

# DIABETES MANAGEMENT™

*The Complete Diabetes Disease State Management Resource*

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**MAY  
1999**

**VOL. 2, NO. 5  
(pages 49-60)**

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## Be a spin doctor: Help your overweight patients lose pounds

*The skinny is to show them simple ways to gain control of their eating*

**A**re your patients with Type 2 diabetes overweight? Chances are good that at least eight in 10 are. The number may even be closer to nine out of ten, says **Richard Dickey, MD**, president of the American Association of Clinical Endocrinologists, and a practicing diabetes specialist in Hickory, NC.

Experts say there are some new drugs and surgical procedures (**see box, p. XX**) and some promising new treatment research. But the bottom line is unchanged: Diet and exercise are the most effective means of losing weight and gaining control of glucose levels. (**For more information on exercise and glucose control, see *Diabetes Management*, March 1999, p. 25.**)

The term “diet” may not be new, but some experts say patients need to get a fresh perspective on getting a handle on their dining habits. That’s where health professionals can help, experts say, by putting the positive spin on something that has had such a negative perception — trying to lose weight.

“I’d rather not use the word ‘diet’ because for so many people, it’s synonymous with deprivation,” says **Linda Haas, RN, PhC, CDE**, the American Diabetes Association’s president for health care and education and a clinician at the Veterans Affairs Medical Center in Seattle. “I’d rather say that by eating healthy and raising metabolism through exercise, diabetics can make a significant improvement in their glucose control.”

Her colleague, **Marian Parrott, MD**, ADA vice president for clinical

## KEY POINTS

- Obesity contributes to insulin resistance.
- As many as 90% of Type 2 diabetics are overweight.
- Losing a small percentage of body weight (5% to 10%) can result in significant reductions in blood sugar.
- Experts say healthy eating habits and exercise are still the best means of achieving weight control.

## Obesity Facts

Nearly one in three Americans is obese: A person with a body mass index (BMI) — a ratio of height to weight — of greater than 27, according to the criteria used in the National Health and Nutrition Examination Survey (NHANES II). Other studies suggest a BMI as high as 29 is the criteria for obesity as people become older. **(See BMI chart, inserted in this issue.)**

- ✓ This is a dramatic increase from the 1980s when just over a quarter of all Americans were obese.
- ✓ Health risks increase as BMI increases, and a BMI of 27 or over correlates with increased morbidity and mortality from all causes.
- ✓ Obesity is more prevalent in minority populations.

Source: to come

affairs in Arlington, VA, agrees. “I would rather suggest that people add something to their diets rather than think of giving something up. Think about adding another vegetable or another piece of fruit.” Filling up on the healthy foods may help patients eat fewer foods that are not as good for them.

### *Small victories bring big results*

It doesn't take a major weight loss for a patient to achieve better glucose control. In fact, a study from Tufts University in Boston recently reported that setting a goal of losing more than 10% of initial body weight is unrealistic for many patients and may promote weight cycling.

Parrott suggests gradual changes can lead to small, but significant weight loss. Identify the occasions where overeating occurs, she says, and decrease eating opportunities. Whether those occasions occur at home, at work, or at social events, “food is everywhere,” she says.

Parrott has these tips to pass on to patients:

- Make a movie or a concert the highlight of an evening out, not an enormous meal at a fancy restaurant. Spending the time hiking or biking is even better.
- Those bulk-style warehouse stores may be great for buying detergents and other household items but avoid buying too much food there. The

trash-bag sized containers of chips, buttered popcorn, and other snacks are just easy pickings. If patients must eat one of those giant muffins often sold there, tell them to eat only a quarter of one muffin at a time.

- Don't be tempted by super-sized portions when eating out.
- Adjusting our attitudes toward food is just as important as adjusting our ideas about what is an ideal weight, Parrott says. “It's the same old boring advice that no one wants to hear.”

Substantial research shows that losing and regaining pounds creates weight cycling that makes it increasingly difficult and eventually almost impossible for a patient to lose weight.

Parrott adamantly opposes diets because the short-term fix does little to improve health in the long run because patients tend to return to their old habits. “It's easier to starve themselves for a couple of weeks than to make long-term lifestyle changes.”

Haas suggests patients keep log books of what they eat, not to create guilt, but to make them more aware of the quantities of food they are consuming.

Blood sugar monitoring is perhaps the most effective means of motivating diabetic patients, Haas says, because the results become apparent

## AACE sounds the alarm

Members of the American Academy of Clinical Endocrinologists are alarmed about widespread obesity. The organization is joining forces with other professional associations to urge the American Medical Association's House of Delegates to become an advocate for the prevention, diagnosis, treatment, and care of overweight patients with diabetes, says **Richard Dickey**, MD, the associations' president and a diabetes specialist in Hickory, NC.

