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Managing Chronic Illness Across the Continuum

INSIDE

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The long and the short of diabetes management

Diabetics get short-term gains from tight control

Tight glycemic control can help diabetics feel better fast, according to a Harvard study that provides the third leg of a now-sturdy tripod of evidence showing control is not only the best way to go, it is really the only way to go.

Adding to the Diabetes Control and Complications Trials (DCCT) and United Kingdom Prospective Diabetes Study (UKPDS) results showing the benefits of tight control for long-term prevention of complications, the Harvard study shows even small improvements in blood glucose levels have immediate and palpable effects on quality of life and work productivity in mild to moderate Type 2 patients.

This is likely to have sweeping effects on diabetes care and on the way managed care and employers look at the disease.

"This study now rounds it out," says **Gerald Bernstein**, MD, president of the American Diabetes Association and a practicing endocrinologist in New York City. "You need to direct patients to get their blood sugars normal, without hypoglycemia, because they will function better in all ways in society."

KEY POINTS

- Patients report improvements in quality of life, energy, vitality, and mental and emotional health over the short term, with improved glycemic control.
- Even moderate changes in HbA1c result in patient reports of feeling better, improving chances of compliance.
- Improved control results in almost immediate reductions in the amount of employee sick leave.
- Improved control results in reduced frequency of doctors' office visits.
- Identification of little-recognized symptoms may result in earlier diagnosis.

Questions Patients Should be Asked

- How well are you feeling?
- Are you anxious?
- Are you depressed?
- How much energy do you have?
- Do you feel a change in your energy?
- Are you having problems sleeping?
- Do any symptoms bother you such as **(see list, p. 15)**?
- Do you have an active sex life?
- Are there any sexual problems?

Where once patients with the disease known as a "silent killer" were told glycemic control would benefit them five, 10, or 15 years down the road, they can now see for themselves that even a small reduction in blood glucose will make them feel better in as little as 24 hours, says the study's lead author, **Marcia Testa**, PhD, MPH, senior lecturer at Harvard's School of Public Health in Boston.

"Even if you can reduce blood glucose levels and HbA1c a half a percentage point, you will probably get some improvement in quality of life and relief from fatigue," Testa says. "Everybody lives on a very narrow edge of what they have to do, and that little bit of fatigue can actually make it impossible to function the way they want."

A better quality of life and healthier patients translates into fewer doctor office visits and hospitalizations, and for employers, an average reduction of $91 per month per employee in paid sick days, the study shows.

Specifically, the study showed even with minor reductions in blood glucose levels, patients slept better, had better cognitive function and measurably better work productivity.

"These are not the life and death symptoms, but they are the ones that make us live from day to day," says Testa. "I think they are very, very important to people who, if they can function just a little bit better, would be very grateful and would almost do anything once they feel that good not to go back to the way they were feeling before."

Diet, exercise, AND medication

The study shows patients were better controlled with the use of oral drug agents than their peers who struggled to keep blood glucose down with diet and exercise alone.

Even a small improvement in the quality of life may be just what patients need to bring them into compliance.

Testa talks about a typical patient, a middle-aged obese woman, newly diagnosed with no real glycemic control.

"It's a Catch-22," she says.

"What's the first thing you tell them? To diet and exercise, right?" Testa asks. "First of all, they don't have the energy, so how are they going to start? Then the patients begin to feel blamed and they have a guilt feeling.

"Actually, if you can give them a kick, by bringing blood sugar down and checking thyroid because the disease goes hand-in-hand with hypothyroidism, their engines get going and all of a sudden they are in a cycle with the ability to have diabetes self-management work."

In addition both Bernstein and Testa say, that attention given to commonly overlooked symptoms of diabetes, such as fatigue, weakness and memory lapses, can lead to early diagnosis and may even bring in from the cold some of the estimated 8 million undiagnosed diabetics in the United States **(see list, p. 15)**.

Bernstein says, "The Harvard study is important because it speaks to what the immediate effects of an elevated blood sugar are. There are many people who walk around with blood sugars of 200 or 300 and are basically unaware of it because they have adapted to it.

COMING IN FUTURE MONTHS

- Trends in chronic pain management
- Using telemedicine in diabetes treatment
- New research on controversial Ornish diet plan for cardiac patients
- Strategies for achieving physician buy-in for diabetes guidelines
- Battling depression in patients with congestive heart failure

Common Unrecognized Symptoms

- Headaches
- Tiredness
- Muscle cramps
- Vertigo
- Dizziness
- Tightness in chest during exercise or emotional stress
- Drowsiness
- Cold sweats
- Confusion
- Foot cramps
- Sweating
- Numbness of lips or mouth
- Blurred or double vision
- Short temper
- General weakness or fatigue
- Dryness of mouth, eyes or nose

"Now that we're getting aware of the long-term effect and with our concerns about blindness and kidney failure, we know an elevated blood sugar is toxic material and it interferes with the function of everything in the body."

