AMERICAN HEALTH CONSULTANTS®

1999 Reader Survey enclosed in this issue

DISEASE STATE MANAGEMENT™

Managing Chronic Illness Across the Continuum

INSIDE

■ ***Inserted in this issue:***
— Provider resources from the Nutrition Screening Initiative

JUNE 1999

VOL. 5, NO. 6 (pages 61-72)

American Health Consultants® is A Medical Economics Company

Nutrition screenings take a bite out of disease management costs

Using simple checklist can improve patient health

Grandma was right: An apple a day keeps the doctor away. In fact, studies prove that adding routine nutrition screening and intervention to your pathways deliver the competitive edge you need to position your disease management programs above others in your market. These are low-cost services with a proven track record of reducing medical costs and improving overall health in the chronically ill.

If you doubt the necessity and potential benefits of adding routine nutrition screening and intervention into your disease management initiatives, consider these findings from several recent studies:

- More than 80% of elderly Americans have one or more chronic conditions known to benefit from nutrition intervention.[1]
- Medical nutrition therapy for hypertension can result in an estimated cost savings of roughly $4,075 per case through a reduction in drug use and by the prevention of drug-related complications, such as stroke.[2]
- Elderly patients with diabetes and/or cardiovascular disease who use the services of a dietician decrease the frequency of their physician visits and their use of hospital services.[2]
- Hospital costs for patients at nutritional risk were $12,683, or four times greater than the $2,968 price tag for patients who were well nourished.[3]

KEY POINTS

- Nutrition screening and counseling are simple, cost-effective services that can be added to any disease management program.
- Malnourished patients are more vulnerable to infection, heal more slowly, and have longer hospital stays.
- Studies have found that improving the nutrition status of patients decreases their medical costs.

• The consistent and appropriate use of medical foods for hospitalized patients prevents complications in the treatment of the critically ill and injured. The routine provision of medical foods or nutritional supplements could save an estimated $1.3 billion in health care dollars in a seven-year period.[4] **(See related story on p. 65 for one health plan's nutrition program success story.)**

"People with sub-optimal nutrition status — particularly the elderly — run a greater risk of falls, disease exacerbation, or at the very least, have compromised immune systems that cause them to get sick more quickly," says **Janis M. Verderose**, RD, MS, CDN, ACCA, manager of clinical outcomes for Prime Care 2000, a large medical practice group in Albany, NY.

"Malnourished chronically ill patients often succumb to their disease or develop co-morbidities that better-nourished patients are able to fight."

As easy as ABC

Assessing your patient's nutrition status is simple. The Nutrition Screening Initiative (NSI) in Washington, DC, developed the DETERMINE checklist, a screening tool that can be used by consumers or providers to evaluate nutrition risk. **(See checklist on p. 63.)**

"When providers first look at the DETERMINE checklist, the language is so simple their first reaction is, 'Oh, I won't learn anything valuable from this.' But to reach your patients and get them to understand what you are asking, the language must be simple," notes **Jane V. White**, PhD, RD, LDN, professor in the department of family medicine at the Graduate School of the School of Medicine at the University of Tennessee in Knoxville and president-elect of the American Dietetic Association in Chicago.

Ironically, the checklist has proven not only to be an effective initial screen of nutrition risk, but has also proven to be an excellent indicator of chronic depression, adds White. "Depression has a big impact on nutrition status and chronic disease. Often, people who score high on the checklist have multiple problems."

The checklist is now incorporated into roughly 60 health plans, says **David A. Smith**, MPP, director of NSI.

"So many chronic disease are directly related to nutrition status — diabetes, high blood pressure, cardiac disease — that assessing nutrition status in patients, especially elderly and/or chronically ill patients, should be an institutionalized part of health care in this country," Smith says. "NSI wants providers to look at the chronically ill and see the whole person, not just the disease. In other words, don't focus on sodium alone when you counsel congestive heart failure (CHF) patients about diet."

NSI has developed a nutrition care manual for patients with chronic disease. **Some of the materials in the manual appear in the supplement inserted in this issue.**

In addition, many chronic conditions respond well to nutrition intervention alone. "Diabetes is an obvious example," says Verderose. "Nutrition intervention can go along with pharmacological intervention or be given a trial as the first step. For example, why not recommend a controlled diet for coronary artery disease before writing a prescription for a lipid-lowering drug? Nutrition intervention is less expensive and often provides greater quality of life."

If you're not ready to add even a simple screening tool to your arsenal, you should, at the very least, measure the height and weight of your patients a minimum of every five years, says White. Some, like CHF patients, should be weighed more often.

"We measure the height and weight of young children every time they come into a pediatrician's office, yet too many providers forget to take routine measurements of height and weight for adults," she notes.

