

Complementary Therapies in CHRONIC CARE™

Practical Applications of Alternative Medicine for CHF, Diabetes, and Chronic Disease

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Don't ask, don't tell: A hazard for both patients and their caregivers

Always ask about supplement, herb use

The military has a “don’t-ask, don’t-tell” policy, but if you take this into your medical practice, you may be setting yourself — and your patient — up for a big headache.

A growing body of scientific and anecdotal evidence shows harmful interactions between some herbs and supplements and pharmaceuticals. Medical and legal experts advise health care professionals always to ask their patients about the use of herbs, supplements, and other complementary and alternative medicine (CAM) therapies as part of a routine patient history.

The failure to do so could result in serious complications for your patient and potentially expose you to malpractice liability as well, says **Michael Cohen, JD**, lecturer on medicine at Beth Israel Deaconess Hospital in Boston. Cohen is the author of *Complementary and Alternative Medicine: Legal Boundaries & Regulatory Perspectives* (Baltimore: Johns Hopkins Press; 1998).

“Ignorance creates risk,” says Cohen. Not only should health care professionals comply with all federal and state laws (which may vary), if a patient is injured and a lawsuit ensues, the failure to ask about herb and supplement use could be considered “below the standard of care.” That is a legal term that means the patient was not given proper care according to the medical standards of the day.

KEY POINTS

- It is in the patients’ and physicians’ best interest to ask patients about their use of herbs, supplements, and other complementary and alternative medicine (CAM) therapies as part of a routine patient history.
- Scientific and anecdotal evidence indicates interactions may occur between some herbs and supplements and other pharmaceuticals.
- Patients should be queried in a matter-of-fact, casual manner without any obvious bias about their use of CAM therapies.

“A good conversation with the patient, noted on the chart, potentially reduces your liability if a patient fails to tell you about herb or supplement use and then has an interaction,” says Cohen.

Those good, open conversations with patients are sometimes difficult, and many patients fear being ridiculed, so they are reluctant to tell their doctors, nurses, or dietitians about their use of herbs or supplements.

The key to developing the trust of your patients is to be informed, says Manchester, CT, cardiologist **Stephen Sinatra**, MD, FACC, FACN, assistant clinical professor of medicine at the University of Connecticut School of Medicine.

Americans spent an estimated \$15.7 billion on nutritional supplements in 2000. At least one-third of Americans report using at least one form of alternative medicine, and one-third of those consult CAM providers, with more than half of them paying entirely out of pocket for their services. Surveys show the most common disease conditions addressed by CAM therapies are back problems, anxiety, headaches, chronic pain, and cancer or tumors. Although 83% reported being under the treatment of a conventional physician, 72% who used CAM therapies did not inform their doctors. In addition, 18.1% of all prescription drug users, 15 million people, reported in 1997 that they took prescription medications concurrently with herbal remedies and/or high-dose vitamins.¹⁻³

“Clearly, the modern physician needs to listen to the voice of the public and at least try to become acquainted with alternative methods as part of continuing medical education,” Sinatra says.

“The modern physician has got to jump into the arena just now and delve into the information available about vitamins and herbs and supplements,” he adds.

It almost can be assumed that patients are using some type of CAM therapy, since more than 80% of Americans have used some sort of CAM therapy in the past year — most of them vitamins, herbs, and supplements. That makes it incumbent for health care professionals to learn

about all types of CAM therapies and not to dismiss any of them as “knee-jerk reactions,” says Sinatra. “Any health care professional who fails to ask all the questions is at risk, and so is the patient.”

That means patient information and history forms should not stop with questions about medications a patient is using; they should specifically mention herbs, vitamins, and supplements. Many patients swear by the efficacy of the herbs or supplements they may be taking, but paradoxically they also view them as “natural” and therefore not worthy of mention to a health care professional.

Beware of interactions

Numerous interactions have been noted, particularly between herbs and pharmaceuticals.

For example, St. John’s wort has been shown to interact negatively with selective serotonin reuptake inhibitors, monoamine oxidase inhibitors, some blood pressure medications, some antivirals, digoxin, loperamide, some birth control medications, immunosuppressive drugs, and warfarin.

Ginkgo biloba has been associated with increased blood clotting time, may interfere with cyclosporine, and may raise blood pressure. Garlic is also an anticoagulant, so it may interfere with the actions of warfarin and other anticoagulants.

