

Spring 3-16-2004

# Patients' Perceptions of Herbal Medicines and Natural Supplements

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PATIENTS' PERCEPTIONS OF  
HERBAL MEDICINES AND  
NATURAL SUPPLEMENTS

By  
Penny L. Vinnedge

*Thesis Proposal Submitted in Partial Fulfillment  
of the Requirements for the Degree of  
Master of Science, Physician Assistant Studies*

*Augsburg College*

*May 2004*



MASTER OF SCIENCE IN PHYSICIAN ASSISTANT STUDIES  
AUGSBURG COLLEGE  
MINNEAPOLIS, MN

CERTIFICATE OF APPROVAL

This is to certify that the Master's Thesis of

Penny Lynn Vinnedge

has been approved by the Thesis Review Committee for the Master of Science in  
Physician Assistant Studies degree

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I dedicate this project to my husband, my family, and my friends all of whom were neglected far more often than they should have been during this project. Thank you all for remaining so supportive.

Thank you also to Dr. Jerome Andres for being my Co-investigator and to him and the staff at the Mosinee Clinic for helping me get a great return for my surveys. I'd also like to thank the Marshfield Clinic for allowing me to do my project at their Mosinee site.

Thank you to Terry Lewis, PA-C for being my advisor through this project and thank you Dr. Sean Truman for helping me with my statistics.

## Abstract

### *Background*

Herbal medicine and natural supplement use is becoming more popular among the general population. They are being used as adjuncts to conventional medicine, in place of conventional medicine, or as a last resort after failure of conventional medicine. There are benefits and downfalls to these alternative therapies. The problem is determining what beliefs patients have about herbs/supplements and how they form these beliefs.

### *Methods*

A written survey was distributed to patients visiting a family practice clinic over a single week. Descriptive statistics were obtained to determine frequencies and totals of data and two types of inferential statistics were performed to look for relationships or correlations among the data.

### *Results*

Participants in this study were more informed in several areas regarding herbs/supplements and were more open to sharing their beliefs and usage with medical providers than those of previous studies had been. Misperceptions about herbs/supplements did exist among the participants and few correlations were found when comparing users versus non-users responses.

### *Conclusions*

While participants were much more informed than originally expected by the investigator, there is room for improvement. More scientific studies, education, and monitoring of herbs/supplements are needed, especially as use of these products continues to increase.

## **Table of Contents**

List of Tables	vi
List of Figures	vii
Chapter 1	1
The Problem	
Chapter 2	7
Literature Review	
Chapter 3	31
Methodology	
Chapter 4	40
Results	
Chapter 5	49
Discussion	
References	57
Appendix A	61
Survey Instructions and Consent Form	
Appendix B	63
Augsburg IRB Approval	
Appendix C	64
Marshfield Clinic IRB Approval	
Appendix D	66
Site Approval Letter	
Appendix E	67
Bouldin et al. Survey Correspondence	
Appendix F	69
Durante et al. Correspondence	
Appendix G	70
Bouldin et al. Survey	
Appendix H	72
Durante et al. Survey	
Appendix I	73
Researcher's Survey Draft 1	
Appendix J	75
Researcher's Survey Final Draft	
Appendix K	78
Likert Scale Results-Table 5	

**List of Tables**

Table 1	Commonly Used Herbal Medicines/Natural Supplements	40
Table 2	Positive and Negative Effects of Herbs/Supplements	42
Table 3	Sources of Information on Herbs/Supplements Chosen by Users Chart	43
Table 4	Sources of Herb/Supplement Information Reported by All Respondents	44
Table 5	Likert Scale Results	78

## **List of Figures**

Figure 1		
	Reason Use Was Discontinued Bar Graph	41
Figure 2		
	Health Professionals Herbal Users Have Monitoring Them	44
Figure 3		
	Effectiveness of Herbs/Supplements	45
Figure 4		
	Opinions on Safety of Herbs/Supplements	45

## Chapter 1

### The Problem

#### *Introduction and Background*

This study was important because it looked at the opinions and knowledge that patients have about herbal medicines and natural supplements and how they obtained their beliefs and knowledge. Herbal medicine and natural supplement use has grown in the U.S., yet education about these products to the general public and even to medical professionals has been and continues to be rather limited. From conversation and interaction of the researcher with conventional medical providers it appeared that conventional medical education of health care professionals has not routinely included instruction on herbal medicines or natural supplements. Conventional medicine has often looked at herbal and natural products as shams. However, some products have been found to have genuine benefits and there has been a change occurring in medical providers practice combining alternative therapies with conventional medicines.

There has been a lack of scientific based evidence about these products. Many herbal and natural products have contraindications, contaminants, side effects and drug interactions. More studies continue to be needed as people continue to use these products so that valid scientifically supported evidence becomes the predominate information available on the market. Monitoring of these products in the U.S. has been inadequate due to lack of manpower, funding, and the federal 1994 Dietary Supplement Health and Education Act (DSHEA) protecting herbs and natural supplements from government control (Greensfelder, 2000; Sardesai, 2002). Herbal and natural products share the shelves with FDA monitored items in grocery stores, department stores, and even



pharmacies. It's easy to see how people may have assumed that these products are being regulated in the same way as over the counter medicines, but they have not been.

Studies in the past looked at pharmacists' perceptions of herbal medicines, specific herbals or natural supplements used by patient's visiting a family practice clinic, and a national survey about consumers' opinions regarding the mainstreaming of alternative medicines (Bouldin, 1996). This study looked at perceptions of both patients who use and those who do not use herbal medicines and natural supplements. This study included questions about specific products and general questions about monitoring, safety, and how the participants obtained their information. People deserve to know the truth about these products and have scientifically based evidence readily available to them to protect them from dangerous products and misinformation.

#### *Statement of the Problem*

This study aimed to answer the question, what beliefs do patients visiting a family practice clinic have about herbal medicines and natural supplements. The question considered both users and non-users opinions, offering a varied study population. The population of family practice patients was chosen because it also allowed for a diverse study population. Participants may have chronic illnesses, but also may be completely healthy only visiting the clinic for routine health maintenance exams.

#### *Purpose and Objective*

This study aimed to determine a knowledge base of patients' beliefs about herbal medicines and natural supplements. This study attempted to assess patients' opinions regarding perceived effects of the products they were using, if they were using any, looked at how people obtain their information about herbal medicines and natural

products, and addressed whether or not patient's who used these therapies informed their medical providers. Also addressed were the general perceptions of patients regarding the safety, quality, monitoring, efficacy, side effects, contraindications, and drug interactions of herbal and natural supplement products. Patients have obtained some misinformation and it's necessary to educate medical professionals about deficient or inaccurate beliefs regarding herbal medicines and natural supplements, so they can better educate their patients. It's important that accurate information be made widely available to the general public about the accepted use, monitoring, regulation, science, contraindications, drug interactions, and side effects of herbal medicines and natural supplements, so they make educated choices.

This study was used to determine what beliefs patients have about herbal medicines and natural products and whether differences in opinion existed between users and nonusers. It expressed whether or not those beliefs are in agreement with available scientific evidence and previous studies about these products. By acquiring this information the researcher was able to determine the general accuracy of patients' beliefs.

#### *Assumption and Limitations*

This study assumed that people were not properly educated about herbal medicines and natural supplements. It assumed that many people did not get appropriate scientific evidence to either support or discredit the use of herbal medicines and natural products. It also assumed that use of herbal medicines and natural supplements has continued to grow in the U.S. It assumed that scientifically based evidence is the only evidence accepted by conventional health care providers.

Limitations of this study included time available, funding available, survey tool and the study population being used. The time to complete this research project was limited because it had to be completed by the researcher's graduation date of May 2, 2004. The project did not begin until the Spring of 2002 and ran concurrently with completion of all other academic and clinical courses for the Physician Assistant program which left the researcher limited in what could be accomplished in that amount of time without sacrificing the other components of her education. The funding available was strictly what could be budgeted out of the researcher's student loans, as all financial support was the responsibility of the researcher. While grants could be used the time available to complete the study and other course work did not allow enough time to search for and complete such applications. The survey tool itself was limited because it was the combination of two separate unrelated studies and original questions written by the researcher. The tool cannot be labeled as valid because it has never been used in this form before and actual calculated validities were not available. The study population was limited because it was representative of the weekly patient population at one clinic and it looked at the perception of patients, not the general public. It would have been more representative of the U.S. population if the survey was distributed to several clinical sites across the nation or to the general public nationally, but time and finances hindered the researcher's ability to perform such a study.

A bias of this study was that the survey relied upon a retrospective recall, remembrance of past events or details, by the participants and assumed there would be some inaccurate information provided. Since the survey was distributed in a clinic, participants may have been less likely to provide honest information if they felt their

medical providers would not agree with use of herbal medicines or natural supplements. The focus group used by the researcher may have been biased; it was comprised of family and friends of the researcher and they may have been less likely to provide honest suggestions to prevent hurting the researcher's feelings.

### *Definition of Terms*

**Alternative Therapies:** Therapies that are different from those available and used by conventional medicine.

**Adulterants:** Agents, which contaminate a product making it impure due to the addition of inferior ingredients, minerals, toxic, and non-toxic chemicals.

**Complementary and Alternative Medicine (CAM):** Medical therapies and products that are different than those used by conventional medicine, may be used instead of or in combination with conventional medicine. Includes treatment modalities such as acupuncture, herbal medicines, homeopathy, massage, meditation, prayer, and natural supplements.

**Conventional Medicine:** Medical practices agreed upon by the majority, customary or traditional ways in providing medical care.

**Family Practice Clinic:** A medical facility caring for a broad scope of medical conditions, serves as a general practitioner for all ages, illnesses and diseases.

**Herbal Medicine:** A plant or plant part consumed for medicinal or health purposes and do not include plants being used solely as food or part of a meal.

**Natural Supplements:** Products intended to supplement the diet or enhance health that contain amino acids or animal products, this does not include mineral or vitamin supplements.

**Patient:** A person receiving medical care whether ill or healthy.

**Perceptions:** Understanding, insight, awareness, or mental impression of an object(s), product(s), or sensations experienced during use of the object(s) or product(s).

**Scientific evidence:** Results obtained in research studies based upon well-established facts, principles, methods and laws of the Sciences. Sciences are composed of such areas of expertise as Physics, Biology, Chemistry, Sociology, and Psychology.

The above definitions were adapted from The New International Webster's Dictionary of the English Language (1995).

### *Conclusion*

Chapter one explained the research question, the study's importance, study's limitations, and study's assumptions. The following chapters review separately the current literature available regarding herbal medicine and natural supplements, methods and design of the study, analysis of the obtained data, and a discussion of the results of the study.

## Chapter 2

### Literature Review

#### *Introduction*

The sources used in this literature review were obtained via the internet and the online journal database PubMed. Articles were directly printed from websites or obtained from the Augsburg College library either directly or through interlibrary loans. The chapter has been split into several categories discussing the background of herbal medicines and natural supplements, the reasons for their use, prevalence of their use, monitoring and regulation of Complementary and Alternative Medicines (CAM), drug interactions, contraindications, efficacy, side effects, safety, studies and testing, consumer information sources, and health professional's role in herbal medicines and natural supplements. Each section summarizes the literature's view on that subject.

A brief review of some previously preformed studies is then presented and gaps in the studies identified. The conclusion sums up the importance of this study for filling in research gaps and presents the goals of the study.

#### *Background*

Historically medicine has often been practiced without scientific evidence; patient's were once bled to dispel their ills or given poisonous or addictive chemicals on the basis of sketchy reports of previous healing successes (O'Matthúna, 2001). Even in the current practice of medicine, some drugs are approved for the treatment of medical conditions because they have been found in research studies and practice to be effective at improving a condition, but the actual mechanism by which it works is unknown.

In traditional Chinese medicine, herbal use is based on thousands of years of experience; whole components are used, not isolated active portions of the herbal substances (Hohman and Koffler, 2002). The isolation of active ingredients may disrupt the natural balance of ingredients in a substance potentially creating side effects (Hohman and Koffler). One such example was the discovery of salicylic acid from willow bark. The Native Americans found that chewing willow bark relieved pain; scientists isolated salicylic acid as the active component responsible for these effects and began marketing it as the drug aspirin. However, the isolated salicylic acid was found to cause damage and irritation to the mucosal lining of the intestinal tract while the willow bark did not because other constituents in the whole provided a buffer (Hohman and Koffler).

The medicinal properties of herbals may be supported by years of use; however, the structure and function claims on the labels of some products can suggest results that are not achievable (Bouldin, Smith, Banahan, McCaffery, and Croom, 2000). Herbs have been used for food and medicines for centuries. Over 2.5 billion individuals and almost fifty percent of medical providers in India, China, and the Middle East base their medicine and healing on the use of herbs and herbal related products (Joshi and Kaul, 2001). Approximately eighty percent of the world's population relies on traditional medicine involving plant extracts or their active components for their health needs, according to the World Health Organization (Sardesai, 2002).

Medicinal potential of plants or plant-derived substances are often overlooked in the U.S.; many physicians are not aware of how often they are prescribing a natural compound (Plotnikoff and George, 1999). CAM is believed to have huge potential in the future, as it's estimated that one third (Sardesai, 2002) to greater than half (O'Matthúna,

2001) of the prescription drugs in the U.S. are based on natural plants and plant products. In the development of many prescription drugs active ingredients of plants are identified, synthesized, and mechanisms of action studied until safe, effective, and toxic and non-toxic levels are determined before their approval as drugs (Sardesai, 2002). Plants have therapeutic activity, but to ensure they are in doses that are both safe and effective they must be standardized to produce consistent products (P. Goldman, 2001).

Alternative medicine often has a negative undertone in the health care field, considered unconventional, unorthodox, quackery, or unproved. It's viewed as a threat to conventional therapy because it is often marketed as a replacement to traditional medicines. A less threatening view of herbal and natural supplements would be as complementary therapy, suggesting these items are complements to traditional medicines not replacements (Abdel-Rahman and Nahata, 1997). In a 1997 U.S. survey approximately fifteen million adults reported use of prescription medications together with herbal remedies or vitamins (Eisenberg, et al., 1998).