Getting everyone to recognize the seriousness of patient obesity is an urgent mission, Dickey says. He notes insurance companies, for example, routinely deny reimbursement for the 278.0 diagnostic codes for obesity, not only for drugs and treatment, but even for office visits, “So we have to call it something else — hypothyroidism, hypertension, high cholesterol, whatever. In fact, they usually have one of these anyway.” ■

## Communication Skills Get the Message Across

### When advising patients on weight management, avoid these obstacles to good communication:

- Avoiding eye contact may make the patient feel ignored or question adequacy of care or attention.
- Arguing with patients may intimidate them and cause them to “shut down” or disengage during the office visit.
- Placing blame could make patients doubt their self-worth or feel hopeless.
- Failing to address patients’ requests can make them feel they lack control over their own health care.
- Failing to explore patients’ health history and congratulating good practices may cause patients to become dejected or despondent.

### Use these effective communication aids:

- Engage patients in a discussion about health routines — lifestyle, diet, and exercise — and encourage them to make needed changes.
- Review weight management options, including pharmacotherapy and surgery and ensure patients are aware of all options that are important to developing a well-integrated weight management plan.
- Treat patients as partners in developing an effective weight management program to empower them to take control of their own health care.
- Ask questions, rather than making authoritative statements. Ask about the types of weight management efforts patients have attempted in the past to show you will provide individual attention, rather than just dictate instructions.
- Help patients set modest, realistic goals. Setting the standard too high may be overwhelming and increase the likelihood patients will drop out of the weight management plan.
- Follow up with patients. Show patients that you care about them as a partner in the weight management process.

### Get your office staff involved:

- Tell employees which patients who are trying to lose weight so staff will ask patients how their routines are going.
- If staff see these patients are making progress, the employees should say so. The extra support provides a network for the patients and encourages them to continue.

Source: Adapted from *Obesity: Weighing in on a National Health Problem*. Executive Summary. Mount Olive, NJ: Knoll Pharmaceutical Co.; year?

very quickly. “When they start to lose weight, they will see results in their blood sugars long before they see it on their waistlines or even on the scales, and they’ll feel better,” she says.

### *Don’t place blame*

Haas says clinicians are walking a fine line in helping diabetics achieve weight and glucose control. “It’s essential to understand that stress can play a very big role in elevated blood sugars,” she says. “If a patient is stressing about the weight issue, reducing glucose levels will be very difficult.”

Most importantly, she advises, “Remember that it’s very tough to lose weight, and people who are overweight are not bad people.”

[Richard Dickey can be reached at (828) 322-7338, Linda Haas at (206) 764-2721, and Marian Parrott can be reached at (703) 549-1500.] ■

## Joslin: There is no such thing as a diabetic diet

### *Eat anything, but counting carbs is the key*

**T**est yourself with the following true-or-false statement: People with diabetes can’t eat sugar. False. Totally cutting out all sugar is one of the most common myths clinicians and patients follow in planning healthy eating programs for diabetics.

“With proper education and within the context of healthy eating, a person with diabetes can eat anything a nondiabetic eats,” says **Karen Chalmers, RD, MS, CDE**, director of nutrition services at Joslin Diabetes Center in Boston.

Guidelines for the management of diabetes issued five years ago state it is OK for people with diabetes to substitute sugar-containing foods for other carbohydrates as part of a balanced meal plan. But many patients and even clinicians and educators aren’t up to date on those dietary recommendations.

The Arlington, VA-based American Diabetes Association committee on nutrition reports there is little scientific evidence to support the old theory that simple sugars are more rapidly digested and absorbed than starches, and therefore, both

## Weight Reports on the Wire

This is a list of drugs currently available and under study and some of the latest research in the field of weight control:

- Meridia** (sibutramine): A neurotransmitter reuptake inhibitor of serotonin and norepinephrine, the chemicals that regulate appetite. Recommended for obese diabetic patients with a body mass index of over 27. Patients can expect a 5% to 10% reduction from their baseline weight.
- Studies show **sibutramine** helps reduce serum uric acid and other beneficial changes in serum lipids.
- Xenical** (orlistat): A lipase inhibitor approved by the FDA in late April, orlistat interferes with the absorption of fat from the GI tract, a chemical derivative of lipstatin, a natural product that irreversibly inhibits pancreatic lipase. It also reduces serum lipid concentrations. Expected to be available by prescription very soon, orlistat promotes modest weight loss of about 10% of body weight while minimizing the rebound effect of weight increase. Swedish researchers say orlistat users experienced significant, healthy reductions in their blood sugar, insulin and cholesterol levels. It reduces absorption of fat-soluble vitamins A, D, E and K, so users are advised to take dietary supplements. Approval by the FDA was delayed for two years because of fears Xenical increase the risk of breast cancer. Later studies showed those risks did not exist.
- MGH** (melanin-concentrating hormone): Researchers at Joslin Diabetes Center and Beth Israel Deaconess Medical Center in Boston found in a group of mice without the small peptide that acts like a hormone weighed less and burned more energy than animals with MGH. It's being considered an important avenue for drug research, says Joslin's Terry Maratos-Flier, MD, one of the investigators working on MGH at Joslin.
- PTP-1B** (protein tyrosine phosphatase -1B): a gene found by Canadian researchers to suppress insulin resistance and weight gain. Very early studies may lead to the development of a drug.

