

Thesis Approval Form

NURSE PRACTITIONERS' EXPERIENCE WITH HERBAL THERAPY

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## ABSTRACT

Use of herbal therapy has dramatically risen in the last decade. Advertisement and access to these supplements has also grown. Patient use, benefits, and potential adverse effects of herbal therapy have been well documented in the literature, but provider response to this phenomenon has not been well documented. The purpose of this study was to explore and describe nurse practitioners' experience with herbal therapy. Grounded theory methodology, a qualitative research approach, guided the research process. A purposeful sample of 8 Air Force nurse practitioners was interviewed. Data collection and analysis occurred simultaneously using coding and categorization until saturation had been established and a core variable emerged. Results identified nine theme categories related to knowledge, safety, validity and effectiveness, responsibility, time, cost, complementary vs. Western medicine, patient/provider relationship, and prescribing vs. recommending. Knowledge of herbal therapy and the acquisition thereof emerged as the core variable in this study. Knowledge influenced how much herbal therapy was incorporated into practice, which contributed to overall experience. As experience expanded, this further contributed to the body of knowledge on herbal therapy. As more and more patients use herbs to attain or maintain a state of well-being, this study highlights the need for nurse practitioners to remain current and focus on knowledge acquisition regarding herbal therapy.

Key Words: **nurse practitioner**, **herbal therapy**, **complementary medicine**,  
**knowledge acquisition**

NURSE PRACTITIONERS' EXPERIENCE WITH HERBAL THERAPY

by

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## DEDICATION

To the many people who supported me in my efforts to develop this paper, I hereby dedicate this thesis. From the instructors and faculty who guided me through the process and advised me along the way to my fellow colleagues who encouraged me and assisted me with their wisdom and positive attitude, I heartily thank you. I also owe a debt of gratitude to my parents who instilled in me a strong work ethic and a sense of compassion for others. Finally and most importantly, I dedicate my efforts to the two most important people in my life, my husband Brooks and my son Noah, whose love, support, and frequent hugs made this all possible.

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## CHAPTER I: AIM OF THE STUDY

### Introduction

This chapter will introduce the issue concerning herbal therapy and provide a background for the purpose of this study. The research question, guiding questions, and definition of terms will also be presented. A brief discussion of the conceptual framework and qualitative methodology will be provided. And finally, justification for this study, assumptions and limitations will be discussed.

### Background

The use of herbal therapy has become increasingly popular in the United States over the last few years. Multiple studies indicate a significant rise in the use of herbs (Bartels & Miller, 1998; Eisenberg, et al., 1998; Ernst, 1998; Greenwald, 1998; Johnston, 1997). According to Johnson (1997), over 60 million adults in the United States use herbs to treat common health conditions such as headaches, allergies, burns, colds, rashes, insomnia, pre-menstrual syndrome, and depression. This has created a \$3.24 billion market for these botanically based remedies. Recognition of this trend along with the use of other non-traditional and complementary therapies led to the establishment of the Office of Alternative Medicine by the National Institutes of Health (NIH) in 1992 (Winslow & Kroll, 1998).

Unfortunately, the pharmacological actions of these herbal supplements remain poorly understood, leading to potentially dangerous interactions when taken in conjunction with other prescription and non-prescription medication (Crone & Wise, 1997). In addition, according to Greenwald (1998) several large pharmaceutical companies such as Warner-Lambert (Sudafed™, Benadryl™, & Listerine™) and Whitehall-Robins Healthcare (Centrum, Advil, Robitussin) are now marketing herbal remedies, with some companies adding herbs to their traditional vitamin and mineral preparations. This situation poses a significant challenge for providers caring for individuals who are self-treating with these supplements. Moreover, patients may often

neglect to inform their providers when medication histories are obtained that they are taking herbal supplements because they do not consider them "medications."

Recent literature abounds with studies indicating a rise in the use of herbal supplements, safety concerns, and identified interactions. Efficacy and adverse effects are just now being addressed via clinical trials (Winslow & Kroll, 1998). The effect this phenomenon has had on the practitioner caring for these individuals appears to be lacking in the literature. Because the cornerstone of the nurse practitioner's role is health promotion, disease prevention, and patient education through accurate assessment and diagnosis, adverse side effects and potential drug-herb interactions may have a profound effect on the nurse practitioner's ability to accomplish those tasks. This emerging phenomenon both necessitates a response and affords an excellent opportunity for intervention.

American medical schools are beginning to recognize the growing trend of patients resorting to complementary and non-traditional therapies, including the use of herbal supplements. Sixty-six of the 124 medical schools accredited by the American Association of Medical Colleges have responded by incorporating alternative medicine courses into their curriculum (Bhattacharya, 1998). However, little research has investigated the extent to which nurse practitioners and other providers educate themselves and their patients on herbal therapy issues or what impact this surge in alternative or complementary medicine has had on traditional health care practices.

This broad topic raises many unanswered questions. Many military installations have herbal products available in their commissaries. In addition, vendors who sell nutritional products, such as General Nutrition Center (GNC), are found on military installations providing easy and convenient access to numerous herbal supplements. With this in mind, the military nurse practitioner may encounter this subject on a more frequent basis than those in the civilian environment.

Purpose Statement:

The purpose of this qualitative study is to explore the nurse practitioner s experience with herbal therapy.

Research Question

What is the nurse practitioner s experience with herbal therapy?

Justification for the Study

Numerous studies have been conducted documenting the use of herbal therapy both in the United States and worldwide. Providers' response to this growing trend has not been well documented. Because patients are at an increased risk for medication-herb interactions, adverse side effects, and possible misdiagnosis resulting from uninformed use of such therapies, it is critical to explore and describe how providers are addressing this phenomenon.

Conceptual Framework

The phenomenon of patients treating themselves and wanting control over their health and wellness is not a new one. For centuries people have been using home remedies, modifying their providers instructions, and attempting to maintain or improve their health through natural methods. Orem s Self-Care Model (1995) emphasizes the patients' need and ability to care for themselves. Orem describes a person's state of health as a reflection of the integrity of the whole. When a self-care deficit occurs, it is the nurse's role to help the patient return to a state of self-care. Nursing practice should involve promoting the patient's ability for self-care. It is evident many patients are turning to herbal therapy to attain or maintain a state of well being. Nurse practitioners must understand and be able to evaluate the impact this self-care behavior is having on the patient.

This study will explore the nurse practitioner's experience with herbal therapy. The

qualitative research technique best suited to answer these research questions is grounded theory. According to Burns and Grove (1997), grounded theory methodology is useful in exploring a social problem and describing the processes with which people handle this problem. This approach is ideal for this study. The descriptive mode will be used, as it will help answer the question what's going on. Grounded theory methods will guide the interview process and assist in producing rich data on the experience of nurse practitioners as they deal with the explosion of herbal supplements on the market and the patient's use of these products.

#### Operational Definitions

For the purpose of this study, the following definitions will be used:

Herbal Therapy: Jonas and Levin (1999) define herbal medicine as "a healing approach that uses medicinal plants singly or in combination to treat disease and as a preventive to promote well-being" (p. 579). In the literature the terms herbs, herbal medicines, herbal therapy, herbal supplements, and herbal preparations were used interchangeably.

Military Nurse Practitioner: A military nurse practitioner is an Army, Navy, or Air Force Nurse Corps officer and Registered Nurse who has completed a formal nurse practitioner program and obtained national certification as a nurse practitioner. He or she has assumed the role as a primary care provider on a military installation caring for military beneficiaries of all ages. This role includes the assessment, diagnosis, and treatment of patients with a focus on health promotion and disease prevention.

#### Assumptions and Limitations

##### Assumptions

- The participants have some experience with herbal therapy.
- The participants are complete and honest in their responses to the interview questions.
- The participants are acting in a clinical role and see patients on a routine basis.

- The participants have varying degrees of knowledge and education related to herbal therapy.
- The phenomenon under investigation has clinical relevance to the participants.

#### Limitations

- This investigation is limited to those members who agree to participate in this study.
- This study is limited to military installations
- Only nurse practitioners who provide care to military beneficiaries will participate.
- As knowledge on this subject becomes increasingly more available over time, the responses of those who are interviewed early in the study may vary considerably from those interviewed later in the study.

#### Summary

This chapter introduced the growing issue of the therapeutic use of herbal supplements in the United States. The impact this issue may have on the nurse practitioner's ability to accurately assess, diagnose, and treat the patient is profound. The purpose of this study is to explore the nurse practitioners experience with herbal therapy. This study provided insight in to how nurse practitioners may ensure safe and effective, quality health care in the future.

## CHAPTER II: EVOLUTION OF THE STUDY

### Introduction

The purpose of this chapter is to provide a review of the literature regarding herbal therapy. Epidemiological studies will be examined demonstrating the prevalence of herbal therapy in the United States and worldwide. Research that addresses the safety and efficacy of herbal supplements will also be presented. Finally, provider issues addressed in the literature will be discussed.

### Epidemiological Studies

Many recent studies have been conducted that document a surge in the use of herbal supplements (Coss, McGrath, & Caggiano, 1998; Crone & Wise, 1997; Eisenberg et al., 1998, Frate, Croom, Frate, Juegens, & Meydrech, 1996; Gordon, Sobel, & Tarazona, 1998; Johnson, 1997). The primary means of data collection in such research was telephone survey or questionnaire. Some of the studies (Coss et al., 1998; Crone & Wise, 1997; Eisenberg et al., 1998) examined the use of alternative or complementary therapies in general and included herbal supplements in the survey. The largest survey noted in recent literature was conducted by Eisenberg and colleagues (1998) where 2,055 adults were randomly selected and interviewed via telephone survey. Results were compared with a parallel survey of 1,539 adults conducted in 1991 (Eisenberg et al., 1993). The surveys were limited to those adults who speak English. Eisenberg et al. (1998) found in 1997 that 4 in 10 American adults used at least one form of alternative therapy, including herbal therapy. They also documented use of herbal supplements rose 380% from 1990 to 1997.

In a smaller study of 1,008 adults, conducted in 1997 by International Communications Research, estimates of herbal supplement use was even higher (Johnson, 1997). Johnson states that findings, when extrapolated to the general population, indicated that 32% of American adults have used herbal remedies to treat one or more health conditions. Cost analysis suggests a \$3.24 billion market exists for herbal



supplements.