Despite dramatic increases in CAM use, the number of patients informing their conventional health practitioners of their CAM use remains low (Eisenberg, et al., 1998). It is estimated that 63-75% of patients do not inform their primary conventional health care providers of their CAM use (Abdel-Rahman and Nahata, 1997; Eisenberg, et al., 2001). It is believed that many users are self-diagnosing and then choosing an herbal or supplement treatment without consulting their conventional medical providers (Plotnikoff and George, 1999). In a 1997 study conducted by Eisenberg, et al., 96% of participants saw a medical doctor in the prior twelve months, but only 38.5% discussed their use of CAM with the doctor. In a study conducted by Durante, Whitmore, Jones, and Campbell,



2001) 74% of participants greater than 50 years old informed their conventional health provider of their CAM use compared to only 30% of participants less than 50 years-old. A 1998 national survey conducted by the Journal of the American Medical Association discovered that patients using CAM did not tell their conventional health providers about 60% of their CAM therapies (Consumer Reports, 2000). Common reasons given by CAM users for not disclosing their use to conventional health providers were: “they never asked, it wasn’t important for them to know, it’s none of their business, they wouldn’t understand, thought the provider may refuse to see them, and thought the provider wouldn’t approve” (Eisenberg, et al., 2001). Herbal medicine users are not only hesitant to reveal their use to health care providers, but other medical professionals. In a 1996 national survey of pharmacists only nine percent reported counseling patients about CAM twice a week and participants reported an average of only two to five patient requests per week (Bouldin et al., 2000).

#### *Prevalence of CAM Use*

The use of CAM including herbal medicines and natural supplements is showing an increase in the U.S. as well as other countries throughout the world. In analyzing data from several studies conducted between 1997 and 2001 it was determined that 32-68% of the U.S. population has been reported to be using alternative therapies or supplements (Eisenberg, et al., 1998; Hudson, Brady, Rapp, 2001; Bauer, 2000; Abdel-Rahman and Nahata, 1997; Astin, 1998; Kessler, et al. 2001). A repeat of a 1997 national U.S. study by Eisenberg, et al. in 2001 reported a 25% increase in the prevalence of CAM use in the population when compared to the results of the 1997 study. Use of herbal medicines alone was up from 2.5% in 1990 to 12.1% in 1997 (Eisenberg, et al., 1998). Other recent

surveys have reported herbal use by U.S. consumers to be between 12-37% (Roblatt, 1999). In a study conducted by Durante, et al. (2001) the use of herbs accounted for 23% of supplement use by patients visiting family practice clinics in the U.S. It's estimated that 60 million U.S. adults use herbal medicines (Plotnikoff and George, 1999).

Supplement use in the U.S., 34-49% from 1993-1998, in the Durante, et al. (2001) survey was higher than supplement use in Canada, 15%. A 1993 survey of Australians reported that 48.5% had used CAM in the previous year at least once (Drew and Meyers, 1997). The authors (Bouldin et al., 2000, p. 1339) summed it up best when they said, "The continuing phenomenon (herbal renaissance) has figured prominently in the media and in the pharmaceutical industry and consumer interest does not appear to be waning in the slightest."

#### *Reasons for Complementary Medicine Use*

There are number of reasons why individuals may choose to use CAM. A few of the most common reasons that have been reported are: CAM uses different theories to explain cause and cure of illness (Furnham and Smith, 1988; Astin, 1998; Eisenberg et al., 2001; O'Matthúna, 2001); people are not satisfied with the attitudes and behavior of conventional medicine or its practitioners (Furnham and Smith, 1988; Sardesai, 2002; Astin, 1998); patients, especially those with chronic problems, are unhappy with the results of their conventional treatments (Eisenberg et al., 1998; Durante et al., 2001; Astin, 1998; Abdel-Rahman and Nahata, 1997; Jugens, 2001; Bauer, 2000); people believe the CAM therapies will be safer and more effective than conventional treatments (Durante et al., 2001; Abdel-Rahman and Nahata, 1997; Roblatt, 1999; Jugens, 2001; Bauer, 2000); the cost is lower than prescription drugs (Bouldin et al., 2000; Bauer,

2000); users need more personal control in their health care (Astin, 1998; Jugens, 2001); and people believe it will prevent illness (Kessler et al., 2001).

CAM may be preferred because of its holistic approach to heal mind, body, and soul or the belief that it gives more attention to personal comfort of the patient (O'Matthúna, 2001). Patients with chronic problems such as arthritis, chronic pain, back pain, migraines, allergies, and gastrointestinal problems turn to CAM either because they have exhausted all conventional medicine modalities or have become tired, disappointed, or frustrated with repeated failure of conventional treatments (Eisenberg, Davis, et al., 1998 and Ernst, 1995). Also, when conventional medicine offers no or little chance of cure patients will often turn to CAM, such as in inoperable cancers (Durante et al., 2001).

Some CAM users have chosen these products because pharmaceuticals are becoming too expensive or they felt their medical provider does not involve them in choosing what medications to use and prefer to choose their own drugs (Bauer, 2000 and Jugens, 2001). Patients who use CAM have reported feeling their medical providers do not listen to or respect their cultural beliefs, are not knowledgeable in CAM, and are more focused on curing the disease and not meeting the needs of the patient (Sardesai, 2002). In some cases patients used CAM because they believed the products were safer as they are made from plants or are natural and assume it will be gentler or have less side effects (Durante et al., 2001; Roblatt, 1999; and Jugens, 2001). Other individuals used CAM simply because they are satisfied with the results (Levy, 1999).

The use of CAM is usually not due to a complete rejection of conventional medicine, but rather out of a hope that the users will get the greatest benefits through the combination of both styles of medicine (O'Matthúna, 2001). Participants in one study

reported that they believed the use of both conventional and CAM was better than either used alone (Eisenberg, Kessler, et al., 2001).

#### *Monitoring and Regulation of CAM*

One of the most prominent concerns of conventional medicine providers about CAM is the lack of regulation or monitoring these products receive, especially in the U.S. Current regulation systems for CAM in the U.S. allow poor quality products in the market (O'Matthúna, 2001). Food products, food additives and pharmaceutical drugs must endure strict pre-marketing tests for safety and efficacy before they can be used in the general population. However, products labeled herbal medicines or dietary supplements can enter the consumer market untested because of the 1994 DSHEA (Greensfelder, 2000; Sardesai, 2002).

The U.S. Food and Drug Agency (FDA) is powerless against dietary supplements or herbal medicines, unless substantial harm to users can be proven and is documented (Greensfelder, 2000; Bauer, 2000; Roblatt, 1999; P. Goldman, 2001). The FDA cannot investigate an herbal medicine or natural supplement until a consumer complaint has been filed (Hudson, Brady, and Rapp, 2001; Consumer Reports, 2000; Plotnikoff and George, 1999). When a report is filed against an herbal medicine or natural supplement, the FDA often can not find the source of the problem, given the agency's limited financial and manpower resources set aside for alternative therapy investigations (P. Goldman, 2001).

The DSHEA requires that a disclaimer be placed on every product label of a CAM product stating that the product has not been evaluated by the FDA and that the product is not intended to treat, cure, or prevent any disease (Bauer, 2000; Bouldin et al.,

2000). However, the DSHEA allowed manufacturers to print suggested dosages on the labels, put descriptions of the herbs effects on labels, and specifically stated that unlike pharmaceutical preparations, dietary supplements can be marketed without proven safety or efficacy (Bauer, 2000; Roblatt, 1999; P. Goldman, 2001). Essentially the product manufacturers can place a statement about the herb's or supplement's medicinal effects whether it's actually effective or not (Roblatt, 1999).

The U.S. pharmacopia (USP), a non-profit group that sets standards for the pharmaceutical industry issued standards for manufacturers of herbal medicines and dietary supplements; however, in contrast to pharmaceutical manufacturers, CAM companies are not required to adhere to these standards (Hudson et al., 2001). Dietary supplements may carry the USP symbol if they adhere to USP standards of identity, strength, purity, and labeling (Bauer, 2000; E. Goldman, 2001; Roblatt, 1999). A dietary supplement that has been used extensively without documented adverse safety risks can carry the National Formulary (NF) symbol; this means it meets USP standards, but is not USP endorsed (Bauer, 2000; Roblatt, 1999). The government needs to provide a level of monitoring to CAM therapies at least as strict as that currently being used on pharmaceuticals (Drew and Meyers, 1997).

Other countries have had federal monitoring organizations in place for CAM, including herbal medicines or natural supplements. Canada, United Kingdom, Germany, and France have regulatory agencies to enforce safety standards on herbal manufacturers (Sardesai, 2002). In 1978 Germany, instituted a regulatory agency to study and regulate plant-based products (Hudson et al., 2001). The German organization requires absolute standards of quality and safety in their herbal products (Roblatt, 1999). Currently in the

U.S. there is no formal regulatory committee ensuring that all herbal and supplement manufacturers follow safe production standards (Bauer, 2000). In 1995 the U.S. congress converted the small office of alternative medicine into the National Center for Complementary and Alternative Medicine (NCCAM) under control of the National Institutes of Health (NIH) to evaluate alternative therapies using accepted controlled studies (Kaul and Joshi, 2001; Abdel-Rahman and Nahata, 1997). Only 0.05% of the \$42 million NIH budget, or \$2.1 million, was available for research of CAM in 1997 (Abdel-Rahman and Nahata, 1997).

There are some private voluntary programs that currently monitor supplements in the U.S. The Consumer Health Products Association (CHPA) is one example. CHPA has asked member companies to place warning statements on the labels of their products for pregnant or nursing mothers to consult a health professional before use, to add a statement that if the user is taking a prescription drug they should consult a health professional before use, to place the toll free FDA adverse event phone number on the product label, and required member companies to provide analyses that prove the herbs they are selling contain no adulterants (E. Goldman, 2001). Another example of a voluntary program is the National Nutritional Foods Association (NNFA). The NNFA has a database of over 20,000 product members on whom NNFA randomly conducts spot checks through independent laboratories to determine if the products' contents correspond to the labels. The manufacturer of any product with discrepancies between the label and content are notified and the product retested through the independent laboratories (E. Goldman, 2001). If the manufacturers do not comply with NNFA requests they are prohibited from the trade shows for two years (E. Goldman, 2001).

Many voluntary programs are limited because of a lack of funding, lack of scientific studies, and lack of significant penalties to non-compliant manufacturers (E. Goldman, 2001). Even if the contents of the product and the label are in agreement there is no guarantee that the product will be effective or not have adverse effects on users (E. Goldman, 2001). Some voluntary programs suggest to improve monitoring of CAM, that U. S. federal agencies, private corporations, and academic institutions should push to implement more scientific research, educational curricula, improved control over dietary supplements, and post market monitoring (Eisenberg et al., 1998).

### *Effectiveness*

In a survey conducted by Durante et al. (2001) 82% of the respondents less than 50 years old believed supplements to be more effective than pharmaceuticals, versus 43% of those participants greater than 50 years old. Studies have shown St. John's Wort to be effective at relieving mild to moderate depression (O'Matthúna, 2001). Hypericum, the believed active component of St. John's, was 1.5 times more likely to be effective at reducing depressive symptoms on the Hamilton and Von Zerssen depression scales than placebo (Joshi and Kaul, 2001). The fact that St. John's Wort showed efficacy in treating depression in the studies does not guarantee that every preparation of St. John's Wort on the market will have similar effects (P. Goldman, 2001). A review of 18 randomized and 11 double blind controlled trials of Echinacea extract, considered an immune booster, found a reduction in chemotherapy side effects and immune enhancement (Plotnikoff and George, 1999) in the users studied. It was found that Echinacea reduced the incidence of post chemotherapy leukopenia, prevented and speeded recovery time for respiratory

infections, improved T-cell numbers, and improved recovery time for influenza and the common cold (Melchert, Linde, Worku, Bauer, and Wagner, 1994).

There have been some randomized controlled trials (RCT) performed that established efficacy of a few herbal products relative to the placebo group's results (Durante et al., 2001). Clinical studies have found Gingko to be protective against memory loss, Black Cohash effective at reducing menopausal symptoms (Joshi and Kaul, 2001), and St. John's Wort to be effective against mild-moderate depression (Joshi and Kaul, 2001; Vickers and Zollman, 1999). In the Gingko studies eighteen double blind studies were performed using Gingko extract; six were placebo-controlled and twelve were parallel studies (Joshi and Kaul, 2001). All but one of the above studies showed Gingko to be more effective at reducing memory loss than placebo (Joshi and Kaul, 2001). Eight studies were performed involving Black Cohash root; six were open, one was a randomized comparative study, and one a randomized, placebo controlled double blind study (Joshi and Kaul, 2001). All studies showed Black Cohash root to improve menopausal symptoms, such as hot flashes, depression, profuse sweating, and insomnia when compared to placebo (Joshi and Kaul, 2001). Twenty-three RCTs were performed involving hypericum, the believed active component of St. John's Wort, prior to 1996; fifteen were placebo controlled and eight compared hypericum to tricyclic antidepressants (TCA), pharmaceutical medications (Joshi and Kaul, 2001). Hypericum was found to be 1.5 times more likely to reduce depressive symptoms on the Hamilton and Zerssen depression scales than was placebo and was considered to be an equivalent to the TCAs (Joshi and Kaul, 2001).



However, even supplements and herbs that have scientifically established efficacy are not always reliable (Roblatt, 1999) because the manufacturing practices differ so much and the products are not often standardized. In one analysis of St. John's Wort products a seven-fold difference existed between the believed active ingredients among the products. A study of garlic preparations found a forty-fold difference between products (Roblatt, 1999); in a comparison of 50 separate brands of Ginseng sold internationally the active ingredient concentration varied from 1.9%-9%, with six containing no active ingredients (Drew and Meyers, 1997). Pharmaceutical aspirin tablets on the other hand are required by law to contain 95-105% of the active ingredients in order to reach the consumer market (Roblatt, 1999). Standardized products are believed to be more effective because they contain a guaranteed percentage of active ingredients (Hudson et al., 2001). However, plants are complex in their chemistry making it difficult to determine the single active component and reducing the ability to truly produce standardized products (Plotnikoff and George, 1999; E. Goldman, 2001) and many companies do not even strive to achieve standardization among batches (Plotnikoff and George, 1999).