Source: to come

are apt to produce higher blood glucose levels.

Instead, over the past five years, diabetics have been advised to focus on their total daily grams of carbohydrates so they can keep their blood sugars under closer control.

Clinicians frequently receive requests from patients for lists of foods they can and cannot eat. "There aren't any foods that are off-limits," says Chalmers. "Rather the patients just need to learn how to spend their grams of carbohydrate wisely over the course of the day."

She recommends patients and dietitians sit down together and look at diet, food preferences, and weight loss goals, if appropriate. Then they can come design an individualized food plan aimed at even carbohydrate distribution during the day.

### *A carbohydrate bank account*

For example, Chalmers says, if the patient is a 6'2" man with diabetes who weighs 180 pounds and wants to maintain his current weight, the dietitian may recommend he eat 350 grams of carbohydrate spread over the day. The goal is to spread those grams over the course of the day so blood sugar doesn't shoot up at any one time.

"We now know that, in general, a sugar-containing food like a piece of angel food cake may have 30 grams of carbohydrate in it. But that piece of cake will have the same effect on your blood sugar as a 2/3 cup of rice or one cup of applesauce, both of which have about 30 grams of carbohydrates in them," she explains.

"So, if this man's meal plan that he's developed with a dietitian says he can eat 60 grams of carbohydrates at a meal, it's his choice to decide where he 'spends' them."

It's not a matter of having your cake and eating it, too, Chalmers cautions, because the meal plan must fall within the boundaries of healthy eating. Therefore, a piece of angel food cake at every meal isn't a particularly healthy choice.

She also says those who are on weight-loss plans or patients with cholesterol concerns need to reduce calories as well by eating low-fat diets, since one gram of fat contains nine calories while a gram of carbohydrate or protein contains only four calories.

"You get your meal plan budget and then you decide how to spend it at each meal," Chalmers says. "Just as a nondiabetic can't eat cookies and cake all day long and expect to be healthy, if you have diabetes, you have to eat a balanced diet to

remain healthy. But within limits, and with proper education, if you have diabetes, you can eat whatever anybody else does.”

*[Joslin Diabetes Center has a Web-based discussion group at [www.joslin.org](http://www.joslin.org), hosted by Chalmers. Joslin moderates discussion and answers questions from people with diabetes.*

*The diabetes center has also published a cookbook, Joslin Diabetes Quick and Easy Cookbook.*

*Karen Chalmers can be reached at the Joslin web page, [www.joslin.org](http://www.joslin.org) or by phone at (617) 732-2415.] ■*

## Unconventional surgery yields dramatic results

*Eliminates need for insulin in some patients*

A surgeon who has performed more than 1,000 gastric bypass procedures on morbidly obese patients at East Carolina University in Greenville, NC, is quick to admit the procedure is controversial among many of his colleagues.

But he notes while the technique is not widely accepted among the medical community, it can have dramatic benefits for obese diabetic patients.

“I can’t tell you what it’s like to have a patient who needs 90 units of insulin and a few days later needs none at all,” says **Walter Pories**, MD. The professor of surgery and biochemistry at East Carolina is a pioneer of the surgery designed to reduce caloric and nutrient absorption which has had unexpected results for diabetics. The procedure bands or staples the patient’s stomach into a small pouch, then attaches a Y-shaped section of the small intestine that allows food to bypass the duodenum and part of the jejunum.

The downside of gastric bypass surgery is the potential for serious vitamin and mineral deficiencies, the potential for serious side effects from those deficiencies, and the certain need for supplementation throughout the patient’s life.

Pories, however, says those are issues the patient and physician can easily handle. He speaks with a passion about routine medical recommendations for diet and exercise: “To recommend exercise to a patient who weighs 400 pounds is simply cruel.”

Pories says he is so excited he “can hardly stand it” about the impact of the surgery on diabetic patients: the 200 who underwent the gastric

bypass suddenly and dramatically eliminated their need for insulin.

Pories is the first to admit he has no idea why gastric bypass surgery has such a remarkable effect on diabetic patients, but he has some ideas.

“I believe we are bypassing an overactive signaling mechanism from the intestine. I think diabetes is a disease where the intestine oversignals the pancreas,” says Pories.