Variations are seen in the literature regarding location and prevalence of herbal therapy use. For example, in a survey conducted in a large Northern California health maintenance organization (HMO), out of 1,507 adults, use of herbal medicines was only 7.5% (Gordon et al., 1998). On the other hand, a survey of 233 adults living in rural central Mississippi found that over 70% of adults used at least one plant-derived medicine in the past year (Frate et al, 1996). Despite the geographical variations, all the literature reviewed indicates herbal supplement use is on the rise.

#### Safety and Efficacy

As the use of herbal supplements rise, so do the concerns of these products' safety and effectiveness. According to Bartels and Miller (1998), in the United States under the 1994 Dietary Health Supplement and Education Act (DSHEA), herbal supplements are not considered drugs but dietary supplements. Therefore, the Food and Drug Administration (FDA) has limited ability to regulate these products. Without FDA regulation, controlled studies on herbal supplements are not required, and, at an average cost of \$350 million to approve a new drug with absolute proof of safety and efficacy, it is considered not profitable (Winslow & Kroll, 1998). On the other hand, Germany requires evidence of absolute proof of safety and *reasonable* proof of effectiveness; thus requirements are less stringent than the FDA, but herbal supplements are regulated and sold as drugs in Germany (Bartels & Miller, 1998). According to Bartels and Miller information on herb safety and effectiveness has been compiled in the German Commission E monographs which has recently been translated into English.

On the issue of safety, Drew and Meyers (1997) classified adverse effects of herbal medicines as either intrinsic or extrinsic effects. Intrinsic effects encompass those outcomes related to the herb itself such as allergic reactions, adverse or toxic effects, and drug-herb interactions. Extrinsic effects deal with not the herb itself but rather the selection, preparation, and manufacturing of the herbal compound. Both may have a

significant impact on the practitioner's ability to diagnose and treat the patient.

Winslow and Kroll (1998) acknowledge all conventional medications have potential for adverse effects and toxicities. But, by regulation, these effects are defined and documented based on the therapeutic dosages so the practitioner can weigh the risks and benefits of their use. Herbal preparations, on the other hand, are not regulated in the same way as FDA approved medications, so adverse effects are often reported and compiled as they occur. In Ernst's recent review of the literature (1998), allergic reactions ranged from contact dermatitis to anaphylactic shock. Other adverse reactions included liver failure, chronic diarrhea, hemolytic anemia, hepatitis, renal failure, and death to name a few. Miller (1998) provides detailed examples of drug-herb interactions. For instance, feverfew, garlic, ginkgo, ginger, and ginseng may alter bleeding time and should not be taken with warfarin. Licorice, plantain, hawthorn root, and ginseng may interfere with digoxin levels. Concomitant use of Kava and aprazolam has resulted in coma. Because of underreporting, present findings may only represent a small percentage of actual reactions. Edwards (1995) found that the World Health Organization (WHO) has over 5,000 herb-related adverse effects on file. The list of adverse effects continues to grow as the use of herbal preparations grows.

Drew and Meyers (1997) identified extrinsic effects of herbal medicines based on misidentification, contamination, substitution, adulteration, incorrect preparation, and inappropriate labeling/advertising. Because plants can have four different names (English name, a transliteration, latinized pharmaceutical name, and scientific name), it becomes increasingly difficult to correctly identify and track adverse effects. Drew and Meyers (1997) offers this example: the scientific name of the Chinese herb transliterated as dong quai is *Angelica polymorpha*. The latinized name "Radix Angelica" and the English name *angelica* can refer either to this herb or the to European species of *Angelica archangelica*. Lack of standardization has significantly contributed to variations in both therapeutic and adverse effects. Unless the herbal products are grown, stored,

processed, and labeled consistently and uniformly, different dosages, ingredients, and overall effects will vary. Researchers agree it is this lack of consistency that further complicates the discussion and understanding of herbal supplement use.

Despite the abundant literature on the adverse effects of herbal supplements, Ernst (1998) cites several clinical trials that found herbal remedies to be as effective as synthetic medications with fewer adverse reactions. Bartels and Miller (1998) also cite multiple clinical trials that found statistically significant therapeutic effects of some herbal preparations. In addition, they list several herbal books and journals available to providers as references for both the appropriate use and known adverse effects of a number of herbal preparations.

#### Provider Issues

Provider issues related to herbal supplement use are many. Most of the literature focuses on why patients are using herbal supplements, how patients obtain their information on herbal supplements, and whether or not they inform their providers that they are using herbal supplements (Coss et al., 1998; Drew & Meyers, 1997; Eisenberg et al., 1998; Johnson, 1997; Miller, 1998; Pearson, 1998; Winslow & Kroll, 1998; Wood, 1997). Wood (1997) simply states today's society has shifted their focus from "what foods can do *to* me to what foods can do *for* me" (p. 50). As many foods are plant derived, the consumer today looks to foods and natural herbs to help with everything from daily stress to chronic pain of arthritis to cancer prevention.

In Winslow and Kroll's (1998) review of the literature, they identified several reasons why patients resort to herbal therapies. Some of these reasons include a sense of control, a loss of faith in conventional medicine, cultural beliefs, and a perception that plant derived products are more natural and safe. Pearson's (1998) case study clearly illustrates this point. A woman with metastatic breast cancer rejected conventional treatment in hopes of miracle cures offered by alternative therapies. A contributing factor identified was a dispassionate physician's scientific explanation of options. Pearson

urges practitioners to take the necessary time to show patients genuine care and educate them on viable options. Of course, that assumes the practitioner is aware of all available options.

When it comes to education on health care, studies have found (Crone & Wise, 1997; Johnson, 1997) people turn to friends and family for advice before asking their provider. In a telephone survey of 1008 adults in 1997, Johnson (1997) reports patients consulted doctors only 9% of the time regarding herbal remedies. Forty-one percent of the patients receive their information via family and friends (37%) and others turn to magazines and books (35%). Crone and Wise (1997) looked at alternative medicine use among organ transplant patients. 323 out of 520 self-report questionnaires were returned. Forty-nine patients reported using herbal supplements and cited family and friends as the major influence on their decision to use these products. These results further emphasize the need to expand the role of the practitioner in the patient's decision to use herbal supplements.

The challenge that exists for practitioners is one of the unknown. Eisenberg and colleagues' telephone survey of 2055 adults found that more than 60% of patients failed to tell their provider about their alternative medicine involvement (1998). Similarly, Drew and Meyers (1997) cite a study in which 325 emergency department patients were surveyed and only 35.5% of herbal supplement users informed their providers (p. 538). Coss, et al. (1998) conducted a telephone survey of 503 cancer patients and found that one third of the patients felt their doctor would be critical of their use of alternative care, however, 85% favored the incorporation of alternative care into their oncology treatment. Miller (1998) stresses the absolute necessity of providers to be aware of known or potential herb-drug interactions as well as to assess patients use of herbs. Most researchers agree patients' use of herbal supplements or remedies needs to be documented when completing their health histories (Crone & Wise, 1997; Drew & Meyers, 1997; Frate et al., 1996; Miller, 1998; Shaffer, 1998; Winslow & Kroll, 1998).

Summary

As the use of herbal supplements and remedies grows at a tremendous rate in the United States and worldwide, providers are faced with the increasing responsibility to arm themselves and their patients with the knowledge to safely and effectively use these substances. Current research focuses on the rise in the use of supplements, safety concerns regarding adverse effects and drug-herb interactions, and the prevalence of patients not informing their providers of their use of these products. What appears to be lacking in the literature is how this phenomenon has effected the provider and influenced their ability to care for the patient. Crone and Wise (1998) aptly summarize by stating "whether or not the medical community accepts alternative medicine as a viable therapeutic option, patients will continue to use herbal medicines despite our arguments and hesitations" (p. 10).

## CHAPTER III: METHOD OF INQUIRY

### Introduction

The purpose of this chapter is to discuss in detail the methodology used in this study of nurse practitioners' experience with herbal therapy. Qualitative research and grounded theory will be discussed at length. Topics will also include method of sampling, collection and analysis of data, and issues of rigor and trustworthiness. Finally, human subject considerations will also be presented.

### Method of Inquiry: General

"Qualitative research enables us to make sense of reality, to describe and explain the social world, and to develop explanatory models and theories" (Morse & Field, 1995, p.1). Whereas the goal of quantitative research is to provide numbers and statistics, qualitative research reaches beyond the numbers and delves into the individual experiences and broadens the scope of understanding. Burns and Grove (1997) describe qualitative research as a holistic method by which we gain insight into meanings through exploring the complexity of a phenomenon. They further explain that meanings derived from qualitative research will vary from person to person based on their individual perceptions.

One method of qualitative research is grounded theory. Glaser and Strauss (1967) introduced the term grounded theory in the 1960's to describe a method of data collection and analysis through identifying basic social processes (Morse & Field, 1995). Chenitz and Swanson (1986) describe grounded theory as a "method to study fundamental patterns known as basic social-psychological processes which account for variation in interaction around a phenomenon or problem" (p.3). According to Streubert and Carpenter (1995) the philosophical underpinnings for grounded theory are based on symbolic interaction which is a theory of human behavior. Symbolic interaction proposes that behavior and interactions are based on individual interpretation of symbols in life and are a result of this interpretive process. Glaser and Strauss (1967), both

sociologists, used this theory to develop a method of research now known as grounded theory to explore social processes within human interaction. The goal of grounded theory methodology is to collect and analyze the data simultaneously, while identifying patterns in behavior or responses. Ultimately an explanatory model of human behavior or theory may be derived from this method of inquiry.

Qualitative research methods are used when little information is available regarding the phenomenon or problem being researched. Multiple quantitative studies have been conducted documenting a rise in the use of herbs in America. However, little has been documented regarding the provider reaction to this situation. Grounded theory was specifically chosen as the research method as it guides the study in providing insight into the social processes between the provider and the patient related to herbal use.

The process of grounded theory is specific. Grounded theory method usually involves in-depth interviews and/or observations of a sample population. Samples are purposeful and utilize the technique of theoretical sampling. Theoretical sampling involves collecting data and obtaining more participants as the data dictates. Interviews are conducted and data collection and analysis occur simultaneously. Chenitz and Swanson (1986), and Morse and Field (1995) stress simultaneous collection and analysis as a critical component of grounded theory. Data are categorized and coded at each step and are tested and compared to incoming data. Based on these results, further interviews may need to be conducted to ensure adequate representation and saturation of each category has been documented. Finally, emerging categories are compared, relationships established, and patterns analyzed until a core category is identified that best describes the process under study.

