons, J., Johnson, M., & Chandler, M. (1992). Sources of self-treatment information and use of home remedies and over-the-counter medications among older adults.

 *Journal of Geriatric Drug Therapy, 7, 71-82.
- Costa, P., Williams, T., & Somerfield, M. (1996). Early identification of Alzhiemer's disease and related dementias. Clinical practice guideline, quick reference guide for clinicians, No. 19. Rockville, MD: U.S. Department of Health and Human Services. (AHCPR Publication No. 97-0703)
- Cramer, J. (1998). Enhancing patient compliance in the elderly: role of packaging aids and monitoring. *Drugs & Aging*, 12(1), 7-15.
- Drug Information Online. (2005). *Prescription drug information for consumers* & *professionals*. Retrieved March, 2005, from http://www.drugs.com
- Esposito, L. (1995). The effects of medication education on adherence to medication regimens in an elderly population. *Journal of Advanced Nursing*, 21, 935-943.
- Fick, D., Cooper, J., Wade, W., Waller, J., Maclean, R., & Beers, M. (2003). Updating the Beers criteria for potentially inappropriate medication use in older adults.

 *Archives of Internal Medicine, 163, 2716-2724.
- Foreman, M., Fletcher, K., Mion, L., & Simon, L. (1996). Assessing cognitive function. *Geriatric Nursing*, 17(5), 328-233.
- Fratiglioni, L, deRonchi, D., & Aguero Torres, H. (1999). Worldwide prevalence and incidence of dementia. *Drugs & Aging*, 15(5), 365-375.

- Fu, A., Liu, G., & Christensen, D. (2004). Inappropriate medication use and health outcomes in the elderly. *The American Geriatrics Society*, *52*, 1934-1939.
- Giron, M., Claesson, C., Thorslund, M., Oke, T., Winbland, B., & Fastborn, J. (1999).

 Drug use patterns in a very elderly population: A seven-year review. *Clinical Drug Investigation*, 17(5), 389-398.
- Hanlon, J., Fillenbaum, G., Ruby, C., Gray, S., & Bohannon, A. (2001). Epidemiology of over-the-counter drug use in community dwelling elderly. *Drugs & Aging*, 18(2), 123-131.
- Hanlon, J., Linblad, C., Hajjar, E., & MaCarthy T. (2003). Update on drug-related problems in the elderly. The *American Journal of Geriatric Pharmacotheapy 1*(1), 38-43.
- Hanlon, J., Schamder, K., Ruby, C., & Weinberger, M. (2001). Suboptimal prescribing in elderly inpatients and outpatients. *Journal of the American Geriatrics Society* 49(2), 200-209.
- Howard, M., Dolovich, L., Kaczorowski, J., Sellors, C., & Sellors, J. (2004). Prescribing of potentially inappropriate medications to elderly people. *Family Practice*, *21*, 244-247.
- Hughes, C., McElnay, J., & Fleming, G. (2001). Benefits and risks of self medication. *Drug Safety*, 24(14), 1027-1037.
- Kawas, C., & Katzman, R. (1999). *Alzheimer's Disease* (2nd ed.). Philadelphia: Lippincott, Williams and Wilkins.
- King, R. (2004). Nurses' perceptions of their pharmacology educational needs. *Journal of Advanced Nursing*, 45(4), 392-400.

- Korner, A., Lauritzen, L., & Bech, P. (1996). A psychometric evaluation of dementia rating scales. *European Psychiatry*, 11, 185-191.
- Lehne, R. (2004). *Pharmacology for Nursing Care* (5th ed.). St. Louis: W.B. Saunders Company.
- Manias, E., & Bullock, S. (2002). The educational preparation of undergraduate nursing students in pharmacology: perceptions and experiences of lecturers and student.

 International Journal of Nursing Studies, 39, 757-769.
- Miller, C. (2002). Anticholinergics: The good and the bad. *Geriatric Nursing*, 23(5), 286-287.
- Mintzer, J., & Burns, A. (2000). Anticholinergic side-effects of drugs in elderly people. *Journal of the Royal Society of Medicine*, 93(9), 457-462.
- Norwood, S. (2000). *Research strategies for advanced practice nurses*. Upper Saddle River, NJ: Prentice Hall Health.
- Orem, D. (1995). Nursing: Concepts of practice (5th ed.). St. Louis, MO: Mosby, Inc.
- Orem, D. (2001). Nursing: Concepts of practice (6th ed.). St. Louis, MO: Mosby, Inc.
- Perry, P., & Lund, B. (1996). *Anticholinergic Psychosis*. Clinical Psychopharmacology

 Seminar. Retrieved April 21, 2004, from

 www.vh.org/adult/provider/psychiartry/CPS/25.html
- Pitkald, K., Strandberg, T., & Tilvis, R. (2001). Is it possible to reduce polypharmacy in the elderly? A randomized, controlled trial. *Drugs & Aging*, 182, 143-149.
- Porth, C. (2002). *Pathophysiology: Concepts of Altered Health States* (6th ed.).

 Philadelphia: Lippincott Williams & Wilkins.