He also was surprised to find a dramatically reduced mortality in patients who underwent the gastric bypass, compared to a group of 72 patients who underwent the work-up for the gastric bypass but later decided not to have the surgery for a variety of reasons.

“There was a 1% mortality rate per year for those who had the surgery, and that’s a little higher than in the normal population,” says Pories. But the patients who did not undergo the surgery had a much larger annual mortality rate: 4.5% per year. “This is the first demonstration of any surgery that can reduce mortality from all causes,” he says.

The positive results seen in about 87% of his patients have been dramatic in terms of weight loss, says Pories. Most lose 30 pounds in the first month, 60 pounds in six months, and 100 pounds in a year.

### *No supermodels, modest losses*

He warns his patients they will never look like supermodels. In fact, for reasons he does not understand, Pories says most of his patients come to a weight loss plateau at 10% to 20% over their optimal weight. “I guess that’s good, or they’d just keep on losing and eventually disappear,” he adds.

**Rewrite too awkward:** The National Institute of Diabetes and Digestive and Kidney Diseases of the National Institutes of Health (NIH) in Bethesda, MD, includes gastric surgery (gastric banding, bypass, and extensive bypass) among its options for weight reduction in severely obese people (those with a body mass index (BMI) of over 40) and for those with a BMI of 35 to 40 who with diabetes and patients with life-threatening cardiopulmonary problems.

NIH literature warns that the gastric bypass works by causing a malabsorption of food and may result in a variety of side effects including deficiencies of iron, vitamin B12, and calcium as well as a variety of complications associated with those deficiencies.

Pories says medical insurers will usually pay for the surgery because of the NIH's endorsement.

**Marian Parrott, MD**, vice president for clinical affairs of the American Diabetes Association, says gastric surgery has its merits, but expresses reservations because it is risky and drastic. "I would like to see people try nonsurgical treatments before they consider surgery."

*[Walter Pories can be reached at (252) 816-4629.] ■*

## Participants are being randomized for DPP

*Study of patients with impaired tolerance starts*

The recruitment has ended and the randomizing is under way for the largest clinical trial for the prevention of Type 2 diabetes in those at high risk for developing the disease.

The Diabetes Prevention Program (DPP) has an ambitious goal of using lifestyle changes and drug therapy to reduce by one-third the number of glucose-impaired patients who go on to develop Type 2 diabetes.

DPP researchers have targeted people at the highest risk of developing diabetes by recruiting those in impaired glucose tolerance, with at least 50% of the participants members of minority groups (African-Americans, Hispanics, Native Americans, Asian-Americans, and Pacific Islanders), 50% women, and 20% over age 65.

All participants in the DPP have been diagnosed with impaired glucose tolerance (IGT), defined as fasting plasma glucose of 95 to 125 mg/dl or a two-hour plasma glucose at 140 to 199 mg/dl.

"This is a very important group of individuals who have never been studied and many of whom we think we can prevent from converting to Type 2 diabetes," says **Sanford Garfield, PhD**. Garfield is project director for the DPP at the National Institute of Diabetes and Digestive and Kidney Disorders (NIDDK) of the National Institutes of Health in Bethesda, MD.

Garfield says recruiters at the 27 clinical settings across the United States have probably exceeded the target population of 3,000 patients and have at least met the goals for minority and gender. But because there was some difficulty

recruiting elderly participants, The study may not get enough participants over 65 to represent 20% of the cohort.

The primary purpose of the study is to determine the effects of three separate intervention plans in preventing conversion to diabetes:

**1. The first intervention is an intensive lifestyle intervention** with a projected weight loss of at least 7% of body weight through a program of diet, exercise (at least 150 minutes per week) and behavioral modification counseling (psychotherapy).

**2. The second intervention is to use standard lifestyle recommendations plus a placebo.**

**3. The third intervention type is standard lifestyle recommendations combined with metformin**, beginning with 850 mg daily and increased to 850 mg twice daily.

A planned fourth intervention using standard lifestyle recommendations plus troglitazone was dropped last summer after a small percentage of patients using Rezulin began experiencing acute liver failure.

Secondarily, Garfield expects the DPP to produce data on cardiovascular disease and its risk factors, changes in glycemia, beta-cell function, insulin sensitivity, obesity, diet, physical activity, and health-related quality of life.

### *Do DCCT and UKPDS findings apply?*

Garfield says the DPP is intended to translate earlier findings in favor of tight glucose control to the prevention of the disease in those at risk. The DCCT and the UKPDS showed tight glucose control prevents complications. Researchers say they expect the DPP will show that tight glucose control among those who are glucose impaired will delay or even prevent the onset of Type 2 diabetes.

The Diabetes Control and Complications Trial (DCCT), which ended in 1993, produced results on Type 1 diabetes that showed unequivocally that tight glucose control can prevent complications of the disease and the United Kingdom Prospective Diabetes Study (UKPDS) of 1998 showed the same results for Type 2 diabetes.