While the labels and packages of CAM products contain effective dose values, the specific active ingredients are seldom known, and the true efficacy also remains a mystery (Hohman and Koffler, 2002). Many herbal medicines and natural supplements available to consumers have never been tested for efficacy (Durante et al., 2001; Eisenberg, Kessler et al., 2001). Herbal medicines have been found to be less effective than conventional pharmaceuticals (Plotnikoff and George, 1999). One example is a study of Ginger for osteoarthritis that showed no significant differences between the

Ginger treated group and the placebo group (Kaul and Joshi, 2001). Preparation methods for herbal medicines and natural supplements vary so widely and the activity of the same name herbal can have different effects depending on the processing methods (Plotnikoff and George, 1999).

### *Side Effects and Adverse Effects*

It is often widely believed that products labeled 'natural' are safe, but evidence exists to the contrary. Herbal medicines and natural supplements can have side effects in users, just as any drug or food can. However, just because herbal medicines and natural supplements can have adverse effects does not mean they are more toxic than conventional preparations (Bauer, 2000). Some side effects are tolerable and not harmful, but others can be deadly. Risks associated with herbal and supplement use include life threatening allergic reactions, poisoning from contaminants within the products, and interference with metabolism of other drugs (Durante et al., 2001).

Adverse effects can be either caused by the medicine itself or by the user or other external factors, such as contaminations of the products, inappropriate or incorrect labeling, dose, or preparation of a product (Drew and Meyer, 1997). Adverse effects of herbal use can be reduced if the user consults a qualified practitioner educated in herb-drug interactions (Hohman and Koffler, 2002). In most reports of adverse events with herbals or supplements the products used were self prescribed (Vickers and Zollman, 1999). It can be difficult to track the adverse effects of herbs and natural supplements as the products can often have up to four different names (Drew and Meyers, 1997). The FDA received 2,621 adverse events reports related to herbal medicines and natural supplements in the time period from January 1993 to October 1998 (Hudson et al., 2001)

and greater than 5,000 herb related adverse events were reported to the World Health Organization (WHO) prior to 1996 (Sardesai, 2002). When reports are made, often the adverse event is caused by allergic reactions, adulterations in the products, toxicity either due to improper labeling or incorrect dosage use, and peculiar reactions (Plotnikoff and George, 1999).

Many specific side effect or adverse event examples exist; the following are only a few of them. In a study of 90 rheumatoid arthritis patients, 82% stated they had tried alternative medicines and 31% of those reported experiencing at least one side effect (Drew and Meyers, 1997). The herb *Aristolochia*, which damaged the kidney of dozens of users in Belgium and in the 1990s began causing cancer, was banned in Belgium in the early 1990s and Germany in the 1980s. There is nothing to prevent an incident such as this from occurring in the U.S., as it has not yet been banned here (Greensfelder, 2000). *Ephedra* or *Ma Huang* has been associated with reported deaths, strokes, heart attacks, and seizures, yet it's withdrawal from the U.S. market had been voluntary for manufacturers meaning it was still available for use in the U.S. until recently (Roblatt, 1999). *Ginkgo* has been tied to reports of intracranial bleeds (Roblatt, 1999), when given to guinea pigs has caused paralysis and convulsions, and in clinical trials reports of allergic reactions, headaches, and dizziness were received (Joshi and Kaul, 2001). *St. John's Wort* has been associated with sunlight reactions and rare neuropathies (Roblatt, 1999).

Positive effects have also been reported in products. *Garlic* has been shown efficacious at improving lipid panels in several open trails and has been suggested it may lower one's blood pressure (Kaul and Joshi, 2001). Overall data on *Garlic* use in relation

to blood pressure was insufficient to draw any conclusions; a trial of Garlic users in Germany failed to show any reductions in the user's lipid profiles (Kaul and Joshi, 2001). Valerian a popular herbal medicine because of its success in treating insomnia is generally safe for use, but discontinuing it abruptly can trigger withdrawal symptoms in long-term users (Sardesai, 2002). Saw palmetto has been widely and successfully used in Europe for years in treating benign prostatic hypertrophy, but large doses and extremely prolonged use can cause liver toxicity (Sardesai, 2002). Ginger was found to improve vertigo symptoms by reducing nausea, cold sweating, and the spinning feeling in users, but had no effect on nystagmus (Kaul and Joshi, 2001). Additional medical research on herbal medicines and natural supplements for efficacy, education of conventional medical practitioners in alternative therapies, and open discussions between conventional practitioners and their patients can help to decrease the number of adverse effects occurring with use of alternative therapies (Kessler, Davis et al., 2001).

### *Safety*

The public belief that products deemed natural are safer than pharmaceuticals prejudices CAM users against an association of CAM therapies and adverse effects (Drew and Meyers, 1997). Identity of a marketed herbal or supplement product should not be assumed because adulterations are possible under the current monitoring system (Hudson et al., 2001; Roblatt, 1999). Natural products are currently regulated under the same standards as any food product (E. Goldman, 2001). Yet, contaminants such as lead, benzodiazepines, and steroids have been found in herbal supplements (Hudson et al., 2001). Approximately 40% of North Americans are using CAM therapies that have not been tested for purity, safety, or efficacy (Durante et al., 2001). Five patients in the

United Kingdom suffered lead poisoning after using traditional Asian remedies; the products responsible were contaminated with 6-60% lead by weight (Drew and Meyers, 1997). Several American herbal manufacturers have voluntarily adhered to strict production practices and USP standards allowing them to guarantee their products are not contaminated (Hohman and Koffler, 2002).

Lack of regulation in the U.S. has allowed for large variability in the active ingredients among product manufacturers resulting in under or over doses and contaminants (Hudson et al., 2001; Drew and Meyers, 1997; Roblatt, 1999). Herbal makers are not required to perform pre-marketing or post marketing studies for safety or efficacy of their products (Roblatt, 1999; Eisenberg et al., 2001). The U.S. manufacturing industry is driven to isolate the active components of products to reduce the costs of processing and side effects, but isolation comes with its disadvantages. The complexity of plants generates the possibility that there are multiple active ingredients in an herb (Plotnikoff and George, 1999). Raw plant materials can differ greatly in toxicity from purified components because parts of the whole plant can alter the toxicity of each other (Drew and Meyers, 1997). Currently there is insufficient regulation and scientific studies of herbal quality and safety in the U.S. to reduce the above hazards (Plotnikoff and George, 1999; Roblatt, 1999; P. Goldman, 2001).

#### *Drug Interactions*

Just as certain foods can affect the activity of pharmaceuticals, so can herbal medicines. Therefore, it is important that users are aware of the possibility their herbal medicines can interact with pharmaceuticals (Hudson et al., 2001; Jugens, 2001). As herbal remedies began to be used more often in Western societies, whether users were

monitored by natural remedy practitioners or not, problems of drug interactions began to arise (Joshi and Kaul, 2001). Patients with chronic diseases, as those suffering from AIDS, HIV, chronic back pain, arthritis, allergies, and digestive problems (Eisenberg, et al., 1998) are more apt to use herbal remedies and to be on more pharmaceuticals; yet, they are at an increased risk of drug interactions (Hudson et al., 2001). There are documented drug-herbal interactions that have been determined through scientific studies and experiences of long-term herbal users. Echinacea interacts with steroids causing liver toxicity (Vickers and Zollman, 1999). Garlic, ginseng, ginkgo, and ginger interact with warfarin potentially causing a dangerous increase in bleeding times (Vickers and Zollman, 1999). St. John's Wort interacts with antidepressants, birth control pills, and certain antibiotics by altering their levels in the body to either too high or too low (Vickers and Zollman, 1999; Sardesai, 2002). St John' Wort has also been found to reduce absorption of digoxin and warfarin creating the potential for reduced effects of these drugs on controlling arrhythmia and anticoagulation (P. Goldman, 2001).

#### *Contraindications for Herbals and Natural Supplements*

Just as some pharmaceutical drugs have contraindications for use so too can herbal medicines and natural supplements. Pregnant women, nursing mothers and children are often contraindicated in using many pharmaceutical medicines because the effects or risks are undetermined, yet because herbal medicines and natural supplements are deemed natural, these same populations may resort to use of these products not realizing potential risks exist. Pregnant women, nursing mothers, and children under two years of age should not use herbs or natural supplements because effects and dangers to these populations are not known for many herbals and natural supplements (Hudson et

al., 2001). People with chronic illnesses are often on more medications and should avoid herbal medicines and natural supplements because of their increased risk of drug interactions (Hudson et al., 2001). People on warfarin, aspirin, or aspirin like products should not take garlic because of the increased potential for spontaneous or excessive bleeding (Kaul and Joshi, 2001). Herbal supplements should be avoided in the elderly because often they are taking more conventional medications meaning a greater health risk because of potential drug-herbal interactions (Sardesai, 2002).

In the prescription of pharmaceutical medicines it is the responsibility of the health care providers and the pharmacists to be familiar with contraindications to use of certain drugs and be sure they are not given to the wrong people. There are no such protective measures in place with herbal medicines and natural supplements because they are available over the counter without a prescription and many users are not consulting with conventional medical professionals or naturopathic professionals before using these products. This opens up the possibility for further dangers of these products on uninformed users.

### *Studies and Testing*

One of the general characteristics of CAM is a lack of scientific studies supporting the safety and efficacy of these treatments (O'Matthúna, 2001). Many CAM therapies are accepted on principles and theories that contradict long standing scientific paradigms (O'Matthúna, 2001). CAM has often been rejected by traditional western medicine based on scientific reasoning, but sometimes these approaches have been rejected without a justifiable reason (O'Matthúna, 2001). In pharmaceutical medicine, products must endure RCTs as a gold standard before they are marketed (O'Matthúna,

2001). Clinical studies that have been conducted on existing herbal products have found most products are generally safe (Roblatt, 1999). The difficulty in analyzing such results is that often these clinical trials have been poorly designed or final reports are incomplete (Abdel-Rahman and Nahata, 1997). More randomized controlled trials are needed to ensure the safety and efficacy of herbal medicines and natural supplements (Bauer, 2000).

There are several formal research organizations currently studying CAM therapies in the United States. Organizations include the Herb Research Foundation, The American Botanical Council, the NCCAM (Hudson et al., 2001), the Office of Dietary Supplements, the Center for Disease Control, and many academic institutions (Bauer, 2000). The NCCAM is currently funding eleven research centers for CAM therapies (Consumer Reports, 2000). Many of the research organizations conducting studies on CAM therapies are adamant about making sure that consumers understand they support research of CAM, but are not endorsing the use of CAM therapies (Abdel-Rahman and Nahata, 1997).

#### *Consumer Information Sources*

There is an abundance of information available to the general public, especially in this advanced age of technology and the Internet, but the difficulty lies in finding quality information (Bouldin et al., 2000). There is a difference among age groups as to the sources on which they rely for their information. Patients less than 50 years old in the Durante et al. (2001) study listed family, friends, and stores as their common sources. Older respondents, greater than 50 years old, reported physicians and lay press as their primary sources (Durante et al., 2001). A poll conducted by Jugens (2001) found that



consumers were hesitant to ask for the pharmacist's help regarding herbal medicines and natural products because they feared the pharmacist would not approve of their use of alternative therapy. In the Jugens (2001) study it was more common for them to ask a friend before asking a health food store employee.

Most frequently reported sources for herbal medicine and natural supplement information in descending order, were: friends, labels, books, magazines, pharmacists, physicians, natural medicine practitioners, internet, television, and retail clerks (Bouldin et al., 2000). While conventional health practitioners were used rarely the respondents in Bouldin et al. (2000) and Levy (1999) rated their opinions at a higher level than their more commonly used sources. Information listed as important by consumers when making their decision about herbals and supplements were indications for use, side effects, product content, recommended doses, safety, and effectiveness (Bouldin et al., 2000). The danger is that some of these sources give dangerous advise regarding doses and use of toxic herbs for treatment (Bouldin et al., 2000). A 1999 national survey of herbal medicine and natural supplement consumers found that 73% of consumers were not completely satisfied with the information currently available to them regarding CAM (Levy, 1999).

Another difficulty in ensuring proper education of consumers regarding herbals and supplements is their availability. Herbal medicines were traditionally only available in health food stores and the wild. Now these products are found on the shelves of pharmacies, grocery stores, discount stores, mail order catalogs, and internet websites (Jugens, 2001; Plotnikoff and George, 1999; Sardesai, 2002). Materials available in the same health food store and on websites contain conflicting statements about doses and

toxicities of herbs (Plotnikoff and George, 1999). An additional roadblock to quality consumer information is that most of the statements from the FDA and USP have been negative, creating the impression that all of conventional medicine is anti-herbal (Bouldin et al., 2000).

#### *Conventional Medical Providers' Role in CAM*

It is important that conventional medical providers realize that many patients are not informing them of CAM use and are self treating with such products without accurate advice (Hudson et al., 2001). It is important to ask specifically about herbal medicine and natural supplement use in the medical interview because many users do not consider them to be drugs and to reassess their use at every visit because patterns of use change frequently (Durante et al., 2001).