- Reuben, D., Herr, K., Pacala, J., Polock, B., Potter, J., & Selma, T. (2003). *Geriatrics at your fingertips* (5th ed.). Malden, MA: Blackwell Publishing, Inc.
- Roe, C., Anderson, M., & Spivack, B. (2002). Use of anticholinergic medications by older adults with dementia. *Journal of the American Geriatrics Society*, 50, 836-842.
- Ryan, A. (1998). Medication compliance and older people: A review of the literature. *International Journal of Nursing Studies*, 36(2), 153-162.
- Skidmore-Roth, L. (2003). Mosby's Nursing Drug Reference. St. Louis, MO: Mosby.
- Sloane, P., Zimmerman, S., Brown, L., Ives, T., & Walsh, J. (2002). Inappropriate medication prescribing in residential care / assisted living facilities. *Journal of the American Geriatrics Society*, 50, 1001-1011.
- Stuart, B., Kamal-Bahl, S., Briesacher, B., Lee, E., Doshi, J., Sucherman, I., Verovsky, et al., (2003). Trends in the prescription of inappropriate drugs for the elderly between 1995 and 1999. *The American Journal of Geriatric Pharmacotherapy* 1(2), 61-74.
- Towers, C. (2001). *Medical issues and drug interactions: over-the-counter antihistamine*drugs. Pharmcredits.com. Retrieved March 25, 2005 from https://e-edcredits.com/pharmcredits/article.asp?TestID=4
- Tune, L. (2001). Anticholinergic effects of medication in elderly patients. *Journal of Clinical Psychiatry*, 62(21), 11-14.
- Vangala, V., & Tueth, M. (2003). Chronic anticholinergic toxicity: Identification and management in older patients. *Geriatrics*, 58(7), 36-37.

- Varcarolis, E. (2002). *Foundations of Psychiatric Mental Health Nursing: A Clinical Approach* (4th ed.). Philadelphia: W.B. Saunders Company.
- Venes, D., & Thomas C. (Eds.). (2001). *Taber's Cyclopedic Medical Dictionary* (19th ed.). Philadelphia, PA: F.A. Davis Company.

APPENDIX A



Medical College of Ohio

INSTITUTIONAL REVIEW BOARD

Department for Human Research Protections

Block Health Science Building - Room 140 3035 Arlington Avenue, Toledo, Ohio 43614-5804 Phone: 419-383-6796 Fax: 419-383-3248

(FWA00007382)

MEMORANDUM

TO:

Cletus U. Iwuagwu, M.D.

MCO Department of Medicine

FROM:

Eric Schaub, M.D., M.P.H.

Chair, MCO Institutional Review Board

DATE:

January 18, 2005

SUBJECT: IRB #104638- Office Based Evaluation of Older Adults with Potentially Reversible Dementias

The above project was reviewed and re-approved by the Vice-Chair of the Medical College of Ohio Institutional Review Board as an expedited review. The Chair noted that enrollment is closed at this site and all data collection is complete. This review and approval includes the amendment (add Rachel Kemper and Carrie Blanchert as study personnel). The full board will review this research at its meeting on 01/20/2005.

RE-APPROVAL DATE:

01/18/2005

EXPIRATION DATE:

01/17/2006

NOTE: ALL of the materials (data, documents, records, or specimens) to be utilized in this project must "have been collected, or will be collected solely for nonresearch purposes* (such as medical treatment or diagnosis)" [Expedited category description as revised, effective November 9, 1998]. (* MCO IRB emphasis)

All information - that which is pertinent to the research project and that which is incidental to the project - must be handled at all times in a manner to protect patient confidentiality and privacy.

It is the Principal Investigator's (P.I.'s) responsibility to:

- Abide by all federal, state, and local laws and regulations; the MCO federal assurance and institutional policies for human subject research and protection of individually identifiable health information including those related to record keeping and be sure that all members of your research team have completed the required education in these areas.
- Promptly notify the MCO IRB at (419) 383-4251 of any untoward incidents or unanticipated adverse events that develop in the course of your research. Please complete and submit RGA Form 317 for ALL SUCH REPORTS for this protocol. The Principal Investigator is also responsible for submitting to the MCO IRB reports of adverse events that occur at other sites conducting this study and for maintaining an up-to-date cumulative table of adverse events (RGA Form 316) and submitting it to the MCO IRB for each research project. The Principal Investigator is responsible for reporting adverse events to the appropriate federal agencies and the sponsor (when one exists).
- Report promptly to the MCO IRB any deviations or violations from the MCO IRB approved protocol in accordance with the procedures outlined in RGA Form 309. In your report include the protocol number and title, the subject's initials/specimen identifier (as appropriate) and study I.D. number, date of the event, a brief description of the occurrence and a description of any corrective actions taken. The Principal Investigator is responsible for reporting deviations, violations and participant non-compliance to the appropriate federal agencies and the sponsor (when one exists) in accordance with federal regulations, institutional policy and any other legal agreements with these organizations.

ABSTRACT

The purpose of this study was to determine the frequency of over-the-counter and prescription medications with anticholinergic side effects being used in a sample of 193 older adults with memory problems seen an outpatient setting between October 1999 through April 2004. Medications with anticholinergic side effects are contraindicated in this population because they can worsen memory impairment, increasing confusion.

Using data from a retrospective chart review, this study was a secondary analysis of the medications that adults (>50 years of age) were taking at their initial clinic visit. Mintzer and Burn's (2000) list was used to identify drugs posing an anticholinergic danger.

Findings revealed that 10.3% of these adults were consuming one or more medications with anticholinergic side effects. These finding demonstrate a need for continued and perhaps, increased education for medical personal and healthcare consumers concerning the dangers of medications with anticholinergics side effects.