

DIABETES IN CONTROL.com Newsletter

The Newsletter for Professionals in Diabetes Care

October 4, 2006 Issue #332

Top Diabetes Stories:

How to Screen a Community for PreDiabetes & Diabetes*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4186>

Abbott's Continuous Blood Glucose Monitor Approval Soon*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4185>

Breast-Feeding Lowers Mom's Risk of Diabetes*

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New DPP-4 and Glitazone Diabetes Drugs Will Account for 72% of the Diabetes Market*

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Understanding Food Nutrition and Reading Food Labels is a Major Challenge for Most People*

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Docs Overlooking Flu Shots*

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From the editor's desk

We try to give our patients the best care, but sometimes our own devices do more harm than good. **Thomas J. Lamb, Attorney at Law**, represents patients in drug injury cases and this week explains how the [FDA-MIT Database Project Should Improve Drug-safety Monitoring](#). Read part 2 of *Extent Of Serious Adverse Drug Reactions In The U.S.*, [by clicking here](#)

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4167>

The competition is heating up as another CGMS system is about to arrive on to the market, see this weeks Item #2

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4185>

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Last time **Sheri Colberg, Ph.D., FACSM** had some great insight as to why patients do not lose weight even though they exercise. This week she helps you give your patients a proper start. Learn what to do by reading [Getting Started Is the Hardest Part](#). Check out [this week's tool](#) for more help.

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4188>

October 8, 7PM ET dLife on CNBC

Experts debate just what "good diabetes control" really is; one of America's premiere endocrinologists talks about high tech advances in patient care; and low-carb cooking, Southern style, with dLife Chef Franklin Becker. Tune in to this re-broadcast of dLifeTV: Sundays on CNBC at 7 PM ET, 6 PM CT, and 4 PM PT. Check your local listings for details.

We can make a difference!

This week's overview:

Item #5: Big Waist, Heavy Weight Both Raise Diabetes Risk

Item #6: Salad Is Even Healthier Than You Thought

Item #9: Many Patients with Diabetes and Heart Disease Quit Medicine Too Early

Item #11: Doxazosin and Acarbose Improve Glucose Tolerance

Item #12: Diabetes, Not Obesity, Raises Risk of Organ Failure and Death

Item #13: Benfotiamine Prevents Postprandial Symptoms in Diabetes Glycemia

Check out this weeks "Test Your Knowledge" question.

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4189>

Dave Joffe, *Editor-in-Chief*

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NEWS FLASH:

BD Announces that it will Exit the Blood Glucose Monitoring Market, Effective Immediately: BD (Becton, Dickinson and Company) announced last Thursday, that it will exit the blood glucose monitoring (BGM) market. This action impacts BD's blood glucose monitors and test strips only. Strips will be available through 2007. They will continue to supply products to MiniMed until they can find a replacement product. Abbott, Bayer and Lifescan announced they will replace all BD monitors at no cost, just call their customer service 800 numbers and ask to replace your BD monitor.

Abbott's Continuous Blood Glucose Monitor Approval Soon: Expected approval sometime in

November: See this weeks Item #2

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4185>

Lilly's Arxxant Drug for Treatment Diabetic Eye Disease, Delayed for Up To 5 Years

The Food and Drug Administration is calling for additional efficacy data before it will consider approving the molecule for the treatment of moderate to severe diabetic retinopathy. Lilly will evaluate its options for further development.

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Tools for Your Practice:



Seated Exercise Series: Chair Calisthenics

This handy printable sheet is a must have for your older patients that need physical activity, and can even be done while watching TV.

[Chair Calisthenics](#)

<http://www.diabetesincontrol.com/sandstedt/is146.pdf>

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New Product:

Contrave™ (Orexigen) Reports Positive 24-Week Data on Obesity Treatment

Orexigen Therapeutics announced that top-line results for the company's lead obesity compound, Contrave™, demonstrated significant advantages in weight loss in a 24-week multicenter, placebo-controlled, Phase III trial. The trial will continue unblinded for an additional 24 weeks. See this week's Item #15

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4172>

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This Week's Items:

1. **How to Screen a Community for PreDiabetes & Diabetes***

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4186>

2. **Abbott's Continuous Blood Glucose Monitor Approval Soon***

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3. **Breast-Feeding Lowers Mom's Risk of Diabetes***

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4. **New DPP-4 and Glitazone Diabetes Drugs Will Account for 72% of the Diabetes Market***

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6. Salad Is Even Healthier Than You Thought

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7. Understanding Food Nutrition and Reading Food Labels is a Major Challenge for Most People*

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12. Diabetes, Not Obesity, Raises Risk of Organ Failure and Death

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13. Benfotiamine Prevents Postprandial Symptoms in Diabetes

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ITEMS For The Week:

Item 1

How to Screen a Community for PreDiabetes & Diabetes

Evaluation of a campaign that screened a community of 95,000 via 530 pharmacies.

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4186>

We know that there are 42 million people in the US with prediabetes and if found early, we can possibly prevent them from getting diabetes by 70%, which comes from the results of the recent Dream study and the Diabetes Prevention Trials (DPPT). In the following abstract you can see that there is an effective way to screen a population that is cost effective.

Sequential screening for diabetes—evaluation of a campaign in community pharmacies

The purpose was to detect for early detection of persons at risk for type 2 diabetes, a combination of risk factor assessment and glucose measurement could be a promising approach and an opportunity for health promotion. The object of this study was to develop a sequential screening concept and to evaluate it in a national pharmacy based screening campaign.

Method: Community pharmacies of the German speaking part of Switzerland participating in the national Self Care campaign "Stop diabetes-test now" offered a free of charge "sequential screening" with (a) diabetes risk assessment, (b) consecutive capillary blood glucose measurement and (c) assessment of the motivation for lifestyle change based on the Transtheoretical Model (TTM) of behaviour change. A 35 items data sheet served as a structured screening protocol and enabled quick and reliable documentation of all relevant data. Outcomes measures were: age, sex, cigarette smoking, total score of the ADA diabetes risk-factor questionnaire, family history of diabetes, body mass index, insufficient physical activity, blood pressure, capillary blood glucose, motivation for lifestyle change, counselling activities and triage decisions of the pharmacy team.

