Complementary/Alternative Medicine Use: Responsibilities and Implications for Pharmacy Services

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INTRODUCTION

Complementary/alternative medicine (CAM) is known by a variety of terms, such as complementary, holistic, integrative, unorthodox, and natural medicine. Some types of alternative medicine include acupuncture, aromatherapy, chiropractic, folk medicine, homeopathy, and herbal medicine. A treatment is called “alternative” when it is used instead of conventional treatment. A “conventional” treatment is one that is widely accepted and practiced by the mainstream medical community. If alternative treatments are used in addition to conventional treatments, they are referred to as “complementary therapies.”

There is a need to integrate these treatments into conventional medical practice and to examine the prevalence of herbal use across ethnic, age, economic, and other strata as studied by the regular medical hierarchy. These therapies are often implicated in patients’ responses to treatment of their chief complaints as well as the progression of their underlying diseases. Hence, herbal therapies affect the patient’s response to conventional patent medicines, surgery, anesthesia, and healing. In addition, patients receiving acute care will have differing responses, depending on their underlying cardiovascular, renal, hepatic, and immune system pathology, along with their conventional and alternative drug therapies. Any effort on the part of pharmacists to raise these issues with treating physicians must be combined with a presentation of the prevalence of CAM use in their patients.

This presents a challenge to community and institutional pharmacists as they strive to ensure rational drug therapy. Pharmacists must obtain and provide information relating to all therapeutic agents the patients are receiving in the following situations:

- when the patient begins a new conventional therapy
- when the patient presents for emergent or urgent care
- when the patient presents for surgery and other invasive procedures
- when the patient is considering a new CAM therapy

PREVALENCE OF CAM USE

According to a study reported in *JAMA*, 40% of Americans use some form of alternative medicine.1 Americans visited alternative therapy practitioners 629 million times in 1997, which is a 47% increase over the 427 million visits made in 1990. Americans spent approximately $27 billion out-of-pocket (not covered by insurance) on alternative medicine treatments. This is equivalent to the out-of-pocket expense for the same period on U.S. physician services. The use of herbal medicines increased fivefold between 1990 and 1997; the use of folk remedies increased at a similar rate; and the use of megavitamins and homeopathy more than doubled.1 According to the National Institutes of Health (NIH) National Cancer Institute, the use of CAM is even more prevalent among cancer patients. One study published in the July 2000 issue of the *Journal of Clinical Oncology* reported that 83% of 453 cancer patients had utilized at least one CAM therapy as a part of their cancer treatment.2

In this article, we discuss herbal and homeopathic remedies. Herbs and homeopathic medicines involve the use of various parts of plants to treat symptoms and promote health. These plant extracts are utilized homeopathically to stimulate the body sufficiently to trigger a healing or prophylactic response. The U.S. Food and Drug Administration (FDA) does not currently regulate herbal products, which can be marketed only as dietary supplements. Manufacturers and distributors cannot make any specific health claims without FDA approval.3

Of the 44% of all respondents in the *JAMA* study (Eisenberg et al1) who indicated that they took prescription medication in 1997, 18.4% indicated that they also utilized herbal products. However, in respondents who had a medical condition requiring treatment, more than 33% used herbal products as well. Therefore, more than 15 million Americans are taking both prescription drugs and herbs or high-dose vitamins.

There is a potential for adverse interactions between prescription drugs and herbal products. This problem is compounded because ample data are available about which prescription medications a particular patient is taking, but poor communication between patients and physicians limits our knowledge of the true extent of alternative therapy usage.

Gray et al4 demonstrated this gain in popularity by pointing out that 42% of patients reported using at least one CAM therapy, the majority of patients being younger, better educated, and employed. Almost all of these patients integrated CAM as an adjunct to conventional therapies but clearly not as a substitute for conventional preventive health care.

In a *Lancet* article, Ernst5 reported that more than 50% of cancer patients were using CAM either with (as supportive care) or before or after conventional therapies.

Cherniack et al6 studied the prevalence of CAM use in the geriatric population. They reported that 58% of these patients had used at least one CAM in the previous year. A higher proportion of use was reported in patients receiving treatment for thyroid disorders and arthritis. This study also upheld the idea that CAM prevalence exists in highly educated groups.
Robinson et al\(^7\) studied the prevalence of use in individuals who attended health fairs. In this group, 61% reported CAM use. The investigators also noted that patients using CAM also used conventional care.

Oldendick et al\(^8\) reported that 44% of telephone interview respondents used CAM. This study also associated CAM with a high level of education. The majority of CAM users had a high level of satisfaction with their therapy. The authors also reported that 57% of CAM users had not informed their physicians of their CAM use.

In a study of cancer patients by Bernstein and Grasso,\(^9\) the prevalence of CAM use was even higher. Eighty percent reported some use of CAM, with the majority utilizing herbal products and vitamins.