Steven Edelman, MD, diabetologist at the University of California San Diego Medical Center and staff member at the Veterans Hospital in San Diego says, "Diabetic care has not been changing because of lack of patient education, motivation, and involvement in their own care."

Now, the Harvard study provides impetus to patients, Edelman says.

"There's a huge emotional component to the disease that includes guilt and fear — a lot of fear," he says. "There's no question people feel better on the short term, too. And when people are under control, there is a level of confidence that they are doing everything they can to prevent some of the complications of diabetes."

Edelman, a Type-1 diabetic himself who was diagnosed 28 years ago, thinks the short-term quality-of-life improvements will also provide an incentive for patients to tackle the admittedly tedious task of managing their disease in the long term.

"The biggest problem is being tethered to a schedule. It gets tiring to do everything right — eating and testing and exercising properly — day in and day out."

In addition, Edelman says, "The study is a way to tell managed care companies, 'Don't be short-sighted. It means long-term savings; even if your patient switches to another HMO seven years from now, you'll still have cost savings.'"

Testa's 15-week study, conducted with **Donald Simonson**, MD, of Brigham and Women's Hospital, Joslin Diabetes Center and Harvard Medical School in Boston, involved 569 male and female volunteers with mild to moderate NIDDM.

Patients were taken off all oral agents for three weeks and divided into two groups, one receiving glipizide gastrointestinal therapeutic system (Glucotrol XL) for 12 weeks and the other receiving a placebo.

Patients completed a confidential form containing more than 100 questions detailing their experiences in a variety of areas of physical health, psychological well-being, mental abilities, and sexual functioning. They also reported number of days missed from work and days where ill-health curtailed their normal activities. **(See sample questions, p. 14.)**

As expected, patients on glipizide had significantly better blood glucose control (7.5% vs. 9.3% for the placebo group), but those on oral agents consistently reported better quality of life on all areas assessed in the questionnaire.

Factoring in work loss and increased doctor office visits, the improvement resulted in concrete dollar savings. Testa found that the group on diet alone was nearly five times more likely to miss work because of illness.

Those numbers provide employers with a powerful tool when selecting managed care plans for their employees, Testa says.

"The employer is paying for it when he has an employee who is tired and can't think and doesn't come to work," she says. "I don't think employers do enough to evaluate plans."

She urges employers to ask what programs the companies have in terms of education and prevention, which can — and will — result in real savings.

"One of the reasons we focused on the economic side of it was to make the point that managed health care groups who are denying what I call diabetes specialist care could have detrimental effects," Testa says.

"Saying we only need one diabetologist per million people or that they won't fund diabetes nurse educators or dietitians was a move in the wrong direction," she concludes.

For more information, contact Marcia Testa, Harvard School of Public Health. Telephone: (617) 432-2818. ■

ADA, AAHP jointly combat diabetes complications

Aggressive plan targets physicians, patients

Common causes make unusual alliances. Now the driving mission to contain the devastatingly destructive — and costly — complications of diabetes has brought together organizations that are often adversaries: the American Diabetes Association (ADA) and the American Association of Health Plans (AAHP), a giant group representing more than 1,000 managed care companies with nearly 150 million enrolled Americans.

The early stages of the initiative promote screening, early intervention, and state-of-the-art treatment for the populations served by managed care companies.

Given that many diabetes advocates see managed care as the bogeyman, "It is an unusual alliance," admits **Peter Fitzgerald**, MSc, AAHP's director of outcomes research in Washington, DC.

"We think it's historic that we are partnering with a consumer organization to address a chronic illness. It's unprecedented for us," Fitzgerald says.

Gerald Bernstein, MD, president of the ADA, notes, "The ADA is not an advocate for anybody except people with diabetes.

"Sometimes, on the professional level, it becomes a little confusing," Bernstein adds, "but here is an opportunity to work with a group that delivers care to the population as a whole. If we can get care delivered to the diabetic population in the right way, then it's the right thing."

At the launch of the initiative in late October, Bernstein said the alliance is an unprecedented effort in terms of its scope and potential to fight the disease and improve the quality of life for people with diabetes.