Results: During the 5 weeks of spring 2002, 530 pharmacies screened a total of 93,258 persons (33.1% male, mean age 60.9 years \pm 14.1 (SD)). Risk profile: family history of diabetes 26.4%; BMI = 25 kg/m² 49.3%; low physical activity 27.2%; elevated blood pressure 45.7%. Stratification into risk groups: < 2 risk factors 21.6%; = 2 risk factors 71.5%; borderline glycemia >95mg/dL- FG 5.3–6.1 mmol/l, confirmed in a second measurement) 2.5% and hyperglycaemia FG 109mg/dL (FG = 6.1 mmol/l or NFG = 11.1 mmol/l) 4.4%.

Of all persons screened, 6.4% were referred to a physician and 73.7% got targeted advice with respect to physical activity and/or nutrition based on their specific risk profile.

Conclusion: The sequential screening could successfully be implemented into pharmacy practice. Of the generally elderly persons screened, 6.9% were detected with suspicion for diabetes type 2 and 71.5% had at least two risk factors. This provided an opportunity to initiate targeted counselling regarding therapeutic lifestyle change.

Publishers Note: *What are we waiting for? If we can prepare for the dire flu epidemic by stock piling drugs for something that we don't even know will ever happen, why not actually do something for an epidemic that we know is happening right now?*

Journal: [Pharmacy World & Science](#) Publisher Springer Netherlands

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Item 2

Abbott's Continuous Blood Glucose Monitor Approval Soon

The expected 1 Billion dollar market for CGMS (Continuous Blood Glucose Monitor), will soon have another competitor to compete with MiniMed and DexCom, it's the Navigator from Abbott Diabetes Care. This was one of the main reasons Abbott bought Therasense, to gain control of the new sensor technology. It looks like they could get approval for the navigator CGMS this November.

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4185>

Abbott Laboratories Inc. is talking tough about the competitive prospects for its soon-to-be approved continuous glucose monitor, feeding what some analysts see as a coming "dogfight" for control of the fledgling market.

Abbott's Freestyle Navigator is expected to win U.S. Food and Drug Administration approval by year-end, making the company the third this year to get the nod from U.S. regulators for the sophisticated devices that help diabetics better manage their disease.

Medtronic Inc., the No. 1 maker of insulin pumps, and DexCom Inc., a smaller player that went public in April 2005, also got approval for continuous glucose monitors this year.

Medical device makers and drug companies are clamoring to develop products to address the diabetes epidemic, which is growing at a rate of about 7 million new cases worldwide a year.

Ed Fiorentino, president of Abbott's diabetes unit, said he believes Abbott's product will set the bar for these high-tech tools, which the company estimates could represent an annual \$1 billion market. "When you think about our product, you think about two things: better accuracy and better information for the patient," he said.

Some on Wall Street agree and think that Abbott's Freestyle Navigator could be the device of choice in this segment, given its accuracy and ease of use.

Instead of sporadic readings, the new devices track blood sugar constantly and sound alarms if it goes outside of safe ranges. The pager-sized tools take readings from a tiny sensor inserted just under the skin and held in place by an adhesive patch. A transmitter relays the minute-by-minute findings to a wireless receiver. Anybody who needs a lot of information about their blood glucose levels probably will be using one of these at some point. The Abbott device will kick off a "marketing dogfight" over product features.

Better accuracy and longer-wearing sensors -- five days with the Abbott product vs. three days with the Medtronic and DexCom devices -- will give Abbott an edge. Its first approval will be labeled for use with the current finger-stick method for tracking diabetes. The next step will be to claim a so-called "reportable result," meaning the patient won't have to verify the findings with a finger-stick test. They already have the studies to submit after they get their first approval.

A replacement claim may be key to winning support from payers and private insurance companies, which will likely pay for the lion's share of the devices. Analysts think that it will take at least two years before companies develop a "reasonable number of payers." But they expect to see a lot more positive pay decisions in the next 12 months.

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DID YOU KNOW:

Fruit and Vegetables Cut Heart Disease Risk, Says Study: Every extra of fruit or vegetable consumed daily could cut the risk of heart disease by four percent, says a meta-analysis of almost a quarter of a million people, giving people even more reason to seek out the nutrient-rich foods. Recent studies have shown that the average consumption of people in developed countries is three portions a day. The analysis, found that the risk of coronary heart disease (CHD), conditions that cause of 20 per cent of deaths in the US and 17 per cent of deaths in Europe, was cut by four per cent for each additional fruit and vegetable portion consumed, and by seven per cent for fruit portion intake. *Journal of Nutrition* (Vol. 136, pp. 2588-2593),

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Item 3

Breast-Feeding Lowers Mom's Risk of Diabetes

Breast-feeding your baby can cut your risk of developing type 2 diabetes by 15% a year and reduce the risk of breast and ovarian cancer.

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4184>

"We found that breast-feeding is really good for mothers. Each year she breast-feeds cuts the risk of type 2 diabetes by 15 percent," said study author, Dr. Alison Stuebe, a clinical fellow in maternal fetal medicine at Brigham and Women's Hospital, and an instructor at Harvard Medical School in Boston.

Breast-feeding offers a host of health benefits for babies. Along with providing optimal nutrition, breast milk also provides compounds that boost babies' immune system and help protect against bacteria, viruses and parasites, according to the U.S. Food and Drug Administration. In addition, breast-fed children have lower rates of childhood illnesses and tend to be leaner than their formula-fed counterparts.

And research has shown mothers benefit as well: Breast-feeding helps a mother's body return to normal faster after pregnancy, according to the FDA. Some studies have suggested that women who breast-feed for long periods of time may have lower rates of breast and ovarian cancer.

But, no long-term studies had examined the effect of breast-feeding on maternal risk of diabetes, Stuebe said.

Stuebe and her colleagues suspected breast-feeding might affect type 2 diabetes risk because it substantially changes a mother's metabolic requirements, and research has shown that breast-feeding improves insulin sensitivity and glucose tolerance.

The researchers used data from the Nurses' Health Study and the Nurses' Health Study II, which together included more than 150,000 women who had given birth during the study period. More than 6,000 of these women were diagnosed with type 2 diabetes.

After controlling for body mass index (BMI) -- because a high BMI is a known risk factor for type 2 diabetes -- the researchers found that long-term breast-feeding reduced a woman's risk of developing diabetes. The risk was decreased by 15 percent for each year of breast-feeding for women in the Nurses' Health Study, and by 14 percent for each year for those in the Nurses' Health Study II.