Conventional health providers must take it upon themselves to push for research of safety and efficacy of CAM products, standardized formulations of all CAM products, and scientific support for all claims on CAM products (Plotnikoff and George, 1999). Despite conventional health providers' personal opinions regarding herbal medicines and natural supplements the most important point is that an open dialogue is kept with their patients regarding CAM (Bauer, 2000). Discussions with patients should include explanations of the current regulations of CAM, that 'natural' does not mean harmless, manufacturing practices, possibilities for drug interactions, contraindications, and possible side effects (Bauer, 2000; Sardesai, 2002). Advise about what products to use should include choosing formulations carrying either the USP or NF symbols or the word "standardized" (Roblatt, 1999). Conventional health providers should try to participate in continuing education on CAM therapies so they can give accurate advise to their patients

and do it in a non-judgmental way encouraging patients to approach them regarding such subjects (Abdel-Rahman and Nahata, 1997; Astin, 1998).

#### *Summary of Surveys*

This study used a written survey to look at patients visiting a family practice, but addressed the opinions of both users and non-users of CAM therapies. It looked at the general opinions patients have about all herbal medicines or natural supplements rather than individualizing each herbal or supplement, yet allowed for comment about individual products too. It assessed patients' opinions regarding perceived effects of the products they were using, if they were using any, and was concerned only with plant or animal derived substances. Durante, Whitmore, Jones, and Campbell (2001) conducted a phone interview survey on patients who attended family practice clinics about their general opinions and use of herbal medicines and natural supplements. However, their group looked only at the surveys of those whom reported using an herbal medicine or natural supplement and did not pursue the opinions of non-users; it was designed so that the questions were answered for each different herbal or supplement the responder was using. The Durante et al. study also included vitamins and minerals in addition to plant and animal derived substances.

This study looked at a single group of patients at one clinic because of resource problems discussed earlier in limitations. It used open-ended multiple-choice questions to assess what information the consumer wants about herbal supplements and where these individuals get their information. The study addressed whether or not patient's who use these therapies inform their medical providers and if not, why. Additionally, this study looked at opinions regarding individual herbs/supplements. Bouldin, Smith, Banahan,

McCaffery, and Croom (1996) conducted a national written survey that similarly addressed what information the consumer wants about herbal supplements and where they get their information. The Bouldin et al. (1996) study did not look into any specific herbal medicines and focused on the labels of herbal products to assess the information desired most by consumers. Bouldin et al. (1996), have found that people more often use family or friends over medical professionals, which is why it has been included in this study.

This survey used non-leading statements some of which were true and some of which were false regarding the safety, quality, monitoring, efficacy, side effects, contraindications, and drug interactions of herbal medicines and natural supplements; it's hoped this format allowed better assessment of whether the patients' are correctly informed regarding herbal and natural supplements. Consumer Reports conducted a national written survey that also looked at consumers' opinions about safety, efficacy, information sources, and available scientific support, but as it applied to mainstreaming of these products.

### *Conclusion*

This study, although limited in that it assessed the opinions of one family practice clinic, addressed both users and non-users of CAM. Specific characteristics of individual herbal and supplement effects, broad general opinions about the available consumer information, monitoring and regulation, efficacy, safety, contraindications, and drug interactions of herbal medicines and natural supplements were addressed.

One goal of this study was that a better understanding of patients' general opinions and knowledge regarding herbal medicines and natural supplements would be obtained. Another goal was to determine patients' opinions regarding the safety and

efficacy of herbal medicines and natural products. An additional goal was to determine what patients are using, if users of these therapies are experiencing any effects from these products, and whether those effects were positive or negative. In addition, this study also hoped to determine how people obtained their information about these products and where they would be most likely to look for information regarding these products.

## Chapter 3

### Methodology

#### *Introduction*

The purpose of this study was to look at the opinions and knowledge that patients visiting a family practice had about herbal medicines and natural supplements and how they obtained their information. Goals of the study were to:

1. Determine what products patients were using.
2. Determine any positive or negative effects of these products the patients experienced.
3. Determine how people obtained their information about these products.
4. Determine where patients were most likely to look for information regarding these products.
5. Determine patients' opinions regarding the safety and efficacy of herbal medicines and natural products.
6. Obtain an understanding of patients' general opinions and knowledge regarding herbal medicines and natural supplements.

#### *Description of Methodology to be Used*

The researcher performed a descriptive exploratory study regarding perceptions about herbal medicines and natural supplements. Specifically the researcher focused on perceptions of patients visiting a family practice clinic. A descriptive study is non-experimental. It does not manipulate the sample being studied; rather it describes characteristics of the sample. The major characteristics studied include use or non-use of herbal medicines and natural supplements, why herbal medicines and natural

herbal medicines and natural supplements, why herbal medicines and natural supplements were used, common positive and negative effects users had experienced from herbal medicines and natural supplements, how users obtained their information about herbs and supplements, whether users informed their health care providers of their use, and perceptions about the safety, quality, monitoring, and manufacturing of herbal medicines and natural supplements. The researcher obtained input from both users and non-users of herbal medicines and natural supplements. Non-users' perceptions were important because their answers provide characteristics of herbal medicines and natural supplements that a user may not be willing to provide. Users' beliefs were important because they provided reasons for herb and supplement use. Both groups' opinions were important in determining whether their beliefs were formed on accurate or inaccurate information.

The environment of a family practice clinic was an optimal setting because of the variety of patients who visit a general practitioner. This variety of patients more closely simulated the general population.

Patients' perceptions were determined by the answers they provided to written survey questions. The questions asked either for simple responses regarding the patients' herb and supplement use or asked them to rate their level of agreement or disagreement to general statements about herbal medicines and natural supplements.

#### *Design of the Study*

The researcher asked patients over the age of eighteen at the Mosinee Clinic of the Marshfield Clinic System to complete a written survey about their herbal medicine and natural supplement use and beliefs. The survey was distributed by the clinic

receptionists to patients along with their other admission paperwork. The researcher used a survey because it is a common research tool used in descriptive studies, provides an easy route for the participants' answers, required less time commitment by the participants to complete, and was appropriate for the information the researcher was trying to obtain. By providing the survey at the clinic when the patients were already filling out paperwork and waiting, it was hoped the survey response rate would be higher. The survey was returned to a drop box before the patients left the clinic to eliminate additional effort required by the participants and to increase the response rate. A drop box return was chosen because it typically results in a sixty percent response rate.

The instruction form for the survey was the cover page to the survey packet and explained that completing the following survey was voluntary and for the benefit of a research study. The consent form for participation followed (see appendix A). The consent form explained what the study hoped to achieve and that the study was being performed to fulfill requirements for the researcher's masters thesis in physician assistant studies at Augsburg College. The benefits and risks of participating in this study were also included in the consent form. Since this is a written survey returning the survey was consent to participation in the study.

The patients each received a pen as a direct benefit to the study that they could keep whether or not they actually participated. Providing the pen hopefully improved the response rate by eliminating the task of finding a writing utensil to complete the survey. The indirect benefit to the participants was aiding in furthering the knowledge available about patients' perceptions of herbal medicines and natural supplements.



The survey required very little writing, most responses were chosen by checking or circling an answer. The decreased amount of writing required by the participants hopefully increased response rates. It should have taken most participants an average of five to fifteen minutes to complete the survey.

Institutional review board (IRB) approval from both Augsburg College (see appendix B) and The Marshfield Clinic System was obtained (see appendix C). The survey was conducted once approval was granted from each institution and the clinic site (see appendix D).

### *Sample and Population*

The Mosinee clinic of the Marshfield clinic system was chosen because it is a family practice clinic and the researcher will be training at that site. The training period allowed time for the researcher to establish a rapport and connections with the staff essential to distribution and completion of the research study.

A family practice clinic was chosen because it has a diverse population of patients. There were various adult ages, education levels, occupations, illnesses, both sexes, and even healthy patients in this population. This degree of variety was more representative of the general population than of patients at a specialty clinic.

The sample size was devised by averaging the number of patients seen by each health care provider at the clinic in a week; this averaged approximately to 420 patients. The average weekly population was then multiplied by one percent to arrive at the sample population size of at least 4.2 or rounded up five. One percent of the population is a value considered a representative sample in research studies (D. Ludwig, Research III lecture, September 12, 2002). However, five was consider too small a sample by the

box method yields only about a 60% response rate. The sample population size of 42 was then divided by 60%, to determine the number of surveys that would need to be distributed in order to achieve the desired sample population of 42. This needed value of surveys was 70. If 70 surveys were distributed and the response rate is 60% of that then theoretically the researcher should be able to achieve a return of her desired 42 participants. Seventy was also chosen because it was a manageable sample size for the principal researcher to handle independent analysis on and large enough a number to perform statistical analysis on. The downfall to this sample size was that while it represented 1% of the weekly population it did not represent 1% of the yearly patient population. The Mosinee clinic saw 18,568 patients in 2002. One percent of this equals 185.68 or 186 patients, but taking into account the 60% drop box response rate and the amount of data obtained on every survey the representative population size for this value would have been unmanageable. If all 70 responses were received it would have equated to approximately 0.4% of the yearly patient population.

### *Instrumentation*

Several research studies have been conducted concerning perceptions of herbal medicines and natural supplements. Most notable are Bouldin (1996), Bouldin et al. (2000), Durante et al. (2001), and Eisenberg et al. (2001). Research tools were sought in all the previously mentioned studies and the choice of which tool to use was based upon response to the researcher's request to use a tool and the usefulness of the tool itself. Each group was contacted requesting their tools for possible use in the researcher's own study and thesis project. E-mail correspondence was sent to Bouldin (see appendix E) and Campbell of Durante et al (see appendix F), requesting a copy of their research tools.

Bouldin et al. (2000) was not used because it had no additional benefit over the questions already asked in the Bouldin (1996) study. It was, however, directed at a patient population, which is preferable over the 1996 study because it would have required fewer modifications. The disadvantages were that it was obtained much later in the literature review process, the study focused on the labels of herbal medications, and necessary modifications had already been made to the 1996 questions.

Of the research tools received Bouldin's (1996) article "Pharmacist Perceptions of Herbal Medicines" (see appendix G) and Durante et al.'s (2001) article "Use of Vitamins, Minerals, and Herbs: A Survey of Patients Attending Family Practice Clinics" (see appendix H) were the two studies that resulted in the most useful tools. These two sources together covered virtually every characteristic desired for the study. Permission to use the tools was obtained and each was modified as needed.

No validity calculations exist for either tool used. However, Bouldin's survey has been distributed as a geographically stratified random sample of community pharmacies by the University of Mississippi. Five hundred and twelve usable responses out of a sample size of 1,937 were received, equaling 26.3% of the study population. Durante et al. used a random sample of every 30<sup>th</sup> family practitioner name listed within a computer database to obtain a sample size of 20. Sixteen of 20 agreed to participation, equaling 80% of the sample population. Three pilot studies were then preformed to assess adequate patient population size, 128 patients in this case. One hundred and three usable responses of the 128 were received, 80% of the population size.

The interview questions used by Durante et al. (2001) addressed the many of the characteristics of this study and the population being studied consisted of patients visiting

a family practice clinic. Characteristics included: what herbal medicines and natural supplements patients used, positive or negative side effects they experienced, length of use, sources of education about their herbals and natural supplements, whether they informed their health care provider about herbal and supplement use, and whether they believed their herbals and natural supplements were as safe and effective as prescription medications.

The survey questions designed by Bouldin (1996) provided many of the remaining characteristics. These characteristics include: statements about the monitoring of herbals and natural supplements, where the consumers believed these products should be sold, whether consumers were aware of contraindications of use or interactions with other medications, and how happy the consumers were with the information they have about herbal medicines and natural supplements.

Initial modifications to Bouldin's survey included adding the words "natural supplement" to each statement because they were worded only with "herbal medicines", elimination of those questions that were specific to the pharmacist study population, and rephrasing of several questions to fit this study's patient population. Initial modifications to Durante et al.'s interview questions were that many of the questions had to be more fully explained and rephrased to fit a written survey format and in several cases words "mineral" and "vitamins" had to be removed. A few additional areas not addressed by either study were added by the researcher, but tailored to fit with the other two study designs.

The combined product was a written survey. A first draft of the survey (see appendix I) was revised after discussion with the researcher's thesis advisor. This revised

survey (see appendix J) was tested in a focus group of 10 individuals. The individuals in the focus group consisted of family and friends of the researcher. This sample was used because it provided a large range of ages and the participants were more willing to cooperate because of their desire to help the researcher. The limitation of using this group was that they should be less likely to criticize the researcher because of their personal feelings for the researcher. However, the group understood the impact false approval of the survey design would have on the researcher's final results and because of those same personal feelings should have been more willing to give constructive criticism. The focus group's input resulted in a change in the survey's format to make it easier to read and faster to complete, changes in some of the wording to make individual remarks easier to understand for the population, and removal of several confusing or non-beneficial statements and questions.

#### *Data Collection and Data Analysis*

The data was collected through participants' responses to the written survey. The clinic receptionists at the Mosinee clinic distributed the written survey when the patient checked in at the reception desk before their appointment. The survey denoted that it was optional and that the patient was to fill it out while waiting to see their health care provider, but after completing their other clinic paperwork and should be returned to a locked drop box at the reception desk before leaving the clinic that day. The survey return instructions were printed on the sheet of instructions as well as repeated again on the last survey page. The researcher dropped off the surveys and the drop box with clinic staff to be distributed during an agreed upon week in May 2003. The researcher then

staff to be distributed during an agreed upon week in May 2003. The researcher then picked up the drop box with the completed surveys from the clinic following the distribution week.

The study collected a combination of nominal, ordinal and continuous data. The data was analyzed using the Statistical Package for the Social Sciences (SPSS). This package was chosen because it was available at the college and help was available because several Augsburg College professors were familiar with that package. Basic statistical analyses were performed. Appropriate descriptive statistics such as percentages and totals were determined for the some of the data. Appropriate inferential statistics were determined using one-way Analysis of Variance (ANOVA) and Spearman two-tail bivariable analyses to establish any correlations of responses to whether or not the participant was a user or non-user of herbal medicines and natural supplements. ANOVA was chosen because it can be used to analyze a continuous variable against multiple nominal variables; this is clarified further in chapter four. The Spearman statistical procedure was performed at the request of an advisor for the thesis and because looked at whether there was a correlation between two different variables, one nominal and one ordinal or continuous, to determine if a relationship exists between the two variables.