“You need to assume your patients are using some of these therapies, and they may be giving them great benefits. You need to explain to them that, like any other medication, they could be harmful if combined improperly with other medications,” Sinatra says.

Leaving your personal biases outside the door is the first step to developing a rapport with your patients that will bring out all the information you need to make a professional diagnosis and write a prescription, says New York City physician **James Dillard**, MD, DC, CAC, assistant clinical professor of medicine at the Columbia University College of Physicians and Surgeons.

“It needs to be simple and conversational —

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■ Stroke: Negative attitude may hasten death

and most importantly, nonjudgmental," he says.

"You don't need to go over the top. Be offhand and relaxed. Take a generally professional attitude, but be warm and friendly. This question shouldn't be any different than any other question you'd ask

Talking to Your Patients about CAM Therapy Use

QUESTIONS

- ☞ Are you taking vitamins, dietary supplements, or herbal remedies? If so, which ones?
- ☞ How much are you taking of each? How often and how long have you been doing this?
- ☞ What are the symptoms you want to treat?
- ☞ Do you have a prescribed medication for the same symptoms? If so, are you still taking it?
- ☞ Have you noticed any improvement or worsening of symptoms since taking the supplement or remedy?

INFORMATION

- ☞ Natural does not always mean safe.
- ☞ Commercial availability does not guarantee safety and efficacy. Advertisers are not legally required to back their claims with scientific studies.
- ☞ The quantity of active ingredients in the product may vary.
- ☞ The risk of contamination is greater than in more strictly regulated products.
- ☞ Supplements and remedies may interact with prescribed medications or with each other, with possibly serious consequences.
- ☞ Some products are safe for short-term, but not long-term use. Long-term studies with appropriate controls generally are lacking.
- ☞ Infants, children, pregnant women, women trying to conceive, and the elderly should not use any complementary or alternative medicine without medical supervision.

Source: Sharon Kolasinski, Chief of Clinical Service of Division of Rheumatology, University of Pennsylvania, Philadelphia.

a patient," Dillard explains.

It's all part of developing that relationship of trust that should be part of any physician-patient, nurse-patient, or dietitian-patient relationship.

"You'd ask any patient if he has pain or a family history. This doesn't have to be a big deal, but you just have to do it," says Dillard.

"If you don't, you're a bad doctor," he adds.

The bottom line for all three experts interviewed for this article: Always ask.

[For more information, contact:

• **Michael Cohen, JD, Beth Israel Deaconess Hospital, Boston.** Telephone: (617) 267-0723. Web: www.michaelhcohen.com.

• **IBISmedical.com Integrative Medical Arts Group Inc., Beaverton, OR.** Integrated BodyMind Information System and The IBIS Guide to Drug-Herb and Drug-Nutrient Interactions. Telephone: (503) 641-6541. Web: ibismedical.com]

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Natural gains against the pain of arthritis

Some therapies may offer more than pain relief

The vast majority of Americans using complementary therapies are those seeking relief from some kind of pain: arthritis, chronic back pain, and musculoskeletal pain.

Arthritis pain alone has driven more Americans to seek complementary and alternative medicine (CAM) therapies than any other single affliction. And although most patients using CAM therapies for arthritis employ them as a supplement to rather than a replacement for mainstream medical care, they tell researchers they do so because their medications do not provide complete relief.

"Whatever the reason, the use of CAM therapies corresponds to the severity of the pain, and some patients do find pain relief with the CAM therapies

KEY POINTS

- There are many natural ways to address osteoarthritis and rheumatoid arthritis. Most can provide some pain relief, but there is no solid evidence they can address the disease.
- Experts have varying viewpoints on the most effective tools. Some of the most widely used CAM therapies for all types of arthritis include: glucosamine sulfate with or without chondroitin, massage, acupuncture and acupressure, and diet therapy.
- Results are widely varied and seem to be individualized, so experts recommend trying other remedies if one is not effective.

they use,” says **Sharon Kolasinski**, MD, FACP, FACR, assistant professor of medicine, chief of clinical service of the Division of Rheumatology and director of the Rheumatology Fellowship Program at the University of Pennsylvania in Philadelphia.¹

“In treating arthritis, we don’t have a cure for anything, so anything that provides relief is certainly worth a try,” she adds.

Glucosamine and chondroitin

The use of glucosamine sulfate with or without chondroitin sulfate is “by far and away” the most popular supplement for the treatment of osteoarthritis.

