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FEATURES

Are Herbal Therapies Worth the Risks?

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Nurses have a powerful opportunity to correct the current problems of poor provider-consumer communication, false information, and inadequate monitoring of outcomes and interactions related to herbal therapy. This article explores the current trends in herbal therapy as well as the benefits and risks. Potential tools that nurses can use in caring for patients who use herbal therapy are included. **KEYWORDS:** *botanicals, herbal tvedicines, herbal plants,herbal therapies HoUst Nurs Pract 2003; 19(1):44-47*

Nearly 16% to 18% of all adults in the United States regularly use herbal products as part of a dietary or health regimen. In 1999, \$3.3 million were spent on the purchase of herbal medicines. An estimated 15 million adults in 1997 combined herbal and/or vitamin therapy with prescription medications, which accounted for 18.4% of all prescription users. Currently, there are approximately 15 million adults, at risk in the US for potential adverse interactions from prescription medication, herbs, and/or vitamin supplements, including nearly 3 million adults age 65 or older.' People consuming herbal therapies generally do not disclose these activities to healthcare providers for cultural or personal reasons, so potentially positive and negative outcomes are not readily identifiable. Healthcare providers unfamiliar with the uses and actions of herbs often fail to assess and monitor patients when providing services. This results in potentially negative outcomes on health and dissatisfaction with healthcare services.

HERBAL THERAPY IN THE UNITED STATES

Herbs are seed-producing annuals, biennials, or perennials that do not develop woody tissue, die at the end of the growing season, and have medicinal, savory, or aromatic qualities.'[^] To avoid confusion regarding many available products, the terms "botanicals" or "phytotherapeutics" may be used instead to describe any plant-derived product used for medicinal or health purposes.'^{^*} Herbal therapy was the mainstay of pharmacopeia during the early 1900s in the US. Today, nearly one-quarter of current pharmaceutical agents originated in whole or in part from naturally occurring chemicals in plants. Three plant therapies are still part of standard therapy in cardiovascular disease: Digitalis, reserpine, and aspirin.'" In one study of 1539 adults in 1991 and 2055 in 1997, investigators examined the use of alternative therapies.[^] Results suggested that the estimated out-of-pocket expense for herbal remedies in the US was \$5.1 billion, representing a 380% increase in the use of herbal agents. Why the increase in use? Certainly, public knowledge of herbals has increased over the last decade. Information is readily available through the media, journals, magazines, family, and friends. The Internet also contributed to the explosion of information and enables consumers to order products from anywhere in the world. Herbal agents are readily available in drug stores and supermarkets. Unfortunately, Web sites may not always contain reliable or accurate information. Whereas pharmaceutical agents are often perceived as expensive, costly, high-risk, and for the treatment of disease, herbs are perceived as natural, safe, and for promoting health. However, "natural" does not necessarily equate to safe. Lack of standardization in

preparation and packaging of herbs, as well as potency problems, has resulted in variable and nonreproducibile outcomes."*

Most herbal products sold in the US are marketed as dietary supplements and subsequently are not required to have Food and Drug Administration (FDA) approval or regulation. Moreover, most herbs do not qualify for United States Pharmacopeia (USP) designation for meeting standards of strength, quality, purity, and labeling. Products without FDA approval or USP designation may carry a National Formulary (NF) symbol, which indicates the product has been used extensively without documented adverse risks.* The 1994 Dietary Supplement, Health, and Educational Act (DSHEA) requires manufacturers to ensure that products placed on the market are safe. Therapeutic claims can be disseminated into the marketplace as long as the information is not misleading or product-specific. Manufacturers do not have to submit data to the FDA if product ingredients were marketed before 1994. However, new food ingredients require safety information for FDA review 75 days before the product goes to market. If the FDA suspects that an herbal agent is unsafe, the product can be removed from the market.^ ^ With the increasing popularity of alternative therapies and increasing demand for information, the National Institutes of Health (NIH) established the Office of Alternative Medicines (OAM) in 1992.*'

Since herbal products are not required to be tested in clinical trials before marketing, evidence for efficacy and interaction effects are limited. Clinical trials often have small sample sizes, short study timelines, and variable outcomes that fail to demonstrate efficacy of the agent.' The historical use of herbs over the centuries is a strong argument against supporting evidence-based studies. Furthermore, herbs cannot be patented; therefore, the incentive for manufacturers to pursue clinical trials is low. The average cost to bring a new medication to market is an estimated \$350 million to fund research and regulatory requirements.* Therefore, adverse effects, drug interactions, dependence issues, and even favorable effects of herbs are usually identified only after many people experienced the effect of a particular herbal agent. Differences in quality, batch-to-batch variability, and the current regulatory environment suggest that consumers should exercise caution in purchasing and using herbal therapies.

TABLE 1. Factors affecting active plant constituents of herbal plants and subsequent outcomes

Manufacturing/Preparation	Daylight length	Atmosphere	Sampling
Toxic Residues/Heavy metals	Temperature	Deterioration	Environment
Microbial contaminants	Altitude	Soil	Rainfall

The process of assuring quality is difficult because so many factors influence the herbal plant and associated benefits (Table 1). In Germany, herbal medications are standardized to increase the likelihood of consumers obtaining the same dose and active ingredient over time. The Federal Health Agency in Germany also developed specific monographs on various herbs through Commission E, a group that disbanded in 1994. Through the Commission, 300 herbs were evaluated and 190 were recognized as suitable for medical use. Currently, approximately 70% of German healthcare professionals prescribe phytopharmaceuticals in their practice. The monographs developed by Commission E have been translated and can be found on the Web site of the American Botanical Council (<http://www.herbalgram.org>). In the US, The MedWatch Program provides a searchable database for consumers and healthcare professionals for information about herbs and medications. The database not only provides information, but is also a place to report adverse events.