## Chapter 4

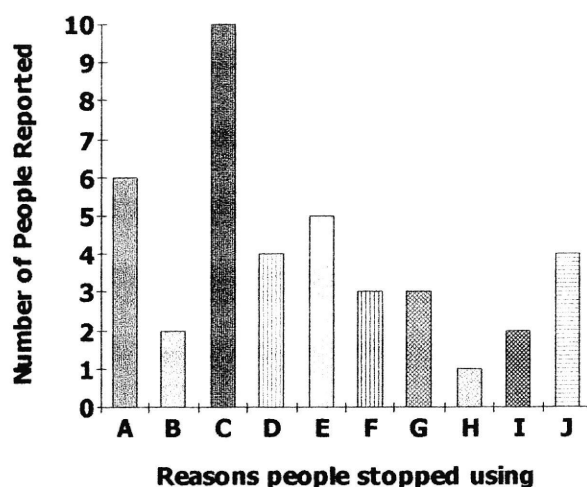
## Results

Forty-six of seventy surveys were returned, for a response rate of 66%. Of those returned 45 were useable. One survey was excluded because of the large number of questions left unanswered by the respondent. Forty percent (18) of the respondents reported they were not users of herbal medicines or natural supplements. Sixty percent (27) of the respondents reported that they were users of herbal medicines or natural supplements. The mean number of months herbs/supplements have been used by respondents was 70 months. The maximum number of months of use reported was 420. The minimum number of months reported was 0.5.

The four most commonly reported herbs/supplements used were glucosamine-chondritin, garlic, ginkgo biloba, and ginseng. These values included current as well as former users of the herbals/supplements. The number of respondents who have reported they stopped using specific herbs/supplements is displayed in Table 1.

<b>Herbal medicine/Natural supplement</b>	<b>Number of users</b>	<b>Number who stopped using</b>
Glucosamine Chondritin	15	6
Garlic	12	4
Ginkgo Biloba	11	7
Ginseng	10	4
Chamomile	8	1
St. John's Wort	6	2
Cayenne/Capsacian	4	1
Valerian	4	1
Thyme	2	0
Goldenseal	1	0
Milk Thistle	1	0
Saw Palmetto	0	0
Others	9	N/A

There are a number of reasons that were reported explaining why the respondents stopped using the herbs/supplements. Participants were asked to check all reasons that applied. The most common reason given was that the herbs/supplements “didn’t seem to help.”

**FIGURE 1****Reasons Use Was Discontinued****KEY****A** = Did not stop taking**C** = Didn't seem to help**E** = Kept forgetting to take the pills**G** = Health provider told me to stop**I** = Pharmacist told me to stop**B** = Too Expensive**D** = Didn't like taking all the pills**F** = Interfered with other medicines**H** = Made me feel worse**J** = Other

Users of herbs and/or natural supplements were asked to check off all effects they experienced if any while using specific products. The effects listed were both positive and negative, but the survey respondents were not formally informed which category each choice fell into. The effects were determined to be positive or negative by using ones previously defined by Rural Health School Students of New Ulm (2000), Keville



(1994), and Cawood (1995). Examples of positive side effects reported by participants include chamomile decreased nervousness, garlic reduced blood pressure and LDL cholesterol, ginkgo biloba enhanced memory, ginseng increased energy, glucosamine-chondritin decreased pain in joints and increased ability to move joints, and valerian caused sleepiness just to name a few. Examples of negative effects reported include, but were not limited to increased odor of breath of sweat with garlic, increased bleeding time with ginkgo biloba, diarrhea and increased blood pressure from glucosamine-chondritin, and constipation with St. John's Wort. Table 2 provides a breakdown of the total positive and negative effects reported by users.

<b>TABLE 2</b>		
<b>Herb/Supplement Name</b>	<b>Number Positive Effects</b>	<b>Number Negative Effects</b>
Cayenne/Capsaicin	4	1
Chamomile	8	0
Garlic	8	4
Ginkgo Biloba	8	4
Ginseng	10	4
Glucosamine Chondritin	17	5
Goldenseal	0	0
Milk Thistle	1	0
Saw Palmetto	0	0
St. John's Wort	4	1
Thyme	0	0
Valerian	3	1

Herb/supplement users only were asked to indicate all the sources they have used in learning about the herbs/supplements they use. The source reported most frequently was friends. The sources of nurse and nurse practitioner were not selected by any of the respondents and have been excluded on Table 3.

**TABLE 3****Sources of Information on Herbs/Supplements Chosen by Users**

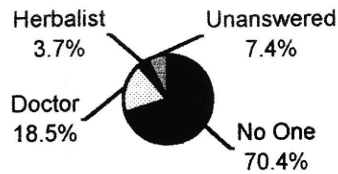
<b>Information Source</b>	<b>Percent who chose it</b>
Friends	15.6%
Books	13%
Family	11.7%
Health Food Store	11.7%
Magazine	10.3%
Television	7.8%
Doctor	6.5%
Newspaper	3.9%
Chiropractor	3.9%
Internet	2.6%
Journals	2.6%
Product Label	2.6%
Herbalist	2.6%
Other	2.6%
Physician Assistant	1.3%
Pharmacist	1.3%
Nurse	0.0%
Nurse Practitioner	0.0%

Users stated that they inform their health care provider that they are using herbs/supplements 70.4% of the time. While 22.2% reported they do not inform their health provider of their use and 7.4% left the question unanswered.

User respondents were asked what health professional if any monitors their herb/supplement use. Figure 2 shows their responses “No one” was the most common response, doctor was chosen next, and herbalist was chosen least often as the health professional that monitors their use, and a fair percentage left the question unanswered.

**FIGURE 2**

**Health Professionals Herbal Users Have Monitoring Them**

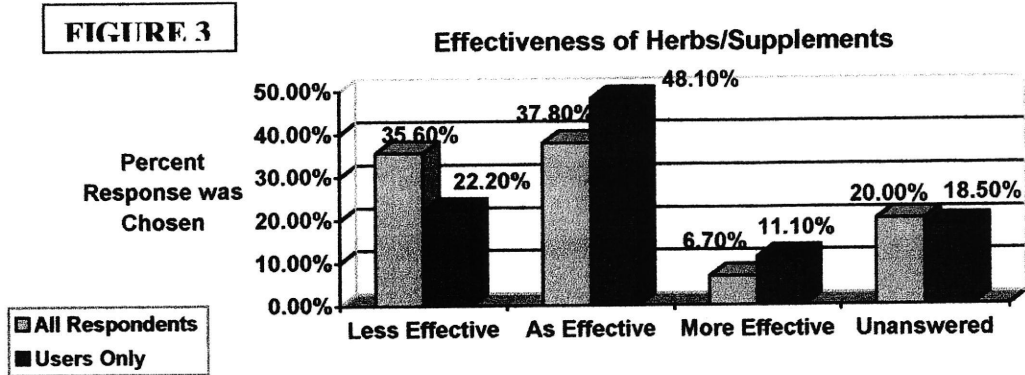


In a separate question, both users and non-users of herbs/supplements were asked to select all sources from which they would seek more information about herbals/supplements. This information is presented in the following chart. The most common response was doctor at 21.9%. Television was the lowest rated response because it was not selected by any of the respondents. Nurse Practitioner was the next least common chosen by 0.9%.

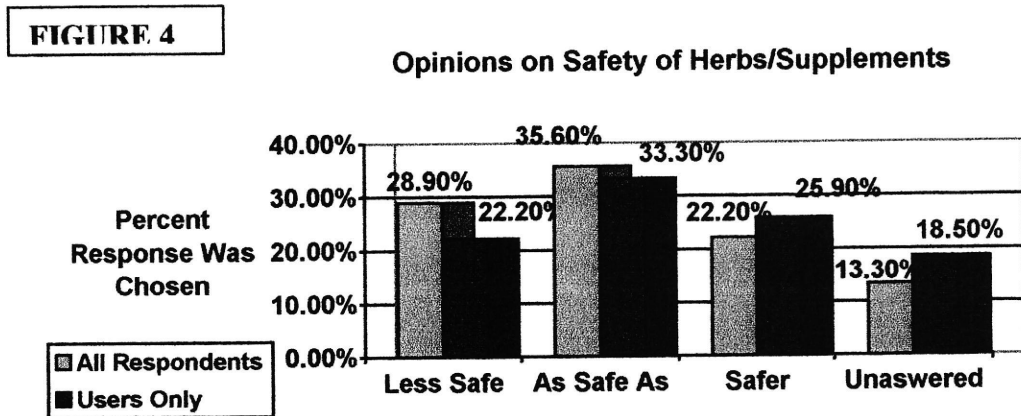
**TABLE 4**  
**Sources of Herb/Supplement Information Reported by All Respondents**

Information Source	Percent who chose it
Doctor	21.9%
Internet	13.2%
Books	10.5%
Health Food Store	9.7%
Family	7.9%
Friends	7.9%
Pharmacist	7.0%
Herbalist	4.4%
Nurse	3.5%
Chiropractor	2.6%
Journals	2.6%
Magazines	2.6%
Newspaper	2.6%
Physician Assistant	1.8%
Nurse Practitioner	0.9%
Other	0.9%
Television	0.0%

Users and non-users were asked whether they believed herbs/supplements are more effective, as effective, or less effective than prescription medications given to them by their health providers. As effective was the most common response when looking at all respondents, as well as when looking at user only responses. Percentages have been reported in Figure 3.



Users and non-users were asked whether they “believe herbs/supplements are safer, as safe as, or less safe than medications available over the counter”. “As safe as” was the most common response for all respondents and also when the users only responses were separated out. Percentages for each response are shown in Figure 4.



Participants were asked to check “all that applied” regarding whom monitors or supervises manufacturing and sales of herbs/supplements, accounting for the total

percentage being slightly greater than 100%. “No one” and the “FDA” were both chosen by 33.3%, NCCAM was chosen by 20%, office of dietary supplements and board of medicine both were chosen by 6.7%, other was chosen by 7.4%, and board of pharmacy and world health organization were each chosen by 2.2% of the respondents.

Participants were asked to rate numerous statements about herbs/supplements on a Likert scale of strongly disagree, disagree, neutral, agree, and strongly agree. The frequency of the responses and the percentage of the study population that it represented are reported out in Table 5 (see appendix K). Also, addressed was the number of participants who left a particular question unanswered; overall this remained a small proportion with a maximum of four non-responders to any question.

Several of the statements used in the Likert scale have literature and research supporting a particular answer. Since an answer for these particular questions can be rated as in agreement with existing research or not in agreement, a value of one through five was assigned to the responses strongly disagree, disagree, neutral, agree, and strongly agree. Five represented the most supportable answer and a score of one represented the least supportable answer. However, not all the questions were asked in a way in which five always would be strongly disagree and one would be strongly agree. Questions 15-22 and 31 are scored as described above, but for questions 26 and 29 a reverse score was calculated and used for these questions so that strongly agree was equal to five and strongly disagree was equal to one. After assigning these values to the responses a subscale variable was created for the total value calculated for each respondent's answers to these particular questions. From this, a one-way Analysis of Variance (ANOVA) was run on the variables “herb/supplement user” and the newly

formed subscale variable “total knowledge score”. This analysis was performed to see if there was a statistically significant difference in the scores between herb/supplement users and non-users. Also, it allowed the researcher to view the total score values and to see if the users scored higher, indicating more supportable answers chosen, than the non-users or vice versa. The statements from the researcher’s survey corresponding to questions 15-22, 26, 29, and 31 of the survey (see appendix J) were used for the above described subscale.

The significance value obtained using the one-way ANOVA analysis for the above was  $p = 0.819$ ,  $p \leq 0.05$  was considered statistically significant in this study. Thus there was no significant difference between answers given by users versus non-users. Additionally when looking at the actual scores in the total knowledge subset there was no obvious association that users or non-users scored higher or lower than the other group when looking at the averages of the scores for the group. So, there is no evidence at least with this population that users were more or less informed than non-users and vice versa.

Another subscale was created to score the responses of participants responses to whether herbs/supplements are more, less, or equally effective as prescription drugs. To allow for a comparison between groups a value of one was assigned to the answer less effective, a value of two was assigned to the answer as effective as, and a value of three was assigned to more effective. A one-way ANOVA analysis was then performed to determine whether users and non-users gave a significantly different response to the question and whether users believed they were more effective more often than non-users or vice versa. The significance value was  $p = 0.006$ ,  $p \leq 0.05$  was considered statistically significant in this study. Thus the two groups gave statistically different responses.

Users believed herbs/supplements were more effective more than non-users did. A similar subscale was done to determine whether there was a significant difference between users and non-users regarding the question whether herbs/supplements are safer, less safe, or equally as safe as over the counter medications. A value of one was assigned to less safe, a value of two was assigned to equally as safe, and a value of three was assigned to safer. The one-way ANOVA analysis was performed. The significance value was  $p = 0.267$ ,  $p \leq 0.05$  was considered statistically significant. There was not a statistically significant difference between the two groups.

A bivariable Spearman two-tailed analysis was done on the same Likert statements as in the first above one-way ANOVA analyses to see if there were any correlations between the information. The Spearman analysis was done using the nominal variable user or non-user and the continuous variable total knowledge score calculated from the individual ordinal variables for each statement corresponding to questions 15-22, 26, 29, and 31 (see appendix J). The calculated correlation coefficient was  $-0.044$ , a value of  $-1$  or  $1$  signifies there is a correlation, the significance value for the two tailed test was  $0.796$ ,  $p \leq 0.05$  was considered statistically significant in this study. Thus the results were not significant using the Spearman two-tailed bivariable analysis for this study.

The next chapter will discuss whether the results were as the researcher expected. Theories will be given as to what may have caused any discrepancies from what was expected and what should be addressed in the future.