"A decline in height is an early symptom of osteoporosis, but too many providers simply ask patients their height without taking a

COMING IN FUTURE MONTHS

- Future watch: New therapy helps the body build its own immunity to chronic illness
- Who is qualified to direct your disease management efforts?
- Find out whether your noncompliant patient is really suffering from mental illness
- Why your next initiative should focus on allergy management
- Acid reflux, GERD can trigger asthma attacks

DETERMINE Checklist

Read the statements below. Circle the number in the yes column for those that apply to you or someone you know. Then, total your nutritional score.

	Yes
I have an illness or condition that made me change the kind and/or amount of food to eat.	2
I eat fewer than 2 meals per day.	3
I eat few fruits or vegetables, or milk products.	2
I have 3 or more drinks of beer, liquor or wine almost every day.	2
I have tooth or mouth problems that make it hard for me to eat.	2
I don't always have enough money to buy the food I need.	4
I eat alone most of the time.	1
I take 3 or more different prescribed or over-the-counter drugs a day.	1
Without wanting to, I have lost or gained 10 pounds in the last 6 months.	2
I am not always physically able to shop, cook and/or feed myself.	2
	TOTAL

DETERMINE YOUR NUTRITIONAL HEALTH

Total Your Nutritional Score. If it's —

0-2 Good!
Recheck your nutritional score in 6 months.

3-5 You are at moderate nutritional risk.
See what can be done to improve your eating habits and lifestyle. Your office on aging, senior nutrition program, senior citizens center or health department can help. Recheck your nutritional score in 3 months.

6 or **more** You are at high nutritional risk.
Bring this checklist the next time you see your doctor, dietitian or other qualified health or social service professional. Talk with them about any problems you may have. Ask for help to improve your nutritional health.

Source: The Nutrition Screening Initiative, Washington, DC.

measurement. Involuntary weight change can be an ominous sign of impending problems from cancer and heart disease to depression and poor oral health," says White. "By simply improving our patients' diets, we can intervene early and prevent serious complications."

The long and short of it

Even bedridden patients should be routinely weighed and measured, adds **Albert Barrocas**, MD, FACS, a general surgeon and medical director of nutrition support and home health services at Pendleton Memorial Methodist Hospital in New Orleans.

"We must start looking at height and weight as routine vital signs, just as we do blood pressure and temperature," he says. "You wouldn't let your patients walk in and tell you their blood pressure based on a reading now five years old. You wouldn't simply ask patients what their temperature is today. You shouldn't do that with their height and weight."

Barrocas screens all of his new surgical patients using the DETERMINE checklist. "The receptionist helps patients fill it out. If there are any positive findings, my LPN addresses them, or brings them to my attention. I don't know of any condition or disease where starvation is a recommended therapeutic modality. If my patients are malnourished, I want it taken care of before surgery."

The relationship between chronic disease and nutrition is symbiotic, Barrocas says. "Poor nutrition may contribute to the disease, or perhaps, the disease interferes with appropriate nutrition. Nutrition is the basis of all physiologic and structural functions of the body, and it also plays a role in the pathology. Nutrition, put simply, can either cause or contribute to chronic disease but must always be considered," he says.

Even very healthy patients can be at nutrition risk, White notes. "Women who are running or

Group applauds diabetes, blood pressure measures

But nutrition parameters are still needed

The Nutrition Screening Initiative (NSI) in Washington, DC, recently responded to proposed changes to the National Committee for Quality Assurance's (NCQA) Health Plan Employer Data and Information Set (HEDIS).

In its response, NSI applauded NCQA's addition of specific measures for diabetes and high blood pressure, yet at the same time, criticized HEDIS 2000 for its lack of specific nutrition parameters:

"It is clear that NCQA is concerned about controlling these and other chronic conditions. However, by omitting specific nutrition parameters from HEDIS, NCQA has missed an opportunity to give health plans the incentive to use the most cost-effective and least invasive therapies available. Furthermore, this omission could unwittingly increase pharmacological interventions — driving up health care costs and denying patients the opportunity to manage chronic conditions with the highest-quality therapies.

"Nutrition interventions — particularly in the areas of diabetes and blood pressure — have been held to scientific rigor; they are researched, peer reviewed, and published. The data on the efficacy of disease-specific nutrition care and geriatric nutrition screening and interventions are extensive." ■

exercising vigorously without adequate calcium intake, or who have a low percentage of body fat, which alters their estrogen production, run a high risk of developing osteoporosis early in life. By routinely measuring height and weight, providers can catch changes in height early enough to intervene before these women develop vertebral fractures."

White says providers can also catch early signs of malnutrition by simply looking at routine laboratory reports with new eyes.