"To steal a basketball analogy," he said, "it amounts to a full-court press against diabetes and its consequences."

AAHP officials hope the power of the managed care plans and the expertise and community presence of the ADA will change the face of diabetes management in terms of "quality of care and quality of life for people with diabetes throughout the country."

The 10-year "Taking on Diabetes" initiative calls for:

- reducing the incidence of irreversible vision loss by 40% through early detection and intervention;
- reducing the development of end-stage renal disease by 30%;
- reducing the incidence of new foot ulcers by 50%;
- reducing the number of foot amputations by 40%;
- reducing the risk of cardiovascular disease associated with diabetes.

To date, approximately a quarter of AAHP's member plans representing more than 75 million people (4 million of them diabetics) have signed on to participate in the largely unstructured drive targeting what Fitzgerald calls, "real benefits in terms that would be meaningful for people with diabetes."

"We didn't talk about HbA1c levels, the control of which is a means to avoid complications," Fitzgerald says. "We talked about the complications themselves. Our end results are very much what we want for people with diabetes to experience — a higher quality of life than they might otherwise have. We want them to retain their vision. We want them to retain their limbs. We want them to avoid end-stage renal disease and not experience cardiovascular disease. Our end results are very much aimed at consumers."

There is no prescribed formula for AAHP's managed care companies to follow other than the ADA guidelines.

Fitzgerald says each company implements its diabetes management plan as it sees fit, with guidance from AAHP.

"We are looking at identifying best practices," he says. "We are looking at what kind of programs have actually worked to move the delivery of care, and move patients in the right directions so they can avoid these complications."

In addition, Fitzgerald says, AAHP plans to form a communitywide network of plans and subscribers "so we won't have patients floating in and out of networks that provide the kind of care they need, so we'll be able to provide consistency of care" and to bring education programs to the workplace to target undiagnosed diabetics.

Experts are beginning to perceive a change in the attitude of managed care toward diabetics as study after study shows the long- and short-term benefits not only of glycemic control, but of diligence toward screening.

"They know they'll save money through prevention," Bernstein says. "They are beginning to

see the short-term savings just by keeping people out of the hospital."

For its part, AAHP is soft-peddling the concept of saving money through prevention, declining to estimate how much money can be saved by early diagnosis and prevention of complications.

"We haven't approached it in that way," Fitzgerald answers. "We know there are complications associated with diabetes that can be reduced, and we aim to reduce them."

For more information, contact the ADA at (703) 549-1500 or the AAHP, (202) 778-3200. ■

Asthma project cuts hospitalizations by 95%

ER visits drop 87% after benchmarking effort

When patients with severe asthma receive extensive patient education and close follow-up care, emergency room visits and hospital admissions can drop dramatically. You've probably heard that before, but now you can see it in action: A quality improvement project at the Burlington, MA-based Lahey Clinic slashed hospitalizations by 95% and emergency room visits by 87% in a year and a half.

At the Lahey Clinic, quality improvement has become an integral part of routine practice in many areas. However, asthma specialists felt not enough attention was being paid to improving care for their sickest patients, so they formed a multidisciplinary team to study the issue.

"We were frustrated that we really didn't have a good system for taking care of a certain fraction of asthma patients," says **Andrew Villanueva**, MD, a pulmonologist and critical care specialist who is director of the Lahey Clinic's Asthma Center. "Most of the time, asthma is a mild or moderate disease that you can take care of in a routine office visit, but there are some patients that really are quite costly. Between 5% and 10% of patients account for 70% to 80% of costs because they use the emergency room a lot and are hospitalized frequently."

KEY POINTS

- Multidisciplinary asthma care team members see patient and develop treatment plan during office visit.
- Education sessions and packets teach patients how to handle flare-ups without going to the emergency room.
- Patients are monitored for correct use of peak flow meters, metered dose inhalers.

Collecting and using data

The team — made up of pulmonologists, allergists, pediatricians, internists, emergency room physicians, respiratory therapists, nurses, pharmacists, and quality resource personnel — included benchmarking in the process. External benchmarking included conversations with Boston-area physicians and a literature review, while internal benchmarking came through data collection on four parameters: clinical outcomes, functional health status, patient satisfaction, and cost.

Data collection is ongoing in these areas, Villanueva says. Clinical measures include number of prescriptions of beta agonists filled each month, use of anti-inflammatory medications, and average morning peak flows. The team wants to see patients using less than one canister a month of a beta agonist and have 80% to 90% of patients taking anti-inflammatory medications. Functional health status is measured using the SF-36 quality of life survey as well as anxiety and depression scores. Satisfaction is measured through questionnaires for patients and referring physicians will be added soon. Cost will be measured on emergency visits and hospitalizations.