#### Method of Inquiry: Applied

"Grounded theory offers a systematic method to collect, organize, and analyze data from the empirical world of nursing practice" (Chenitz & Swanson, 1986, p. 14).

Grounded theory is ideal in exploring the nurse practitioners experience with herbal

therapy. Use of this systematic method provides rich, comprehensive data regarding the phenomenon of herbal use in America and how providers are reacting to this situation. Military nurse practitioners comprised the sample and in-depth interviews were conducted. Sample questions listed below were used to guide the interview process:

- How has the use of herbal therapy impacted your practice?
- What is your attitude toward safety and effectiveness of herbal therapy?
- To what extent would you like to discuss herbal therapy with your patients?
- How have you obtained information, if any, on herbal products?
- How hesitant are your patients to acknowledge their use of herbal supplements?
- What is your personal experience in taking any herbal supplements?
- Are there any situations where you would like to suggest the use of herbal therapy?
- How often is the subject of herbal therapy addressed in your workplace?

#### Sample and Setting

A purposeful sample of 8 military nurse practitioners was obtained by contacting and requesting a list of candidates for interview from the Chief Nurse Executive and/or Squadron Commander assigned to local military treatment facilities (MTF). Although 8-10 was a proposed sample size, the actual number of participants was dictated by saturation of the data. In this case, theoretical sampling technique was utilized. Theoretical sampling is a technique of data collection dictated by the emerging analysis of current data. Theoretical sampling is based on the need for additional participants in order to ensure adequate representation is seen in each identified category. Participants were contacted by phone, informed about the purpose of the study, and scheduled for an interview. Interviews were conducted at the participants' convenience at a place and time of minimal anticipated interruptions. Confidentiality was also maintained as names, telephone numbers, and the audiocassettes of the interviews were maintained by the researcher in a secured and locked cabinet and were not available to anyone. Participants were assured anonymity, as the interviews were coded by number and not associated with



the participant's name. In addition, the person hired to transcribe the taped interviews was instructed to maintain confidentiality. All interview recordings were destroyed at the conclusion of the study.

#### Data Collection

After a brief introduction, the purpose of the study was reviewed and questions answered as necessary. Interviews lasted approximately thirty minutes although this time varied. Interviews were taped with an audiocassette recorder. Open-ended questions were asked with ample time allowed for response. Responses were clarified and validated throughout the interview. Immediately following the interview, the researcher recorded observations and made brief field notes which were reviewed by thesis committee chairperson. Coding, categorizing, and comparing data also occurred after each interview, as subsequent interviews were influenced by previously collected data.

#### Data Storage and Analysis

Data were transcribed from audiotape after each interview and stored both in hard copy and on computer to facilitate data analysis. Researcher's field notes were also maintained with transcribed interviews. Using grounded theory methodology, data collection and constant comparative analysis occurred simultaneously with the goal of identifying a core variable. Data were analyzed using Burns and Grove's (1997) stepwise model of data analysis for grounded theory which included: category development; category saturation, search for additional categories, category reduction, search for negative instances of categories, linking of categories, selective sampling of the literature, and emergence of the core variable. Concept development, modification and integration finalized this process as the core variable emerged and contributed to the development of a theory.

Analysis began by examining the data line by line and identifying categories through coding. Data collection continued until the emerging data were falling into the existing categories or the categories became saturated. Data were analyzed again to

identify additional categories that may have been overlooked. Next, the existing categories were combined based on similar concepts in an effort to organize the data and reduce the number of categories. Clusters were identified within the categories. Efforts were made to seek out instances where information contradicted existing categories. Categories were further reduced through linking of common concepts and ensuring each category was mutually exclusive of other categories. Based on the existing data, the literature was again reviewed to identify any published information on the emerging concepts or ideas. Finally, a core variable was identified which best integrated all the existing categories. The core variable became the focus of the central theme of the study.

#### Trustworthiness/Rigor

Rigor, which is striving for excellence in research through meticulous attention to detail, is required if qualitative research is to be accepted as trustworthy. Morse and Field (1995) summarize four aspects of trustworthiness relevant to this study. Lincoln and Guba first described these elements in 1985: (a) Truth-value or credibility, (b) Applicability, (c) Consistency, and (d) Neutrality or confirmability.

The first component of trustworthiness is credibility and parallels internal validity in quantitative research. Chenitz and Swanson (1986) claim researcher bias represents the greatest threat to credibility in qualitative research. Methods such as prolonged engagement, persistent observation, and triangulation should be used to ensure credibility. Triangulation, according to Burns and Grove (1997), involves comparison of all measures from different sources to validate findings. In this study, information was gathered from observation during the interviews, listening to the audiocassettes and reading both the transcripts and field notes. In qualitative research, one recognizes that multiple realities exist and the complexity of the variables serve to validate the findings. Morse and Field (1995) suggest the researcher present the participants' perspectives as clearly as possible to improve credibility. The data presented in Chapter Four demonstrates the participants' perspectives.

Applicability is the next component of trustworthiness. In qualitative research, the term transferability is also described. Applicability is related to external validity in quantitative research and refers to how well findings can be applied in other circumstances. The onus of being able to apply or transfer findings to another setting rests not with the original investigator, but with the investigator attempting to transfer the findings. Chenitz and Swanson (1986) suggest transferability be handled by providing detailed descriptions and vary the sample as much as possible. As previously discussed, in this study multiple participants with a variety of backgrounds were interviewed and data was collected both through audio recordings and observation.

Consistency describes the ability to replicate the findings of the research method or tool. In other words, if the study were repeated using the same or similar conditions, would the results be the same? While quantitative research looks for consistent results, qualitative research recognized that multiple realities exist and each human situation is unique, therefore variation in results is expected. Chenitz and Swanson (1986) state the true test of reliability in grounded theory is through the application of the resulting theory in similar settings and obtaining a predictable outcome. As this is an original study, consistency will be demonstrated when comparing its findings to similar future research.

The final element of trustworthiness is neutrality or confirmability, which refers to the freedom from bias regarding the research method and results. Morse and Field (1995) recommend the researcher identify his or her own bias both in memos and through other researchers in order to maintain neutrality. Personal biases and biases in the literature were identified prior to collecting the data. These biases were discussed with other researchers and attempts were made during the interview process to maintain neutrality. Adherence to a well-established process and maintenance of an audit trail also increases the validity and reliability of the study as other researchers, using the original data and field notes, may arrive at similar conclusions. Members of the thesis committee reviewed field notes and transcriptions for acceptability of interpretations.

Throughout this study, the participants were notified of the findings. Copies of the study were made available upon request. Confidentiality and anonymity was maintained at all times.

### Summary

The purpose of this chapter was to describe the method of inquiry, both general and applied, for the qualitative study examining nurse practitioners' experience with herbal therapy. Details on qualitative research, grounded theory, sampling, data collection and analysis, and components of trustworthiness were provided. Information on human subject considerations was also included. When performed as described as above, the qualitative research methodology of grounded theory provided a comprehensive analysis of provider reaction to the rise in the use of herbal preparations.

## CHAPTER IV: STUDY OF FINDINGS

### Introduction

This chapter encompasses the analysis of collected data. It includes a description of the sample, theme categories and clusters identified, and significant statements supporting the themes. The results described were based on recurring themes extrapolated from statements made by the participants. Data collection concluded when saturation of the data had occurred.

### Description of the Sample

Eight military nurse practitioners were interviewed regarding their experience with herbal therapy. All eight practitioners were on active duty working in an Air Force medical treatment facility at the time of the interview. Five of the nurse practitioners were certified in women's health, two in family practice, and one in pediatrics. The years of experience ranged from three years to 10 years. The average experience was 6.6 years of practice as an Advance Practice Nurse.

### Results

The statements from the interviews were analyzed and separated into theme categories and, in some cases, theme clusters that fell within those categories. The following Table summarizes those theme categories and theme clusters identified during the analysis of the interviews. Following the table, each theme category is briefly described with subsequent statements that support each topic. Some of the statements overlap in theme categories or clusters.

**Table 1.**

**Theme Categories and Theme Clusters**

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Theme Category 1: Knowledge

Theme Cluster 1A: Education

Theme Cluster 1B: Resources

Theme Category 2: Safety

Theme Cluster 2A: Dosage Ambiguity

Theme Cluster 2B: Drug Interactions

Theme Cluster 2C: Side Effects

Theme Cluster 2D: Co-morbid conditions

Theme Cluster 2E: Lack of Regulation

Theme Cluster 2F: Lack of Scientific Data

Theme Category 3: Validity/Effectiveness

Theme Category 4: Responsibility

Theme Cluster 4A: Provider Responsibility

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Theme Cluster 4C: Legal Issues

Theme Category 5: Time

Theme Category 6: Cost

Theme Category 7: Complementary Medicine vs. Western Medicine

Theme Category 8: Patient/Provider Relationship

Theme Cluster 8A: Acceptance/Stigma

Theme Cluster 8B: Provider Attitudes

Theme Category 9: Prescribe vs. Recommend/Suggest

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Theme Category 1: Knowledge

Throughout this study, the nurse practitioners identified key issues related to their knowledge of herbal therapy. Most discussed how they were educated, both formally and informally through courses, seminars, journals, and personal research. In addition, each identified particular resources they used as references either for personal use or as referrals for their patients. Lack of good references was also an issue. The following statements illustrate the themes expressed by the participants.

Theme Cluster 1A: Education

Significant statements regarding education.

Well, actually, in my class in my Nurse Practitioner program, we did have a couple of lectures on herbal therapy.

Then actually, some of the Nurse Practitioner conferences or even probably the medical conferences as well — I don't remember which ones I've been to in the three years since I've been out — but there usually is a seminar on herbal medicine therapy. Some of them — I think a large majority for me personally - have been disappointing.

If I had more if I could remember more and I did it on a more frequent basis, I would probably talk about it a little bit more.