"Providers are already receiving useful information about nutrition from the routine screens taken to monitor chronic conditions, but they simply don't think of the data in terms of nutrition risk," she says.

For example, one of the most sensitive indicators of initial nutrition status in an ambulatory population is serum albumin level.

"A serum albumin level of less than three is associated with poor outcomes for a number of diseases, including pneumonia, CHF, failure to thrive, and chronic obstructive pulmonary disease," notes White. "I think it's important as providers look at blood pressure, blood sugars, and lipids that these are as much an indicator of nutrition status as of disease state. And, also remember that poor nutrition definitely could adversely affect the disease state being monitored."

Nutrition screenings are on report cards

Health plans and providers that add nutrition into their disease management initiatives also may improve their scores on managed care report cards and accreditation surveys. The Health Plan Employer Data and Information Set (HEDIS) and the National Committee for Quality Assurance (NCQA) in Washington, DC, do not yet have specific performance measures for nutrition care and screening; however, the standards do include implications for nutrition. For example, NCQA and the Joint Commission on Accreditation of Healthcare Organizations in Oakbrook Terrace, IL, both require health plans and providers to demonstrate the delivery of preventive health services, an area where nutrition can clearly play a significant role. **(See box on left for a recent statement from NSI to NCQA about proposed changes to HEDIS 2000.)**

And remember, sometimes the simplest interventions are the most effective. "When a patient walks in with a complaint, nutrition is not the thing that providers consider. Sometimes, we neglect the simple things that can have a big impact on health outcomes," says White.

Barrocas agrees that providers should always ask patients about their nutritional status. "If you don't care to use the DETERMINE checklist, at least ask several questions directly related to nutrition." He suggests providers ask:

- **Who last asked you about your nutrition?**
- **Who does the shopping and cooking at your house?**
- **How many medications are you taking?**
- **Are you taking your medications as prescribed?**
- **Are you taking any medications that have not been prescribed by a physician?**
- **What do you normally eat each day?**

Resources

The following groups offer a wide range of free or low-cost provider and consumer resources on nutrition:

- The Nutrition Screening Initiative, 1010 Wisconsin Ave., Suite 800, Washington, DC 20007. Telephone: (202) 625-1662. Fax: (202) 338-2334.
- The Nutrition Institute of Louisiana, 5620 Read Blvd., New Orleans, LA 70127. Telephone: (504) 244-5078. The institute has a consumer brochure and poster set that helps professionals teach patients the basics of good nutrition, including tips for interpreting the food pyramid.
- The American Dietetic Association, 216 W. Jackson Blvd., Suite 800, Chicago, IL 60606. Telephone: (312) 899-0040. Or, telephone the ADA's National Center for Nutrition at (800) 366-8114. Web site: www.eatright.org. The ADA is currently completing an education module on dietary supplements, due out in early fall. ■

• What dietary supplements are you taking?

"Dietary supplements often interfere with the absorption of food and prescription medicines, yet few providers ask questions about supplements," notes Barrocas. "Two-thirds of patients try integrative therapies without telling their physicians. Don't leave out questions about supplements." **(For more information on herbal supplements, see p. 66.)**

References

1. Peter D. Hart Research Associates. National survey on nutrition screening and treatment for the elderly. Washington, DC; 1993.
2. Lewin Group. The cost effectiveness of covering medical nutrition therapy under Medicare: 1998 through 2004. *J Am Diet Assoc* April 1997.
3. Reilly JJ, et al. Economic impact of malnutrition: A model system for hospitalized patients. *JPEN* 1988; 12:371-376.
4. Barent's Group: Peat Marwick. The clinical and cost effectiveness of medical nutrition therapy: *Nutrition Screening Initiative.* Washington, DC; 1996.

Note: The Nutrition Screening Initiative is a project of the American Academy of Family Physicians, The American Dietetic Association and the National Council on the Aging. It is sponsored by Ross Products Division of Abbott Laboratories. ■

Chew on this: Program delivers 538% return

NY practice gets its just dessert

Oxford Health Plan, an independent practice association (IPA) in White Plains, NY, implemented a simple nutrition screening and intervention program that delivered a more than 500% return on its investment.

The IPA screened its Medicare members in the mid-1990s using the DETERMINE checklist developed by the Washington, DC-based Nutrition Screening Initiative.

The initial screening effort found that 22% were at high nutritional risk and another 30% were at moderate nutrition risk. **(The DETERMINE checklist appears on p. 63. See also related stories on nutritional screening on pp. 61 and 64.)**

Registered dietician consults with patients

The health promotion department mailed at-risk members nutritional information, or directed them to appropriate community resources, based on their levels of need.

Members found at risk were managed through both clinical and nonclinical interventions. Oxford developed a structured benefit for a nutrition visit with a contracted registered dietician.