Stuebe said the researchers weren't able to determine how breast-feeding might offer some protection against diabetes, only that breast-feeding was associated with a drop in the rate of type 2 diabetes. However, she said, the researchers suspect that breast-feeding may help keep blood sugar in balance, or "homeostasis."

Breast-feeding mothers burn almost 500 additional calories daily, according to the study. That's equivalent to running about four to five miles a day, Stuebe noted. "If done for a year, it's not surprising that it might have an effect on how the body takes care of insulin and glucose," she said.

Dr. Loren Wissner Greene, an endocrinologist at New York University Medical Center in New York City, said the explanation for why women who breast-feed for long periods may have lower rates of diabetes could be a simple one: "The small weight changes from lactation can make a significant impact on diabetes risk." In fact, Wissner Greene said, the best advice for anyone to avoid type 2 diabetes is to maintain a healthy weight, and lose weight if you're carrying excess weight.

Another potential explanation could be that women who breast-feed for a long time are more health-conscious than other women, and may have a healthier diet, may exercise more and do other health-promoting activities that could reduce their diabetes risk.

Stuebe said the researchers tried to take lifestyle factors into account and still saw an association between breast-feeding and reduced diabetes risk.

The bottom line, said Stuebe: "We're talking about an intervention that doesn't cost anything, has no side effects and has other potential benefits."

SOURCES: Alison Stuebe, M.D., clinical fellow in maternal fetal medicine, Brigham and Women's Hospital, and instructor, Harvard Medical School, Boston, Mass.; Loren Wissner Greene, M.D., endocrinologist, New York University Medical Center, and clinical associate professor of medicine, New York University School of Medicine, New York City; Nov. 23/30, 2005, *Journal of the American Medical Association*

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Item 4

New DPP-4 and Glitazone Diabetes Drugs Will Account for 72% of the Diabetes Market

According to a new report from Decision Resources, the New Novel Drug Classes Will Account for 76% of the Type 2 Diabetes Market by 2020, even though they are not even available in the US at this time.

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4183>

One of the world's leading research and advisory firms for pharmaceutical and healthcare issues, finds that Merck's Januvia (sitagliptin) and Novartis's Galvus (vildagliptin) will achieve blockbuster status by 2015 for the treatment of type 2 diabetes, joining the current market-leading blockbusters -- Takeda's Actos (pioglitazone) and GlaxoSmithKline's Avandia (rosiglitazone). However, all four of these drugs face extensive loss of market share by 2020 because of patent expiries and the emergence of biogeneric insulins.

The new special Pharmacor report Emerging Therapies in Type 2 Diabetes finds that overall growth in the type 2 diabetes market will be significantly constrained during the second half of the 2005-2020 study period. The loss of patent protection for a number of drugs and the emergence of biogeneric insulins has the potential to take away an estimated \$10 billion in potential sales from Januvia, Galvus, Actos, Avandia, Aventis' Lantus, Novo Nordisk's Novolog, and Eli Lilly's Humalog by 2020. These factors will drive an overall decline in sales as the market matures in the United States, Japan, France, Germany, Italy, Spain, and the United Kingdom.

"In addition to the significant share that biogeneric insulins will garner, inhaled insulins will also become major market players during the forecast period," said Donny Wong, Ph.D., analyst at Decision Resources, Inc. "Leading the way in this class is Pfizer's Exubera, which was launched in the United States and the United Kingdom earlier this year. Although it is the first agent in this class to enter the market, we forecast that Exubera will be quickly overshadowed by other emerging inhaled insulins and, subsequently, by novel transdermal and oral insulin formulations. Novel drug classes, including transdermal and oral insulins, will account for 76% of the type 2 diabetes market by 2020."

The report also finds that drugs that stimulate the incretin pathway are drawing significant attention in the medical community. The first marketed drug with this mechanism of action, Amylin/Eli Lilly's Byetta (exenatide) has been highly successful despite its twice-daily injectable formulation. Although a once-weekly injectable formulation, Byetta LAR, is currently in clinical development, exenatide will be overshadowed by DPP-IV inhibitors, which affect the same pathway but are available in oral formulations.

Decision Resources, Inc. (<http://www.decisionresources.com>)

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DID YOU KNOW:

Americans Unaware of Significance of Triglycerides: A survey conducted by the National Lipid Association (NLA) has revealed that 87% of patients are unaware of the importance of high triglycerides in risk of heart disease. Fewer than half say they have discussed the topic with their physicians. *Survey conducted by the National Lipid Association (NLA)*

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Item 5

Big Waist, Heavy Weight Both Raise Diabetes Risk

Having either a large waistline or being overweight raises a person's risk of developing type 2 diabetes, but the combination of the two is most dangerous, a study shows.

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4182>

It's well known that overweight and obese adults stand a greater chance of developing type 2 diabetes than those who are leaner. Also, many studies have found that excess abdominal fat may carry a particular risk, though not all have reached that conclusion.

As a result, there's some controversy over which measurements should be used to estimate an adult's diabetes risk, according to the authors of the new study. Body mass index (BMI), a measure of weight in relation to height, is the standard way of classifying people as normal weight, overweight or obese. But taking a tape measure to the waistline is a more precise way of gauging abdominal obesity.

In the current study, BMI and waist circumference were each found to be strong predictors of diabetes risk. The risk was greatest among men and women with both a high BMI and large waist.

Dr. Christa Meisinger, the study's lead author stated that, "Doctors should measure waist circumference in addition to BMI to assess the risk of type 2 diabetes in both sexes." Waist size did, however, seem to be particularly important for women, she pointed out. Women who were overweight but not "apple-shaped" did not have an elevated risk of diabetes, whereas a large waistline conferred a higher risk regardless of BMI -- a pattern that was not true of men.

The study included 6,012 men and women ages 35 to 74 who were followed over 8 years. At the outset, all were free of diabetes and underwent medical exams that included measurements of BMI and waist and hip circumference. By the end of the study period, men with the highest BMI were four times more likely than their normal-weight peers to have developed diabetes. The risk was even greater among the heaviest women, who had a 10-fold greater risk than the thinnest women.

Similarly, waist size also predicted diabetes risk, with the relationship being stronger in women than in men. Women with the largest waists were again 10 times more likely to develop diabetes -- with risk factors like age, exercise habits and parents' history of diabetes taken into account.