## Chapter 5

## Discussion

*Introduction*

This chapter is used to compare the results of this study to the results of prior studies, take a look at the limitations and address whether any additional ones developed over the duration of the study. This chapter will also look at the researcher's personal opinions regarding the results of the study and recommendations for the future regarding this subject area. Then the chapter will wrap up with a summary/conclusion section. This study answered the question, what beliefs do patients visiting a family practice clinic have about herbal medicines and natural supplements.

*Implications*

Sixty percent of this study's population were users of herbal medicines and natural supplements. Several studies performed from 1997-2001 found a range of 32-68% of U.S. population was using herbs and/or supplements (Eisenberg et al., 1998; Hudson, Brady, and Rapp, 2001; Bauer, 2000; Abdel-Rahman and Nahata, 1997; Astin, 1998; Kessler et al., 2001). One study by Roblatt (1999) found herbal use for U.S. consumers to be between 12-37%.

This study found that 70.4% of respondents told their health care provider about their herbal/supplement use. A much smaller percentage was found in prior studies. Eisenberg et al. (2001) and Abdel-Rahman and Nahata (1997) reported that 25-37% of patients did not inform their health care provider of their CAM use. A separate study found that 74% of respondents greater than 50 years old informed their health care provider of their CAM use; while 30% of participants less than 50 years old did (Durante,



Whitmore, Jones, and Campbell, 2001). The difficulty in comparing the last study to this one is that no separation in ages was made in this study.

Respondents were asked whom they believe monitors herbs and supplements. Participants chose both no one monitors and the FDA 33.3% of the time, NCCAM was chosen by 20%. As described in chapter two there are few organizations that actually monitor herbs/supplements. The federal government is represented by the NCCAM's small branch that does monitoring, and private organizations of the CHPA, USP, and NNFA also do some monitoring (Kaul and Joshi, 2001; E. Goldman, 2001; and Hudson et al., 2001). The latter three are voluntary programs and the first is currently only budgeted to evaluate controlled studies of alternative therapies. The truth is no regulatory agency exists to monitor manufacturing practices of all herbal and supplement producers (Bauer, 2000).

Participants in this study were asked whether they believed herbs/supplements were more effective than, as effective as, or less effective than prescription medicines. The choice of more effective was selected by 6.7% of all respondents and 11.1% when looking at users only. In a study done by Durante et al. (2001) 82% of those less than 50 years old and 43% of those 50 or older believed that supplements were more effective than prescriptions.

Thirty-eight (84.5%) of participants in this study agreed or strongly agreed with the statement that herbs/supplements have side effects and 77.7% agreed or strongly agreed that herbs and supplements can interact with prescription and over-the-counter drugs. Many specific positive and negative side effects of herbs/supplements were discussed in chapter two. In general it's been found that drug and herb/supplement

interactions exist (Joshi and Kaul, 2001; Vickers and Zollman, 1999; and Eisenberg et al., 1998).

Several studies found a large variability in the ingredients among herb/supplement manufacturers (Hudson et al, 2001; Drew and Meyers, 1997; and Roblatt, 1999). Makers of these products are not required to perform studies for safety, but over the counter and prescription medicine producers are (Roblatt, 1999 and Eisenberg et al., 2001).

Respondents in this survey were asked to respond to the question of whether they believe herbs/supplements are safer than, as safe as, or less safe than over the counter medicines. Participants believed herbs/supplements were safer 22.2% of the time and less safe 28.9% of the time. Other studies have reported that there is a lack of scientific studies about herbs/supplements (O'Matthuna, 2001 and Bauer, 2000). Approximately 55.5% of respondents to this survey did not believe there is enough research existing for herbs and supplements and 40% were unsatisfied with the currently available information. A previous study found 73% of respondents were unsatisfied with current herb/supplement information (Levy, 1999).

In the 2001 Durante et al. study participants less than 50 years old listed family, friends, and stores as the common sources of information about herbs/supplements; participants 50 or older listed physicians and lay press as their main information sources. A 2000 study by Bouldin et al. reported the following as information sources, in descending order, friends, labels, books, magazines, pharmacists, physicians, natural medicine practitioners, Internet, television, and retail clerks. This study found, in descending order, the sources of herb/supplement information were friends, family, health food store, magazines and other media sources, health providers, and labels.

The methodology of this study was somewhat different than that done previously. This study was a written survey given to a single family practice population for one weeks time. The Bouldin et al study was a written survey distributed nationally to pharmacists. The Durante et al study was a phone interview conducted on patients who had recently visited a family practice clinic.

### *Limitations*

As predicted the sample size was limited because of the time and resources available to the researcher. The project needed to be completed by May of 2004 and was not begun until spring of 2002. During this time period IRB approval, survey tool design, data collection, and data analysis needed to be completed. The smaller the sample size the quicker collection and analysis could be completed. The researcher, also, was limited to using her own finances, which meant the sample size would be limited to keep costs to a minimum. To save on costs the researcher analyzed the data herself rather than using a statistician thus sample size was kept to a manageable level.

The sample population was limited because it represented one week of patients at a single clinic in a smaller rural community. It would have been easier to generalize to the general public if it had taken a sample over a longer period of time or had included more clinics in various locales or if the survey had been distributed to the general population nationally.

### *Discussion*

Participants were more educated regarding herbs/supplements than the researcher originally anticipated. An initial assumption was that since there are few scientific

studies on herbs/supplements and massive amounts information about these products from manufacturers that consumers would have more false beliefs about these products.

The researcher had expected that more people would believe that the FDA monitors herbs/supplements, but in fact this was chosen equally with no one. While one would hope that more people would be aware that the FDA is not monitoring these products, it was expected the even fewer participants would know no one is officially monitoring all herbs/supplements.

It was also anticipated that more respondents would believe that herbs/supplements did not have side effects or drug interactions that was actually reported. Additionally the researched felt a larger percentages of participants would believe that pharmacists and conventional health care providers approve of herbs/supplements and accept them as safe and effective.

The researcher believed that there would be a significant difference between users and non-users regarding whether herbs/supplements were more effective than prescription medicines and safer than over the counter medicines. It was expected that users would respond more often they were more effective and safer. There was a statistically significant difference between users and non-users regarding effectiveness, but not regarding safety.

It was also thought that there would be a significant difference between users and non-users about their education level regarding herbs/supplements. What was unknown was whether the users or non-users would have a significant statistical difference in scores or if there would be a correlation between scores and users vs. non-users. The ANOVA between users and non-users responses on questions deemed to have a correct

answer did not reveal a statistical difference in scores and the Spearman analysis showed no correlation.

This study focused primarily on what people were using, if they were using and what their opinions about herbs/supplements were. While there were surprisingly larger percentages of participants properly informed about herbs/supplements many of the actual numerical values are still too low to ensure people are making educated decisions about these products.

### *Recommendations*

Further studies are needed to determine the areas of misconception members of the general population, and or medical professionals have regarding herbs and supplements. When this information is available and hopefully found to have consistent trends then conventional health care providers will hopefully realize the need to better educate themselves regarding herbs and supplements so they can better educate their own patients. More studies can be done on opinions of family practice patients or lay public regarding herbs/supplements, as this study was not exhaustive. Also, a study could be done looking at why users would not inform their medical providers of their herb/supplement practices. A future replication of this researcher's study could be done on a separate patient population, the same population, or a larger population. If this replication was done the researcher(s) could consider using a Factor Analysis statistical procedure in place of the ANOVA test that was used in this study

Herbs and supplements are growing in use and yet our government does not see the need to increase funding for research and monitoring of these items. More

studies about effects, interactions, and safety are needed to provide support for lobbyists to convince the government they need to be more involved.

### *Summary/Conclusions*

It was expected that participants would not inform their health care providers of their herbal/supplement use, yet in this study the majority did. It was thought that many participants would be misinformed regarding monitoring of herbs/supplements and a significant amount was, but a significant amount were still misinformed with 33.3% believing the FDA was involved. The prior research and literature leads one to believe that many people will believe herbs and supplements are safer than, more effective than, and have less interactions and side effects than conventional treatments. This study's participants did believe herbs and supplements to be more effective, but not safer and large percentages agreed that herbs and supplements have side effects and interactions. Literature has suggested that there are not enough scientific studies and a prior study found people were unsatisfied with current information available about herbs and supplements. The participants of this study agreed with both of the above statements. While some items in this study, as discussed above, were in agreement with prior literature and studies most of the available literature and many of the prior studies would lead most to expect there to be a larger amount of people who are misinformed than was actually reported in these findings.

It's hoped that with studies aimed at understanding why patients use or don't use herbs/supplements and knowing their knowledge level and sources used for making the decision to use or not use it will be easier to convince conventional medical providers of the importance of properly educating themselves about herbals and natural products. If

they are educated they can better advise their patients regarding these products. Once the general consensus among health care providers and consumers is that more education and scientific studies are needed in the area of herbal and natural supplements, perhaps more support and funding for such studies will become more prevalent.

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**Survey Instructions****Keep This Page**

1. This survey is optional. It would be best to fill out and return your other clinic paperwork before filling this out to ensure there is no delay in your appointment.
2. Do not write your name anywhere on the survey.
3. Most questions will require you check or circle the most appropriate response, but space has been left for written responses. The average time for completion is between 5-15 minutes.
4. Please read each question and instructions within the survey carefully.
5. Try to answer all the questions; if any question makes you uncomfortable, you are welcome to skip it.
6. The pen is yours to keep regardless of your participation.
7. Keep the attached consent form in case you have any questions.
8. Once you have completed the survey, please return it to the locked drop box located at the reception desk.
9. Thank you for your valuable help in furthering research on herbal medicine and natural supplements.
10. If you have already filled out this survey on a previous visit, please return this packet to the receptionist. Thank you for your previous participation.
11. You must be 18 years of age to participate. If you are not 18 years old, please return this survey packet to the receptionist.
12. For the purposes of this study herbal medicines are defined as a plant or plant part consumed for medicinal or health purposes and do not include plants being used solely as food or part of a meal. Natural Supplements are defined as products intended to supplement the diet or enhance health that contain amino acids or animal products, this does not include mineral or vitamin supplements.

**Keep This Page****Voluntary Nature of the Study:**

Your decision whether or not to participate will not affect your current or future relations with Augsburg College or with the Mosinee clinic or the Marshfield clinic system. If you decide to participate, you are free to withdraw at any time or skip any question without affecting the above relationships.

**Contacts and Questions:**

The researcher conducting this study is Penny Vinnedge. If you have questions later, you may contact me via e-mail at [fleegel@augzburg.edu](mailto:fleegel@augzburg.edu) or phone at (715) 377-7624

You may also contact my advisor Terry Lewis via e-mail at [lewist@augzburg.edu](mailto:lewist@augzburg.edu) or phone at (612) 330-1284

Keep this copy of the consent form for your records.

**Statement of Consent:**

I have read the above information. The return of my survey is my consent to participate in this study.

Institutional Research Board  
Augsburg College  
Box 107

February 12, 2003

To: Penny Vinnedge

From: Norma C. Noonan, Chair



I am pleased to inform you that the IRB has approved your application the project: Perceptions Patients Visiting a Family Practice Clinic Have about Herbal Medicines and Natural Supplements

X as submitted

as revised

with the following conditions:

Your IRB approval number which should be noted in your written project and in any major documents alluding to the research project is as follows:

**2003-9-2**

I wish you success with your project. If you have any questions, you may contact me: 612-330-1198 or [noonan@augzburg.edu](mailto:noonan@augzburg.edu).

c. Terry Lewis ✓

## *Research Compliance*

### *Institutional Review Board*

## *Memo*

To: Penny Vinnedge  
From: Judy Zirnhelt *Judy*  
Date: January 3, 2003  
Re: Exempt Research Review

Your project, VIN20103 Perceptions Patients Visiting a Family Practice Clinic Have About Herbal Medicines and Natural Supplements was reviewed by IRB staff and determined to be exempt from IRB review according to the Human Research Subject Review Decision Chart used to make the assessment. If your protocol is changed to include identifiers or the scope of work changes, you will need to resubmit for further review.

**IRB EXEMPT RESEARCH DETERMINATION FORM**

Use this form for research believed to be exempt from further IRB review. See attached categories/criteria. More information may be requested if your project does not qualify for exemption.

VIN20103

**Principal Investigator:** Penny Vinnedge **Co-Investigator:** Jerome Andres, MD

**Title:** Perceptions Patients Visiting a Family Practice Clinic Have About Herbal Medicines and Natural Supplements

**Purpose and Summary of Project:** The purpose of the project is to obtain a better understanding of what herbals/supplements people are using, why they are or are not using them, where they obtain their information, and what opinions/beliefs people hold about them. These questions are important because they are not typically a part of traditional medical education or the medical interview. If health care providers have a better understanding of what are patients' information sources, opinions/beliefs, and what they are using then health care providers can provide better education about drug interactions, herbal or supplement safety, quality information sources, and advice to their patients regarding use of herbals or supplements. An anonymous written survey will be distributed to patients by the clinic receptionist(s) upon check in. Since this will be a written survey consent will be implied upon return of the survey and no identifying signatures will be collected. Those willing to participate will be asked to fill out the survey after completing all other clinic paperwork and return it to a locked drop box in the reception area before he/she leaves the clinic that day.

**Start Date:** 03 / 01 / 03 **End Date:** 05 / 31 / 03 **Age of Subjects:** 18 and older

**Data/samples used in this project will be:**

- Identified** (contains a clear identifier [e.g., subject's name, address, or phone number])
- Identifiable** (coded but not able to link to the subject without consulting a legend)
- Anonymized** (contained identifier when first collected, but will be stripped of all identifiers or codes allowing link to identifying information prior to the conduct of the research)
- Anonymous** (contains no identifiers or links; is impossible for anyone to link to subjects)

**Are all data/samples to be used in this project currently in existence?**

Yes  No

**Will additional data/samples be collected once the study is initiated?**

No  Yes (If yes, describe the type of data/sample and the time at which it will be collected)

The data will be collected via a written survey distributed to any patient greater than age 18 visiting the family practice at the Mosinee clinic during a one week period of time between March 1, 2003 to May 1, 2003.