However, most of the at-risk Oxford members were helped by simply tapping into underused community services such as Meals-On-Wheels and Congregate Meals.

Intervention costs 21 cents per person

The IPA's outreach department used a tracking form to evaluate whether or not the intervention goals were met for the high-risk members, which programs or interventions members used, and the impact of nutrition on health outcomes.

For a cost of only 21 cents per member per month, Oxford experienced a post-intervention decrease in the number of claims, claim dollars, and emergency department visits in its Medicare members that resulted in an overall 538% return on its investment.

Nutrition screening and appropriate nutrition interventions are now a routine practice at Oxford. ■

KEY POINTS

- Chronically ill patients face risk of potentially dangerous herbal supplement / prescription medication reactions.
- Herbal supplements are rising in popularity, but remain unregulated and widely available to consumers.
- Few providers routinely question their patients about their use of herbal supplements.
- Providers should educate themselves and their patients about the potential benefits and risks associated with herbal supplements.

Are your chronically ill patients turning to herbs?

Some cause potentially dangerous interactions

If chronically ill patients become disenchanted with Western medicine, they often turn to alternative therapies, including herbal remedies and supplements.

"When Western medicine doesn't offer patients an acceptable solution, many start looking for anything that will help them," says **Doug Murray**, PharmD, director of pharmacy and clinical services at Kershaw County Medical Center in Camden, SC, and an adjunct professor at the University of South Carolina College of Pharmacy in Columbia.

Will your patient tell you?

Murray says he also has seen an increase in use of and interest in herbal medicines.

"I see a steady increase in questions from physicians who have patients taking herbs," he says. "They want to know about possible interactions with drugs their patients are taking."

The real risk lies in patients who don't inform their physicians about their herb use, Murray notes.

"Many patients are reluctant to talk to their physicians and care providers about taking herbs. They often feel as if they are doing something their health care providers might not approve of," he says. "Patients have this guilt about herb

Herbs 101: Resources offer good info

Providers who want to learn more about herbal remedies, should consider starting on-line, says **Doug Murray**, PharmD, director of pharmacy and clinical services at Kershaw County Medical Center in Camden, SC. The adjunct professor at the University of South Carolina College of Pharmacy in Columbia says the Internet has several useful sites. These include:

- **www.egregore.com:** This site, called Medicinal Herbs On-line, lists more than 100 diseases and 125 herbs, including extensive descriptions of each. Both diseases and herbs are alphabetized.
- **altmed.od.nih.gov/oam:** This is the Web site for the Office of Alternative Medicine at the National Institutes of Health in Bethesda, MD. Murray notes he has referred to this site for useful information. For other resources available from this government office, contact OAM, 9000 Rockville Pike, Bldg 31, Room 5B-38, Bethesda, MD 20892. Telephone: (800) 531-1794, or (301) 402-2466. Fax: (301) 402-4741.

Scientific and technical journals

In addition to Web sites, Murray notes several publications regularly publish information on herbal remedies. They include:

- ***Professional Journal of Botanical Medicine;***
- ***Alternative Therapies in Health & Medicine;***
- ***Herbs for Health;***
- ***Nutrition Forum;***
- ***Nutrition Science News;***
- ***The Journal of Alternative and Complementary Medicine;***
- ***Alternative Medicine Alert*** **and** ***Alternative Therapies in Women's Health.***

The scientific "gold standard" for information on herbal supplements is the American Botanical Council translation of the *German Commission E Monographs* published in 1996, says Murray. "This is a source many pharmacists, myself included, keep on hand and refer to." ■

Share this advice about supplements with patients

The rapid rise in the popularity and use of herbal supplements in the past few years has sparked a great deal of concern in the health care community.

At a recent professional meeting of hospital pharmacists in South Carolina, **Doug Murray**, PharmD, director of pharmacy and clinical services at Kershaw County Medical Center in Camden, SC, and an adjunct professor at the University of South Carolina College of Pharmacy in Columbia, received the following guidelines on herbal use, which he suggests providers share with their patients:

1. Do not take herbal supplements if you are pregnant or trying to conceive.

2. Do not take herbal supplements if you are lactating.

3. Do not give herbal supplements to infants and young children.

4. Herbal supplements are not miracle drugs. Maintain realistic expectations about the benefits of herbal supplements.

5. Use standardized products when available. Products should have the scientific name and quantity of the botanical clearly identified on the label. The name and address of the manufacturer, lot numbers, and expiration date should also be clearly marked on the label.

6. Stop taking a product immediately if adverse effects occur. ■

use. They also often don't feel that herbs are medicine. They think of herb use as something natural that they are doing for their health."