Glucosamine is extracted from the shells of crustaceans, and chondroitin is prepared from cow trachea or shark cartilage. Glucosamine has been reported to inhibit cartilage breakdown and stimulate regeneration of cartilage after damage. Chondroitin has been reported to block the enzymes that degrade cartilage.

Both supplements have been used for many years in Germany and other parts of Europe, and although their effects on joint damage are being debated, most medical experts agree that glucosamine works as an anti-inflammatory, reduces pain, and is safe.

“Glucosamine has about the same potential for pain relief as NSAIDs [nonsteroidal anti-inflammatory drugs],” says Kolasinski. “Many of my patients take it, and a good number of them get relief.”

The best evidence available to date is a large three-year Belgian study that suggests that glucosamine slows the progression of osteoarthritis.² A similar placebo-controlled trial is underway in

the United States under the auspices of the National Institutes of Health (NIH) and will include chondroitin, glucosamine-chondroitin, and NSAID arms.

The evidence in favor of chondroitin is less convincing, and there have been no clinical trials published on the popular combination of the two supplements. It remains unclear whether patients get any additional benefits by taking glucosamine and chondroitin together.

The operative daily dose for the subjects of the Belgian study was 1,500 mg of glucosamine. It often is divided into two or three doses, and it may take four to eight weeks for effects to become noticeable. Chondroitin usually is used in similar dosages. If neither has an effect within 12 weeks, patients usually are advised to discontinue use.

Because glucosamine may affect glucose metabolism, it is not recommended for patients with diabetes until further trials provide better information on its effects on blood glucose levels.

Massage

“Massage improves circulation throughout the entire body,” says **John Balletto**, LMT, NCTMB, president of the American Massage Therapy Association (AMTA) Foundation in Providence, RI. “So by bringing fresh nutrients to the joint and muscle tissues, it helps them work more effectively.”

A recent survey shows that more than half of osteoarthritis sufferers use massage therapy.³

A study from the University of Miami on children with rheumatoid arthritis showed that subjects with mild-to-moderate forms of the disease who were massaged for 15 minutes daily by their parents for 20 days, experienced immediate lowering of anxiety and stress as measured by cortisol levels, decreased pain, and increased joint mobility.⁴

“Massage is an analgesic, it calms the central nervous system and breaks the pain pattern,” says Balletto. The most effective massage techniques, he says, are stroking, called *effleurage* in traditional massage, and passive joint movement to increase mobility.

“You don’t want anything too extreme, but any movements that help the joint move more freely,” he says.

Patients can be taught simple self-massage techniques that can be very helpful, especially for arthritic conditions of the hands, wrists, and elbows.

Balletto recommends referring patients to trained and certified massage therapists through the AMTA locator service on the Internet at <http://www.amtamassage.org>. All members of the organization hold national certifications and state licenses if they practice in one of the 31 states that require licensure.

Locating the pressure points

Acupuncture, an ancient Chinese treatment, and acupressure, its noninvasive cousin, have become widely accepted in the United States for a variety of medical conditions.

Acupuncture treatments, as prescribed by traditional Chinese medicine, typically involve the insertion of hair-fine needles into the skin along defined tracts called meridians, where they help stimulate the flow of “qi” or “chi,” vital life energy.

Acupressure and shiatsu massage, a Japanese form of acupressure, use no needles, but stimulate the same meridians by applying pressure to certain points on the body. Qualified practitioners can teach patients acupressure techniques.

“Acupuncture and acupressure definitely have a place in pain management in arthritis,” says Kolasinski, who frequently sends her arthritis patients for acupuncture treatments.

A Japanese animal study showed that electrically controlled acupuncture needles appear to delay the onset and reduce the severity of arthritis while reducing the collagen antibody levels. Researchers speculate that acupuncture may inhibit the production of endogenous interleukin-1 beta and prostaglandin by suppressing interleukin and COX-2 gene activations.⁵

After a 1998 consensus panel’s review of the available public data, the NIH concluded that acupuncture is a promising treatment for postoperative pain and for nausea and vomiting associated with chemotherapy.

The agency also has approved the use of acupuncture as primary or adjunctive therapy for osteoarthritis, tennis elbow, fibromyalgia, myofascial pain, low back pain, and carpal tunnel syndrome.

Food sensitivities, vitamins, and herbs

Researchers have long contended that food sensitivities trigger the inflammation of rheumatoid arthritis and perhaps even exacerbate the symptoms of osteoarthritis.