Risks

While there are many potential benefits to herbal therapies, there are also risks. Risks include the product, the interaction of the product with the patient's physiology, and the interaction of the herb with a medication regimen. Since herbal manufacturing is not standardized and quality is variable, patients should check brands, labels, and expiration dates carefully.*' Groups of particular concern are people with chronic illness, impending surgery, or those on prescription medication.*

TABLE 2. Reported toxic and interactive effects of various herbal agents

Coma	Increased bleeding time	Renal failure
Hepatotoxic reactions	Reduction in seizure threshold	Increased sedative effects of anesthetics
Unstable blood glucose levels	Increased anesthetic requirements	
Inhibition of platelet aggregation	Interference and effectiveness with prescribed medication uptake	

Interaction effects are varied and can result in indirect or direct toxicity, organ damage, or decreased bioavailability of current medication therapies (Table 2). With 30,000 over-the-counter products and more than 1000 unique chemicals used in the manufacturing of prescriptions, the interaction possibilities are endless. Symptoms or complaints may be mistaken for exacerbation of the current problem, poor treatment response, or the development of another medical problem, when in fact, the symptoms are related to the direct or interaction effects of the herbal agent. Negative or positive outcomes of herbal therapy also may be unknown because communication between healthcare professionals and consumers regarding alternative therapies is often "don't ask-don't tell." As long as evidence concerning the efficacy and toxicity of herbal agents remains inadequate, hypothetically, herbal agents may inhibit or potentiate the activity of other conventional therapeutic agents. The chronically ill, elderly, persons with existing renal and liver disease, and diabetics should be monitored carefully for risks associated with interaction effects of herbal therapies and concomitant pharmacological therapies. Persons requiring surgery should have an evaluation of potential adverse perioperative herb-drug interactions completed in advance of the surgery and if doubts exist, the herbal agent should be discontinued for 1 to 2 weeks prior to anesthesia and surgery. Other vulnerable populations, such as children and pregnant women who have not been studied with regard to herbal therapies, should be counseled not to use herbal agents. Persons receiving anticoagulants, hypoglycemics, antidepressants, or sedatives should be carefully monitored for herbal therapy use since the potential for interaction effects is very *

Finally, considering the growth of herbal therapy over the past decade and the number of persons using herbal therapy, healthcare professionals need to become more knowledgeable regarding the information available on herbs. NPs should exercise caution in recommending an herbal product because the quality of the product purchased may be poor and result in negative outcomes.

Patient care

To overcome the "don't ask-don't tell" climate of alternative therapy use, NPs must convey a nonjudgmental attitude in assessing for herbal use. Leading questions always collect inaccurate information; don't lose sight of the purpose of observation. It is not for the sake of compiling miscellaneous information or curious facts, but to save lives and increase health and comfort. Patients rarely discuss use of alternative therapies with caregivers for fear of criticism, perceived bias of the medical community against alternative therapies, and lack of knowledge regarding the primary and potential interaction effects of the herb with their disease and/or medication regimen. Since the safety and efficacy of alternative therapies is largely unknown, advising and assessing patients represents a huge challenge to healthcare providers. Patients should be counseled to know the current pharmacokinetics of the herb they are taking or how the herb is absorbed, distributed, possible side effects, and potential interactions. Ultimately, patients should know that "natural" does not mean safe, and "safe" does not mean effective. Eisenberg proposes a strategy for working with patients using herbal therapies. First, know the patient. Discuss the patient's preferences and expectations regarding care. The more neutral the questions during the interview, the more likely the answer will be honest. Leading questions and use of terms such as "alternative" or "unorthodox" may be perceived as judgmental, and patients as a result, will not disclose alternative therapy use. Carefully uncover all the methods the patient uses to promote health without demonstrating surprise or disgust. Teach patients who use herbal therapies to use symptom diaries. Each day, the patient should document symptoms, concerns, medications, or herbal agents taken, as well as the associated times. Symptom diaries should always be part of follow-up where the NP reviews the diary with the patient. Diaries help the

patient and clinician monitor symptoms, responses to medications and herbal remedies, and help discern trends of improvement or decline. Symptom diaries may also help uncover possible interaction effects. Review of diaries can be discussion points for sharing information about herbal remedies, where to obtain more information, what side effects to monitor, and report concomitant therapies that should be avoided. Herbal use patterns should be part of the patient's documented history and treatment plan.[^] Patients should know the risks and benefits of their choices and that herbs have good and desirable effects as well as negative and undesirable effects.^{''*'} Finally, clinicians must be aware of trends in herbal therapy and share that information in patient care, teaching, and writing.

Research

Nature has been and will continue to be a source of medicinal agents. In the future, through combinatorial chemical and biosynthetic technology, natural products and their biologic activities will be used to create more effective chemotherapeutic and bioactive agents.['] For now, there is a need for further research on the risks and benefits of herbal agents, particularly in the vulnerable populations: the elderly, chronically ill, and those on a variety of medication therapy programs.^{''''*} There are few scientifically rigorous, randomized clinical trials that demonstrate the efficacy of herbal therapies.['] Future trials would require larger sample sizes, longer timelines, and standardization of agents to obtain meaningful results. The wealth of information from symptom diaries would also be a great starting point in increasing knowledge of the positive and negative outcomes of herbal therapies. Despite the fact that herbs have been used for thousands of years for health and healing, our knowledge about them is still limited. However, the future has infinite potential for research and further discovery of the risks and benefits of herbal therapy.

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