Congress paved the way to ensure herbal supplements don't have to go through the expensive and rigorous drug-testing process in the United States through passage of the Dietary Supplement and Health Information Act in 1994. When concerned consumer advocates, pharmaceutical representatives, nutritional supplement manufacturers, and health care professionals debated whether herbs were drugs or dietary supplements, the non-drug advocates won. As a result, herbs are not government regulated, meaning anyone with a garden can grow their own herbs and sell them.

A worst-case scenario occurred in 1989 when an outbreak of eosinophilia-myalgia syndrome (EMS) in the United States was associated with the use of L-tryptophan, an over-the-counter dietary supplement used for weight loss. There were more than 1,500 cases of EMS, including 38 deaths, reported to the Atlanta-based Centers for Disease Control and Prevention, according to the U.S. Food and Drug Administration (FDA) in Washington, DC. Some people with EMS experience severe pain and bleeding.

More than 95% of these cases were traced to L-tryptophan supplied by Showa Denka K.K. of Japan. Researchers found some trace-level impurities, suggesting that a contaminated batch contributed to the outbreak. The FDA limited the availability of L-tryptophan supplements, including enforcing an import alert, because of the outbreak.

Products vary by manufacturer

While this type of danger rarely occurs with food supplements and herbal remedies, health care professionals still advise people to avoid purchasing these products from unfamiliar manufacturers. Recently, several major drug manufacturers started producing herbal remedies, so consumers now have choices that include manufacturers with a proven track record, Murray adds.

Providers should urge patients to look for the word "standardized" on the label of their herbal supplements, says **Cyndi Thompson**, PhD, RD, clinical nutrition research specialist at the University of Arizona at Tucson. "Basically, that term means that the product has gone through some analysis to determine its activity."

"One very real problem with supplements that providers should make clear to their patients is that with supplements, what is on the label isn't what's actually in the bottle," Thompson notes. "At least with standardized products, patients are more likely to get what they think they are paying for."

'Put my St. John's Wort on the side'

Herbal supplements are even finding their way into the food supply. Recently several natural food companies have introduced such products as tortilla chips with St. John's Wort and dried ginseng rings.

This surge in the popularity of herbal

supplements has caused concern among providers, because patients may experience dangerous side effects by combining herbs with their prescription medications.

"We found that a lot of patients' doctors were not even aware that their patients were using herbs," says **Kathleen Hughes**, RN, director of home care for Kershaw County Medical Center Home Health Care in Camden, SC. "We have seen such an increase on medication sheets of people taking herbs."

Hughes explains that the agency's nurses record herbs along with prescribed drugs on patients' medication sheets.

"Our concern was how these herbs might be interacting with the patient's other medication," she says. "How could we teach patients what's going on with their medicines?"

What else are you taking?

"If providers take a hard line or defensive approach when discussing different supplements, their patients are going to simply clam up and not share information about the supplements they may be taking," adds Thompson. "That could result in a very detrimental situation. Providers must listen to their patients and provide them with logical information regarding supplement use."

Murray says his hospital now formally asks every patient on admission for a complete medication history, which includes vitamins, over-the-counter and herbal products.

He says it's important for all providers to do the same, but also consider the possibility of herbal supplements when patients report new or unexpected changes in their health status.

"There are some developments that should tip you off, or at least cause you to question the possibility of herbal use," he notes. "For example, if a patient is doing well for several months on blood pressure medication and then suddenly, their medication no longer controls their hypertension. You have to start asking questions. It's like being a detective." **(For more recommendations on the management of your patient's use of herbal supplements, see boxes on pp. 66 and 67.)**

Of course, in addition to possible herbal use, there is the possibility that the patient has stopped taking an old prescription or started a new one, he says. Questions he suggests providers ask their patients include:

• Have you stopped taking any medications or added any new medications since you experienced these symptoms?

• Have you started taking any new vitamins or herbal supplements, or stopped taking any vitamins or herbal supplements since you have experienced these symptoms?

• Have you recently tried a new over-the-counter medication?

Providers should always ask their patients why they are taking herbal supplements, adds Thompson.

"They may be experiencing a problem that you can suggest other solutions for," Thompson notes. In addition, she suggests providers get good answers to questions about how much of the supplement patients are taking.

Cause for concern

American medical journals are taking notice of the trend, Murray notes. The *Archives of Internal Medicine* had a review article on herbs as medicine in its Nov. 9, 1998, issue, and American Health Consultants, publisher of *Disease State Management*, publishes entire newsletters (including *Alternative Medicine Alert* and *Alternative Therapies in Women's Health),* devoted to herbs and other alternative remedies. Articles on herbal supplements have also appeared in recent issues of such reliable, peer-reviewed journals as the *American Journal of Health Services Pharmacy.*

"Look for information in peer-reviewed scientific journals. More information is coming out, and I find most of the information I use in current journals," says Murray, who has prepared lectures for pharmacy students on herbal remedies.