It's clear so far that the dramatic reductions in two problem areas — emergency visits and hospitalizations — can be achieved through extensive education and a multidisciplinary approach to following patients, Villanueva says.

The Asthma Center accepts patients who have been hospitalized or been to the emergency room twice in a six-month period for their asthma.

The patients make an initial visit of about four hours in which they see all of the multidisciplinary care team: a nurse (who will be their permanent nurse), a pulmonologist, an allergist, a pharmacist and a respiratory therapist.

The nurse takes the patient history on a standardized form; the pulmonologist looks at the medication regimen and any medical confounding factors that might be causing the symptoms; the allergist focuses on environmental aspects and skin testing; and the pharmacist goes over the medications. The respiratory therapist

administers pulmonary function tests and watches how the patient uses a metered dose inhaler and peak flow meter.

At the end of the visit, the entire team meets to discuss the patient's status and determine the cause of the difficulty, Villanueva says. The team comes up with a treatment plan, which the physician discusses with the patient before he or she leaves that day. The nurse and pharmacist go over the details, especially the action plan for how to handle symptoms, as well as any changes in medications. The plan always includes keeping in touch with the patient's primary care physician.

"They now have a person they can call if they have any questions or problems. Rather than going to the emergency room, they can call us and we can take care of the asthma flare-ups at home, or they can come to our office right away and we can help them," Villanueva says.

Deborah McManus, RN, an Asthma Center nurse, says the fact that patients see everyone on the team and hear the evaluation of their status on the same day makes a big difference.

"Everyone gets different information from the patient, so collectively we have a better picture of the patient than we would separately," she says.

Patients leave that day with their medications, spacers, peak flow meters, or whatever equipment they need to control their asthma. Follow-up visits are scheduled within a month and then again four to five months later.

"We empower the patient to take care of themselves and understand their own asthma," McManus says. "We want to make life as easy as possible for them." ■

CA HMO gives doctors 'D' for asthma management

Steps promptly taken to improve care

Question: What happens when a major health care provider learns its primary care physicians are, frankly, doing a lousy job of following the guidelines for asthma management?

Answer: A lot.

Health Net, California's second-largest health plan with 1.3 million members, released a groundbreaking report card on itself in early December.

In what is believed to be the first chronic disease-specific report card, the HMO found a disturbing bottom line:

• Only 72% of Health Net's patients with severe asthma reported having a steroid inhaler. Of those, only 54% used it daily.

• In addition, only 26% of patients with severe asthma reported having a peak flowmeter. Of those, only 16% of them reported using it daily.

"Although the National Asthma Education Program (NAEP) guidelines were published seven years ago, compliance with the guidelines was low," says **Antonio P. Legorreta**, MD, MPH, vice-president of the Quality Initiatives Division of Foundation Health Systems, Inc., Health Net's parent company in Woodland Hills, Calif.

KEY POINTS

- The new study found that nearly half of all HIV patients admit to not taking their medications as prescribed.
- Major California health care provider finds "poor" compliance with guidelines for treatment of asthma patients.
- Findings include:
  — Only 72% of severe asthmatics reported having a steroid inhaler. Of those, only 54% used it daily.
  — Only 26% of respondents reported having a peak flowmeter; only 16% used it daily.
- Action: Health Net promptly sent peak flowmeters and educational material to 5,000 severe asthmatics, followed up by weekly calls from nurse educators.

Specialists vs. generalists

In addition, older patients who had been diagnosed for a longer period of time with increasing severity of the disease under treatment by a specialist were more likely to be using inhaled steroids daily. Those who were under the care of specialists had better outcomes than those seeing primary care physicians.

Those least likely to be using inhaled steroids were African-American patients, which resulted in more emergency room visits and hospital admissions for asthma.

Interestingly, Legorreta says, researchers discovered there was an overuse of $ß_2$ agonist metered-dose inhalers, "directly related to the fact that members think bronchodilation is the

backbone of asthma management." Legorreta says.

What did Health Net do with this information?

First of all, post-haste, the HMO sent a peak flowmeter and educational material to each of its 5,000 severe asthmatics.

Then, Legorreta says, "We identified the most severe cohort of asthmatics and added a nurse educator call them weekly, among other things, to help them learn how and when to use the peak flowmeter."

Some good news

The report card wasn't all bad. Of Health Net's 47 medical groups containing 40,000 physicians, nine groups were rated above average, 32 were rated average, and six were rated below average.