All of these prevalence studies confirm a high use of CAM by educated individuals who have access to conventional health care. In many cases, conventional health care provider physicians are unaware of the therapies being used by their patients. This further underscores the need for pharmacists to obtain accurate and complete CAM histories for their patient profiles. This information must be utilized to indicate any interactions and reactions between conventional therapies and CAM.

Conventional approaches to treatment have generally been studied for safety and effectiveness through a rigorous scientific process, including clinical trials with large numbers of patients. Often, less is known about the safety and effectiveness of herbal products. In addition, because of the lower level of FDA oversight, similar products from different manufacturers are not required to demonstrate equivalence.

In 1990, 33% of respondents who used alternative therapies used them not for a particular medical condition but rather for health promotion or disease prevention. In 1997, 58% of alternative therapies were used for these purposes. Despite these dramatic increases in use, the extent to which patients are disclosing their use of alternative therapies to their physicians during history-taking remains low. In the 1990 and 1997 studies, fewer than 40% of patients disclosed their use of alternative therapies to their physicians. Therefore, there has been no increase in patient and physician understanding of the need to include alternative therapies as a part of the patient history. Before we embark on a strategy to develop an increased understanding for the need to incorporate herbal therapy history into the conventional medication history of the patient’s medical record, the reasons for the increased use of alternative medicine need to be explored.

At present, there is no definitive response to this question. In a national study of the reasons for alternative medicine use, Austin’s study demonstrated that most individuals used alternative medicine as an adjunct to conventional medicine.\(^10\) Only 5% used alternative medicine alone. This finding underscores the need to have a complete history of all treatments to take into account the risk of interactions between therapies. In addition, individuals with poorer health status are more likely to utilize alternative therapies. Here again, sicker patients with more complicated treatment regimens increase the risk of untoward events caused by interaction of treatments. Austin’s data were then examined to determine whether any trends were evident regarding which groups were likely to utilize CAM.

In an examination of CAM use and age (Figure 1), the data suggested substantial CAM use across all age groups. The data were then sorted by race and ethnicity (Figure 2). Although there was substantial use across all ethnicities, there was less use among African-Americans and more use among Native Americans. When educational level was examined (Figure 3), CAM was used across all levels but there was a definite trend toward increased use at higher educational levels. Examination of use across income areas demonstrated no significant differences in prevalence (Figure 4).\(^10\)

If conventional health care providers operate from the viewpoint that their treatments may be used together with alternative therapies, it is necessary to consider an impact analysis. Historically, orthodox medicine had combatted alternative practices vigorously by denouncing and attacking them. Access was restricted, and alternative treatments were labeled as unscientific and were considered to be quackery. Often penalties were imposed on practitioners of alternative medicine. When alternative therapies rose in popularity, despite the attitude of the medical establishment, the establishment began to examine them, evaluate them, and consider incorporating them into treatment regimens. Examples include refinement of digitalis into digoxin tablets.

### RATIONALE FOR INCREASED CAM POPULARITY

Jonas addresses issues leading to the increased popularity of alternative medicine.\(^11\) The aging of the population and advances in medicine have led to an increased prevalence of chronic diseases that call for new treatments. In addition, the increase in public access to information and consumerism has led to a de-
CREASED TOLERANCE OF PATERNALISM IN THE MEDICAL PROFESSION. PATIENTS ALSO HAVE AN INCREASED SENSE OF ENTITLEMENT TO A GOOD QUALITY OF LIFE AND HAVE A DECLINING FAITH THAT SCIENTIFIC BREAKTHROUGHS WILL HAVE RELEVANCE FOR THEIR PERSONAL DISEASE TREATMENTS. PREVALENCE IN THE LITERATURE REGARDING THE ADVERSE EFFECTS OF EXISTING DRUG AND CONVENTIONAL THERAPY AND ESCALATING COSTS HAVE FUELED THE SEARCH FOR ALTERNATIVE APPROACHES TO THE PREVENTION AND MANAGEMENT OF ILLNESS. BECAUSE OF DIRECT PATIENT ACCESS TO ALTERNATIVE THERAPIES AND A COMMUNICATION GAP BETWEEN THE MEDICAL ESTABLISHMENT AND ALTERNATIVE CAREGIVERS, THERE HAS BEEN A BROADENING OF THE COMMUNICATION GAP BETWEEN THE PUBLIC AND THE PROFESSION THAT SERVES THEIR HEALTH CARE NEEDS.