A great deal of research is available on herbal remedies. For years in Germany, herbs have been prescribed by physicians and covered by insurance companies.

"The Germans are the backbones of this," Murray notes. "They've done the research and it's been published. The Germans also have a lot of standard review textbooks that are accepted now in the United States."

Know side effects, interactions

Murray has educated himself on herbal remedies, their side effects, and how they interact with prescription medications. He suggests providers learn about these basic herbal remedies and how they might adversely affect patients' health:

• **Feverfew:** This herb is used for prophylactic treatment of migraine headaches. Pregnant

Caution: Avoid these supplements at all costs

Some herbal supplements pose a potential risk of adverse herb / prescription interactions. Other botanicals should be avoided altogether because they are not safe, cautions **Doug Murray**, PharmD, director of pharmacy and clinical services at Kershaw County Medical Center in Camden, SC, and an adjunct professor at the University of South Carolina College of Pharmacy in Columbia.

These herbs might still be found in some stores, or people could find them in the wild, he says. They include:

- **Blue cohosh:** The black cohosh is safe, but the blue cohosh is believed to increase a person's blood pressure and provoke angina.
- **Chaparral:** It's carcinogenic and toxic.
- **Comfrey:** This is potentially a hepatotoxin. It damages the liver and is carcinogenic when taken internally. People sometimes use it to promote bone healing, Murray notes.
- **Deadly nightshade:** As its name suggests, this herb should be avoided because it can be poisonous and produces chemicals similar to atropine, which is used as an anticholinergic.

Murray says he also worries about people buying herbs from questionable sources, such as small, fly-by-night manufacturers, because the quality and even the actual ingredients may not be inspected. **(A list of herbal usage guidelines providers may wish to share with patients appears on p. 67.)** ■

women should avoid it. It also can slightly increase a person's heart rate, Murray says. Because of this potential side effect, medical experts now think people should avoid using feverfew if they are taking any of these medications: calcium channel blockers; ticlid, an antiplatelet drug, or Coumadin.

"With these drugs, you could have a potentiation of the effects, so it's something to be careful about," Murray says.

- **Garlic:** Garlic pills, pushed as the great cholesterol reducer on radio and television advertisements, can also decrease blood pressure, as well as cholesterol. "There are some warnings that people who take anticoagulants like Coumadin while taking garlic may increase their chance of bleeding," Murray says.
- **Ginkgo biloba:** This herb has received a lot of news coverage recently about its ability to increase circulation to the brain and extremities. Some researchers claim it might be a good antioxidant, and they're studying it for use with Alzheimer's disease patients as a way to improve short-term memory. It's also thought to help with ringing in the ears. Less well known are its adverse side effects, which include restlessness, insomnia, nausea, and vomiting, Murray notes.

"In the literature, there are three cases of spontaneous bleeding from people taking it. Because of this, some literature is saying you shouldn't take this with heparin or Coumadin."

In addition, people who have hemophilia or von Willebrand's disease, should avoid gingko because of the bleeding potential. Experts also warn people on nitrate drugs and antidepressants to avoid the herb.

- **Asian ginseng:** "Asian ginseng is a real popular drug that is thought to increase energy, improve mood, and improve resistance to infection," Murray says. "It's the top-selling herb in the U.S., with $78 million in sales annually."

The herb has been studied for use by postmenopausal women and Alzheimer's disease patients. There are some potential adverse side effects, such as insomnia, nervousness, and irritability. Pregnant women should avoid this herb, he says. "They think people with coronary artery disease, hypertension, or arrhythmia should be cautious in taking it, also."

Research shows that Asian ginseng might interact with digoxin and increase the levels of digoxin in the blood. This could be a serious problem, because digoxin is a dangerous drug that has a narrow therapeutic window, meaning that the amount thought to be effective isn't far from the amount that is toxic, Murray explains.

Medical experts also are concerned about people taking this herb while they are on Coumadin because it also has a narrow therapeutic window.

- **St. John's Wort:** This herb has also been widely publicized in recent years. Research shows it helps alleviate depression and anxiety. Its side effects may include restlessness and fatigue.

"They say until more is known, you probably

shouldn't take St. John's Wort with prescription antidepressants," Murray says. This is because selective serotonin re-uptake inhibitors (SSRIs) like Prozac are a powerful chemical class of antidepressants that are fairly new.

Practitioners should conclude antidepressant therapy at least three weeks before patients begin taking St. John's Wort, he adds.