The HMO's experience does not apply exclusively to California. An-eight state study of Foundation's patients produced "similar results," in terms of compliance with the NAEP guidelines for patients across the nation, Legorreta says. Those results are expected to be published soon.

In California, 5,580 patients enrolled in Health Net for at least a year and were identified through the HMO's pharmacy database as having received prescriptions for inhaled corticosteroids, $ß_2$ agonists, or theophylline were surveyed. Patients who answered the questionnaire saying they were not being treated for asthma were screened out.

The questionnaire asked a series of questions about symptoms, treatment, knowledge of disease self-management, use of medical care (emergency department visits and hospital admissions), medical history and satisfaction with care.

The questionnaire measured four areas of function on a scale of 0 to 100, including:

- General health perception
- Physical functioning
- Social functioning
- Limitations due to:

— physical conditions
— emotional conditions
— bodily pain
— mental health
— energy or fatigue

Primary care physicians are once again bearing the brunt of the responsibility for the lack of compliance.

Health Net has addressed that problem by sharing the results of the survey with doctors. Doctors are getting guidelines from Health Net as well as personal report cards showing how they compare with their peers.

In addition, the company has sent individual profiles to incorporate into the patients' medical records that include an assessment of functional status.

The California study was published in the *Archives of Internal Medicine*, which was also part of Health Net's strategy to get the physicians' attention.

"Quite honestly," Legorreta says, "If we just sent out a report in a slick folder with some charts, it probably would have wound up in the garbage. By publishing in a peer journal, we let them know this material has been scrutinized. It's a way of getting them to read it."

Other California HMOs have had their own experiences with asthma management compliance and have somewhat different methods of approaching the same problem.

Mike Ralston, MD, director of quality demonstration at Kaiser Permanente-Northern California, Oakland, says informal internal surveys in recent years have shown, "we had room for improvement."

While being less specific about it, Ralston says Kaiser employed a slightly different methodology from Health Net by asking providers which of the NAEP guidelines were most relevant and pushing compliance in those areas.

Giving providers feedback

Ralston says, "We created an asthma registry and it's based on looking at pharmacy data to see who's had a prescription for an asthma medication; who's had an asthma-coded visit in the medical office; who's been in the emergency room and hospitalization discharge codes."

Those patients, Ralston says, are coded and matched to pharmacy files "to see who's not appropriately been medicated."

That list of names is linked to providers, and they're sent a list of the patients.

"It seems to be working," Ralston says. "What our providers are really crying for is they want to do the right thing, but they need the right information to do it.

"We send them a list of something they have preliminarily agreed to, such as, 'Yeah, I agree that moderate to severe asthmatics ought to be taking inhaled steroids.' If we send them a list of the patients who are not, they say, 'Great, this is just what I need.' They'll get the nurse to call them in and maybe just automatically get a prescription or

get them into an education program."

"It's been very successful with the providers," he adds.

Kaiser did not study use of peak flowmeters, an area the NAEP says is crucial to effective asthma management.

Ralston says Kaiser has the same experience as Health Net in terms of better outcomes for patients seeing specialists.

For more information, Antonio Legorreta of Foundation Health System can be reached at (818) 676-7912. ■

A bit of needling can help asthma patients

Acupuncture may help chronic, acute asthma

Acupuncture was once thought to be akin to voodoo, but Western medicine is becoming more and more aware of the numerous medical benefits of the ancient Chinese art of placing needles into the body's energy meridians to achieve a wide variety of effects.

From relief of postoperative pain and chemotherapy nausea and vomiting to treatment for addiction, headache, menstrual cramps, tennis elbow, fibromyalgia, myofascial pain, osteoarthritis, low back pain, and carpal tunnel syndrome, studies have shown acupuncture can be quite useful.

Now add asthma to that list.

The National Institutes of Health (NIH) in Bethesda, MD, reported in its consensus paper that "promising results" have been shown for all these conditions, including asthma.

A British study reported in the September issue of *Respiratory Medicine* shows acupuncture, both real and sham, improves quality-of-life scores in patients with stable asthma.

That study showed no improvements in respiratory function after either real or sham acupuncture (needles placed on random points of unrecognized value on the chest wall), but with both real and sham acupuncture, there was a "significant improvement" in asthma quality of life scores and "a parallel reduction in the usage of bronchodilators."

KEY POINTS

- NIH consensus conference says acupuncture may be useful in treating asthma.
- UK study shows acupuncture improves quality of life and reduces use of bronchodilators for asthma patients.
- Clinical trials are difficult because of the nature of acupuncture.