One of the workshops was herbal therapy. I thought, Oh great! I'm going to be able to go and get some references that I can use and be able to confidently prescribe some things for my patients. Unfortunately, the speaker pretty much said that there is not enough research done and the herbal therapy is not FDA approved. So, she could not support it. She mentioned a few things this particular plant might be good for this but we don't know what the dosage is. So, I really came away disappointed. I

appreciated her opinion of it but I expected to be able to take something out of it that I could prescribe to my patients.

My experience is, for formal training, if you look at what I was formally trained, I didn't really have any. It was from my Air Force certification program. The training I have had has been through either reading, personal experience, or friends or colleagues who talk to me about how different herbal therapies can work.

I had no formal herbal pharmacology courses or anything like that although I understand there's several good ones out there you can go to. I picked up what I needed to know from my patients and from spot CME lectures given here at the family practice residency. But it's still new. So, basically (my experience) it's anecdotal.

The funny thing is that the patients hear things a lot before we do. I guess they have more time probably to sit down and watch. So, they tend to get things heard before you do. You're reading your magazine and before it gets to you, they are already asking you. I think it's not bad because keeping up with information is good.

A little bit was addressed in school; otherwise, just basically reading - my own reading.

Then Nurse Practitioners and providers in general really aren't educated. They are coming up now with more seminars on herbal therapy but it could be a problem. I wouldn't tell people to go do those things; to go take St. John's Wort or whatever but a lot who come in are already on it.

I attended one (seminar) that talked about it. She actually grew her own herbs and talked about it. That was kind of interesting. I didn't really find that it was that useful. It was interesting but not really useful.



I did my own research. I popped on the Internet. That's how I found out a lot about it (St. John's Wort). It was the number one prescribed medication in Europe. I read all about it.

### Theme Cluster 1B: Resources for Information

#### Significant statements regarding resources for information

when someone would come across a good handout with the down and dirty of herbal medicines, etc., we'd mimeograph it and send it around to each other. I ordered a book on my own out of a journal written by Pharm D's on herbal medicine and their know a little bit about each one, like their benefits, why people take them and any known drug interactions with the western medicines.

I would be interested in having a list of reputable sources if patients wanted things I could refer my patients to: a reliable journal or if there's an Internet address. I would like to have something like that for my patients.

When you really want to get into herbal therapy and try it a lot, you need to make sure you know exactly where it's coming from. Sometimes the people at the stores may not know exactly what they're talking about but some do. So, there are good herbalists out there who can help you a lot. There are good books out there that you can learn a lot from. That's how I learned some of my stuff; from the lectures that I've gone to.

Either the Internet or to go to an herbal place and see if this person knows about it because I don't know anybody around here that would know about it. I say just check to see. See if someone there is an herbalist who knows about it. Some people are good and some people aren't.

I have a subscription to the *Alternative Medicine* magazine.

Once it comes out and it's backed by NIH, then I can feel safe about it (You use NIH as your resource?) Basically, medical, legal, yes. I feel they're very dispassionate. They're not pushed by the drug companies. I trust NIH and their alternative medicine. Some of the articles from the *Alternative Medicine* magazine are pretty good too. They're getting more and more scientific in their data.

I have a book that's actually natural medicine. It has a whole list of ones that if people are having a hard time, I'll try and read it through and see what they have to say.. The other thing is the Internet. I did a lot of research on the Internet and pulled out a bunch of stuff because when you do a general search on menopause, you get a lot of natural therapies coming out of that.

It's hard to do only because it's not like they come out in your journals all the time about it. They come out in your nutrition journals but I don't read nutrition journals on a routine basis. So, keeping up with it can be difficult. That's why I like that book because it seemed to help out a little bit more so that I could look at it and say, this makes sense, or well, I don't really like this one or it would have whether you could get toxic from it.

I do have a magazine to subscribe to alternative therapies, *American Health Consultant*. I (also) go on the Internet and sometimes pull things up.

Sometimes I'll refer them to the *Prevention* magazine at the grocery store. You always see that. That's got even special issues on herbal therapy. I will usually tell patients to search the Internet if they're interested in that or possibly look at that *Prevention* magazine. That is very detailed. It talks about a lot of that stuff.

### Theme Category 2: Safety

An overwhelming common theme emerged from the interviews regarding safety

and the use of herbs. The nurse practitioners addressed several aspects of safety such as dosage ambiguity, drug interactions, adverse effects, and co-morbid conditions. In addition, lack of regulation of herbs and lack of "scientific" data was also a major concern discussed. The following statements clearly express those concerns.

### Theme Cluster 2A: Dosage Ambiguity

#### Significant statements regarding dosage ambiguity.

Probably the most concern would be if they're taking estrogen-type replacement in lieu of estrogen replacement therapy. I'm not sure what kind of a dose are they getting. Are they at risk for uterine cancer because perhaps they're taking too much of an estrogen replacement how do you know what dose it is that you're taking and are you taking something that has like progesterone-type properties? That probably is the most concern for me. The main thing is the dosage. How do you know how much you're getting and what's the safe range?

I don't know about interactions between the two different ones but black cohosh, you can overdose on it. It can make you really sick. So, I also point that out to them and say "Read the box. Make sure you don't go over what it says on the box." If I give them that handout, I tell them that the average dose is this and that if they go past it — they shouldn't go past it.

Well, general safety in terms of whether they're taking too much. If they're taking it the way they're supposed to. I feel pretty confident, that if people read the directions on the back, they're going to adhere to them and that's going to be safe for them.

### Theme Cluster 2B: Drug Interactions

#### Significant statements regarding drug interactions.

For example, St. John's Wort — the number one prescribed antidepressant in Europe —but we don't prescribe it here. So, it is over the counter and people take it for depression. However, if you're starting somebody on a SSRI, you really cannot be on St. John's Wort and a SSRI at the same time. So, you have to know those.

If they told me they're on I say, You know, I just don't know enough about it to say that that's okay because I don't know if it's okay. You're on all of these other medicines. Some people are on 12 to 20 medicines and I don't think it's okay. I don't think it's okay they're on that many medicines, period.

I also don't have enough time to go look it up to tell them the accurate information. Typically, what I say if I have to put them on a drug that I don't know the interactions, I tell them, and I feel it would be unsafe. My recommendation would be, I don't know how it is metabolized. I don't know what this is but I know how this drug works. So, this is what I want you to take. When you're all done with this and you want to take that, I'm not going to argue with you. I don't know all the ramifications for this. You just need to know that.

It has (impacted my practice), especially with drug interactions. When I go and ask what medications they are on, I also ask for over the counter, I include birth control pills and I also include any herbals.

You don't know how it's going to respond to antihypertensive medications or antiarrhythmic medications. I really hate to interfere with people's heart and blood pressure, you know? For that reason, I would love to see more not necessarily how does it work or how well does it work but how does it interfere with other medications. That, to me, is a little bit more concerning.

Mainly in people that are on other drugs that could interact. If a person's on a lot of medication, that could be a concern.

### Theme Cluster 2C: Adverse Effects

#### Significant statements regarding adverse effects.

It is a very huge topic. I have a lot of really good information on it. Some can be dangerous. So, you have to be careful with them. I haven't gotten into that part and that's why, if I were to prescribe, I just go to the really safe ones. Ginger is super safe. Peppermint's really safe. Routine foods are really safe. I don't have to worry about any of those.

The safety business I'm really worried about because what I did see I saw a lot of rashes associated with ginkgo two patients who had rashes from what we think was ginkgo, they didn't bring their bottles in but it was the latest drug they were taking. I said, It might not be the ginkgo. It could be the stuff that they use to mix it up - the inert stuff or whatever. So, stop that and your rash will go away.

You don't know how one drug interacts with the other. There's a little bit of anxiety there in the back of my mind and this is why I need to know more I want to feel comfortable and tell a patient Yes, I want you to take For instance, now I can tell them to take 750 mg of magnesium because I know that's what will help to balance your chemicals and that's recommended. It's proven. I don't know how much to tell them; how much pills of dong quai or ginkgo biloba to take each day that won't affect you or cause other untoward effects. We don't know.

### Theme Cluster 2D: Co-morbid Conditions

#### Significant statements regarding co-morbid conditions.

There's a lot of people taking a lot of different things out there. I think some have to be careful if they have medical problems but, basically, for the most part, I think herbs are pretty safe.

I think that, used appropriately, they can be safely done. There's certain ones that you shouldn't use

and that article talks about ones that you should never use. So, if you see somebody, because they increase heart rate or whatever; that would be inappropriate.

Also, there are certain ones — I think it's like if you're asthmatic, you shouldn't use the black cohosh. You have to be sure that their whole disease panel or whatever you want to call it is taken into account as well. If they're diabetic, I'm less inclined to tell them take things that I know might hurt them. If they're a pretty healthy person to begin with and this is the only medication that they're taking, I feel pretty comfortable with that. I'm not going to be hurting them in any way by adding this approach to it.

During pregnancy, things are a little different because you always have those two people that you're dealing with. If you don't have the efficacy behind you or the safety behind you, you don't know for sure. At that point, I think it is more important to err on the side of caution and probably not give it. The raspberry tea really does help soothe to help you deliver. You're 40 weeks or 41 weeks already, the chance is pretty good it's not going to hurt the baby if it causes contractions. So, that one is about the only one I'll actually do.

### Theme Cluster 2E: Lack of Regulation

#### Significant statements regarding lack of regulation

Number one, you can't prescribe them. They haven't been studied and researched and put through the FDA.

I tell her that I think there is a place for herbal therapy but because it is not well studied and that the ability to regulate the dose that you get has not been established, what's safe? If you want to take a phytoestrogen, how much do you take? How much is safe? The guidelines have not been established. So, I don't feel like I can confidently make a recommendation. It's like, Yeah, I know it's out there and there's some good stuff and it could work for you but I am just not aware.

It's when they're sold by a company over the counter and they don't have any restrictions people will hear about it and then they just take it and they think the more they take the more they're going to lose (weight) That's not too good.

There's a lot more stuff out on the market nowadays but I always worry when it's up to them (the patients) because that is the one area the FDA does not regulate. As a result, you may have all these great things that they say that it does and it really doesn't. How do you know for sure?

It is more unregulated and that's why I don't like that there's so many different things. That's why I try to stick to the capsules because I figure that, hopefully, the amount is going to be about the same so that whatever brand they get, it's not going to hurt.

I just have to follow what's on the bottles or whatever the herbalists put on there. I don't know how much is approved. I don't know if they are FDA approved. We are very conscious about FDA approved stuff.