• **Valerian root**: People often take this herb as a sleep aid for nervous disorders. Although it appears to be safe as far as adverse side effects are concerned, medical experts advise people to take it for only one week at a time, Murray says. "If you get it really concentrated, when you make your own teas for example, it can actually decrease your blood pressure a little."

It also could cause orthostatic hypotension, the dizziness that occurs when a person who is sitting or lying down stands up quickly and loses his or her balance. For this reason, people who are taking blood pressure medications should take precautions when using valerian root.

The herb also acts in a similar way to benzodiazepines in that it has a sedative effect. For this reason, people taking the herb should be cautious about driving cars.

• **Chamomile tea:** People sometimes take chamomile tea to help settle an upset stomach or to relieve tension. The medical literature warns people who have ragweed allergies to be cautious because they might also have an allergy to chamomile.

• **Purple cone flower:** Also called Echinacea, the herb is used to improve the healing process or boost the immune system. Current medical literature suggests the herb actually does have some properties which might temporarily improve an individual's immune system.

"Some authors are thinking the effect decreases after eight weeks, so it's better to take it intermittently," Murray says. **(For a list of herbs you should caution your patients to steer clear of completely, see article on p. 69.)**

For more information on herb-prescription interactions, see: Miller LG. Herbal medicinals: Selected clinical considerations focusing on known or potential drug-herb interactions. *Arch Intern Med* 1998; 158:2,200-2,211. ■

Does the Y2K bug threaten the insulin supply?

Producers are confident, pharmacists concerned

The Y2K computer glitch could quickly create life-threatening problems if it impedes the flow of insulin from manufacturers to patients who need it on a daily basis.

The two insulin manufacturers in the United States say not to worry. Meanwhile, the American Pharmaceutical Association Foundation and industrial consultants warn a bit of concern is appropriate, advising diabetics to begin slowly to accumulate an extra 30-day supply of essential prescriptions, just to be safe.

They all agree on one thing: If health care providers, pharmacies, and patients worry too much and begin to accumulate larger stockpiles than 30 days, they could create a "self-fulfilling prophecy," resulting in a shortage of insulin.

The bottom line is that the Food and Drug Administration (FDA) is calling on pharmaceutical manufacturers to determine the vulnerability of the supply of prescription drugs in the face of the challenges presented — if computer programs won't recognize the rollover to the year 2000.

Known by the shorthand Y2K, the problem arises from older computer systems programmed to recognized the year by two digits, as in "99" for 1999, which will refuse to function in 2000 because it will be unable to distinguish it from 1900. Business and industry are urgently implementing remedies for the problem, but some won't finish before 2000, and others are dependent on vendors and those who could fail to be compliant in time.

KEY POINTS

- Insulin producers take steps to ensure insulin stream will be uninterrupted after 1999.
- Pharmacists and others express concern and recommend patients keep an extra 30 days of medication on hand.
- Producers and pharmacists fear stockpiling will make insulin shortage a "self-fulfilling prophecy."

Eli Lilly and Co. in Indianapolis, the country's largest insulin producer, expects to be fully Y2K-compliant by mid-1999 and Novo Nordisk Pharmaceuticals in New York City says its compliance will be complete by the third quarter of this year.

Utility shutdowns could cause problems

But spokeswomen for both companies caution their ability to produce insulin will be based on the assumption that computer-dependent municipal electric and water supplies remain uninterrupted.

"It's obviously a complicated issue," says **Susan Jackson**, spokeswoman for Novo Nordisk. "Our manufacturing process is very dependent on the delivery of electricity and water. If there was an interruption, all our manufacturing processes would stop and fermentation tanks would have to be emptied."

Novo's plant in Clayton, NC, will continue its ordinary insulin production, which keeps ahead by three to six months, not including "any stores already sold but not in patients' hands yet," Jackson says.

Lilly's spokeswoman, **Doyia Chadwick**, says at the beginning of the fourth quarter (Oct. 1), her company will have a 40- to 80-day supply of insulin, based on normal buying patterns. She says Lilly always has a minimum of 45 days' supply of insulin on hand. She confirms that Lilly's Indianapolis manufacturing facility could be vulnerable to any power or water system failures from its surrounding community. "We're doing everything in our means to be ready."

Both firms say they are concerned that fearful suppliers and patients may create shortages by stockpiling supplies of insulin. "We're not recommending stockpiling in any way," Jackson says. "We believe patients will have the product they need."

In a story published in the *Washington Post* on March 22, the American Red Cross recommended patients have several days to a week's supply of prescription medications on hand before the end of 1999.

Ben Bluml, RPh, the American Pharmaceutical Association Foundation's senior director for research in Washington, DC, takes a more cautious stance by recommending that consumers get a month ahead on their medications. "People should start stocking up in late summer or early fall," he says. "If people all start to get prepared ahead of time, we'll all start to feel comfortable without creating an excessive burden on the supply chain."