Ischemic heart disease, uncontrolled hypertension, and aortic stenosis were excluded from the study because of the requirement for increased physical activity. In addition, the DPP excludes

## DDP Details

Recruiting for the Diabetes Prevention Program (DDP) is now closed and randomization is in progress, to be complete by the end of May.

### Expected population:

- ✓ 3,000 people with impaired glucose tolerance considered at high risk for developing Type 2 diabetes to participate for 2 2/3 years, to be followed up for 3 1/3 to 6 years.
- ✓ All participants have impaired fasting plasma glucose between 95 and 125 mg/dl or a two-hour post-load plasma glucose of 140-199 mg/dl.

### Target populations:

- ✓ Half the study participants will be members of ethnic minorities:
- ✓ African-Americans, Hispanics, Native Americans, Asian-Americans or Pacific Islanders.
- ✓ Half the study participants will be women.
- ✓ One-fifth will be over the age of 65.
- ✓ Most will be overweight (BMI of 24, 22 for Asian-Americans) and over 35.

### Three treatment plans:

- ✓ Intensive lifestyle interventions including weight reduction of at least 7%.
- ✓ Standard lifestyle recommendations plus placebo.
- ✓ Standard lifestyle recommendations plus metformin.

Source: National Institute of Diabetes and Digestive and Kidney Disorders (NIDDK) of the National Institutes of Health in Bethesda, MD.

patients with renal insufficiency or congestive heart failure because of their increased risk of lactic acidosis with metformin.

Pregnant and nursing women and those who intend to become pregnant during the program were also excluded because metformin has not been shown to be safe during pregnancy or nursing.

Most of the recruitment was aimed at participants 35 and older, Garfield says, although the lower age limit is 25 to include high-risk groups at a younger age, particularly Native Americans.

Prospective participants were recruited with series of interviews and examinations, including:

- prescreening telephone assessment interview;

- single glucose measurement;
- interview in which a medical history is taken;
- measurement of body mass index (BMI) and blood pressure;
- measurement of fasting plasma glucose;
- two-hour plasma glucose test;
- other laboratory tests including liver function, electrolytes, serum creatinine, plasma triglycerides, complete blood count, thyroid-stimulating hormone and urinalysis;
- run-in/behavioral trial to test compliance with pill taking and record keeping;
- clinical evaluation including history and physical examination;
- electrocardiogram to detect exclusion factors;
- pregnancy test and review of eligibility and, if eligible, referral for randomization.

Garfield says in those assigned to the standard lifestyle category, the time to developing diabetes is expected to be 6.5 per 100 person years, and in those in the intensive lifestyle and metformin interventions, the rate of developing diabetes is expected to be reduced by one-third to 4.33 per 100 person years.

[Sanford Garfield can be reached at (301) 480-3503.] ■

## Interviewing techniques keep patients on track

### Ways to identify pitfalls in advance

Motivating patients and keeping them motivated to stay with their diabetes management plans is the biggest challenge of the Diabetes Prevention Program (DPP). It's a challenge that translates to virtually every aspect of treating diabetes.

A technique called motivational interviewing is used by DPP recruiters to find motivated study participants. This technique could be helpful for anyone working with patients facing major lifestyle changes, says **Richard Rubin**, PhD, CDE, a psychologist at Johns Hopkins University School of Medicine in Baltimore. The behavioral scientist is working with the Johns Hopkins DPP program and is national chairman of the behavioral sciences working group with the DPP.

Clinicians may ask a question such as: "And so, Mr. Jones, why do you want to lose weight?" The patient with diabetes may reply: "Because I want to stay alive to see my grandson."

The answer is then used six months later, when the patient is struggling with his exercise program and feeling discouraged because he hasn't met his weight goal.

The clinician can ask, "Remember six months ago when you said you wanted to lose weight because you wanted to see your grandchild grow up?"

It's a simple technique, Rubin says: First, assess a motivation for a behavior change; second, help the patient set realistic goals; and third, re-motivate the patient to stick with the original goal.

"Participation in the DPP requires a really big commitment, especially for those who might be placed in the intensive lifestyle intervention group," says Rubin.

"I want to be sure they are really motivated, that they understand how much this commitment

entails and that they will stick with it."

He gives an example of a woman who wants to lose weight because a spouse thinks she should. "This may not be the best motivation, so I might help her find another motivation, like feeling healthier," Rubin says.

He also cautions clinicians to help patients form realistic goals so they have the best possible chance of success. "If a patient tells me he will exercise an hour and a half a day seven days a week, I might suggest he start out with 30 minutes of exercise three days a week."