Oh, I think there could be a problem with safety because of the different manufacturers. There could be different levels of the herb and they really aren't regulated very well. So, I guess that could be a problem.

### Theme Cluster 2F: Lack of Data

#### Significant statements regarding lack of data.

I'm just not well educated about it. I'm interested in it but I don't know a lot about it. I am certainly all for it if it is well controlled and there are research (studies) that can support the safety of it.

I can tell patients that anecdotally the different kinds of studies I've seen or heard from patients about how that works for them. For dosing, it's a little harder with infants. I have a difficult time knowing exactly what to dose because I don't have any empirical studies.

I think NIH has got a study out on that (St. John's Wort). They're looking at that one. Once it comes out and it's backed by NIH, then I can feel safe about it.

I tell them that it's anecdotal. That's all the research that I have right now and that there are no good medical studies. I believe that there are some coming out because the more I read about it, the more they talk of that it seems to have good properties.

Yeah, that's a little bothersome because you don't know how much. You don't know how toxic these things are because you haven't used them and there's not a lot out there that tells you about what they are.

### Theme Category 3: Validity/Effectiveness

How and if herbs were effective seem to emerge as a theme for several of the nurse practitioners. Most relied on current literature or patient reports as a method to validate their recommendations. However, some found that their personal use of an herb had a dramatic impact whether or not they would bring up the subject or make any suggestions.

#### Significant Statements Regarding Validity/Effectiveness

They've actually reported effectiveness. Echinacea - I've had people use it and you'll have parents tell me that my kids don't get sinus infections anymore when I start it with a cold or whatever. I have actually only had people share with me when they've had positive interaction with it, not negative and that



may be because if they get a negative, they don't want to admit that they've done it. So, you are probably getting skewed data because they'll be embarrassed.

I have a lot of women who say that St. John's Wort helps them sleep and a lot of men tell me that ginkgo seems to work.

I believe they're effective to some degree but just like there's not one medication that works well for everybody, there's not one therapy that works well for everybody either. So, it is a trial and error approach. I think that you have to be careful with it.

I've tried St. John's Wort. And it worked in my opinion but I would say I would often say to my husband, This could totally be psychological. I don't know. I don't know but it works. So, who cares? Who cares if it is a placebo effect? It doesn't matter. If it works, it works. I did feel much more stable emotionally. Sometimes with patients, if I had a good rapport with them, I'd say, Hey I take it. It didn't bother me.

I've found evening primrose oil to be very effective for breast tenderness. I can't say much about my ginkgo biloba because I don't take it as I should. If it is something that I know and that I've used before and I feel that I'm knowledgeable enough, then I say yes. I usually don't try to give my opinion on something that I don't know enough about. I love telling them about evening primrose oil tablets, dong quai, ginkgo biloba, and St. John's Wort. Those mostly I tell patients about.

#### Theme Category 4: Responsibility

Many nurse practitioners felt a certain level of responsibility toward their patients regarding their use of herbal therapy. Most felt the need to at least have some knowledge of the subject in order to properly advise them. On the other hand, many of the nurse

practitioners expressed that the patient should assume some responsibility for their own healthcare. Some would recommend that the patient do their own research on the subject, especially if the provider was not familiar with the herb in question. Finally, legal responsibility was mentioned by a few of the participants. Responsibilities of both the provider and the patient and some legal concerns were described.

#### Theme Cluster 4A: Provider Responsibilities

##### Significant statements regarding provider responsibility.

I feel compelled you have to get a book. As an advanced practice nurse, I think you need to have a book at least because I think you have to show an effort towards your patients. I really do. If they ask you about something, say Let s look it up. Let s see what we can find out about it. Now, sometimes it hasn t been in my book and I then I have to say, I don t know.

I don t have a specific one (resource) and so if I were to say, go to the Internet and they went to one that provides bad information then I would feel partly responsible. So, I don t recommend that.

I also think that people should be informed about the options that are available to them. They make the choice. That s part of informed consent. Then, depending on what they want to do, I m happy to back them up.

I think Hippocrates said, First, do no harm. If we know that it doesn t do any harm — raspberry tea, it doesn t do much. I think licorice is in there too; it can help but you can overdose on licorice. So, certainly, you have to make sure that you know the limits. If you can tell them that but yet offer them something that may ease their symptoms, I think we do a disservice to our patients if we don t offer that.

Well, I think it s a thing of the future. I think as a Nurse Practitioner, if we want to stay in practice

we're going to have to start learning more about it or to go to conferences; get more involved so that we can be informed so we can keep our patients informed. I believe in prevention. I think these things can help to prevent things. It makes sense. Why not employ them? Why not learn about them so that you can educate your patients?

So, I feel compelled that I really have to learn more about it if I want to be able to practice and to keep up with today's happenings in health care practices. I find that it is impacting our practice a lot. So, I find I have to learn more about it.

Recently, though, I've been made to study more or to read up more on that because patients are asking more about it. I think, initially, I didn't feel comfortable — even now I'm not comfortable because I don't know enough. I don't have the details, history and background on some of the drugs and stuff that they do ask about. So, I don't feel comfortable enough telling them about it or telling them to go and use it.

#### Theme Cluster 4B: Patient Responsibility

##### Significant statements regarding patient responsibility.

I just let them know that they can go and get this over the counter and make sure they read about it. Make sure they understand the risks and the benefits.

I let them know that there are books out there and that it is important that they know whether they get it from the root or the stem part because it has different potencies and I am not familiar with all those things.

I think that the public has to be really informed because you can get herbalists that may not tell you side effects of the herbs or contraindications to the herbs. So, you have to be really careful and you need to be an informed consumer.

I don't have a handout per se but I tell them to go look it up on the Internet. I let them do it. I tell them to go to Yahoo search engine and go to herbal medicine

All people want is to feel well and to feel normal. To have control over it and that's not a bad thing. That's a good thing. Let them have their own control. They'll do much better as a patient.

They at least could do some research and they're welcome to I cannot prescribe those things. They could go and see if it might work for them.

It lets people (know), Hey, you need to take some responsibility for your own health care. This is an area that's wide open. It's on the Internet. They can go to a GNC or herbal medicine person and they'll discuss it with them all day long because those people are pretty educated.

#### Theme Cluster 4C: Legal Issues

##### Significant statements regarding legal issues.

I'd say, I am really uncomfortable with you being on these herbal medicines but that's your decision. Look at all these medicines that you're on. If I know that they're on it and I chart that they're on it, then maybe down in the PE part, you might have to say, discussed to decrease or discontinue the herbal remedies because I don't support it in that case because I just don't know enough about it.

I am really careful with my terminology because I don't ever want to say, Well, I highly recommend because there's no scientific (evidence), in western medicine, for me. Who am I to recommend that? I haven't really been formally educated on that. So, you have to be careful. It's practice in defensive medicine.

Echinacea, that's probably safe but I'm not willing to really say that because I don't have anything

to back me up. That's probably more of a medical/legal type thing that no, I'm not willing to put myself on a limb when I don't have anything to say that or to support what I'm doing.

#### Theme Category 5: Time

The issue of time was another theme which emerged from the interviews regarding nurse practitioners' experience with herbal therapy. Several nurse practitioners expressed frustration regarding the inability to discuss herbs with their patients because of limited appointment time. Lack of time significantly influenced the nurse practitioners' ability to either look up the information or stay up to date on emerging findings.

#### Significant Statements Regarding Time

I would like to have the knowledge base to be able to discuss it with them. Would I discuss it with every patient? No, because of time. Would I want to discuss it with every patient? No. I don't have the time you know, this is reality- with everything though, not just herbal medicines - it's almost a blessing to be able to say, Well, we can't prescribe those medicines and I really don't know a lot about it because you've just saved yourself a 20 minute conversation. You can get on to your next patient.

I haven't I've been too busy. I haven't kept up.

I say if they want to try a natural therapy, this is what they can do I would love to get into it more but at this point in my career it's like one more thing. I want to but I just don't have the time to really study it and to really get into it.

I just have a lot of information from my lectures. I have to organize it. Organize it sometime I have to organize a lot of things. That's just one of them I need to do.

I don't usually look them up because my time just to find that information would take you forever.

In a 20-minute Pap smear appointment, it's really not a whole lot of time to be discussing all that.

### Theme Category 6: Cost

Some of the nurse practitioners identified cost as an influence on patients' use of herbal therapy. Some found that patients were willing to pay out of pocket to go the "natural route." However, a few nurse practitioners described cases where military members who are accustomed to getting free medications, found herbal therapy desirable, but cost-prohibitive. Another aspect of cost discussed was the possibility that herbal use could be cost-effective from the perspective that health maintenance would preclude office visits.

### Significant Statements Regarding Cost

So, they're in the same classification as any of the over the counter. A lot of times in the military, most of the medications are free. Medicines are free. So, patients come in and they just want their medication. Prescribe it for them so they can go get it for nothing.

Some people get sick of paying for it and then they do come back and say, I changed my mind. What are those medicines that you were talking about? The SSRIs? Let me try one. Zoloft or something like that.

I would mainly (like to discuss herbal therapy) because if it would keep our pharmacy budget down

and they're willing to pay out of pocket, by all means. Part of the way Nurse Practitioners are looked at is how much money they spend on the pharmacy budget How expensive am I?

Evening primrose for breast pain, PMS. They have to take lots of it and it's very expensive. It's about ten dollars a bottle and it lasts two weeks. I get maybe, I would estimate 20 percent of the women say it works; 80 percent say it's not worth it. We don't have evening primrose on the formulary, so they have to buy it and it's one of the more expensive ones.

The research has shown that they're spending millions and millions of dollars every year on nontraditional therapies and that includes not just acupuncture and massage therapy, but herbal remedies and aromatherapy and all those things that are coming out: the magnets, the magnetic braces and the copper insoles or magnetic insoles and copper bracelets; all of those things. I think people are grasping for what will help them. I would tell you that probably those things cost less on the average than some of the medications that they get.

That is, to buy a natural thing over the counter is probably more cost effective than surgical procedure or medical practices.