The findings, according to Meisinger's team, highlight the importance of measuring body size in more than one way. Waistline measurements, Meisinger noted, could be particularly helpful in judging a woman's risk of developing diabetes.

American Journal of Clinical Nutrition, September 2006.

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See clinical data on the sustained benefits of BYETTA for the treatment of type 2 diabetes. BYETTA delivers sustained glycemic control, with most patients losing weight, and simple, fixed BID dosing before morning and evening meals.

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Item 6

Salad Is Even Healthier Than You Thought

Eating just one salad a day provides even greater health benefits than previously thought.

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4181>

This comes from a new study that, examined salad consumption by more than 17,000 adults. The study, conducted by the UCLA School of Public Health and Louisiana State University Health Sciences Center, supported by The Association for Dressings & Sauces, revealed that those who eat salads and raw vegetables with salad dressing have considerably higher levels of vitamins C, E, B6, and folic acid—key nutrients in promoting a healthy immune system and reducing the risk of obesity, heart disease and other chronic illnesses.

“Eating a salad a day is a convenient way to easily improve your nutritional status,” said Dr. Lenore Arab, professor of epidemiology at UCLA School of Public Health and lead researcher of the study, titled “Salad and Raw Vegetable Consumption and Nutritional Status in the Adult US Population”. “Just one salad daily helps to satisfy the 2005 Dietary Guidelines for Americans, which recommends eating two and a half cups of vegetables each day for a 2000-calorie diet.”

According to the study, less than 50% of the US population meets the daily recommendation for vegetables necessary for healthy living. Americans do not get enough of the water-soluble vitamins of which salads are a rich source. The raw vegetables in salads also offer the added benefits of fiber for better digestion and antioxidants for boosting immunity.

Interestingly, clinical trials have shown that adding salad dressing to a salad not only adds a delicious flavor, but also increases the absorption of certain nutrients being consumed. “It’s not just the leafy greens and vegetables that are doing a body good,” said Arab. “Some fat can also enhance the absorption of nutrients such as lycopene and alpha- and beta-carotene.”

The findings of this study are consistent with the government’s new push for more fruit and vegetable consumption. Though it’s already known that salad was a healthy meal option, the bottom line, according to the UCLA study - eating one salad a day is a simple way to live a healthier lifestyle.

The study has been published in the September issue of the Journal of the American Dietetic Association. For more information, visit

<http://www.saladaday.org>.

The Association for Dressings and Sauces is an international trade association representing the manufacturers of salad dressings and condiment sauces and the suppliers to the industry. For more information, visit our website at <http://www.dressings-sauces.org>.

The study was supported with funding from the National Institutes of Health.

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Item 7

Understanding Food Nutrition and Reading Food Labels is a Major Challenge for Most People

Only 32% of patients could correctly calculate the amount of carbohydrates consumed in a 20-ounce properly labeled bottle of soda that had 2.5 servings in the bottle.

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4180>

In one of the most rigorous studies ever conducted to determine how well people comprehend the information provided on food nutrition labels, researchers have found that the reading and math skills of a significant number of people may not be sufficient to extract the needed information.

Using standardized and validated tests for literacy and numeracy, researchers from Vanderbilt University Medical Center surveyed 200 primary care patients from a wide socioeconomic range. A Nutrition Label Survey (NLS), designed with input from registered dietitians, primary care providers, and experts in health literacy/numeracy to evaluate patient understanding of current nutrition labels, was used to measure comprehension of current food nutrition labels. One part of the NLS asked

subjects to interpret food labels, such as determining carbohydrate or caloric content or an amount of food consumed. In the other part asked patients to choose which of two foods had more or less of a certain nutrient, giving patients a 50/50 chance to guess the correct food item. Also, half of the survey questions involved products that were clearly labeled on their package as "reduced carb," "low carb," or designed for "a low-carb diet."

Sixty-eight percent of patients had at least some college education, and 77% had at least 9th-grade level literacy skills. However, 63% of patients had less than 9th-grade numeracy skills. Over 40% had a chronic illness for which specific dietary intervention is important (e.g., hypertension, diabetes), and 23% reported being on a specific diet plan. Most patients reported using food labels and found labels easy to understand.

Overall, patients correctly answered 69% (SD 21%) of the NLS questions. For example, only 32% of patients could correctly calculate the amount of carbohydrates consumed in a 20-ounce bottle of soda that had 2.5 servings in the bottle. Only 60% of patients could calculate the number of carbohydrates consumed if they ate half a bagel, when the serving size was a whole bagel. Only 22% of patients could determine the amount of net carbohydrates in 2 slices of low-carb bread, and only 23% could determine the amount of net carbohydrates in a serving of low-carb spaghetti. Common reasons for incorrect responses included misapplication of the serving size, confusion by extraneous material on the food label, and incorrect calculations.

According to Russell L. Rothman, MD MPP, "The study showed that many patients struggle to understand current food labels, and that this can be particularly challenging for patients with poor literacy and numeracy (math) skills. Poor understanding of nutrition labels can make it difficult for patients to follow a good diet. Of particular concern are situations that involve interpretation and application of serving size. There are many opportunities for health care providers to improve how they talk to patients about using food labels and following diets. There are also opportunities for the FDA to improve how food labels are designed in order to improve how patients take care of their nutrition.

The article is "Patient Understanding of Food Labels: The Role of Literacy and Numeracy" by Russell L. Rothman, MD MPP, Ryan Housam, BS, Hilary Weiss, BS, Dianne Davis, RD CDE, Rebecca Gregory, MS RD CDE, Tebeb Gebretsadik MPH, Ayumi Shintani, PHD MPH, and Tom A. Elasy, MD MPH.

*The article appears in the American Journal of Preventive Medicine, Volume 31, Issue 5 (November 2006)
Full text of the article is available upon request*

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Dr. Bernstein will be doing another live teleconference call soon. If you would like to ask a question or just register for the free teleconference call, just go to www.askdrbernstein.com and register. There were over 600 people on the last call. More info at www.diabetes911.net

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Item 8

Small Changes in Diabetes Care Exceeds All Expectations

A series of fairly low-tech innovations radically transformed diabetes care in a busy family medicine program in just over a year's time, exceeding insurance company pay-for-performance benchmarks.