Finally, Rubin suggests helping a patient identify personal barriers to compliance by asking, "Do you think it might be too much for you?" or "Do you think you would have trouble maintaining your weight loss?"

"If we look at the things that get in the way of success, we can address those problems before they start," Rubin says.

*[Richard Rubin can be reached at (410) 243-6565.] ■*

## Controversy erupts over new diagnosing criteria

*Will low-level diagnosis invite discrimination?*

It has taken a couple of years for the experts to get around to writing their opinions about the change in diagnostic baselines for diabetes recommended by the American Diabetes Association in Arlington, VA, and the World Health Organization in Geneva.

That controversy has suddenly become heated in the past couple of months. In an article and an editorial published in the April 7 issue of the *Journal of the American Medical Association*, a member of the original expert committee, which recommended re-setting the diagnostic criteria, and an epidemiologist at the Centers for Disease Control and Prevention in Atlanta went head to head over the benefits of lowering the bar.

**Mayer Davidson**, MD, who is a member of the American Diabetes Association expert committee on the diagnosis and classification of diabetes mellitus, argues that diabetes should not be diagnosed at plasma glucose levels under 140 mg/dl unless the patient also has an elevated glycosylated hemoglobin (HbA1c). Davidson is also a professor of medicine at the University of California at Los Angeles and director of the clinical trials unit at

Charles R. Drew University of Medicine and Science, also in Los Angeles.

Patients without elevated HbA1Cs should be diagnosed as having impaired fasting glucose, Davidson says, so early intervention can take place "without subjecting these persons to the potentially negative insurance, employment, social, and psychological consequences of a diagnosis of diabetes mellitus.

"The decision of where to draw the line is somewhat arbitrary," he says. "In fact, the recommendation for diet and exercise modification would be the same whether a person has been diagnosed or not."

### KEY POINTS

Controversy erupts over changing diagnostic criteria for diabetes. ADA guidelines changed in 1997 call for a diagnosis of diabetes:

- when patient has symptoms of diabetes plus casual plasma glucose concentration of 200 mg/dl;
- fasting plasma glucose of 126 mg/dl;
- two-hour plasma glucose at over 200 during an oral glucose tolerance test.

Some experts say lower level diagnoses make patients vulnerable to psychological setback and discrimination by employers and insurance companies.

Using data from NHANES III and Meta-Analysis Research Group, Davidson and his colleagues found 86.7% of patients diagnosed with impaired fasting glucose based on the old criteria (140 mg/dl) had HbA1cs in the normal range, and diabetics diagnosed under the old criteria, 18.6% were in the normal HbA1c range.

Davidson also argues that many patients now fall into a “gray area” since testing glycosylated hemoglobin (HbA1c) is now considered a more accurate gauge of long-term plasma glucose than the two-hour glucose tolerance test. “Sixty percent of the people with OGTT results over 200 mg/dl have a normal HbA1c,” says Davidson, who was one of the early proponents of using the HbA1c test as a standard in the early 1990s.

### **Earlier interventions, less complications**

Because of the new criteria, more people will be diagnosed with diabetes. In addition, less people with diabetes will go undiagnosed, resulting in earlier interventions and more potential to prevent complications, says **Frank Vinicor**, MD, MPH, director of the division of diabetes at the centers for Disease Control and Prevention (CDC) in Atlanta, who wrote a *JAMA* editorial opposing Davidson’s findings.

In the editorial, Vinicor wrote, “It is important not to tell a person that diabetes is present when it is not; likewise, to not identify diabetes when it exists is to ultimately deny benefits of improved metabolic control.”

He suggests the appropriate way to address insurance and employment considerations for patients with diabetes is not by lowering the diagnostic criteria, but the way to handle this is to deal with the insurance companies. **(Deal with them how?)**

Vinicor agrees that a large number of people, perhaps as many as two million, fall within the “gray area” between the old and new criteria.

He says the ease of testing will encourage doctors to order the HbA1c test more often, resulting in more diagnoses. “These were people who always had diabetes, we just didn’t know about them,” Vinicor says.

The increased numbers are unlikely to affect funding for diabetes research, he says, because “federal legislators don’t respond only to the size of a problem.”

*[Mayer Davidson can be reached at (323) 357-3439 and Frank Vinicor at (770) 488-5000.] ■*

## **Deaths from heart disease increase in diabetic women**

*Death rate for men declines slightly*

**D**iabetic women are experiencing a significant increase in heart disease deaths, while mortality from coronary artery disease is declining in the general population, as well as in diabetic men.

In data just released from the First National Health and Nutrition Examination Survey (NHANES I), researchers at the National Institute of Diabetes and Digestive and Kidney Disease (NIDDK) in Bethesda, MD, found the age-adjusted heart disease mortality rate increased by 23% from 1971 to 1993 in women with diabetes, while it fell 27% in nondiabetic women during the same period.