Bluml says health care professionals should be sure the message is delivered in a way that "ensures responsible behavior."

Bluml adds health care providers recommending their patients get an extra month's supply of insulin should be aware that health plans often restrict prescription refills to one every 30 days, so patients may have to fight for reimbursement or finance the extra medications themselves.

The ECRI (Emergency Care Research Institute), a nonprofit global think tank in Plymouth Meeting, PA, is conducting its own research on Y2K issues, largely those involving the functioning of biomedical devices, and is offering telephone seminars on preparedness for health care professionals.

[Contact Susan Jackson at (212) 867-0123, Doyia Chadwick at (317) 277-6990, and Ben Bluml at (800) 237-2742.] ■

Disease State Management™ (ISSN# 1087-030X) is published monthly by American Health Consultants®, 3525 Piedmont Road, Building Six, Piedmont Center, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodical postage paid at Atlanta, GA 30304. POSTMASTER: Send address changes to **Disease State Management**™, P.O. Box 740059, Atlanta, GA 30374.

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Subscription rates: U.S.A., one year (12 issues), $429. Outside U.S., add $30 per year, total prepaid in U.S. funds. One to nine additional copies, $257 per year; 10 or more additional copies, $172 per year. Call for more details. Missing issues will be fulfilled by customer service free of charge when contacted within 1 month of the missing issue date. **Back issues**, when available, are $72 each. (GST registration number R128870672.)

Group Publisher: **Brenda Mooney**, (404) 262-5403, (brenda.mooney@medec.com).

Executive Editor: **Park Morgan**, (404) 262-5460, (park.morgan@medec.com).

Managing Editor: **Valerie Loner**, (404) 262-5536, (valerie.loner@medec.com).

Production Editor: **Nancy McCreary**.

Editorial Questions

For questions or comments, call **Valerie Loner** at (404) 262-5536.

Surgeons focusing on the mitral valve

A change of heart for appropriate patients

A new surgical procedure may focus more attention on the role of the mitral valve in treating patients with heart failure.

The technique uses a ring to reinforce the valve so it can keep more blood from flowing backward into the left atrium. With a more efficient blood flow through the heart, patients may be able to regain cardiac performance over time. For now, the procedure may help some patients in advanced heart failure live longer, even if they are not candidates for a transplant. Researchers hope that as they learn more about who is right for the procedure, they can use it to help their patients avoid the downward spiral of heart failure.

"We think this is a viable alternative," says **Steven Bolling**, MD, a cardiothoracic surgeon at the University of Michigan Medical Center in Ann Arbor. He says when the heart enlarges during failure, its inner walls pull at the mitral valve. The pressure causes a problem, not in the organic makeup of the valve, but in the way it functions. Because it can't stay closed when it should, half of the blood that should be exiting the heart goes back into the atrium. This reverse flow becomes an obstacle to circulation the heart has to overcome.

Going in to replace the valve has meant robbing the heart of some pumping power. Because the patients were already compromised by heart failure, the loss was too much. Bolling says these patients just "have nothing more to give."

Surgeons learned to leave the valve alone when the ejection fraction (EF) was low. Bolling says this procedure is different than traditional attempts to replace the mitral valve. Instead of replacing it, his procedure involves "scrunching it down" and keeping it in place so the heart won't pull it open when it should stay closed. Better flow is restored without the loss in power.

"We are taking no function away from the heart," he says, which could make the procedure available to a broader spectrum of CHF patients.

"We have to change our thinking about these patients," he says.

He recently operated on a patient with an EF of 5. The patient came into the surgical program after living with CHF for years. Bolling says he wishes he could have performed the operation on her 10 years ago, before her quality of life declined to a point where she had to spend most of her day sitting in a chair.

It will take about two years to be more certain of the long-term benefits, Bolling says. Right after surgery, her EF probably was the same as before. But without the regurgitation, her heart has a better chance of regaining some lost ground.

Changing the way doctors think about these patients, he says, begins with understanding the relationship of valve and ventricle. Both elements are working together and should not be seen as separate parts. "We are not treating a ventricular problem with a valve solution," he says. "We are treating a ventricular problem with a ventricular solution."

In the first phase of his study, Bolling says he operated on nearly 100 patients, and 70% to 80% were alive two years after surgery (compared to about 10% if the patient didn't have the surgery). He reported his findings at the American Heart Association conference in November.

"He is getting some marvelous results," says **Mehmet C. Oz**, MD, a cardiothoracic surgeon at Columbia-Presbyterian Medical Center in New York City. Oz says his hospital has performed a dozen mitral valve procedures with similar outcomes. ■