PATIENT SAFETY

What your patient needs to know about CAM

By Susan Ann Vitale, PhD, PNP, ANP-C

COMPLEMENTARY and alternative medicine (CAM) includes many practices and products used to promote and maintain health and wellness or treat human illness. This article deals with biologically based, orally ingested CAM products, including herbs, dietary supplements, and natural products.1 (See What’s CAM?)

Although some healthcare providers specialize in CAM, individuals can buy and use CAM treatments without medical advice or prescriptions. Some of the products most commonly used in the United States include fish oil, flaxseed, omega 3, echinacea, and glucosamine.2 CAM bodily applications such as massage and acupuncture are beyond the scope of this article.

A patient may ask you, “What do you think about this herb that I read about on the Internet?” This article will prepare you to respond with current information about marketing regulations and research standards and offer patient-friendly resources. (See Turn to reliable patient resources.)

What’s CAM?1

The National Center for Complementary and Alternative Medicine (NCCAM) defines CAM as “a group of diverse medical and healthcare systems, practices, and products that aren’t generally considered part of conventional medicine.” Sometimes called Western or allopathic medicine, conventional medicine is that practiced by healthcare providers who are medical doctors or doctors of osteopathy.

CAM may be used as an alternative to conventional treatment, or CAM may complement conventional medicine when they’re used together. When such a combination is backed by high-quality evidence, it’s known as integrative medicine. CAM can include mind and body treatments, such as meditation or yoga, as well as a wide variety of natural products. According to NCCAM, natural products often sold as dietary supplements include herbal medicines, probiotics, botanicals, vitamins, and minerals. Probiotics may be marketed in tablet or capsule form to aid the gastrointestinal system and are also found in foods such as yogurt.

Safety concerns

Intercultural exchanges and CAM use have increased worldwide. New products may appear in a health food store without local community understanding or guidelines for proper use. Acquiring knowledge about what’s safe and effective presents an ongoing challenge to practitioners everywhere. For this reason, the World Health Organization (WHO) has encouraged national dialogue and policy development to prevent misunderstandings, inappropriate use, and harmful indications.3

Very limited research on the use of herbs and dietary supplements such as St. John’s wort, echinacea, ginkgo biloba, glucosamine, chondroitin, and red yeast rice has produced conflicting results. Descriptions of these and other herbs and links to clinical trials are listed on the National Center for Complementary and Alternative Medicine (NCCAM) research website at http://nccam.nih.gov/research/results/.4 Examples of unsafe herbal supplements include comfrey, which can damage the liver, and licorice root, which in large doses may alter BP.5

Another safety concern is that some patients don’t tell their healthcare professional about their CAM therapy or fail to provide a complete list.6 Consequently, they may experience unexpected interactions with prescribed drugs or treatment failure. They may not disclose CAM therapy because they don’t consider these products to be medications or because they fear criticism or lack confidence in the healthcare professional’s knowledge about CAM.

Regulatory issues

The FDA approves an over-the-counter (OTC) drug only when it’s proven safe and efficacious for treating the indications for which it’s marketed. The container must display a prominent standardized label with
In contrast, most herbal products distributed in tablet or capsule form lack similar controls and labels. Patients may assume they’re safe because they look like drugs and are often sold at pharmacies. Herbs sold as dietary supplements are subject to alternative regulations, but proof of efficacy or safety isn’t required.7

A therapeutic herbal supplement may be composed of a plant or botanical or a portion of a plant’s roots, leaves, flowers, or seeds.8 Although herbal products are purchased OTC, their manufacture and delivery to the consumer differ from that of other OTC drugs that are fully FDA-controlled. According to federal regulations, herbs are considered dietary supplements as defined by the Dietary Supplement Health and Education Act of 1994. Companies are required only to follow good manufacturing practices and to post a label stating that the product hasn’t been evaluated by the FDA.8

The NCCAM cautions consumers that a herbal supplement may contain more or less than the labeled amount of its ingredient. It may also contain many unexpected or unknown ingredients, including other plant species, pesticides, metals, or prescription drugs. Although the FDA doesn’t routinely screen herbal supplements for these ingredients, if any are reported, the FDA may issue a warning to the manufacturer or in some cases ban the product’s sale.