Pain-safe Foods

These foods appear not to trigger arthritis pain:

- ♥ Brown rice
- ♥ Cooked or dried fruits
- ♥ Cooked green, yellow, and orange vegetables
- ♥ Water (plain or carbonated)
- ♥ Condiments: Modest amounts of salt, maple syrup, and vanilla extract usually are well tolerated

“Not all patients show food sensitivities, but for many, identifying food sensitivities has made an enormous difference. Some of these patients had suffered with arthritis for years, never realizing that simple diet changes could help,” says **Neal Barnard**, MD, president of the Washington, DC-based Physicians Committee for Responsible Medicine and author of *Foods That Fight Pain*, (New York City: Three Rivers Press; 1999).

Barnard theorizes that some autoimmune responses are triggered by food sensitivities, particularly to certain types of proteins. **(For more food tips, see box, above.)**

The key, says Barnard, is to put patients on a supervised elimination test for several days, eliminating suspect foods, and then re-introducing them one at a time to identify specific triggers.

“The most common triggers, by far, are proteins in dairy products and eggs, followed by corn and peanuts,” says Barnard, who says in his experience, food sensitivities appear in 20% to 60% of subjects.

The theory was tested by a Norwegian study published in *Lancet* in 1991 in which common arthritis food triggers were eliminated with what Barnard calls “dramatic” results: “Joint stiffness melted away, swelling and tenderness decreased, and grip strength improved. The average pain score dropped from greater than 5 on a 10-point scale to less than 3. Most importantly, when patients were checked a year later, the benefits were still there.”⁶

A vegetarian diet appears to benefit about 50% of patients, including those without specifically identified food triggers, says Barnard.

The jury is still out, but the Framingham Heart Study suggests that vitamins D supplementation may be helpful in alleviating symptoms of

osteoarthritis and preventing deterioration.⁷ And positive results also have been reported for supplementation with vitamins C, E, B₁, and B₆, niacin, and folate, says Kolasinski.

Patients should be advised not to exceed 400 IU of vitamin D daily because higher dosages have been shown to be toxic.

Herbal anti-inflammatories such as willow bark, devil's claw, feverfew, and Chinese thunder god vine also may have some pain-relieving effects. Other commonly used, herbal anti-inflammatories include boswellia, turmeric, ginger, and nettles. There also have been reports that supplementation with fish oil may be beneficial.

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Native Americans return to their roots with garden

Innovative approach to diabetes epidemic

An apple a day, and a bunch of broccoli, and maybe a handful of carrots, keeps the endocrinologist away. Plant an apple tree or a vegetable garden, and you have the double-edged sword of exercise and improved diet to combat diabetes. At least that's what the Bad River Chippewas on the Bad River Reservation near Odanah, WI, are hoping.

Since Native Americans are at two to 25 times the risk for diabetes as the general American population, members of the Bad River Chippewa

KEY POINTS

- The Bad River Chippewa tribe's community gardening project is seen as a way of improving nutrition and providing exercise opportunities to a diabetes-prone population.
- Tribe members of all ages have planted fruit trees and individual garden plots with advice and assistance of the U.S. Department of Agriculture. Cost for one tribe's project: \$30,000. Savings in terms of health care costs as yet unknown, but likely to be substantial.
- Tribal health officials say garden project is gaining popularity with all ages.

band in northwestern Wisconsin decided to the confront the threat of diabetes from a number of directions.

"This is a problem with life-and-death implications," says **Mary Bigboy**, the tribe's health department director.

The reservation of 1,400 people has 200 confirmed cases of diabetes, and 35% of the tribe's members older than age 40 have the disease. At least five new cases of diabetes are diagnosed each month. "It seems like those new patients are younger and younger," says Bigboy. In fact, the use of insulin is so widespread that public restrooms at a tribal restaurant have needle disposal containers.

Enter **Luis Salas**, director of the Northern Native American Health Alliance, offering gardens as a long-range plan to address the diabetes crisis.

"It's so simple; I wonder why no one seemed to think of it before," says Bigboy. "[Salas] suggested that getting people involved in gardening would be a great way to improve the quality of nutrition, on the theory that what you raise tastes better and you're more likely to eat it."

"The gardens are meant as a catalyst to get people to start thinking about the food they consume," adds Salas.

It took just \$30,000 in seed money from the U.S. Department of Agriculture's (USDA) Natural Resources Conservation Service.