The news is better for diabetic men, who saw a 13.1% decline in heart disease deaths over those 22 years, compared to a much larger 36.4% decrease for nondiabetic men.

Lead author **Maureen Harris**, PhD, MPH, director of the NIDDK’s Diabetes Data Group says the data suggest “diabetic patients, particularly women, may not have benefited from the improvement in heart disease risk factors and better medical treatment for people with coronary artery disease.”

She says she hopes to get more information from the NHANES II data that are just becoming available.

Because of the increasing prevalence of diabetes and the recent upsurge in Type 2 diagnoses in younger people, even in children, “we can expect diabetes to become an increasingly important reason for heart disease mortality in this country,” Harris says. She adds that 50% of all

### **KEY POINTS**

- The death rate from heart disease in diabetic women increased by 23% from 1971 to 1993, while the death rate for non-diabetic women decreased by 27% in the same time period.
- Diabetic men saw a 13% drop in their death rate from heart disease, while deaths in non-diabetic men declined by 36%.
- Heart disease accounts for about 50% of deaths in people with diabetes.

diabetic deaths are attributed to heart disease.

While it is well recognized that post-menopausal women lose their estrogen protection against heart disease, diabetic women have higher risks. Diabetic heart disease is “a different kind of heart disease. It’s a small vessel disease that is not as amenable to surgical therapy,” says **Richard Dickey**, MD, president of the American Association of Clinical Endocrinologists (AACE) and a practicing endocrinologist in Hickory, NC.

Dickey says the new mortality statistics carry some credence with him because of an often-ignored condition among diabetic women — autonomic neuropathy. Sufferers, most of them women, don’t recognize the pain of a heart condition. It is sometimes called silent angina or silent ischemia and **results** from damage to the sympathetic and parasympathetic nervous system, **resulting** in higher heart rates.

“I have seen women who don’t recognize the chest pain. They may not complain at all when they are having a heart attack, and they die without ever having been diagnosed,” Dickey says.

AACE guidelines call for 24-hour screenings for silent angina for women who may be at risk, especially if they have signs of diabetic neuropathy elsewhere.

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## Risk of colon cancers very high in diabetic women

*Insulin and low motility may be the culprits*

**R**ecent studies that show an elevated risk of colorectal cancer among diabetic women may soon prompt a change in recommendations for early screenings for those at risk.

The Harvard School of Public Health study

### KEY POINTS

- Women with diabetes have a 43% higher risk of developing colorectal cancer than non-diabetic women, according to a Harvard study.
- Diabetic women have a 49% higher risk of developing colon cancer, the study says.
- Researchers say hyperinsulinemia and slower bowel transit in those with impaired glucose tolerance may be the cause.

based on data from the 18-year, 118,000-participant Nurses’ Health Study shows diabetic women have a 43% higher risk of colorectal cancer and a 49% higher risk of colon cancer than nondiabetic women.

“I am surprised. This is not something I have ever considered myself,” says **John H. Bond**, MD, chairman of the American Digestive Health Foundation’s colorectal cancer awareness campaign.

He says he is particularly surprised that even after correcting for obesity and low exercise levels, known to be associated with both cancer and diabetes, there was still a positive association. “That is statistically significant,” Bond says.

“Diabetics are clearly at higher risk for colorectal cancer, so they should clearly raise the radar screen for physicians seeing them,” says **Michael Thun**, MD, MS, head of epidemiology at the American Cancer Society in Atlanta.

He recommends all women over 50 get an annual fecal occult exam and a sigmoidoscopy every five years or, in the alternative, a barium enema and colonoscopy.

In diabetic women, he says, physicians need to be particularly alert and perform those screenings earlier if there are any reasons for concern. “Colorectal cancer deaths are almost all avoidable by doing the appropriate screening,” Thun says. “We can identify benign polyps and prevent the disease or cure it if we catch it early enough.”

**Bernard Levin**, MD, a gastroenterologist at the MD Anderson Cancer Center at the University of

### COMING IN FUTURE MONTHS

■ Highlights from the ADA’s 59th Scientific Sessions

■ Hypertension education: A neglected part of diabetes management

■ Management strategies for primary care physicians

■ Prioritizing and managing comorbidities and complications

■ Age and diabetes: Pediatric, teen, adult and geriatric issues

Texas in Houston, says the elevated risk among diabetic women is "worth noting," and "physicians taking care of diabetic patients need to be aware of it."

Researchers, led by Frank B. Hu, PhD, a nutritionist at the Harvard School of Public Health in Boston, theorize that hyperinsulinemia may promote the growth of cancer cells in the colon. They also note that the elevated fecal bile acid may cause slower bowel transit, exposing diabetics to more toxic substances and carcinogenic bile acids.

Thun adds that several studies show that hormone replacement therapy for post-menopausal women decreases the risk of colon cancer.