In 2006, the U.S. Congress passed Public Law 109-462, known as the Dietary Supplement and Nonprescription Drug Consumer Protection Act. This act requires manufacturers, distributors, and importers to self-report any adverse events to the FDA. Events such as related injuries, hospitalizations, or birth defects traceable to a herb or dietary supplement must also be reported.8 (To learn about an interesting trend in making CAM products safer, see Taking an innovative approach to CAM safety.)

Nursing considerations

During medication reconciliation, determine whether patients use or intend to use CAM, including herbal supplements. Assess their knowledge of their health status, diseases, and treatments. Identify any potential interactions of drugs and herbal remedies and document them in the medical record, then follow up with the patient and provider as indicated. Obtain information about potential interactions at http://nccam.nih.gov/health/herbsataglance.htm. Consider a patient’s economic constraints and cultural preferences.

Help educate patients about how to make informed choices. Evaluate their understanding of the difference between OTC “drugs” and “food supplements,” such as herbs provided in tablet or capsule form that are unregulated and lack FDA approval. Caution patients about the potential for fraudulent advertising, especially on the Internet. Warn patients that advertisers who lack scientific data to support their claims often use testimonials from users.9 Encourage patients to fully disclose their CAM supplement use to their healthcare providers.

Caring for special populations

Take heed when older adults, pregnant patients, and pediatric patients use CAM products.

Older adults. Researchers assessed OTC medication and supplement use from 2005 to 2006 in community-dwelling residents ages 57 to 85. One out of 25 older adults who combined prescription and nonprescription medications was found to be at risk for major drug-drug interactions. Supplements these older adults used included calcium, vitamin D, glucosamine-chondroitin, omega-3 fatty acids, garlic, coenzyme Q, and saw palmetto.10

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In a national health survey of adults over age 65, herbs were found to be an important factor in self-managed healthcare. Predictors of herbal use included gender, ethnicity, culture, and level of education. Educate older adults about potential drug-drug interactions, including those caused by mixing prescription or OTC drugs and herbs.

Cheung and colleagues evaluated oral nutritional supplement usage (including mega-vitamins and herbs) in older adults. The investigation didn’t yield any demographic differences between CAM users and non-users. However, they discovered that over half of the CAM users didn’t reveal their CAM use to their primary care providers. More research needs to be done to predict which patients are less likely to disclose their use of CAM. Always query older patients about their CAM use.

**Pregnant patients.** The use of herbal preparations in pregnancy hasn’t been directly measured and isn’t well understood, but an integrative literature review and meta-analysis from 1995 to 2006 found that pregnant women use a wide variety of OTC drugs and herbal supplements. More research is needed about the use of prescription and OTC drugs during pregnancy, but clinical trials involving pregnant patients raise ethical considerations due to fetal risks, making evaluation difficult.

When a medication’s safety during pregnancy hasn’t been established, a pregnant patient shouldn’t use it unless its benefit is clearly greater than any potential fetal risk. Safe use of herbs, CAM, and dietary supplements in pregnancy hasn’t been definitively established yet. Pregnant women need to consult their obstetric healthcare provider before using any of these products.

**Taking an innovative approach to CAM safety**

A large managed-care network in the northwestern United States, Kaiser Permanante, has created an innovative plan in response to its participants’ desire to use herbs and supplements.

The network’s pharmacological formulary evaluates and stocks a selection of herbs and vitamins that meet its high standards. The list of herbs and vitamins is distributed and the products are dispensed to enrollees through the plan’s prescribing clinicians. This initiative provides reliable patient education and quality-controlled products as well as serving as a model for other organizations.

**Pediatric patients.** Oral CAM therapy in children also needs further study. Little research supports the efficacy of herbs for chronic diseases such as asthma in pediatric patients. One study evaluated whether a combined herbal product would reduce signs and symptoms in children with asthma who use inhaled corticosteroids. It was prompted by surveys indicating that CAM use might be high in children with asthma who have adverse reactions to steroids, which drives their parents to seek alternatives. The double-blind placebo-controlled study didn’t provide evidence supporting the herbal remedy.

Ask parents if they administer any CAM products or supplements to their children. Advise them to get their pediatric healthcare provider’s advice before doing so.

**Best choices**

Encourage patients to share, question, and exchange ideas and practices about their healthcare choices. Be prepared to help patients express their beliefs and preferences, identify dependable information, and avoid making uninformed decisions and purchases.

**REFERENCES**


9. FDA. Health Fraud Awareness. 2012. http://www.fda.gov/ForConsumers/ProtectYourself/HealthFraud/default.htm


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