All ages meet in the garden

Now the Bad River community is dotted with freshly planted fruit trees — more than 300 apple, pear, cherry, and crab apple trees planted in 100

yards. Dozens of gardens just now are beginning to yield the abundance of the harvest with juicy ripe tomatoes, beans, squash, and corn bursting with flavor and nutrition.

Tribe members, from the kids to the elders, helped till and plant in the spring and have maintained gardens in individual yards and in a few communal plots throughout the summer.

That activity alone has provided the gardeners with exercise, another powerful tool against diabetes. “We needed a way to get people, especially the kids, more active and more aware of what they are eating and its nutritional value,” says Salas. “And we needed a way to make healthy food easily accessible to the community.”

Now it’s time to reap the fruits of their first year’s labor and preserve their harvest with the help of tribal women who are experienced in canning and other food preservation methods.

The Bad River Chippewas have life challenges similar to those faced by the general population, which also is suffering an explosion in the prevalence of diabetes.

“We’ve got families with two working parents who travel long distances to get to work, and when they get home, they’re just too tired to plan a nutritious meal for their families, much less to exercise or encourage the kids to exercise,” says Bigboy.

The easiest solution, but far from the cheapest or healthiest, is to pile everybody back in the car for a 22-mile trip to the nearest pizza joint. That’s a solution that feeds what some researchers say is a genetic predisposition toward obesity and diabetes for Native Americans and some other ethnic minorities.

Back to the roots

“This is a get back-to-the-roots project. The Upper Midwestern tribes always had an agrarian culture,” says **Jack Brickner**, national tribal government liaison for the USDA in Washington, DC.

Over the past 50 years, the Bad River Chippewa reservation has moved from the flood plain along the southern shores of Lake Superior further inland. What was once a thriving agricultural culture has been almost forgotten, Salas explains.

“The Chippewas had the most wonderful gardens imaginable, but over these two generations, not only were the gardens lost, so was the skill,” he says. So the garden project serves yet another purpose: to re-educate tribe members in their traditional ways of gardening and to re-connect

them to their spiritual roots, which hold many plants and the cultivation of the Earth Mother as sacred traditions.

The newly acquired land is hard pan — rock-hard clay soil, which is inhospitable to any type of gardening. So the gardeners among the new generation of Chippewas are working in raised beds with a nutritious mix of sand and trucked-in soil and chicken and turkey manure. They’re learning about composting and soil amendments from **Tom Cogger**, the USDA’s tribal liaison in Wisconsin, who worked with Salas for three years getting the garden program plans in place.

Among the other adaptations devised by Cogger and Salas: 4- by 10-foot hoop houses — miniature greenhouses constructed of flexible plastic tubing and plastic to extend the growing season in the harsh northern climate.

Training, gardening tips available

In addition, the USDA offers the Chippewas and a growing number of other tribes expert advice in laying out the beds, irrigation, soil testing, soil amendments, and greenhouse construction and the start-up money to get the projects going.

The Chippewa gardeners are working organically as much as possible, for health reasons and because that is the way their ancestors would have worked.

Cogger offers training classes for the budding gardeners, and he’s regularly on site to answer questions and handle problems as they arise.

“Prevention is better than dealing with a disease after it’s already there, and that was the thinking behind this project,” says Cogger.

“I can’t believe how it has taken off. Everybody wants to be involved,” he says. “The whole thing has taken on a life of its own. It’s become a community project, and it’s really bringing people together.”

Down the road, there are plans for a community composting program and for community greenhouses to give plants a head start in the short growing season — and maybe even to offer some fresh produce during the winter months.

“Like most of us, the Chippewas and other Native American tribes don’t eat enough fruits and vegetables, so this project is a creative way to encourage them to change that and reduce their risk for diabetes and other diseases,” says **Brenda Broussard**, national coordinator of the American Diabetes Association’s Native

American Outreach program in Albuquerque, NM.

At a national conference for tribal health leaders, Broussard recently threw out a challenge: “Many people complain that fruits and vegetables are too expensive, and they can’t afford them. Yet they load up on Coke and potato chips, and those are very expensive with no nutritional value at all.

“I sent them to the supermarket to compare prices and see what they could buy if they stopped buying Coke and potato chips, and they were amazed at what they really could afford that would be good for them,” she says.