#### Theme Category 7: Complementary Medicine vs. Western Medicine

Throughout this study, the participants echoed a common theme regarding conventional or Western medicine and alternative medicine. The nurse practitioners interviewed found that patients wanted choices other than prescriptive medicines. Many patients were frustrated with traditional therapies or preferred natural remedies. A common belief expressed was "natural is better" and "herbal medicines have been around a long time." On the other hand, many providers hold to the belief that clinical proof is required before recommendations are made. The following statements reflect those

beliefs expressed by both patients and providers.

### Significant Statements Regarding Complementary Medicine and Western Medicine

It's a deviation from western medicine but I think, as a Nurse Practitioner, you need to know about them, get as educated as you can on them, and incorporate as much as you can into your practice.

I think, largely overall, they're pretty safe and effective. I do. I have not heavily researched this area but my hypothesis going into this area of research would be that there is an old, ancient foundation for them. They're natural from the environment and probably what they say they're good for, if I could look 20, 30, 40 years into the future, the research will probably come out that that's true.

They're hesitant to use prescription medication. Some are. Some people will come in with very low energy, fatigue — everybody's fatigued it seems — but you rule out organic causes. Then, when you get down the road, some people just are adamant about a medicine. I don't push it right off anyway. I'm more into the diet and exercise.

Any natural remedy that is safe to use, I fully would support as opposed to taking a synthetic form of something, if we can find it naturally and it can be administered safely. The main concern would be safety.

You know, this is how I feel about it. Herbs have been around since the beginning of time. The Chinese have used these herbs for thousands and thousands of years and they've been doing just fine. They got this down to an art. We don't know enough about it. So, we just assume that they don't know the dosage but, actually, people know how to dose it and they put it to the patient's requirements. When you know enough about herbs, you can get it down to where you know, like this one person who taught us. She knows enough about herbs, has been practicing it and has really gotten into it. There are a lot of studies out there and so on. A lot more than what we think there is and it just proves the herbs right. You do it to



the patient's needs. We are so accustomed to, you have to take 5 mg or whatever and you have to have this dosage but the Chinese have been doing it for thousands and thousands of years and they do it to the patient's needs. It's been doing really well, otherwise it wouldn't still be around.

Really, herbs are the early drugs.

Well, I think that from my perspective, it hasn't been control over their own health. It's been the conventional therapy is not working and I want to do something else or I want to augment something else and it's okay to try it with this. So, that's what I find it is. It's typically when they are dissatisfied or that they have alternative thought. They think western medicine isn't everything.

the Premarins and all that — are giving them fits and starts and they can't tolerate the patches and they want to go natural. So, we sit down and talk and I make sure they do a lot of Internet research and come back to me. I tell them there's a healthy bias against it (herbal therapy) from the medical establishment. If they've done their research and they want to try it, I give them a three-month trial. I've got two ladies now on a three-month trial.

This is a big departure from the traditional medicine approach but that's where we should be. We should be looking at it all and not just one version of it.

They (patients) are into prevention more. They don't want to take a lot of patients just don't want to take medicine. They don't like to take synthetic stuff. So, they'd rather take drink teas or something that they think is more natural — that are all natural - even though none of the medicines that are supposedly herbs are 100 percent natural because they are manufactured. They have the feeling that it's all-natural so they do ask about it.

Theme Category 8: Patient/Provider Relationship

Many practitioners interviewed found that their relationship with their patients influenced whether or not patients were hesitant to acknowledge their use of herbal therapy. Acceptance or whether a stigma was associated with herbal use also influenced their conversations. The findings indicated that the more open the practitioner was to the use of herbs, the more frequently the subject would be addressed. In addition, provider attitudes, especially nurse practitioners and MD's, were discussed.

Theme Cluster 8A: Acceptance/Stigma

Significant statements regarding acceptance and stigma.

you'll get the person that there's still the social stigma, Well, I don't really want to go on antidepressant medicine. That is when I'll say, I can't really prescribe but have you ever heard of St. John's Wort?

So, if you're worried about the stigma of "I don't want to be on antidepressant medication. It'll get on my record". I've had a patient that was a pharmacist's wife who didn't want the whole pharmacy to know that his wife was on antidepressant medication.

No, they'll tell you. Some of them don't mention it unless you ask. So, you have to ask. Some come right out with it. If asked, Yeah, I'm on this and this and this. They're more stigmatized by other things than they are by herbal medicines because it's so accepted because it's natural.

I would say, probably as a general rule, patients might not be as willing to share because I think the medical community might have a stigma; We want to prescribe medicine and you want to go the natural route. Well, there's a little bit of boundary there. So, I think that yes, patients might be more hesitant to admit that.

I have had people tell me, I heard you talk about vitamins and herbs, so I just wanted to tell you this is what I do.

You found the people that were very interested and people that were not interested in that. There's certainly a period of trust or a bonded trust has to be developed before someone's going to tell you to use any of it because they're actually concerned about ridicule.

So, you drop the question until you legitimize yourself in the community and then it's okay to bring it up. If you bring it up right when you first get into the community, they look at you like you're weird. You know, How do you feel about alternative therapy?

So, I think they're safe if used wisely and there's a trust environment that people can tell you about it.

If you don't see any benefit and you tell people you don't see any benefit, they're not going to be open to tell you.

When I do ask them, it might be the way I ask, but they spill it usually. If I ask. If I don't ask, they wouldn't volunteer it. Some don't even think of it as medicine.

I don't think it's something that they offer voluntarily unless they know that you're willing to accept it. I think that the example of the physician is a pretty good idea of how the general acceptance is in the medical community. Overall, there's a skeptical attitude about things until it's been proven. Evidence-based medicine, right? We hear that all the time but in reality until you can tell me that it isn't any good why should I not use it if it is good? I think anecdotally, those case studies can really help us to figure out if it's good or bad. If they don't know the person that they're seeing, the health care provider, I think

they are really reluctant to speak up and say oh yes, I've been taking this medication even though they have because they don't want that doc to say, I don't want you taking it. That means they've been told they shouldn't and that's much more difficult to go against. If you don't ask the question, you don't have the answer no.

Patients are open. They ask about, Have you heard about this? I find a lot of my patients asking me questions.

### Theme Cluster 8B: Provider Attitudes

#### Significant statements regarding provider attitudes.

Really it's very difficult to get docs to believe this stuff. So, as a clinic, we don't say it. Just as individual practitioners, we say it. I have to laugh because one of the docs actually gave me an article that said these different things are not studied very well and so how can you really recommend them if you don't have any studies to back you up? Really, it's more of an anecdotal-type thing, that if this works then try it out on somebody else and see if it works for them as well.

(Do you think that overall that Nurse Practitioners are more open to using alternative methods such as herbal therapy?) S: I think that, yes. I think we are and that may be unfair to say about physicians but, overall, they're really trained that if there's not a study saying that it's any good, then it's not any good. I disagree with that thinking. I think the study is there to reinforce what we know but not to be the only thing that we know. Otherwise, we're doing our patients a great disservice because we're not studying all the things that could potentially be helping them.

My colleagues — the Nurse Practitioner colleagues — we speak of it (herbal therapy) quite often but my physician colleagues, not very often at all.

My colleagues, my coworkers, we talk about it all the time. Not so much the M.D. staff. I think they just don't. They stick to the medical model. So, they're a little bit more closed minded when it comes to alternative or herbal treatment. That's my experience at least.

I think the Nurse Practitioners are more open to it. Not all the physicians, but many of the physicians just absolutely say no. Our Nurse Practitioners are more open to it. It's something to offer somebody at least if they don't want to take the Premarin or whatever.

### Theme Category 9: Prescribe vs. Recommend/Suggest

This study elicited certain terminology regarding nurse practitioners experience with herbal therapy. Although most identified the fact that they were unable to "prescribe" herbal therapy, many would certainly make recommendations or suggestions based on anecdotal information, current research, or personal use. On the other hand, some mentioned that they wouldn't even make "recommendations." The following statements illustrate the use of language.

#### Significant Statements Regarding Prescribing vs. Recommending/Suggesting

Number one, you can't prescribe them.

That is when I'll say, I can't really prescribe but have you ever heard of St. John's Wort? I am really careful with my terminology because I don't ever want to say, Well, I highly recommend because there's no scientific (evidence), in western medicine, for me.

I have some of my patients will mention that they take herbal therapy. I'm interested and I ask them specifically what are you taking and what do you use it for but I myself don't make recommendations for herbal therapy.

St. John's Wort, right? I've read up a little on that. I don't treat depression but it's something if they're not on any other antidepressant and you let them know to be sure not to go on any other antidepressants because you can't take the two at the same time. That you might want to try St. John's Wort if it is just mild (depression) and they're looking for something. Maybe they just need a mild antidepressant. As a Women's Health Nurse Practitioner, I don't feel comfortable in that area as much with the Prozac and things like that. I just don't feel comfortable with prescribing it. So, I prefer them to try it. Even with PMS. Different things with PMS, I'll try. I'll have them go ahead and try the St. John's Wort but if it doesn't work, follow-up with family practice.

Why should I prescribe a diuretic when someone can just take dandelion tea, PMS-wise, and it just resolves it? They just pee a little bit more and they don't have to be on a diuretic. I think that's kind of nice.

So, I'll say, There is such a thing (as St. John's Wort). You might want to try it. It is totally up to you, of course.

They don't come out and say, Are there herbal therapies? They'll say, What other things are there that I can do? . It's an indirect request to me. It's still a request for information and so I hand out my sheets and tell them these things are good. I asterisked the things I heard from other people have been really helpful and tell them Go out and look over this list and see what you like. I also tell them go to the Internet because the Internet has a lot of information and information can only be good is my motto because it provides you with the power to make an informed choice. So, go to the Net.

Once in a while I will mention that (Ginseng) if somebody said that they're having problems with decreased sex drive. I was in Asia for three years before I came here. So, one of the Asian things is to try Ginseng. I say, Well, I don't know if it helps but in Asia some of the people use Ginseng and that helps

some people with their sex drive.

I recommend that they should try maybe to increase the soy in their diet. Try tofu and soymilk.

Sometimes I will mention that to them.

### Summary

This chapter begins by describing the sample of individuals used for this study. Next, the theme categories and clusters identified through the analysis of data are introduced. Each category is described and followed by theme clusters and supporting statements from the transcripts of the interviews.