Recent studies back up NIH

A 1995 British study published in the *Journal of Complementary Alternative Medicine* showed acupuncture for patients with bronchial asthma "facilitate[d] reducing pharmacologic medication and is safe."

A 1995 study published in a Russian medical journal says acupuncture resulted in a reduction of bronchial hyperreactivity.

Studies of the value of acupuncture are difficult, researchers agree, since its true placebo acupuncture points are impossible to establish because virtually any point on the body may have an effect on a condition.

Majid Ali, LAc (licensed acupuncturist), certified nutritionist, of M.M. VanBenSchoten Associates in Los Angeles, says acupuncture works by sending messages to the brain through energy meridians that tell the central nervous system to "fix whatever is wrong."

Doctors are unlikely to start sticking needles into patients, although some are learning about acupuncture through a variety of courses, including "quickie weekend" seminars that acupuncturists find as dangerous as if a layman took a weekend course and hung out a shingle claiming to be a doctor.

"Many people don't realize that legally, the scope of our practice is the same as a primary care physician," says **Louis Kiwala**, LAc, MTOM (Master of Traditional Oriental Medicine), director of the New York Center for Acupuncture and Alternative Medicine and co-founder of the Institute for Advanced Pain Management in New York City.

Chinese medicine is a complex art — part science, part poetry — with its foundations in anecdotal evidence gathered over 2,500 years of practice, he says.

"Chinese medicine is more systemic than Western medicine," Kiwala says. "In Chinese

medicine, we would look at asthma as a an excess or an attack on an organ."

Consequently, he treats the entire system and often asks questions that seem unrelated to the lungs in his quest to strengthen the weak organs.

Kiwala and his colleagues rarely prescribe acupuncture alone for most conditions, including asthma. Generally, they will prescribe a combination of herbs to help the condition, so it is difficult to separate the effectiveness of each method.

"Western medicine is a step behind because they find a single chemical to treat a condition, and that often results in side effects," Kiwala says. "We find a variety of chemicals in herbs that interact with one another to restore balance and provide checks on one another, therefore avoiding side effects."

Ali starts his asthma patients off with herbs and acupuncture, and tells them the process isn't as fast and dramatic as Western medicine.

"We look for imbalances, internal and external," Ali says. "Some asthma is congenital; but most of it is environmental. We see a great deal of it here in L.A. with all the smog."

Bridges in treatment

Ali says sinus infections are a major underlying cause of asthma and estimates half of his patients have sinus triggers for asthma.

Another significant percentage of asthma patients suffer from chronic intestinal infection, Ali says.

When those conditions are treated, Ali says, patients find improvement or even the disappearance of their asthma.

Yet, he recommends that asthma patients combine their inhaled steroids and bronchodilators with the alternative route.

"My goal is to get [off of] them; but if you need them, you have to take them," says the acupuncturist who works closely with many physicians, including neurologists, internists and psychiatrists and is working to bridge the gap between Western and traditional Chinese medicine.

Ali calls himself a "former asthmatic" who still has an inhaler, but hasn't used it for several years. "I'd be stupid not to use it if I needed it," he says.

Roberta Lee, MD, a fellow of the integrative medicine program at the University of Arizona in Tucson, says she has found that in a handful of asthma patients experiencing mild bronchospasms she treated with acupuncture "over the course of one hour, they became less symptomatic."

"I think there is some kind of energetic relationship to bronchospasm," Lee says.

She believes an East-meets-West scenario will ultimately prove to be beneficial to patients, as does the NIH consensus report which says for asthma "acupuncture may be useful as an adjunct treatment or an acceptable alternative or be included in a comprehensive management program."

For more information on acupuncture for asthma management, contact: Majid Ali, (818) 344-9973; Louis Kiwala, (718) 377-3829; and Roberta Lee, (502) 626-6478. ■

Tamoxifen may be magic pill against breast cancer

STAR trials to compare tamoxifen, raloxifene

The cancer treatment community is buzzing with barely suppressed excitement over the FDA's approval of tamoxifen as a preventive measure for women at high risk for developing breast cancer.

Experts say the drug, approved in October by the FDA for prophylactic purposes, is likely to change the face of cancer management the same way cholesterol-lowering drugs and ACE inhibitors changed heart disease management.

"There is huge support for the concept," says **Harmon Eyre**, MD, chief medical officer of the American Cancer Society (ACS) in Atlanta. "This is the first broadly indicated chemopreventive agent that has been proven in very wide-scale trials.