**If data/samples are in existence, were they collected for purposes of this research project?**

Yes  No (If no, indicate why the data/samples were collected)

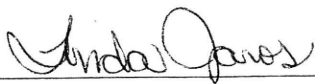
None of the data is currently in existence.

**Describe anticipated risks/discomforts:** Anticipated risks include possible invasion of privacy of subject or probing for personal information in the survey. The personal information is limited to the participants' opinions about herbal medicines and natural supplements, the types of herbals or supplements used, and any effects experienced during their usage.

----- IRB Use Only -----

*The research described above falls under exemption 46.10 (b)(2) (options attached). No further review of this research by the IRB is necessary unless answers to the above questions change.*

For your reference, the SP Code assigned to this exempted protocol is VIN20103

  
IRB Representative

1/3/02  
Date



Appendix D  
Site Approval Letter

501 ORBITING DRIVE 66  
MOSINEE, WI 54455-1752

FAX 715-693-1274

715-693-9100



MARSHFIELD CLINIC®

MOSINEE CENTER

January 16, 2003

Penny L. Vinnedge, P.A.S.

Dear Penny:

In response to your letter requesting permission to distribute surveys at the Mosinee Clinic as part of your Master's Thesis Research Project, I am happy to inform you that I and my partners and the Marshfield Clinic as a whole have consented to support your project.

As you know, our Institutional Review Board has determined your project to be exempt and your protocol has been approved.

Our Mosinee Center has discussed your project and agreed unanimously to allow you to survey our patients.

As a formality, I am happy to serve as your co-investigator and wish you well on your project.

Sincerely,

JEROME C. ANDRES, M.D., F.A.A.F.P.  
Department of Family Practice

JCA:smd

**WebMail - RE: Pharmacist's Perceptions of Herbal Medicines Survey**

Delete File Create Reply Reply All Forward Previous Next Options Index Help

**Date Sent:** Tuesday, October 01, 2002 3:30 PM

**From:** Alicia Bouldin <abouldin@olemiss.edu> [Add to Address Book](#)

**To:** fleegel

**Subject:** RE: Pharmacist's Perceptions of Herbal Medicines Survey

Status:  Urgent  New

Dear Ms. Vinnedge,

I apologize for the delay in reply to your message. We would be glad for you to use our questions in your interviews, and would be very pleased to hear of the results of your efforts. We did a subsequent project exploring patient's use of information in their self-care decisions regarding herbs. I do not know the exact nature of your project, but that might be helpful to you also. An article about this patient information project is available online in [Drug Information Journal](http://www3.diahome.org/htmlabstr/English/dij344-1339-1470.htm) via pdf. (Click on the article's title at this URL, and it will pull up the whole article.)

<http://www3.diahome.org/htmlabstr/English/dij344-1339-1470.htm>

Please let me know if I can be of further assistance.

Sincerely,  
Alicia S. Bouldin, R.Ph., Ph.D.  
Research Assistant Professor for Instructional Assessment and Advancement  
The University of Mississippi School of Pharmacy  
207 Faser  
University, MS 38677  
abouldin@olemiss.edu  
662-915-7262 (phone)  
662-915-5102 (fax)

At 08:50 PM 9/15/2002 -0500, you wrote:

Dear Dr.. Alicia Bouldin,

My thesis advisor ran across your survey "Pharmacist's Perceptions of Herbal Medicines Survey". I found it very interesting. I believe it could be useful to me as a survey tool.

I am currently a graduate student working towards my masters and a Physician Assistant certification. We are required to do a thesis and the topic I've

chosen is patient's perceptions about the safety of herbals they are taking.

I would be very grateful if I could use the questions your group used to interview pharmacists. I believe it may be helpful in my thesis endeavors and would of course obtain your group's permission before using any questions in my own study and give appropriate credit for anything used. I may need to make some slight modifications to tailor the questions towards my study group, but I would supply you with the revisions before using the survey.

Please let me know if it is at all possible to use these materials. I would be happy to share my results with you, if you are interested.

Thank you for your time and any assistance you can provide.

Sincerely,  
Penny (Fleegel) Vinnedge  
PA-S  
Augsburg College



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## Durante et al. Correspondence

**Subject: The Article Use of Vitamins and Herbs: A survey of patients attending family practice clinics**

**Date:** Mon, 19 Aug 2002 19:26:24 -0500

**From:** fleegel <fleegel@augsborg.edu>

**To:** ncampbel@ucalgary.ca

Dear Mr.. Norman Campbell:

I recently read the article, "Use of Vitamins and Herbs: A Survey of Patients Attending Family Practice Clinics", that you, Dr.. Durante, Dr.. Jones, and Beverely Whitmore published in Clinical and Investigative Medicine, 2001. I found it greatly interesting. I am currently a graduate student working towards my masters and a Physician Assistant certification. We are required to do a thesis and the topic I've chosen is patient's perceptions about the safety of herbals they are taking.

I would be very grateful if I could get a copy of the questions your group used to interview patients and any other data your group may have, but not published. I believe they could be very helpful in my thesis endeavors and would of course obtain your groups permission before using any questions in my own study and give appropriate credit for anything used.

Please let me know if it is at all possible to receive a copy of these materials and how I may go about it.

If they can be electronically sent they can be returned to this address. If they need to be mailed, my address is: 85 Coulee Road, #4  
Hudson, WI 54016

Thank you for your time and any assistance you can provide.

Sincerely,  
Penny Fleegel  
PA-S  
Augsburg College

*After sending this e-mail I simply received the following survey in an official university of calgary envelope courtesy of Dr. Campbell and the following survey and a brief note stating I could use the survey and good luck.*

## Bouldin et al. Survey

## PHARMACISTS' PERCEPTIONS

For each of the following statements, respondents circled the response below which best indicated their opinions regarding herbal medicines *IN GENERAL*.

(The following scale was provided for each response on the original questionnaire.)

STRONGLY DISAGREE	1	2	3	4	5	STRONGLY AGREE
----------------------	---	---	---	---	---	-------------------

	PERCENT DISAGREE (circled 1 or 2)	PERCENT NEUTRAL (circled 3)	PERCENT AGREE (circled 4 or 5)
a. The quality of herbal medicines is well accepted by the FDA. <i>Natural supp</i>	74%	21%	5%
b. Herbal medicines are well accepted by the National Association of Boards of Pharmacy (NABP).	68%	27%	5%
c. Herbal medicines are not accepted by the majority of my colleagues.	20%	32%	48%
d. Herbal medicines belong in a health food store.	50%	28%	22%
e. Herbal medicines belong in a pharmacy.	18%	31%	51%
f. Herbal medicines should be sold <u>only</u> in a pharmacy.	43%	30%	27%
g. Carrying herbal medicines may have a negative influence on a pharmacy's image.	57%	24%	19%
h. I am well acquainted with the history of herbal medicines.	57%	26%	17%
i. Herbal medicines are only a form of quackery.	59%	26%	15%
j. Herbal medicines are a good <del>economical</del> alternative to conventional medicines for patients <u>who self select</u> .	40%	33%	27%
k. Herbal medicines are efficacious.	28%	45%	27%
l. The doses of commercially marketed herbal medicines have been well standardized.	66%	26%	8%
m. The federal regulations provided for herbal medicines in the Dietary Supplement Health & Education Act of 1994 are adequate.	50%	45%	5%
n. Carrying herbal medicines may increase my liability.	36%	33%	31%
o. The profit potential is high with herbal medicines.	9%	39%	52%
p. I am informed when my patients use herbal medicines.	66%	25%	9%
q. Herbal medicines should not be considered part of an integrated medication program.	46%	30%	24%
r. I usually add herbal medicines to the medication profiles I maintain for my patrons.	80%	13%	7%
s. My pharmacy is equipped to monitor interactions involving herbal medicines.	89%	6%	5%
t. I know of specific interaction problems with some herbal medicines.	59%	19%	22%

*Herbal medicines/natural supp can have interactions w/ prescription & OTC drugs.*

	PERCENT DISAGREE (circled 1 or 2)	PERCENT NEUTRAL (circled 3)	PERCENT AGREE (circled 4 or 5)
u. Most herbal medicines have a high degree of placebo effect.	22%	37%	41%
v. Many herbal medicines should be prescription only.	40%	37%	23%
w. My clientele is very receptive to the use of herbal medicines.	35%	44%	21%
x. Herbal medicines are currently in high demand in the U.S.	17%	30%	53%
y. My pharmacy experiences very little demand for herbal medicines.	29%	29%	42%
z. My pharmacy competitors see a high demand for herbal medicines.	39%	45%	16%
aa. Health food stores experience a high demand for herbal medicines.	5%	17%	78%
bb. I have or someone in my immediate family has used herbal medicines frequently in the past.	54%	15%	31%
cc. I have used herbal medicines for self-treatment before.	64%	9%	27%
cd. I have actively sought information regarding herbal medicines.	37%	20%	43%
ce. I would recommend standardized herbal extracts (the pharmaceutical form of herbs) more often than I would crude herbs.	15%	20%	65%
ff. I am more likely to recommend an herbal product manufactured by a pharmaceutical company than by a vitamin or herb company.	27%	27%	46%
gg. It is likely that I will recommend herbal medicines to my clientele.	39%	30%	31%
hh. It is likely that I will recommend herbal medicines which have been shown to be safe and effective in clinical trials.	12%	23%	65%
ii. It is likely that I will use herbal medicines in the future.	27%	31%	42%
jj. It is likely that I will stock herbal medicines in my pharmacy.	15%	28%	57%
kk. It is likely that I will seek additional information regarding herbal medicines.	10%	17%	73%

How useful do you find the information available to you regarding herbal medicines? (circle one number below)

OF NO USE	1	2	3	4	5	6	7	EXTREMELY USEFUL
	8%	18%	20%	18%	19%	10%	7%	

Do you feel that you have enough information regarding potential interactions involving herbal products?  
 4% Yes      96% No

*Alicia Bouldin, Mickey Smith, Benjamin Barakat III,  
 David McCaffrey III, Edward M. Croem Jr., Thad Cochran*



WOTHILLS HOSPITAL  
Initial Nutrition Services

SUPPLEMENTATION QUESTIONNAIRE

Age:  
Race:  
Country of Birth:

Identification Number:  
Order:

	YES	NO	INITIAL	4 MO	8 MO	12 MO
Do you use any supplements or complementary health products such as herbs, vitamins & minerals?						
How many supplements are you using?						
What is the name of the supplement?						
What brand do you use?						
What dose do you take?						
How long have you used this supplement?						
How often are you supposed to take this supplement?						
How often do you miss taking this supplement?						
Where did you hear about this supplement?						
What were you told about this supplement?						
What positive health effects in the supplement supposed to have?						
What negative health effects have you been told of about the use of this supplement?						
What positive effect have you noticed?						
What negative effects have you noticed?						
Is any health professional checking you regarding the use of this product? • If yes, who?						
Does your Dr. know you are using this supplement?						
Does your Dr. approve?						
If you wanted more information about this supplement or another, where would you go?						
Do you feel herbs/vitamins/minerals are more effective than medications prescribed by your Dr.?						
Do you feel they are safer than medications prescribed by your Dr.?						
Have there been any changes regarding the use of supplements over the past four months? • If yes, please describe.						
If any supplements have been stopped, why did you stop?						
What do you estimate this supplement costs you per week?						

Durante et al. Survey

USE ONE PAGE PER SUPPLEMENT







3. How long have you or did you use herbs or supplements? \_\_\_\_\_
4. If you stopped taking any herbs or supplements, which ones and why?
5. Where did you learn about your herbs and/or supplements? (Check all that apply and circle the one that was/is most influential to your decision.)
- \_\_\_ Doctor    \_\_\_ Nurse    \_\_\_ Physician Assistant    \_\_\_ Nurse Practitioner
- \_\_\_ Family    \_\_\_ Friends    \_\_\_ Pharmacist    \_\_\_ Chiropractor    \_\_\_ TV
- \_\_\_ Newspaper    \_\_\_ Internet    \_\_\_ Herbalist    \_\_\_ Books    \_\_\_ Journals
- \_\_\_ Health Food Store    \_\_\_ Other (please Specify) \_\_\_\_\_
6. Is there a health professional monitoring you regarding the use of these products? (If yes, Who?)
7. Did you inform your health care provider of your herbal and/or supplement use? (If no, please state why?)
8. Does your health care provider approve of your herbal/supplement use?
9. If you wanted more information about herbal medicines or natural supplements, where would you look or whom would you ask?
10. Do you believe herbs/supplements are more effective, less effective, or equally as effective as medications prescribed by your health care provider?
11. Do you believe herbs/supplements are safer, less safe, or equally as safe as medications prescribed by your health care provider?
12. Whom do you believe monitors or supervises manufacturing and sales of herbal medicines or natural supplements?

Please circle the answer that most closely represents your answer to the question.

- |   |                   |          |         |       |                |
|---|-------------------|----------|---------|-------|----------------|
| 13. I believe I have adequate knowledge concerning safety, dosage, and effectiveness of the herbal medicines/natural supplements? | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
| 14. The quality of herbal medicines/natural supplements is well accepted by the FDA?  | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
| 15. The safety of herbal medicines/natural supplements is well accepted by the FDA?   | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
| 16. The efficacy of herbal medicines/natural supplements is well accepted by the FDA?   | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
| 17. Herbals/Natural Supplements are closely monitored by an official organization for safety, effectiveness, and side effects.    | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
| 18. Herbal medicines belong in a pharmacy.  | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
| 19. Herbal medicines should be sold only in a pharmacy.   | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
| 20. Herbal medicines belong in a health food store.   | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
| 21. Herbal medicines are only a form of quakery.  | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
| 22. I know of specific interaction problems with some medicines.  | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
| 23. I have actively sought information regarding herbal medicines.  | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
| 24. Herbal medicines are as efficacious as prescription drugs.  | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
| 25. I inform my health care provider that I am using Herbal or Natural supplements.   | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
| 26. Herbal medicines are a good alternative to conventional medicines for patients.   | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
| 27. I am well acquainted with the safety of Herbal/Natural supplements.   | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
| 28. It is likely that I will seek additional information regarding herbal medicine.   | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
| 29. Herbal/Natural supplements are standardized to contain the exact amount of ingredients listed on the label.                   | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |

**Herbal Survey**

1. Do you use or have you ever used any herbal medicines or natural supplements? (CHECK ONE)  
 Yes (GO TO QUESTION 2)       No (GO TO QUESTION 10)

2. How many herbal medicines or natural supplements are you using or have you used? \_\_\_\_\_  
 3. PLEASE CHECK THE NAMES OF THE HERBS/SUPPLEMENTS YOU HAVE USED AND ANY EFFECTS YOU EXPERIENCED WHILE TAKING THE HERBS/SUPPLEMENTS. IF YOU HAVE STOPPED USING ANY OF THE HERBS/SUPPLEMENTS PLEASE CHECK THE BOX FOLLOWING THAT HERB/SUPPLEMENT.