## CHAPTER V: SUMMARY, CONCLUSIONS, RECOMMENDATIONS

## Introduction

The use of herbs has significantly increased in recent years. Eisenberg and colleagues (1998) found that nearly 40% of U.S. adults are using one form of alternative therapy, with herbal therapy use showing the greatest increase at a 380% rise compared with a similar study conducted in 1990. Johnson (1998) reported that almost 60 million Americans use herbs according to a recent survey. What type of impact, if any has this had on nurse practitioners and their ability to care for their patients? The purpose of this study was to determine the nurse practitioner's experience with herbal therapy. Based on the data collected in the interviews of eight active-duty Air Force Nurse Practitioners, experience with herbal therapy varied considerably. However, several common themes emerged. This chapter highlights those themes, addresses the guiding questions for the interview, and proposes a core theory based on the analysis and integration of the themes.

## Discussion

"What is your experience with herbal therapy?" was the first question asked of each participant. Open-ended guiding questions were then asked. Using Grounded Theory methodology, guiding questions were expanded, modified, or added based on previous interviews as new data arose. Experiences varied, but the predominant answers related in some way to the nurse practitioner's personal knowledge of herbal therapy and how she incorporated that knowledge into her practice. The theme categories and theme clusters identified in Chapter Four resulted from those open-ended questions. After careful analysis of each of the themes, once again using grounded theory methodology



knowledge emerged as the core variable. Using this core variable and integrating the collected data, the following model could serve as the proposed theory of this study:

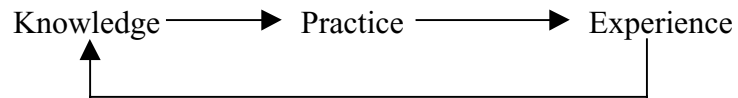


Figure 1. Model of the relationship among knowledge, practice, and experience.

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The level of knowledge of the nurse practitioner had a profound influence on her individual experience with herbal therapy. The more knowledgeable the practitioner, the more she incorporates herbal therapy into her practice, thus contributing to her overall experience. As experience expands this contributes to an increase in knowledge. Much emphasis was placed on formal and informal training, education, and knowledge acquisition. The themes identified in chapter four served as either barriers to their knowledge and experience or outcomes of their knowledge acquisition. The following model illustrates the factors that influence knowledge, the factors that are influenced by knowledge, and the factors which do both.

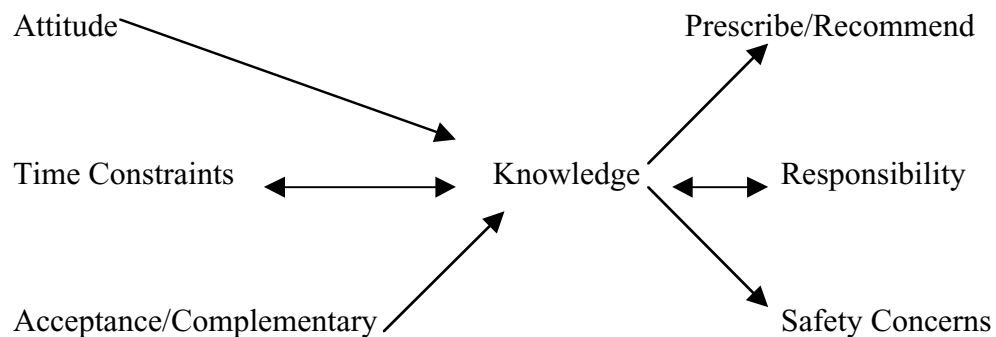


Figure 2. Relationship of knowledge to other identified theme categories

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### Knowledge: The Core Variable

Knowledge, in and of itself was specifically addressed by the nurse practitioners. Most said they had very little knowledge, thus they had many concerns. Several had one or two reliable resources they used as references. Some had taken formal classes to enhance their knowledge although they found most of them disappointing and not helpful. Overall, knowledge appeared to be the dominant theme or core variable throughout the interviews and the other themes expressed can be traced back to the knowledge of the nurse practitioner and how those factors influenced her knowledge, were influenced by her knowledge or both.

### Factors Which Influence Knowledge

Provider attitudes influenced the knowledge of the nurse practitioner. Those who were more open to the use of herbal therapy appeared to have more knowledge and experience on the subject. Those practitioners who had little knowledge of herbs did not appear as open to herbal therapy nor was the subject addressed as frequently at work compared with those practitioners who did have more experience. Many of the nurse practitioners however, felt they were certainly more open to herbal therapy than their physician counterparts whom they thought were very reliant on empirical data and clinical proof, a characteristic of "Western" or "traditional" medicine. The participants acknowledged that many times a social stigma was associated with those patients who wanted to steer away from conventional therapies or Western medicine. This was often reflected by whether or not a patient would acknowledge their use of herbal therapy. The

more open the provider, the more likely the patient would share that information thus contributing to that particular provider's knowledge and experience.

Along those same lines, the notion of complementary therapies and the use of "natural" medicine versus Western medicine and the use of synthetic drugs was a topic of discussion that is expanding. As herbal use becomes more and more commonplace and research continues in this area, the knowledge level will certainly increase. In the past, herbal therapy was addressed primarily in professional journals related to alternative and nutritional medicine. In addition, lay literature frequently addresses the use of herbs and other complementary therapies. The fact that patients are more informed has forced the medical community to respond. As a result, many articles are being published in professional "conventional" medical journals. The idea of herbal therapy as "alternative" may soon diminish with time and the abundance of forthcoming information. Knowledge of herbal therapy will increase as a result of this information expansion.

#### Factors Influenced By Knowledge

Safety, perhaps was the greatest concern of the nurse practitioners. The six theme clusters regarding safety were dosages, drug interactions, adverse effects, co-morbid conditions, lack of regulation, and lack of clinical data. Safety became less of an issue as the practitioner learned more and more about the herbal therapy. Those practitioners who knew more about herbal therapy seemed less concerned with their safety or were able to counsel patients, for example, on how to deal with lack of regulation and which medications should not be taken concomitantly. Therefore, the knowledge level of the practitioner directly affects safety concerns.

Knowledge of herbal therapy certainly affected the practitioner's view of effectiveness and her willingness to recommend such therapy to other patients. Whether through research, personal use, or anecdotal reports from patients, those practitioners who knew more were able to relate effectiveness better than those who did not know were. In addition, they used that knowledge to make recommendations or suggestions to their patients. The term "prescribe" came up several times in the interviews. Although most acknowledged they were unable to "prescribe" herbs in this country, many offered "recommendations" to their patients. Those who knew little about herbs were certainly hesitant to suggest herbal therapy or even bring up the subject.

#### Factors Which Influence and Are Influenced by Knowledge

Responsibility is another theme which is affected by knowledge. For those practitioners who had little knowledge of herbs, they would often advise patients to do their own research---make the patient responsible for their own healthcare decisions. Most agreed a well-informed patient is a good thing. On the other hand, the practitioners felt a sense of responsibility toward the patients to be well informed themselves and be able to give sound advice as to how and where patients could go for more information. In addition, most felt practitioners had a responsibility to "keep up" with current trends in healthcare.

Time, another theme category identified, can also influence and be influenced by the nurse practitioner's knowledge of herbal therapy. According to the participants, acquisition of knowledge takes time. Those practitioners who addressed the time factor expressed a certain frustration related to obtaining, organizing, and disseminating

information. Those who knew more about herbs though were willing to take the time to discuss that option with their patients.

Knowledge, experience, and practice all appear interrelated based on the responses in this study. Experience both affects and is affected by the knowledge of the nurse practitioner. The more a nurse practitioner knows about herbs, the greater her experience, thus the more frequent the subject is addressed at the workplace. On the other hand, the less experienced, less knowledgeable the nurse practitioner, the less the herbal therapy is discussed. Some nurse practitioners felt lack of experience compelled them to learn more, while others would simply not address the subject or would refer the patient to another source. Safety, time, acceptance, effectiveness, responsibility--themes brought out by the data--all relate back to whether or not the nurse practitioner had either knowledge or experience on the subject.

### Evidenced-Based Practice

Knowledge is essential to providing safe, effective care to patients. New information in the field of healthcare can be overwhelming. Due to the increased complexity of health care, many clinical guidelines have been established to both standardize and improve the quality of care. Often it is difficult to "keep up" with advances in medicine. A recent meta-analysis of barriers to following medical guidelines by physicians reflects this phenomenon. Cabana and colleagues (1999) found that doctors don't have enough time, information, or confidence to follow national established guidelines. Bergman (1999) states that ultimately if clinical guidelines are to be followed, there must be an improvement in the evidence on which they are based and a

means of rapid, effective information dissemination.

These principles appear to be true with the clinical use of herbal therapy. In the United States, the concept of using herbs to attain or maintain a state of improved health is also new and complex. The level of knowledge of the practitioner profoundly influences incorporating herbal therapy into practice. According to a recent survey of physicians' attitudes toward complementary and alternative medicine (n=109), Boucher and Lenz (1999) found that most respondents agreed that physicians should be more knowledgeable about alternative therapies. Ness (1999) agrees that knowledge of herbal use and side effects is important in order to determine the best treatment modalities for patients. Barrett, Keifer, and Rabago (1999), and Glisson, Crawford, and Street (1999) echo this sentiment: providers must have a fundamental understanding or at least a familiarity of uses, adverse effects, drug interactions, and precautions associated with herbal therapy.

Once a knowledge base has been established practitioners have foundation for discussing the therapeutic use of herbs. Issues of safety, effectiveness, and responsibility diminish as more and more knowledge is made available and accumulated by the practitioner. The more often the subject is discussed, the more experienced the practitioner becomes. As a result, the practitioner becomes more comfortable and confident addressing this issue. Attitudes and acceptance also change. As herbs are incorporated more and more into practice, patients and providers may even begin to view herbs as less "alternative" and more complementary, however, this will take time to establish.

### Implications

This study highlights the need for knowledge acquisition by the nurse practitioner regarding herbal therapy. Knowledge can be obtained through formal education such as classes, seminars, or lectures or through informal means such as journal reading, personal research, or shared information from patients or colleagues. The information from this study can have a profound influence on the curriculum for graduate education. Herbal therapy can and should be incorporated into pharmacology courses or even separate courses on complementary therapies as are now being seen in over 50% of medical schools in the United States (Bharracharya, 1998).