Broussard applauds the garden program for its simple approach to issues of nutrition, exercise, and reconnection with traditional spiritual value, and a fourth benefit:

“It’s awesome. They’ve brought back gardens as a way to bypass that American ‘get-it-quick’ culture that sets us up for diabetes, heart disease, and all kinds of trouble.” ■

Natural approaches for erectile dysfunction

Many drugs unsuitable for some men with diabetes

Approximately 60% of men with diabetes experience occasional to complete erectile dysfunction (ED). Viagra works for only about 60% of them, and it is contraindicated in many who use nitrosamines for angina.

They’re flocking to waiting rooms full of despair, looking for an oasis in their sexual desert, and clinging to any hope — even those born of late-night television commercials promising this or that herbal formulation works just as well as Viagra.

So what can you do about this emotionally distressing problem in millions of men?

The unfortunate news is that there is little scientific evidence validating herbal remedies or dietary supplements for impotence.

The good news is that almost anything can work, says endocrinologist **Bruce Bower**, MD, FACP, LACP, MACE, clinical professor of medicine at the University of Connecticut in Hartford.

“There is a tremendous amount of placebo

KEY POINTS

- Approximately 60% of men with diabetes suffer from erectile dysfunction. Many of them seek herbal remedies and dietary supplements for this condition.
- Some remedies may have some beneficial effects, and some remedies in conjunction with others may produce positive results.
- Testosterone testing is an essential first step, say experts.
- Health care professionals also should note that placebo effects may make any remedy helpful.

effect in these things, so whether it is actually effective, or it’s placebo, or it’s a combination of the two, everything contributes,” says Bower.

Erectile dysfunction is common in men with diabetes because of microvascular complications and peripheral nerve damage that frequently accompany the disease.

Few men will raise the issue with their physicians, perhaps out of embarrassment, says Bower, so the problem may be even more widespread than is generally acknowledged.

Even with physiological factors that may effect erectile function, fear of failure and other psychological factors may worsen a minor problem. When a man complains of ED, the first step should be to order a testosterone level to make sure it is normal, says **John Seibel**, MD, FACP, MACE, an Albuquerque, NM-based endocrinologist.

“If testosterone levels are subnormal, supplemental testosterone may take care of the problem,” says Seibel. “But in men with diabetes, there is usually a dual problem of neuropathy and microvascular damage, so it gets more complicated.”

Aerobic exercise can help

Whatever the cause, says Seibel, regular aerobic exercise is perhaps the single most effective way of addressing ED in men with diabetes, and it can be a powerful motivating factor.

Not only does aerobic exercise address circulatory issues, it is enormously helpful in controlling blood sugar, says **Ken Snow**, MD, director of the sexual function clinic at Boston’s Joslin Diabetes Center.

“Anything that helps control blood sugar will

have a positive effect on erectile function,” he points out.

A recently published study from New England Research Institutes in Watertown, MA, shows that healthy men who burn 200 calories or more a day in aerobic exercise cut their risk of ED in half.¹

“I wouldn’t be surprised if that would generally apply to men with diabetes, too,” says Snow.

Seibel adds that sexual dysfunction is relatively common, although rarely discussed, among women with diabetes. The underlying causes, he says, are the same as the causes of ED in men: microvascular complications and neuropathy.

For those patients you can’t persuade to get out on the basketball court or to run track with the suggestion they may prevent or alleviate ED, here is the best available information on the herbs and supplements they may bring to your office:

Yohimbe

Made from the bark of a tall African tree, yohimbe is widely used in the United States for ED and as an aphrodisiac. It also is commonly included in multiherb formulas.

While there are virtually no data on the safety or efficacy of yohimbe itself, there have been numerous studies on yohimbine, an indole alkaloid, which is one of the major constituents of yohimbe. Prior to the introduction of Viagra, yohimbine hydrochloride was a commonly prescribed pharmaceutical for male sexual dysfunction.

The Commission E monograph reports a few studies showing the usefulness of yohimbine for impotence, especially for those of vascular, diabetic, or psychogenic origins, to improve the staying power of erections, usually without increasing sexual excitement. Reported side effects include dizziness, nervousness, and anxiety.²

“I have seen some success with yohimbine and it may be even more effective if used in combination with vitamins or other remedies,” Bower says.

Ginseng

While various subspecies of the plant *Panax ginseng* are used as a general tonic and there has even been recent evidence that it may be helpful in controlling blood sugar, there is little evidence that ginseng is helpful as a specific treatment for erectile dysfunction.