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4179>

Improvements were seen over time in both process measures, such as how many patients underwent testing for urinary microalbumin, and outcome measures, such as the number of patients with diabetes whose hemoglobin A1c (HbA1c) levels were brought to less than 7%.

On several measures, the practice surged past national targets for diabetes care and exceeded the median performance of 80 similar practices. Key to the effort at the family medicine residency program of the Washington Hospital in Washington, Penn., were the following elements of active diabetes management:

A chart study revealed that most of the group's roughly 1,000 patients with diabetes were coming into the family medicine office with some regularity but for indications other than diabetes, such as urinary tract infections, colds, and so on. They then skipped routine appointments for their diabetes care, perhaps thinking, "Well, I was in the office. I assumed if I had any problem with my diabetes, you would have said something," surmised Dr. Minter, associate director of the family medicine program.

In addition, there was clearly a problem with continuity of care. The chances of seeing one's own physician in a nonroutine visit was only about 60% in the "organized chaos" of the practice, which includes 24 family medicine residents, 14 faculty members, more than 40 nonphysician staff members, and which deals with 58,000 patient visits a year.

To make sure that patients did not slip through the cracks, the program began color-coding all the charts, assigning a bright yellow file folder jacket to any patient with diabetes. "It's a very low-tech thing to do, but it made a lot of difference," he said. "You know when you're walking down the hall and you see a yellow chart, you should start thinking about diabetes."

A template for diabetes management was soon integrated prominently into the electronic medical records that are accessed by each staff member who scheduled visits or cared for patients. When a patient called for an appointment of any kind, it was evident if he or she was lagging behind schedule on recommended lab tests, specialty examinations, or any routine element of diabetes care.

Standing orders sent such patients to the laboratory prior to the scheduled appointment, so that up-to-date results would be available to whatever physician the patient was scheduled to see. Any test or examination that was still not current—an ophthalmologic examination, for example—was highlighted on the template in the patient's yellow-jacketed chart.

"This is really powerful, because now, I not only know it's a diabetic, I can look at that sheet, and even if it's not my patient, I can get these things ordered." The reminders significantly improved physicians' adherence to department guidelines for diabetes care, said Dr. Minter.

Another important shortcoming identified in the chart review was the lack of follow-up with patients who didn't come in for care of any kind.

A database query identified 469 patients whose most current hemoglobin A1c was greater than 7%, and many of them had not been in for care in more than a year. Of 59 patients with HbA1c measures greater than 10%, 30 were successfully contacted, including 8 who had not been seen in the center for more than a year.

A decision was made in early 2005 to actively pursue these patients, first with a letter and then through follow-up phone calls, to emphasize the need for regular diabetes care. "You have to change the culture," said Dr. Minter. "You can't sit by the phone and passively wait for someone to call." Of the 469 patients, 250 were reached by nurses who had been designated to focus on patients with diabetes.

Appointments were scheduled and barriers overcome. If a patient balked at scheduling an appointment because of a high copay, the nurse or a part-time diabetes educator contacted a social worker and the billing department to arrange for assistance.

The focus on high-risk, elusive patients had the temporary effect of undercutting the practice's on-paper performance measures. The percentage of patients with HbA1c levels less than 7% slipped at first before it improved, Dr. Minter noted.

"These people hadn't been in the office and were out of control," he said. By early 2006, however, the percentage of patients meeting the HbA1c goal "was doggone close to the upper confidence level."

The number of obese patients in the practice appeared to increase, because the information was now being entered into the medical records as never before.

Still, important measures started to improve in a dramatic fashion. For example, the target for LDL cholesterol is now being met in a percentage of patients that exceeds the group's benchmark goal.

Other outcome measures have yet to improve, such as the percentage of patients with diabetes meeting targets for blood pressure. But, "we would expect this not to improve for some time," said Dr. Minter.

Essential to the Washington Hospital's success was buy-in from everyone in the family medicine program, Dr. Minter said. Nine nurses were assigned to become diabetes coordinators, with responsibility for a specific group of diabetes patients in the database. The nurses took seriously their responsibility to contact these patients and improve their care, greeting them when they arrived for appointments and taking pride in the patient's progress.

The hospital's diabetes educator, spent 1 day a week in the primary care office, where she helped keep the program on target and provide feedback about strides that were being made.

In a striking demonstration of the pivotal role of nurses, Dr. Minter displayed charts that showed sudden dips in positive trends that occurred near the very end of the demonstration project.

The hiccups coincided with budgetary cutbacks that left the practice short of its normal nursing staffing.

Almost all outcome measures dipped, he said. I'm using this as a stick with the CEO. Look, this is what we can do when we have the right kind of staffing, and this is what happens when we don't."

He also noted that it was interesting that insurance companies, eyeing the program's improving bottom line, have been helpful in assisting the practice to implement changes and track its progress.

As an added bonus, improved performance on process and outcome measures spilled over into better care of nondiabetic patients as well as those with diabetes, Dr. Minter observed.

"If you do a good job with diabetes, you're probably going to improve your numbers for coronary artery disease, renal disease, hyperlipidemias," he said. "You're killing four or five birds with one stone."

Family Practice: Volume 36, Issue 18, Page 1,19 (15 September 2006)

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FACT:

Poor Adherence to Diabetes Meds Linked with High Mortality: Two new studies show that nonadherence to medication is common among recent MI patients and in those with diabetes, resulting in higher mortality. Nonadherence in the MI study resulted in an almost fourfold increase in the death rate in the first year after hospital discharge, while the diabetes sufferers had almost a twofold increase in mortality following noncompliance.

Arch Intern Med 2006; 166: 1842-1847.

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Item 9

Many Patients with Diabetes and Heart Disease Quit Medicine Too Early

Many patients stop taking their medicine far sooner than they should, researchers say, and that decision can be deadly when the drugs treat heart disease or diabetes. Two new studies show that nonadherence to medication is common among recent MI patients and in those with diabetes, resulting in higher mortality.

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4178>

It took only one month after leaving the hospital for 1 out of 8 heart attack patients to quit taking the lifesaving drugs prescribed to them, a study of 1,521 patients found. One month is very surprising," said study co-author Dr. Michael Ho of the Denver Veterans Affairs Medical Center.