Herbal/Supplement Name

Effects

Effects Cont.

Stopped Using

Cayenne/Capsaicin

- Lower body temperature
- Thinner mucus
- Lower cholesterol levels
- Reduced sensation of pain
- Increased digestion
- Increased circulation
- Lower blood pressure
- Other (PLEASE EXPLAIN) \_\_\_\_\_

- Pain
- Eye irritation
- Upset stomach
- Skin irritation
- Dizziness
- Rapid pulse
- None

Chamomile

- Decreased indigestion
- Decreased nervousness
- Decreased depression
- Headache relief
- Decreased menstrual cramps
- Other (PLEASE EXPLAIN) \_\_\_\_\_

- Drowsiness
- None

Garlic

- Reduced blood pressure
- Decreased LDL cholesterol levels
- Thinner blood       Fewer blood clots
- Clearer sinuses/Reduced nasal congestion
- Reduced chest congestion
- Decreased number of illnesses
- Other (PLEASE EXPLAIN) \_\_\_\_\_

- Odor of breath or sweat increased
- Heartburn/Indigestion
- Longer bleeding time
- Low blood sugar levels
- None
- Improvement in fungal infections

Ginkgo Biloba

- Enhanced memory
- Reduced ringing in the ear
- Reduced dizziness
- Increased circulation
- Fewer leg cramps
- Other (PLEASE EXPLAIN) \_\_\_\_\_

- Irritability
- Headache
- Rash
- Diarrhea
- Fast beating heart
- Gas
- Nausea
- Vomiting
- Seizures
- None

**Herbal/Supplement Name**

**Effects**

**Effects Cont.**

**Stopped Using**

Ginseng

Increased energy

Depression  None

Increased endurance

Increased blood pressure

Increased concentration

Anxiety/Nervousness

Decreased blood sugar levels

Insomnia

Improved mood

Irregular heart beat

Decreased cholesterol levels

Increased menstrual bleeding

Others (PLEASE EXPLAIN) \_\_\_\_\_

Glucosamine-Chondroitin

Decreased pain in joints

Diarrhea

Headache

None

Decreased swelling in joints

Nausea

Vomiting

Increased ability to move joints

Drowsiness

Heartburn

Decreased arthritis flare-ups

Elevated mood

Increased bleeding time

Other (PLEASE EXPLAIN) \_\_\_\_\_

Goldenseal

Faster healing mouth sores

Seizures

Slow heart rate

Relief of sore throat

Nausea

Vomiting

Relieves upset stomach

Diarrhea

Sleepiness

Relief of chest congestion

Stomach cramps

Increased appetite

Development of mouth sores

Relief of constipation

None

Relief of diarrhea

Other (PLEASE EXPLAIN) \_\_\_\_\_

Milk Thistle

Relief of upset stomach

Diarrhea

Increased appetite

None

Alleviation of gallbladder symptoms

Other (PLEASE EXPLAIN) \_\_\_\_\_

Saw Palmetto

Reduced frequency of urination

Headache

None

Increased urine flow/less resistance

Stomach upset

Relief of urinary infections

Testicular growth

Other (PLEASE EXPLAIN) \_\_\_\_\_

St. John's Wort

Improvement in depressed mood

Sensitivity to light

Nausea

Faster wound healing

Fatigue

Diarrhea

Decreased anxiety/nervousness

Vomiting

Indigestion

Fewer bacterial and viral illnesses

Constipation

Reduced inflammation

None

Other (PLEASE EXPLAIN) \_\_\_\_\_

Herbal/Supplement Name

Effects

Effects Cont.

Stopped Using

- Thyme
  - Valerian
  - Others (PLEASE SPECIFY NAMES)
- Reduced cough
  - Soothes sore throat
  - Relaxed muscles
  - Other (PLEASE EXPLAIN)
- Cleared congestion
  - Improved digestion
  - Reduced menstrual cramps
  - None
- Relief of muscle spasms
  - Sedation/Sleepiness
  - Reduced restlessness
  - Other (PLEASE SPECIFY)
- Nausea
  - Blurred vision
  - Excitability
  - None
  - Insomnia
  - Headache
  - None

4. How long have you used or did you use herbs or supplements? \_\_\_\_\_

5. If you stopped taking any herbs or supplements, PLEASE CHECK all reasons which apply to why you stopped taking them ?

- Did not stop taking any
- Too expensive
- Didn't seem to help
- Didn't like taking all the pills
- Kept forgetting to take the pills
- Interfered with my medications
- Health provider told me to stop
- Made me feel worse
- Pharmacist told me to stop
- Others (PLEASE SPECIFY) \_\_\_\_\_

6. Where did you learn about your herbs and/or supplements? (CHECK ALL THAT APPLY AND CIRCLE THE ONE THAT WAS MOST INFLUENTIAL TO YOUR DECISION.)

- Books
- Chiropractor
- Doctor
- Family
- Friends
- Health Food Store
- Herbalist
- Internet
- Journals
- Magazine
- Newspaper
- Nurse
- Nurse Practitioner
- Pharmacist
- Physician Assistant
- Product Label
- TV
- Others (PLEASE SPECIFY) \_\_\_\_\_

7. Is there a health professional monitoring you regarding the use of these products? (PLEASE CHECK WHOM)  No one

- Doctor
- Herbalist
- Nurse
- Nurse Practitioner
- Nutritionist
- Pharmacist
- Physical Therapist
- Physician Assistant
- Other (PLEASE SPECIFY) \_\_\_\_\_

8. Do you inform your health care provider of your herbal and/or supplement use? (PLEASE CHECK ONE)  YES  NO

9. Does your health care provider approve of your herbal and/or supplement use? (PLEASE CHECK ONE)  YES  NO

10. If you wanted more information about herbal medicines or natural supplements, where would you look or whom would you ask?(CHECK ALL THAT APPLY)

- Books
- Chiropractor
- Doctor
- Family
- Friends
- Health Food Store
- Herbalist
- Internet
- Journals
- Magazine
- Newspaper
- Nurse
- Nurse Practitioner
- Pharmacist
- Physician Assistant
- TV
- Other (PLEASE SPECIFY) \_\_\_\_\_

11. Do you believe herbs/supplements are (PLEASE CIRCLE ONE) more effective, less effective, less effective, or equally as effective as medications prescribed by your health care provider?

12. Do you believe herbs/supplements are (PLEASE CIRCLE ONE) safer, less safe, or equally as safe as medications available over the counter?

13. Whom do you believe monitors or supervises manufacturing and sales of herbal medicines or natural supplements?

(CHECK ALL THAT APPLY)

- Food and Drug Administration/FDA
- Board of Medicine
- Board of Pharmacy
- World Health Organization/WHO
- National Center for Complementary and Alternative Medicine/NCCAM
- Office of Dietary Supplements
- No one
- Others (PLEASE SPECIFY) \_\_\_\_\_

PLEASE CIRCLE THE RESPONSE THAT MOST CLOSELY REPRESENTS YOUR ANSWER TO THE QUESTION.

- |   |                   |          |         |       |                |
|---|-------------------|----------|---------|-------|----------------|
| 14. I believe I have adequate knowledge concerning safety, dosage, and effectiveness of the herbal medicines/natural supplements. | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
| 15. The safety of herbal medicines/natural supplements is well accepted by the FDA.   | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
| 16. The effectiveness of herbal medicines/natural supplements is well accepted by the FDA.  | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
| 17. The quality of herbal medicines/natural supplements is well accepted by the FDA.  | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
| 18. The safety of herbal medicines/natural supplements is well accepted by pharmacists.   | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
| 19. The effectiveness of herbal medicines/natural supplements is well accepted by pharmacists.                                    | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
| 20. The safety of herbal medicines/natural supplements is well accepted by health providers.                                      | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
| 21. The effectiveness of herbal medicines/natural supplements is well accepted by health providers.                               | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
| 22. Herbals/natural supplements are closely monitored by an official organization for safety, effectiveness, and side effects.    | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
| 23. Herbal medicines belong in a pharmacy.  | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
| 24. Herbal medicines should be sold <u>only</u> in a pharmacy.  | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
| 25. Herbal medicines belong in a health food store.   | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
| 26. Herbal medicines/natural supplements can have interactions with prescription and over-the-counter drugs.                      | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
| 27. I have actively sought information regarding herbal medicines/natural supplements.  | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
| 28. Herbal medicines are a good alternative to conventional medicines for patients.   | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
| 29. Herbal medicines and/or natural supplements can have side effects.  | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
| 30. It is likely that I will seek additional information regarding herbal medicine/natural supplements.                           | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |

Return This Page



31. Herbals/natural supplements are standardized to contain the exact amount of ingredients listed on the label.	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
32. Labels on herbal medicines/natural supplements are easy to understand.	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
33. It is easy to obtain reliable accurate information about herbal medicines/natural supplements.	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
34. I am satisfied with the current information available about herbal medicine and natural supplements.	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
35. I believe there have been adequate scientific research studies done on herbal medicines/natural supplements.	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
36. Herbal medicines are effective.	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

**Thank you for filling out the survey. Please return it to the drop box located at the reception desk before you leave.**

This survey contains portions designed by Norman Campbell, Dr., Durante, Dr., Jones, and Beverly Whitmore "Use of Vitamins and Herbs: A Survey of Patients Attending Family Practice Clinics." Clinical and Investigative Medicine. 2001. and Alicia Boulden "Pharmacists Perceptions of Herbal Medicines." University of Mississippi Thesis Project.

**Return This Page**

## Likert Scale Results

**KEY**

F = Frequency

% = Percent

SA = Strongly Agree

A = Agree

N = Neutral

D = Disagree

SD = Strongly Disagree

UA = Unanswered

H/S = herbs/supplements

**TABLE 5**

STATEMENT	F SA	% SA	F A	% A	F N	% N	F D	% D	F SD	% SD	F UA	% UA
Have adequate knowledge about H/S	2	4.4%	8	17.8%	12	26.7%	16	35.6%	5	11.1%	2	4.4%
Safety of H/S well accepted by FDA	0	0.0%	5	11.1%	13	28.9%	16	35.6%	8	17.8%	3	6.7%
Effectiveness of H/S well accepted by FDA	0	0.0%	4	8.9%	13	28.9%	19	42.2%	5	11.1%	4	8.9%
Quality of H/S well accepted by FDA	0	0.0%	6	13.3%	11	24.4%	17	37.8%	7	15.6%	4	8.9%
Safety of H/S well accepted by pharmacists	0	0.0%	6	13.3%	21	46.7%	11	24.4%	4	8.9%	3	6.7%
Effectiveness of H/S well accepted by pharmacists	0	0.0%	3	6.7%	22	48.9%	14	31.1%	2	4.4%	4	8.9%
Safety of H/S well accepted by health providers	1	2.2%	6	13.3%	14	31.1%	18	40%	3	6.7%	3	6.7%
Effectiveness of H/S well accepted by health providers	0	0.0%	4	8.9%	20	44.4%	14	31.1%	3	6.7%	4	8.9%
H/S are monitored by an official organization	0	0.0%	6	13.3%	9	20%	20	44.4%	6	13.3%	4	8.9%
H/S belong in a pharmacy	1	2.2%	18	40%	13	28.9%	9	20%	2	4.4%	2	4.4%
H/S should be sold only in a pharmacy	2	4.4%	8	17.8%	13	28.9%	18	40%	2	4.4%	2	4.4%
H/S belong in a health food store	2	4.4%	14	31.1%	15	33.3%	10	22.2%	1	2.2%	3	6.7%
H/S can interact with RX and OTC medicines	15	33.3%	20	44.4%	4	8.9%	3	6.7%	1	2.2%	2	4.4%
I have actively sought information about H/S	2	4.4%	16	35.6%	7	15.6%	14	31.1%	2	4.4%	4	8.9%
H/S are a good alternative to conventional medicines	2	4.4%	15	33.3%	16	35.6%	6	13.3%	4	8.9%	2	4.4%
H/S can have side effects	12	26.7%	26	57.8%	4	8.9%	1	2.2%	0	0.0%	2	4.4%

I will likely seek additional information about H/S	5	11.1%	16	35.6%	9	20%	9	20%	3	6.7%	3	6.7%
H/S are standardized	2	4.4%	6	13.3%	17	37.8%	12	26.7%	4	8.9%	4	8.9%
H/S labels are easy to understand	0	0.0%	7	15.6%	20	44.4%	11	24.4%	3	6.7%	4	8.9%
It's easy to obtain accurate information about H/S	0	0.0%	12	26.7%	15	33.3%	10	22.2%	4	8.9%	4	8.9%
I'm satisfied with current information available about H/S	0	0.0%	10	22.2%	13	28.9%	14	31.1%	4	8.9%	4	8.9%
Believe there has been adequate scientific research done on H/S	0	0.0%	6	13.3%	10	22.2%	20	44.4%	5	11.1%	4	8.9%
H/S are effective	0	0.0%	19	42.2%	18	40%	1	2.2%	3	6.7%	4	8.9%