"In reality, breast cancer is the No. 1 health care concern for women in America, and the drug

KEY POINTS

- The FDA approved tamoxifen as a preventive agent for women at high risk of breast cancer.
- Trials show dramatic reduction in incidence of breast cancer in women ages 35 and up.
- American Cancer Society urges doctors to discuss risks and benefits with all women concerned about breast cancer.

tamoxifen has been demonstrated to have a substantial risk reduction over a period of approximately five years for the women who took the drug."

Tamoxifen and complex advice

Trials showed tamoxifen citrate, marketed by Zeneca Pharmaceuticals in Wilmington, DE, under the brand name Nolvadex, reduced the incidence of invasive breast cancer by substantial numbers **(see box, right)**.

Reductions in the incidence of breast cancer were seen as early as the first year of the trial, which began in 1992 and is continuing through the six-year follow-up.

Researchers used the Gail model to determine high risk for breast cancer. Risk factors included in the model are:

- age (risk of breast cancer increases with age);
- number of first-degree relatives with breast cancer (mother, sister, or daughter);
- previous breast biopsies with or without atypical hyperplasia;
- age at first live birth;
- age at first menstrual period;
- women with a history of lobular carcinoma in situ (LCIS).

Eyre says there is a great deal of confusion among physicians and patients about the use of tamoxifen in balancing risk and benefits.

The National Cancer Institute has produced a "risk disk," a computer program in which a woman can enter her risk factors to determine whether tamoxifen is appropriate for her.

"In my mind, that message is if you have to go to a computer program to determine the applicability of this, that is something that is so far beyond the sophistication level of this country [of] our primary care doctors that it will never happen," Eyre says.

Instead, he makes a personal recommendation since the ACS has not yet issued a formal statement on the issue.

"The message can be incredibly more simple than that," he says.

"All women over age 60 in America in who are concerned about breast cancer should discuss with their health care providers whether or not it is reasonable for them to take the drug tamoxifen for five years," says Eyre. That allows the doctors to discuss with them the potential risk of endometrial cancer or probable phlebitis and pulmonary emboli. Then, make a decision whether or not they should take that drug."

Breast cancer reduction among high-risk women taking tamoxifen in five-year trial:

- Ages 35-49: 44%
- Ages 50-59: 51%
- Ages 60+: 55%

Of the 26 million women in the United States over 60 who are concerned, "there is every reason to feel it is appropriate for them to take the drug, and that's the huge majority," Eyre concludes.

For women between the ages of 35 and 59, personal risk factors must be very carefully assessed, Eyre says. "That's based on a prior history of breast cancer, a biopsy showing proliferative breast disease or a very strong family history and some menstrual- and pregnancy-related risk factors.

Identify potential candidates

"The ACS believes women should be encouraged to take advantage of this opportunity," Eyre says, "and doctors should be able to identify the women for whom such treatment would be appropriate. If they don't want to learn how to monitor or prescribe it, they need to direct women toward an oncologist in their community who would."

The ACS is currently producing educational materials for health care professionals and the public on the issue.

Arthur Michel, MD, medical director of the Highland Park Hospital Breast Center in Highland Park, IL, and a principal investigator for STAR (Study of Tamoxifen and Raloxifene comparing the two drugs that begins this month), says women interested in the drug should participate in STAR.

Raloxifene, another drug considered for prophylactic use for breast cancer and under development by Eli Lilly and Co. of Indianapolis, may have fewer side effects, including less risk of endometrial cancer, researchers theorize.

"If someone at high risk for breast cancer is not eligible for the study, I would have no argument in using tamoxifen as a preventative," Michel says.

"STAR is going to answer some very, very important questions," Michel says. "I would highly recommend that at-risk women participate in the trial."

The thorny issue of cost that will be eliminated for the 22,000 women who participate in STAR, since the drugs will be free.

Managed care has not yet weighed in on the issue of spending an estimated $5,000 for the five-year recommended course of tamoxifen.

Managed care is going to take some convincing of the long-term value of such an expenditure says **Ivor Benjamin**, MD, assistant professor in gynecologic oncology and associate director for clinical information systems at the University of Pennsylvania Health System in Philadelphia.

"They're going to have to be convinced it's effective, since the almighty dollar is all powerful," says Benjamin, while saying the prophylactic benefits of tamoxifen are an "important discovery" that need to be clinically re-confirmed.

The numbers don't lie, so managed care providers need to sit up and pay attention, counters Eyre of the ACS.