The heart patients who stopped taking three proven drugs -- aspirin, beta blockers and statins -- were three times more likely to die during the next year than patients who stayed on the pills. The study didn't examine why people stopped taking their medicine, but the patients who quit were more likely to be older, single and less educated.

They're in good company. Former President Bill Clinton -- a younger, married and well-educated patient -- was prescribed a statin for high cholesterol when he left office. But he stopped taking it at some point. And at age 58, he had to have quadruple bypass surgery because of severely clogged arteries that doctors said put him danger of a heart attack.

The study of heart patients appears in Monday's Archives of Internal Medicine. The issue features a group of studies on patients who stopped taking their medications.

One of the studies reviewed medical records of 11,532 diabetes patients. It found that those who didn't take their drugs -- hypoglycemics, blood pressure drugs and statins -- had higher rates of hospitalization and death. The link was not as pronounced as in the heart attack research, but was still significant.

Some patients assume they quit their pills if the doctor says their cholesterol looks good, said Dr. Kim Eagle of the University of Michigan. "Generally, these medications need to be continued to have their benefit," he said of drugs that fight heart disease. But many factors, he said, conspire against regular drug-taking: cost, side effects, depression, carelessness and a desire not to be someone who takes a lot of pills.

In a study of 13,835 Medicare enrollees, 29 percent of disabled people and 13 percent of the elderly reported they had skipped doses or hadn't filled a prescription because of cost. That research was done before the new Medicare drug benefit took effect and the researchers recommend more study to see what effect the new benefit might have.

One issue arising recently and causing concern among health advocates is the coverage gap in the Medicare drug benefit, which leaves the elderly and disabled paying thousands of dollars out of pocket after their drug costs reach \$2,250.

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For the diabetic patient, it's not the cholesterol that's the problem. It's the number of LDL particles, especially small LDL particles. To see the real risk, use the NMR LipoProfile(r) test, the only test that directly measures the number of LDL particles and the number of small LDL particles - the particles shown to be more predictive of CHD events than LDL-C. Click here to learn more.

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Item 10

Edmonton Islet Transplants Fall Short

The hope for a cure fails: Two years after receiving transplants of insulin-producing beta islet cells, only five of 36 patients with type 1 diabetes remained free of the need for insulin injections.

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4177>

Although most patients in this small multinational trial sooner or later reverted to exogenous insulin, the transplanted cells continued to protect the majority from severe hypoglycemia and helped them maintain lower levels of glycosylated hemoglobin (HbA1c), reported A.M. James Shapiro, M.D., Ph.D., of the University of Alberta here, and colleagues.

The patients were treated under the Edmonton protocol, in which islet cells harvested from the pancreases of brain-dead donors are infused into the portal vein of the liver. The investigators reported two-year follow-up results on the 36 patients in the Sept. 27 issue of the *New England Journal of Medicine*.

In an accompanying editorial, Jonathan S. Bromberg, M.D., Ph.D., and Derek LeRoith, M.D., Ph.D., of Mount Sinai in New York lauded the work of the Edmonton protocol researchers, but noted that the technique is fraught with challenges and may address the needs of only a fraction of patients with type 1 diabetes.

"It is noteworthy that in order to recruit 36 patients, the investigators screened more than 2,000 subjects for eligibility," they wrote. "Only 7% fulfilled the initial screening criteria, which included severe recurrent hypoglycemia, severe glycemic lability, progressive secondary complications, and the failure of conventional therapy."

In addition, they noted that only 45% of islet isolations resulted in transplants, there was a high rate of serious adverse events, and the clinical results were mixed.

The study was designed to test whether the protocol, developed here, could be reproduced successfully elsewhere. To this end, investigators in nine centers in Canada, the United States, Germany, and Switzerland treated four patients each. The patients were all adults from the ages of 18 to 65 with type 1 diabetes who could not achieve good glucose control despite best efforts.

Each patient received infusions into the hepatic portal vein of prepared donor islets from brain-dead multi-organ donors. Post-transplant immunosuppression consisted of five doses of Zenapax (daclizumab) at 1 mg/kg administered intravenously over eight weeks following each transplantation. Rapamune (sirolimus) was administered once daily to achieve a target trough therapeutic range of 12 to 15 ng/ml for three months after transplantation, after which the target trough range was lowered to 7 to 12 ng per ml. Prograf (tacrolimus) was administered twice daily and adjusted to achieve a target trough level of 3 to 6 ng/ml.

The primary study endpoint was insulin independence, which the authors defined as freedom from the need to take exogenous insulin, with adequate glycemic control, as defined by an HbA1c level of less than 6.5%, and a fasting overnight glucose level not exceeding 140 mg/dL (7.8 mmol/L) more than three times in any week (based on the morning fasting glucose level) and not exceeding two-hour postprandial levels of 180 mg/dL (10 mmol/L) more than four times per week.

"We recognize that applying more stringent measures for glycemic control might have altered the outcome," the investigators wrote.

Secondary endpoints included insulin independence with adequate glycemic control throughout follow-up; improved values for levels of HbA1c, the mean amplitude of glycemic excursions, and of basal and stimulated blood C-peptide levels in response to arginine challenge; and a reduction over baseline in the need for insulin.

They found that at one year, 16 of the 36 participants (44%) were insulin independent and had good glycemic control, 10 (28%) had partial function, and 10 (28%) had experienced complete graft loss.

In all, 21 of the 36 patients had achieved the primary study endpoint at some time during the study, but 16 of the 21 (76%) required exogenous insulin again by two years. The remaining five participants remained insulin independent at two years.

There were 38 total serious adverse events, 23 of which were considered to be related to the study therapy; 18 of these events were associated with hospitalization.

Serious adverse events included neutropenia, pneumonia, mouth ulcers, gastrointestinal conditions, fever, chest pain, pericardial effusion, pyelonephritis, worsening genital herpes, and appendiceal abscess

The results suggest that "islet transplantation with the use of the Edmonton protocol can successfully restore long-term endogenous insulin production and glycemic stability in subjects with type 1 diabetes mellitus and unstable control, but insulin independence is usually not sustainable," the investigators wrote.

Nonetheless, there was evidence that residual, persistent islet function even in the absence of insulin independence provides protection from severe hypoglycemia and improved HbA1c levels, the authors wrote.

Both the authors and the editorialists pointed out that pancreatic transplantation was the better option for the general population of patients with type 1 diabetes.