One Korean study suggests it may be effective,³ and the German Commission E monographs say clinical data support its use as a prophylactic and restorative agent for enhancement of mental and physical capacities. . . .”

Horny goatweed (Avena sativa)

Little is known about this herbal agent widely used in traditional Chinese medicine and touted as “natural Viagra.” There are no English-language trials using horny goatweed.

Writing in CTCC’s companion newsletter *Alternative Medicine Alert* (February 2000, pp.19-22), **Michael Cirigliano**, MD, FACP, assistant professor of medicine at the University of Pennsylvania School of Medicine in Philadelphia, says health care professional should discourage the use of horny goatweed because of lack of evidence for its efficacy and the suggestion it may act as a vasodilator, which may be contraindicated for patients using anti-hypertensives and nitrates.

L-arginine

An amino acid used by many patients as an adjunct to therapies for high cholesterol, l-arginine has gained a reputation for enhanced sexual function.

One small clinical study suggests dramatic improvement in sexual function with the use of a supplement called ArginMax, which contains l-arginine, ginseng, *Ginkgo biloba*, antioxidants, vitamin B complex, and minerals such as zinc and selenium.⁴

Researchers theorize that l-arginine is broken down to nitrous oxide which relaxes blood vessels and helps improve blood flow to the penis.

“I think it’s worth trying and worth studying further, since three-fourths of the men with ED reported improvement in their overall sex lives,” says lead author **Thomas Ito**, MD, assistant professor of surgery at the University of Hawaii in Honolulu.

Vitamin supplementation

Many men are using vitamin therapy on the theory that nutrient deficiencies may be responsible for decreased sex drive. Some are using vitamin A because it is an antioxidant and on the theory that it contains the precursor to testosterone (there are no clinical studies to support this theory).

Some men use large doses of vitamin C to boost circulation to the genital area and some takes doses of B vitamins to help calm nerves. Excessive dosages of vitamins, however, can be toxic and lead to a number of adverse physiologic effects.

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FDA may take regulatory action against Synthroid

Natural alternatives are available

The U.S. Food and Drug Administration (FDA) has told Abbott Laboratories of Abbott Park, IL that its thyroid drug Synthroid may be taken off the market after years of regulatory disputes, but a Florida physician is reminding health care practitioners that if this should happen, there is a safe, effective alternative that comes from natural sources.

“Armour Thyroid, taken from bovine and porcine thyroids, has been around for 50 years. I have used it in thousands of patients without

KEY POINTS

- Regulatory squabbles between the manufacturer and the Food and Drug Administration could remove Synthroid, synthetic thyroid hormone, from the market as early as this month.
- Natural thyroid hormone, commonly called Armour Thyroid, is available and has been on the market for more than 50 years.
- Recent research shows natural hormone may be even more effective than synthetic version in combating mood swings and depression common in patients with hypothyroidism.

CE questions

5. Why might patients not tell physicians of CAM use?
 - A. Patients fear ridicule.
 - B. Patients believe CAM treatments are natural and free of adverse effects.
 - C. Patients aren't asked specifically about use of CAM therapies.
 - D. all of the above
6. More patients seek CAM therapies for relief of which condition?
 - A. arthritis
 - B. low back pain
 - C. musculoskeletal pain
 - D. myofascial pain
7. The Bad River Chippewa's gardening project offers which of the following benefits?
 - A. exercise
 - B. better diet with fresh produce
 - C. connection to traditional lifestyle and spiritual practices
 - D. all of the above
8. Which of the following herbs might a diabetic patient with erectile dysfunction be using?
 - A. yohimbe
 - B. ginseng
 - C. horny goatweed
 - D. all of the above

incident in my 40 years of practice,” says **Sanford Siegel, MD, DO**, a Miami physician.

In fact, Siegel says, Armour Thyroid may be superior to synthetic thyroid hormones because research has shown patients who have taken the natural version have clear improvements in neuropsychological function, cognition, and mood.^{1,2}

Some are unfamiliar with older treatments

Extracts of animal thyroid tissue, first used in 1892, contain both thyroxine and triiodothyronine and were the only available treatment for hypothyroidism for 50 years.

Because of concern about their variable

potency, animal-based thyroid extracts have fallen into disuse since synthetic thyroid hormones became available.