There is no explanation for the higher risk among women, but Bond suggests that may simply be a factor of the heavily female-weighted Nurses' Health Study, the source of the data for Hu's analysis.

However, Bond cautions that the correlation showing women diabetics are susceptible to colorectal cancer is a "relatively weak one" and notes the data from the Nurses' Health Study "may or may not be generalizable to the general population."

*[Michael Thun can be reached at (404) 329-5747 and John Bond at (612) 725-2000.] ■*



## Texas Diabetes Institute opens in San Antonio

The Texas Diabetes Institute, a joint venture for diabetes treatment, education and research by the University Health System and the University of Texas Health Science Center, opened in San Antonio in early May.

The 153,000 square-foot, \$28 million facility, specially targeting Type 2 diabetes, is uniquely designed to allow for a continuum of care, including early prevention, patient education, routine treatment, research and statewide professional and physician training. ▼

## Advances in the treatment of erectile dysfunction

Approximately 50% of all diabetic men suffer from erectile dysfunction caused by the disease. Reports have shown Viagra (sildenafil) can often be an effective treatment. Here are some other screenings and treatments becoming available.

American Medical Systems of Minnetonka, MN, has developed NEVA, a home monitoring system that measures several parameters of nocturnal erectile events to help urologists identify the extent of a patient's erectile dysfunction and help select treatments.

ArginMax, produced by The Daily Wellness Co. of Mountain View, CA, is a compound of

Diabetes Management™ (ISSN# 1098-0032) is published monthly by American Health Consultants®, 3525 Piedmont Road, Building Six, Piedmont Center, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Application to mail at periodical rates is pending at Atlanta, GA 30304. POSTMASTER: Send address changes to Diabetes Management™, P.O. Box 740059, Atlanta, GA 30374.

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Subscription rates: U.S.A., one year (12 issues), \$259. Outside U.S., add \$30 per year, total prepaid in U.S. funds. One to nine additional copies, \$207 per year; 10 to 20 additional copies, \$155 per year. For more than 20 copies, contact customer service for special arrangements. 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 \$43 each. (GST registration number R128870672.)

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### Editorial Questions

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herbs, amino acids, vitamins and minerals the company says assists in the production of nitric oxide, the signaling molecule for male erection.

The over-the-counter supplement contains ginkgo biloba, American ginseng, Korean ginseng, L-Arginine, vitamins A, C, E, B complex, selenium and zinc. In addition, the Joslin Diabetes Center in Boston has opened an Internet erectile dysfunction discussion site. The Web site can be found at: [www.joslin.org/education/library/sexualdysfunction.html](http://www.joslin.org/education/library/sexualdysfunction.html).

The site includes a brief interactive quiz to help both men and women discover if they have sexual dysfunction, suggested ways to approach the subject with a partner and a detailed discussion of various treatment options available. ▼

## No-strip monitor introduced

The first “no-strip” blood glucose monitor available in the United States has been introduced by Bayer Corp.

The Glucometer DEX Diabetes Care System contains a cartridge that enables diabetics to perform ten tests before replacing the cartridge and an electronic memory that stores up to 100 test results.

The monitor draws a small amount of blood into a test sensor and makes results available in about 30 seconds. The company says the unit will retail for about \$70, which is comparable to the cost of other types of monitors. ▼

## FDA panel recommends rosiglitazone approval

The Food and Drug Administration’s (FDA) Endocrinologic and Metabolic Drugs advisory committee in late April unanimously supported the approval of rosiglitazone (to be marketed under the brand name Avandia by SmithKline Beecham) as a monotherapy and in combination with metformin for the treatment of Type 2 diabetes. The recommendation is expected to be followed by full FDA approval within a few weeks.

Avandia is being offered as an alternative to another drug in the thiazolidinedione class, troglitazone (marketed as Rezulin by Warner-

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Lambert) after at least 35 cases of acute liver failure, including 28 deaths, were reported among patients taking the drug.

The FDA now recommends the use of Rezulin only in combination therapy, but said that the substantial benefits of the drug outweigh the risks of liver failure.

Shortly after the advisory panel’s recommendation in favor of Avandia, SmithKline Beecham announced it had entered into an agreement with Bristol-Myers Squibb to co-promote the drug in the United States. ■

## CE objectives

After reading each issue of *Diabetes Management*, the continuing education participant will be able to do the following:

1. identify particular clinical administrative, pharmacological, or patient education issues related to the disease state management of diabetes;
2. describe how those issues affect patients, health professionals, diabetes management efforts and diabetes-related medical costs;
3. cite practical solutions to problems associated with diabetes management, based on overall expert guidelines from the federal Centers for Disease Control and Prevention, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the American Diabetes Association, or other authorities, or based on independent recommendations from clinicians at individual institutions. ■