"It is clear that poor long-term results, high costs, and the relatively high incidence of major and minor serious adverse events make it difficult to argue for expansion of islet transplantation to the general population," wrote Drs. Bomberg and LeRoith.

Shapiro AMJ et al. "International Trial of the Edmonton Protocol for Islet Transplantation." *N Engl J Med* 2006;355:1318-30

Bromberg JS and LeRoith D. "Diabetes Cure -- Is the Glass Half Full?" *N Engl J Med* 2006;355:1372-74

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Item 11

Doxazosin and Acarbose Improve Glucose Tolerance

Doxazosin appears to work synergistically with acarbose to improve metabolic control in patients with impaired glucose tolerance.

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4176>

Dr. Guiseppe Derosa of the University of Pavia and colleagues sought to determine whether doxazosin had a synergistic effect when combined with antihyperglycemic treatment with the alpha-glucosidase inhibitor acarbose.

To investigate, the researchers studied 107 patients with impaired glucose tolerance. For 3 months, they received acarbose 150 mg per day and were randomized to also receive doxazosin 4 mg per day or placebo.

They were then titrated to receive up to 300 mg of acarbose daily and to continue with their assigned doxazosin or placebo for a further 3 months.

At 6 months, in both groups, there were significant reductions in body mass index (3.6%), HbA1c (9.9%), fasting plasma glucose (8.4%) and post prandial plasma glucose (16.3%). In addition, all tested patients showed a return to normal glucose tolerance.

There also was a significant improvement in fasting plasma insulin levels in the doxazosin group compared to the placebo group. This was also the case for the significant drop seen in the homeostasis model assessment index.

In addition, there were significant favorable changes in lipid parameters in the doxazosin group and reductions in blood pressure that were not seen in the placebo group.

Compared to use of acarbose alone, the researchers conclude that the benefits of the combination go beyond improvements in blood pressure and appear to enhance both glycemic and lipid control.

Clin Drug Invest 2006;26:529-539.

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DID YOU KNOW:

Exercise in Itself Improves Blood Glucose Control in Type 2 Diabetes: Exercise, dietary changes and medication have long been the cornerstones of managing type 2 diabetes. But few studies examine how exercise actually benefits these patients. [Read and print the full news article at:](http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4190)

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Item 12

Diabetes, Not Obesity, Raises Risk of Organ Failure and Death

Findings from a new study suggest that obesity per se is not a risk factor for acute organ failure or death. However, diabetes, which often develops in obese individuals, does increase the risk.

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4175>

study co-author Dr. David M. Mannino, from the University of Kentucky Medical Center in Lexington stated that, "There are several studies out there showing worse outcomes for people with higher BMIs. "Surprisingly, most of the studies really didn't look at how diabetes entered into the picture."

The present research, which is reported in the September 24th issue of Critical Care, involved an analysis of data from 15,408 subjects who participated in the Atherosclerosis Risk in Communities (ARIC) study, a prospective, population-based study.

BMI and the presence of diabetes were determined at baseline. A subject was considered diabetic if they confirmed that a doctor told them they had diabetes, if they reported recently taking medications for "diabetes or high blood sugar," or if their fasting blood glucose was 126 mg/dL or higher.

The main outcomes were the development of acute organ failure within 3 years of the baseline evaluation, in-hospital death during organ failure, and death at 3 years in all subjects and in those with organ failure.

Consistent with previous research, the risk of diabetes was higher in obese subjects. The rate of diabetes among subjects with a BMI of at least 30 was 22.4%, significantly higher the 7.9% rate noted among subjects with a lower BMI.

As noted, BMI alone had no bearing on the risk of acute organ failure. Diabetes, by contrast, was associated with an increased rate of organ failure, at 2.4% versus 0.7% in nondiabetics ($p < 0.01$).

Diabetes was also associated with an elevated risk of death among organ failure patients compared with nondiabetic patients, while hospitalized (46.5% vs. 12.2%) and at 3 years (51.2% vs. 21.1%).

Given the association between a high BMI and diabetes, obese people are still at elevated risk, albeit indirectly, for developing the adverse outcomes described in the present study, Dr. Mannino noted.

Moreover, due to low subject numbers, "we could not address the effect of morbid obesity," so it is possible that a very high BMI is, in fact, an independent risk factor for organ failure and death, he added.

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Item 13

Benfotiamine Prevents Postprandial Symptoms in Diabetes

Benfotiamine prevents the endothelial dysfunction and oxidative stress that follow a meal rich in advanced glycation end (AGE) products in type 2 diabetics.

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4174>

"Benfotiamine was used for decades as a treatment of diabetic neuropathy, without any exact knowledge of the beneficial mechanism," Dr. Alin Stirban from Ruhr-University, Bochum, Germany told Reuters Health. "Our data bring benfotiamine from the relatively restricted field of diabetic neuropathy into the much larger field of vascular function and prove in humans effects previously postulated."

Dr. Stirban and colleagues investigated the effects of a real-life, cooked, AGE-rich meal on endothelial function and oxidative stress with or without benfotiamine pretreatment in 13 adults with type 2 diabetes.

The high-AGE meal significantly impaired endothelium-dependent vasodilatation, the authors report, but this impairment was completely prevented by benfotiamine.

The high-AGE meal, with or without benfotiamine pretreatment, did not affect endothelium-independent vasodilatation, the results indicate.

Benfotiamine pretreatment also prevented the decrease in reactive hyperemia and the increase in circulating markers of endothelial dysfunction, inflammation, and oxidative stress seen after a high-AGE meal, the researchers note. The beneficial effects of benfotiamine treatment were accompanied by lower serum levels of AGEs and dicarbonyls, the report indicates.

"Our study does not completely elucidate the mechanisms through which benfotiamine prevents postprandial vascular dysfunction but raises some hypotheses," the authors conclude. "Further studies are warranted to bring light into these subtle mechanisms."

"We intend to investigate in a placebo-controlled manner medium-term effects of benfotiamine on endothelial function," Dr. Stirban said. "But we will extend our observation also on other cell types of critical importance for people with diabetes, such as adipocytes."

Diabetes Care 2006;29:2064-2071.

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FACT:

Physicians Often Do Not Communicate Important Medication Information: Physicians prescribing new medication often do not communicate to patients important details, such as potential side effects, how long or how often to take the drug or the specific name of the medication.