"Managed care shouldn't be concerned about the cost. They will be in big jeopardy if the drug is denied, since the No. 1 issue in malpractice cases in America is the failure to diagnose breast cancer."

He concludes, "The risk of malpractice changed attitudes toward mammograms, and it will likely change attitudes toward tamoxifen as well."

Harmon Eyre, MD, medical officer of the American Cancer Society, can be reached at (404) 329-7740. ■

Researchers: Don't take sleep apnea lying down

Fatigue may mean more than CHF is present

Controlling congestive heart failure (CHF) comorbidity is an around-the-clock job, according to Canadian researchers. They recently found that while beta-blockers may keep hypertension under control during the day, the story may be completely different at night: Patients can still experience both higher levels of left-ventricular afterload and increased heart rate. These effects are a result from surges in systolic blood pressure occurring immediately after apnea episodes.

The report indicates it may be helpful for physicians to recognize which CHF patients are at risk of experiencing sleep apnea, so continuous positive airway pressure (CPAP) treatment can be made available. At the researchers' laboratory, 22% of CHF patients were found to have the nocturnal respiratory problem. Overall, experts say CHF patients may face 10 times the risk of sleep apnea than the healthy population.

"There's no doubt in my mind physicians need to know about apnea in patients with congestive heart failure," says **T. Douglas Bradley**, MD, a pulmonologist at the Toronto Hospital and research team member.

"Medications reduce vascular resistance, but the mechanism on which they work probably is different than the mechanism that occurs during apnea," he says. "The rises in blood pressure you see at night are not being blocked by these agents."

The team's latest in its series of studies on the relationship between CHF and apnea, the report

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appeared in the Nov. 24 issue of *Circulation*, the journal of the American Heart Association.

Eight patients receiving drug therapy for CHF and known to have obstructive sleep apnea were studied for two nights in a sleep center.

When subjects were allowed to breathe on their own, Bradley and his group saw apnea occur. An event was followed by a rise in left ventricular transmural pressure of 16 mm Hg. (This was calculated from the rise in systolic BP of 14 mm Hg and a 2 mm Hg drop in esophageal pressure during systole.) There were no significant changes in heart rate, BP, or respiration rate during diastole when patient's breathing went unassisted.

CPAP lowered the heart rate by 5 bpm and reduced the systolic transmural pressure by 20 mm Hg (this was calculated from finding a 16 mm Hg reduction of systolic BP and a 4 mm Hg increase in esophageal pressure). Diastolic BP remained unchanged.

After CPAP, the heart beat at its reduced rate. The systolic left-ventricular transmural pressure times heart rate product increased, but it remained lower than the level before CPAP.

Did apnea contribute to CHF development?

Bradley says that apnea may be a suspect in the development of the disease because of a 15-year span between the time people develop sleep apnea and show signs of CHF.

Apparently, a CHF contributor may be happening long before patients ever show cardiac symptoms. "You're talking about middle-aged men who are in their most productive years," he says.

Asking patients about their quality of sleep can do a lot to determine if a follow-up sleep study should be ordered.

"Cardiologists should be asking patients how they are sleeping," Bradley says. "There are key questions that should only take two minutes to ask." He suggests:

- Do you have difficulty falling asleep or staying asleep because of shortness of breath?
- Do you feel tired or have to nap in the daytime because of fatigue?
- Do you snore habitually?
- Has anyone seen you stop breathing while you sleep?

For patients already diagnosed with CHF, apnea may not be suspected because the fatigue it causes may be automatically attributed to the heart failure.

"If a patient comes in and says he's fatigued, it's easy to say 'Oh, it's just your heart failure,' but if you dig a little deeper, you may see that it's really sleep apnea."

"A good doctor can tell the difference between heart failure and sleep apnea," notes **Gordon A. Ewy**, MD, chief of cardiology at the University of Arizona Health Sciences Center and director of the Sarver Heart Center in Tuscon. "You have to be willing to consider it."

"It helps to know when the patient feels fatigue," says **Marc Silver**, MD, director of the Heart Failure Institute at Christ Hospital in Oak Lawn, IL.

"The patient may say, 'Gee doc, I just wake up feeling all fatigued,' then you can be very suspicious of sleep apnea," he says. "Then, ask more about if they are getting up at night to go to the bathroom. That will be indicating a different problem," he continues. "If the patient is sleeping OK but is tired at the end of the day, you know something else is going on."

To make the differential diagnosis between cardiac and pulmonary problems causing the fatigue, Silver says the best evaluation tool probably would be the cardiopulmonary exercise test. ■