TODAY, A GREATER EFFORT IS BEING MADE TO INTEGRATE ALTERNATIVE PRACTICE INTO MAINSTREAM MEDICINE. MEDICAL SCHOOLS HAVE ADDED THIS TOPIC TO THEIR CURRICULA. HOSPITALS ARE CREATING COMPLEMENTARY AND INTEGRATED MEDICINE PROGRAMS, AND HEALTH CARE SUPPLIERS ARE EXPANDING BENEFITS TO INCLUDE ALTERNATIVE PRACTICES. IN ADDITION, RESEARCH ORGANIZATIONS SUCH AS THE NIH OFFICE OF ALTERNATIVE MEDICINE HAVE DEVELOPED THE NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE. WITH THIS INCREASED ACCEPTANCE, HOWEVER, ONE MUST RECOGNIZE THE BENEFITS AND RISKS ASSOCIATED WITH ITS USE. ALTERNATIVE MEDICINE, LIKE CONVENTIONAL MEDICINE, IS A DYNAMIC PROCESS THAT PROMOTES BAD IDEAS AS WELL AS GOOD ONES AS IT CHANGES AND MODIFIES ITSELF. IT NEEDS THE SAME LEVEL OF CRITICAL ASSESSMENT THAT CONVENTIONAL THERAPIES HAVE THROUGH ORGANIZATIONS SUCH AS NIH AND FDA. WITHOUT CRITICAL ASSESSMENT OF WHAT SHOULD BE ACCEPTED AND WHAT SHOULD NOT, WE RISK DEVELOPING A HEALTH CARE SYSTEM THAT IS LESS EFFICIENT, LESS COST-EFFECTIVE, AND LESS SAFE. THERE IS ALSO THE CHANCE THAT THE SYSTEM WILL FAIL TO ADDRESS THE MANAGEMENT OF CHRONIC DISEASE IN A PUBLICLY RESPONSIBLE MANNER.

THE FOLLOWING RISKS MUST BE EVALUATED;12

FIRST, QUALITY-OF-CARE ISSUES INCLUDE THE FACT THAT MEDICAL PHYSICIAN LICENSURE IS NOT REQUIRED OF ALTERNATIVE MEDICINE PRACTITIONERS. LENGTH OF TRAINING, TRAINING CONTENT, TESTING, CERTIFICATION, AND SCOPE OF PRACTICE ARE NOT DOTTED OUT. PROFESSIONAL LIABILITY, STATUTORY AUTHORIZATION, AND CODIFIED DISCIPLINARY ACTION ARE NOT STATED. ALTHOUGH CHIROPRACTIC IS LICENSED, MANY OTHER PRACTITIONERS GO UNMONITORED.

SECOND, THE QUALITY OF NATURAL PRODUCTS IS LARGELY UNMONITORED AND UNCONTROLLED. PRODUCTS ARE AVAILABLE ON THE MARKET AS DIETARY SUPPLEMENTS AND MAY BE CONTAMINATED OR MAY VARY TREMENDOUSLY IN CONTENT, QUALITY, AND SAFETY. SOME PRODUCTS THAT APPEAR TO HAVE SOME EFFECTIVENESS ARE PREPARED DIFFERENTLY ACCORDING TO THE MANUFACTURER AND MAY NOT BE EFFECTIVE IF PROCESSING METHODS VARY. THERE IS NO CONSISTENCY FOR PRODUCTS DE-
developed by competing manufacturers as there is for drugs. In addition, 15 million Americans are taking high-dose vitamins or herbal preparations along with prescription drugs. The adverse effects from these interactions are not well documented.

Third, the quality of science in the development of alternative treatments is not consistent with the methodology utilized for conventional treatments. Some standardization in the trial of products and expressing the evidence for safety and effectiveness must be established. However, attempting to fit alternative medicine into the framework of conventional medicine will not be effective. For one, alternative medicine systems provide more personal contact and participation in the healing process compared with conventional treatments, which often result in a loss of personal contact in the subspecialization, technology, and economics of modern medicine. This is one of the main reasons for the popularity and effectiveness of some complementary treatments, which would be diluted if they were forced into the conventional framework. The integration of conventional and complementary therapies must recognize the need to personalize both the history-taking and treatment processes.

LIABILITY ISSUES

Liability issues for practicing physicians in the area of alternative medicine are quite broad. Legal authorities like Michael J. Cohen, JD, point out the presence of conflicting licensing, regulatory, and malpractice considerations because of the evolving nature of complementary/alternative medicine. Relatively little has been scientifically proven concerning the efficacy and safety of CAM treatments. Also, such treatments are viewed as “non-standard” care. There is concern about having sufficient safety and efficacy data, such as contraindications to make informed recommendations to patients.

Physicians lack knowledge about the interactions that can occur when a patient “self-medicates” versus when he ingests medications that are prescribed. In addition, they may be uninformed about which complementary remedies a patient is using. Patients taking these agents may require additional precautions before surgery and anesthesia. Examples include complementary therapies, which can affect clotting dynamics or cause additive sedation prior to surgery. This reinforces the need to ensure that health histories elicit information about the patient’s use of herbal remedies. Physicians also need to advise patients to discontinue all herbal remedies for a relatively long period prior to surgery. Physicians can be held liable for the unintended consequences resulting from their patients’ use of CAM products regardless of whether they (the physicians) are aware that the products are being used.