Read and print the full news article at:

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4191>

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Item 14

Docs Overlooking Flu Shots

One in three adults with CVD was vaccinated against flu in 2005. One of the biggest barriers is that only about half of all cardiologists in the US stock flu vaccine in their clinics.

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4173>

The American Heart Association (AHA) and the American College of Cardiology (ACC) have joined forces to advise doctors to administer influenza vaccines to everyone with CVD, because they are missing opportunities to cut deaths and disease due to flu among their patient. Their recommendations are outlined in a scientific advisory published online September 18, 2006 in *Circulation*, by Dr Matthew M Davis (University of Michigan, Ann Arbor) and colleagues.

"Healthcare providers who treat individuals with cardiovascular disease can help improve influenza-vaccination coverage rates by providing and strongly recommending vaccination to their patients before and throughout the influenza season," Davis et al state. Patients with CVD are more likely to die from flu than people with any other chronic condition, they note, and vaccinating just 60% of the 13.2 million people with heart disease in the US could prevent hundreds of deaths and thousands of cases of flu every year.

Yet just one in three adults with CVD was vaccinated against flu in 2005. One of the biggest barriers is that only about half of all cardiologists in the US stock flu vaccine in their clinics, so the advisory outlines how providers can order influenza vaccine and stresses that immunization is covered by most insurance plans.

A recommendation to vaccinate those with cardiovascular disease against flu was included for the first time in an update to secondary-prevention guidelines for coronary and other vascular diseases issued by the AHA and ACC in May of this year.

The new advisory says that evidence from cohort studies and one randomized clinical trial--FLUVACS--shows that seasonal flu represents a major preventable threat to the health of patients with CVD and that vaccination is associated with a significantly reduced risk of cardiovascular death and nonfatal events. One-year follow-up data from the South American FLUVACS trial showed a 50% reduction in cardiovascular deaths in those vaccinated against the flu.

"Influenza vaccination is now recommended with the same enthusiasm as cholesterol and blood-pressure control and other modifiable risk factors for cardiovascular disease," Davis et al state.

Dr Mohammed Madjid (Texas Heart Institute, Houston), who together with his colleague Dr Ward Casscells (University of Texas, Houston) has spent six years researching this subject and lobbying the AHA and ACC to endorse flu vaccine for patients with coronary heart disease, welcomes the advisory.

Dr Mohammed Madjid states that, "We have shown that flu triggers heart attacks and cardiac patients are undervaccinated and have estimated that influenza can kill up to 91 000 people in the US alone just through triggering fatal heart attacks.

The flu-vaccination season begins in October, and vaccinations of the current year's flu strain should ideally be given by the end of November, the advisory states, although it can be given into January, February, and March, when the flu season peaks. Vaccines can be ordered from three manufacturers in the US.

How providers can place an order for influenza vaccine in the US

Manufacturer	How to order for the 2006/2007 influenza season
GlaxoSmithKline	Call Flurix Service Center at 1-866-475-8222 (choose option 1)
Novartis (formerly Chiron)	Call 1-800-244-7668 (choose option 2) to receive a list of vaccine distributors in your area
Sanofi Pasteur	Set up a provider account and then place order at www.vaccineshoppe.com .

The advisory warns, however, that the live attenuated nasal vaccine Fluvacs (MedImmune) is contraindicated in CVD patients because it can cause influenza in this high-risk population.

However, Madjid says this decision is misguided: "This is misleading and not based on any evidence. The authors should have been more careful before making this suggestion," he commented.

But Davis states that, "The caution to *not* use live, attenuated flu vaccine for persons with cardiovascular disease is consistent with existing recommendations from the **Centers for Disease Control and Prevention**. These recommendations state that, until more data are available regarding the safety of live influenza vaccine for persons at high risk for influenza, inactivated vaccine (administered as an injection) should be used."

He adds, "Our expert committee felt this caution was appropriate because abundant doses of inactivated influenza vaccine are available for persons with cardiovascular disease, which means that it is not likely necessary to opt for the live, attenuated form until its safety has been more broadly established."

1. Davis MM, Tauber R, Berlin AL, et al. Influenza vaccination as secondary prevention for cardiovascular disease. A science advisory from the American Heart Association/American College of Cardiology. *Circulation* 2006; 114: 1549-1553.
2. Madjid M, Naghavi M, Litovsky S, et al. Influenza and cardiovascular disease: a new opportunity for prevention and the need for further studies. *Circulation* 2003; 108: 2730-2736.

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Item 15

Contrave™ (Orexigen) Reports Positive 24-Week Data on Obesity Treatment

Orexigen Therapeutics announced that top-line results for the company's lead obesity compound, Contrave™, demonstrated significant advantages in weight loss in a 24-week multicenter, placebo-controlled, Phase III trial. The trial will continue unblinded for an additional 24 weeks.

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4172>

Contrave is a proprietary combination of bupropion, a dopamine and norepinephrine reuptake inhibitor, with one of several different doses of naltrexone, an opioid antagonist used to treat various addictive disorders. The bupropion/naltrexone combination is based on the company's underlying research into the brain's regulation of appetite and energy expenditure, which suggests that combining these two central nervous system drugs may improve the ability to initiate weight loss and to continue weight loss by blocking the body's attempts to compensate for weight loss during the treatment.

In what may become the preferred dose pairing based on performance and tolerability, patients completing the 24-week trial experienced on average an excess of 7 percent weight loss from baseline compared with approximately 1 percent weight loss from baseline on average for patients using the placebo. In addition, the Contrave combination outperformed either naltrexone or bupropion given alone, and the Contrave-associated weight loss trajectory showed no indication of reaching a plateau at the conclusion of 24 weeks of blinded therapy.

The trial involves more than 250 patients at 14 clinical sites and was blinded for the first 24 weeks. A second 24 weeks of open-label treatment is currently under way. The three doses of naltrexone were selected based on the company's innovative use of Positron Emission Tomography imaging of the opioid receptors in the human brain. No serious adverse events attributed to Contrave were reported by the study's investigators at any of the three dosages tested.

Endocrinology/Metabolics, Sept 2006

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Quote of the Week!

***“One man can be a crucial ingredient on a team,
...but one man cannot make a team.”***

***--Kareem Abdul-Jabbar,
U.S. basketball player***

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