The findings of this study are supported by studies which say that knowledge acquisition in the ever-changing field of healthcare can be challenging. To meet those challenges, new and innovative ways are needed assist the provider. Clinical guidelines are one mechanism being developed to assist in standardizing care. However, barriers such as disseminating information and incorporating this information into practice in a timely manner still exist. Graduate programs and continuing education coordinators can use this knowledge in an effort to overcome some of those barriers. In addition, the focus of individual patient care settings such as clinics and hospitals should be to create an environment that is conducive to learning and minimize barriers to knowledge acquisition.

### Recommendations for Further Research

This study should be used as a springboard for further research regarding herbal therapy, alternative medicine, and complementary therapies in general. Several aspects

should be addressed. Provider attitudes could be further explored. The participants in this study claim nurse practitioners are more open to herbal therapy and complementary medicine in general than physicians, and research in this area may serve as a foundation for future studies. Different practice patterns among providers could also be explored.

In addition, nurse practitioners' experience with other complementary therapies could provide some important insight on patient self-care. Orem identified the patient's need to care for himself/herself as fundamental. This study underscores that need for independent decision-making and treatment by the patient. What exactly influences a patient's decision to use herbal therapy? Some interesting issues arose regarding natural versus synthetic medications, free versus out-of-pocket expenses and prescriptive versus not prescriptive. Should herbal therapy become FDA approved and providers become able to prescribe herbs, would patients who "don't like to take medicines" still desire to use herbal therapy? The patient perspective on the use of herbal therapy should also be explored.

All the participants in this study were active duty Air Force nurse practitioners. Interviewing nurse practitioners from other military services or from the civilian sector would add new information. Practitioners in other services or in other regions of the United States may have significantly different experiences.

Finally, accurately identifying barriers to knowledge acquisition among nurse practitioners may profoundly influence future education strategies. Studies examining formal graduate education as well as continuing education and professional journals and their influence on practice could benefit future practitioners and patients.



### Summary

Herbal therapy is becoming more and more popular each day. Based on this study and other studies documented in the literature, nurse practitioners need to learn more in order to provide the safest, most effective care for their patients. This study looked at the nurse practitioner's experience with herbal therapy. This experience as described by the participants varied considerably. The underlying differences in their experience related to their knowledge of herbal therapy. Knowledge acquisition and application of that knowledge into practice is both the key and the challenge.

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APPENDICES

Appendix A: USUHS IRB Approval Letter

Appendix B: Malcolm Grow Medical Center IRB Approval Letter

Appendix C: Air Force Nursing Services Approval Letter

Appendix D: Research Study Information Sheet

APPENDIX A

USUHS IRB APPROVAL LETTER



UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES  
F. EDWARD HEBERT SCHOOL OF MEDICINE  
4301 JONES BRIDGE ROAD  
BETHESDA, MARYLAND 20814-4799



June 8, 1999

MEMORANDUM FOR CAPT VIRGINIA A. GARNER, GRADUATE SCHOOL OF  
NURSING

SUBJECT: IRB Approval of Protocol **T061AE-01** for Human Subject Use

Your research protocol entitled "*Nurse Practitioner's Experience with Herbal Therapy*," was reviewed and approved for execution on 6/8/99 as an **exempt** human subject use study under the provisions of 32 CFR 219.101 (b)(2). This approval will be reported to the full IRB scheduled to meet on July 8, 1999.

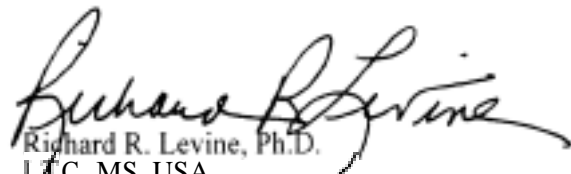
The purpose of this study is to explore and describe nurse practitioner's experience with herbal therapy. A sample of 8-10 military nurse practitioners will be interviewed regarding their attitudes toward and experience with using and/or suggesting the use of herbal therapy. All interviews will be recorded and transcribed. The IRB understands that no identifying information will be collected as part of the interview. *To further enhance subject confidentiality, the IRB requires that all interview recordings and any accompanying subject identifying information be destroyed at the conclusion of the study.*

Based on the nature of your study, an informed consent document is not required for subject participation. *However, in lieu of an informed consent document, subjects who agree to participate in the study should be provided with an information sheet (i.e., your draft informed consent document without the "signatures" section) that describes the study. This study information sheet must also include the assurance that all interview recordings will be destroyed at the conclusion of the study.*

**Once you have prepared the study information sheet please provide this office with a clean copy of the information sheet, on USUHS letterhead, for approval prior to distribution to subjects.**

Additionally, to complete our files, you are also required to submit a copy of any study approval/permission letter(s) obtained from the local MTF(s) to be used for recruiting subjects.

Please notify this office of any amendments you wish to propose and of any untoward incidents which may occur in the conduct of this project. If you have any questions regarding human volunteers, please call me at 301-295-3303.

  
Richard R. Levine, Ph.D.  
LTC, MS, USA  
Director, Research Programs and  
Executive Secretary, IRB

Cc: Director, Grants Administration

**APPENDIX B**

**MALCOLM GROW MEDICAL CENTER IRB APPROVAL LETTER**



Date: Aug. 20, 1999

TO: Principle investigator

FROM: Janice M. Rusnak, Lt. Col.; Chief, Infectious Diseases  
TSgt. Huff; IRB administration

RE: Research study annual/final progress report

Dear Principle investigator:

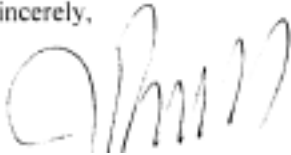
Your study entitled, NURSE PRACTITIONER'S EXPERIENCE WITH HERBAL THERAPY, Captain Virginia Garper, has been approved by the IRB as a human exempt study pending the following changes. This study interviews 8 to 10 nurse practitioners on their experience with herbal therapy. Interviews will be taped. The study was approved by the IRB as a human exempt study pending the following changes with a vote of 8 for, 0 against, and 0 abstain.

1. On page 15, please eliminate the requirement that permission will be obtained from the Chief Nurse Executive. This is not a requirement to proceed with your study as there is IRB approval.
2. If a transcriptionist is used to transcribe the tape, a letter/statement of confidentiality needs to be signed by the transcriptionist.
3. The IRB requires that all interview recordings and any accompanying subject identifying information be destroyed at the conclusion of the study.
4. A consent document is not required for this study. The enclosed Research Study Information Sheet will be sufficient to give to the nurses, which states that the tape will be destroyed at the end of the study.

As a reminder, the study requires that an annual/final progress note be submitted to the Investigational Review Board which is due at 11 months after approval of the study. We will send a notification 2 months prior to the due date. The report must be submitted to the IRB (the educational office/TSgt. Huff). This report is a requirement by the FDA. Failure to submit the report may result in the IRB placing the study on hold (no new enrollments) or even temporary cessation of the study. The format for the report must follow the format as described below. Any abstracts or papers published during the study should also be enclosed, however, they cannot be accepted as an annual or final report as per FDA regulations. If you plan to PCS or retire prior to the report being do, you must either close the study with a final report; or have a letter by a new primary investigator that they will resume responsibilities.

Thank you for participation in research at the 89th Medical Center.

Sincerely,



Janice M. Rusnak, Lt. Col.  
Chief, Infectious Diseases



TSgt. Huff  
IRB administrator

APPENDIX C

AIR FORCE NURSING SERVICES APPROVAL LETTER



DEPARTMENT OF THE AIR FORCE  
HEADQUARTERS UNITED STATES AIR FORCE  
WASHINGTON, DC

27 JUL 1999

MEMORANDUM FOR CAPTAIN VIRGINIA A. GARNER  
GRADUATE SCHOOL OF NURSING  
UNIFORMED SERVICES UNIVERSITY  
OF THE HEALTH SCIENCES

FROM: HQ USAF/SGX  
110 Luke Avenue, Room 400  
Bolling AFB, DC 20332-7050

SUBJECT: Data Collection Request

This is in response to your request for official permission to speak with eight to ten military nurse practitioners as part of your qualitative research study involving their experiences with herbal therapy.

I support your request to contact Air Force nurse practitioners to discuss their experiences with herbal therapy in clinical practice. Once you have received approval from the Institutional Review Board to begin data collection for this study, you may contact the nurses directly to explain the study and to invite them to participate.

Understanding the scope of this phenomenon will be of tremendous help in developing teaching materials and clinical protocols regarding their use. The increased availability of herbals in the commissaries and base exchanges confirms the significance of this effort. It is important that nurse practitioners be able to discuss the use of herbals with their patients. This will be a unique contribution to the Air Force Medical Service as we pursue the goal of creating healthy communities.

I wish you continued success in your academic program and encourage you to share the results of your study through poster presentations and publications.

A handwritten signature in black ink, appearing to read "Linda J. Stierle".

LINDA J. STIERLE, Brig Gen, USAF, NC  
Director, Medical Readiness and Nursing Services  
Office of the Surgeon General

APPENDIX D

RESEARCH STUDY INFORMATION SHEET



## Research Study Information Sheet

### Nurse Practitioners' Experience with Herbal Therapy

#### Introduction

You are being asked to participate in a research study. This information sheet will provide you with some of the details about the study, possible risks and benefits, and privacy/confidentiality issues. Your decision to take part in this study is completely voluntary and you may withdraw from the study at any time.

#### Description of the study

The Department of the Graduate School of Nursing of the Uniformed Services University of the Health Sciences and Capt Virginia A. Garner are conducting a research study to explore and describe the nurse practitioner's experience with herbal therapy. Approximately 8-10 military nurse practitioners will be interviewed regarding their experience with herbal therapy. Interviews will be audiotaped, last approximately minutes, and be scheduled at your convenience.

#### Risks and Benefits

You as a participant will not receive any monetary compensation. You will however be given a copy of the results of the study at your request. Although you may not personally benefit from this study, your participation may contribute to a better understanding of nurse practitioners' experience with herbal therapy. No physical risks are anticipated.

#### Privacy and Confidentiality

The researcher alone will maintain any information which may personally identify you. Your interview will be coded by number. Confidentiality will be protected to the best extent provided under law. All interview recordings will be destroyed at the conclusion of the study. Results of this study will be submitted as a written thesis. The researcher (Capt Virginia Garner) will answer any questions you may have regarding this study.