Doctors and pharmacists must educate patients about the differences between conventional and alternative medicine and about the pharmacological similarities between conventional and alternative treatments. Patients must be made to understand that these therapies affect the chemical balance in their bodies just as prescription medications do. These therapeutic substances also have differing bioavailabilities, pharmacokinetics, elimination times, allergenic properties, and side effects that must be measured and evaluated.

Physicians who sell vitamin and herbal products in their offices may be considered to be selling “drugs” for purposes of legal liability. We recommend that physicians who support or distribute CAM remedies contact their malpractice carriers to determine whether their coverage will be affected. The American Medical Association (AMA) expects an increase in the threat of liability if there are economic variables in some CAM-related decisions made by the physician. Examples include selling herbal products to augment stagnant or declining incomes. The AMA gives scant guidance for CAM because “there is little evidence to confirm the safety or efficacy of most alternative therapies.”

Physicians at Exeter University in the United Kingdom are taking a course entitled “Familiarization in Complementary Medicine.” The course has been well received, and primary care physicians are indicating that they have gained useful information regarding complementary therapies. However, concerns have been voiced regarding poor communication with CAM practitioners, and doubts of competence have been reinforced by a lack of identifiable qualifications.

Physicians must be aware of the possibility of “failure to warn” liability if they do not advise their patients of the untoward effects of some alternative remedies that they may be taking. This exposure may include therapies that the physician becomes aware of as well as therapies actually recommended by the prescriber. If the patient is seeing an alternative practitioner with a bad legal or medical record, the physician might be held liable for failing to warn the patient. However, physicians may also be held liable for withholding information about an alternative method that might be helpful to patients if that remedy has been found to be a useful treatment for a particular disease.

TRENDS IN THE U.S.

Cushman et al augmented the 1997 JAMA study by surveying four focus groups of African-American and Hispanic women in New York City. This was a pilot study for an eventual nationwide survey of women of various ethnic backgrounds.

Few differences in primary health concerns emerged across demographic lines (ethnicity and household income). Herbal medicine was the most common remedy. Younger women expressed more reservations regarding alternative therapies than did older women, and they were skeptical about CAM practitioners. Older women in these groups often preferred CAM practitioners for a variety of reasons, such as payment terms, their use of methods that have been handed down from generation to generation, language differences, and other cultural issues. Survey participants judged the effectiveness of CAM treatments similarly to conventional ones in terms of assessment of how they feel and assessments of how they look to others. Most younger women studied relied on health assessment by regular doctors whether or not they used CAM.

A follow-up study in the Journal of American Medical Women’s Association amplified this issue. This study, in conjunction with Latina Magazine, studied CAM use in Hispanic women. In this study, another important factor was raised. More than 60% of the subjects indicated that their physicians had never asked them if they were using CAM. Forty percent of the subjects indicated that they never voluntarily reported CAM use. Patients sometimes felt intimidated by their physicians and perceived a sense of disapproval with regard to their physician’s views on the use of CAM. As we can see, this is a problem, particularly when one considers drug-CAM interactions and the potential dangers of procedure-related adverse events.
CONCLUSION

A number of issues have been raised regarding the use of CAM in a variety of populations. In summary, the following items should be explored further:

- educating traditional practitioners about CAM and related cultural issues
- developing better evidence-based scientific evaluations of CAM modalities and individual therapies
- learning more about adverse reactions between conventional therapeutic agents and CAM remedies
- improving understanding among traditional practitioners of the prevalence of CAM use
- improving CAM history-taking as a part of the conventional history and physical examination
- developing a history-taking instrument that would effectively elicit complementary therapies during patient and family interviews with conventional practitioners
- obtaining detailed CAM histories

It is clear that CAM usage poses a high level of responsibility for pharmacists. Pharmacists are best positioned to reduce the fear and reluctance on the part of patients to “confess” to their physicians that they are using CAM to augment their prescribed therapies because they are more likely to obtain the required information from their patients. Pharmacists are also best prepared to integrate this information into the patient’s history and to determine the effect of CAM therapy on the patient’s regimen of conventional medicines and other interventions.

Surgeons, anesthesiologists, cardiologists, and gastroenterologists are among those who utilize these pharmacist services, when available, to determine patient suitability for various procedures. Pharmacists can greatly enhance their value to the health care system by increasing their knowledge of CAM and by using the CAM monographs and databases that are available. A significant business opportunity exists for pharmacists who can integrate conventional and complementary patient care.

REFERENCES