"Younger doctors haven't even heard of natural thyroid," Siegel says. "Yet, there are thousands of patients who swear they do far better on the natural hormone than on the synthetic. There is no need for anyone to panic. If Synthroid becomes unavailable, the patient can easily be switched to natural thyroid, and in my opinion, they will respond even better."

The FDA's concerns about Synthroid, which has been in use for 42 years and is the third most frequently prescribed drug in the United States, raise the possibility that regulatory action could be taken against the manufacturers of the drug as early as mid-August.

Eight million Americans use Synthroid (levothyroxine), but it has never been subjected to the FDA testing and approval process.

FDA asking for new drug application

The FDA said four years ago that makers of thyroid medications like Synthroid needed to get FDA approval to continue marketing them. Abbott Laboratories, which acquired Synthroid manufacturer, BASF Pharma/Knoll in March, was informed by the FDA in April that it must file its own petitions to give Synthroid the generally recognized as safe and effective designation.

For its part, Abbott Laboratories says it intends to submit a new drug application to the FDA.

"Like other drugs that were marketed before 1962, Synthroid and all other levothyroxine sodium products did not receive formal approval from the FDA. . . . In 1997, Knoll, the manufacturer of Synthroid at the time, filed a citizen petition requesting that FDA acknowledge that Synthroid be given a legal designation 'generally recognized as safe and effective,'" the company said in a written statement in early June. The statement says Abbott intends to submit similar applications.

"The safety and efficacy of Synthroid has been extensively studied and validated. . . . The place of Synthroid in clinical practice is well-established as a trusted therapy by physicians," the Abbott statement continues.

Albuquerque, NM, endocrinologist **John Seibel**, MD, FACP, MACE, says he prefers synthetic thyroid because it is 100% T4 hormones, compared to Armour thyroid, which is composed of T3 and T4.

"T3 has a half-life of seven hours, and T4 has a half-life of seven days. Since you never know exactly how much T4 you are getting, it could cause a problem, especially in patients with angina. To be sure, patients on Armour Thyroid should take half their dosage in the morning and half at night," says Seibel.

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Editorial Questions

For questions or comments, call **Paula Cousins** at (816) 960-3730.

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Editor: **Kathleen Barnes**, (828) 883-5695.

Vice President/Group Publisher: **Brenda Mooney**, (404) 262-5403, (brenda.mooney@ahcpub.com).

Editorial Group Head: **Leslie Coplin**, (404) 262-5534, (leslie.coplin@ahcpub.com).

Managing Editor: **Paula Cousins**, (816) 960-3730, (paula.cousins@ahcpub.com).

Senior Production Editor: **Ann Duncan**.

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NEWS BRIEF

How would you like a sugar-free sports drink?

Sugar-free drinks may be the buzzword of the day, but a West Palm Beach man and his partner have taken the idea a little farther and added their own personal mission to it.

Until very recently, there were no sugar-free, carb-free sports drinks on the market that an athlete with diabetes could guzzle after a workout.

Alan Posner decided to change all that. Since he was diagnosed with Type 2 diabetes 11 years ago, Posner has struggled to create a diet and exercise routine that keeps him in top form.

Posner joined a gym, consulted a dietitian, and lost 80 pounds after he was diagnosed. But his frustration with sugary sports drinks grew.

Finally, he and his partner, Mark Streisfeld, went to research labs for help in developing a sugar-free, carb-free sports drink that replaces electrolytes like potassium that are lost during exercise.

The result: ChampionLyte, which contains no sugar, no calories, no saccharin, no sorbitol, aspartame, caffeine, or carbonation. What it does contain is a blend of water, citric acids, isotonic salts, flavor, acesulfame potassium, potassium sorbate, sodium benzoate, and color additives.

Posner was so concerned with the quality of his product that he asked Miami's Diabetes Research Institute, affiliated with the University of Miami, to test it. The institute sampled and tested ChampionLyte and agreed to put its endorsement on the label.

It's now available in New York and Florida in 20-ounce bottles in five flavors. Posner says he has plans to broaden distribution in the coming months.

Case lots of ChampionLyte can be ordered wholesale from Jamb Supply at (800) 237-1804. ■

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CE objectives

After reading *Complementary Therapies in Chronic Care*, the health care professional will be able to:

1. Identify management, clinical, educational, and financial advantages of complementary therapies for chronic care.
2. Describe how those therapies affect chronic patients and the providers who care for them.
3. Describe practical ways to incorporate complementary therapies into chronic disease management based on independent recommendations from clinicians at individual institutions. ■