

DIABETES IN CONTROL.com Newsletter

The Newsletter for Professionals in Diabetes Care

March 14, 2007 Issue #355

Click on <http://www.diabetesincontrol.com/siteupdates.php> to see the changes

Top Diabetes Stories:

New Study Shows That Low Carb Diets Are Healthier Than Critics Contended*

<http://www.diabetesincontrol.com/results.php?storyarticle=4633>

Risks OF Tight Glucose Control In ICU Outweigh Benefits*

<http://www.diabetesincontrol.com/results.php?storyarticle=4632>

Health Care Spending in the U.S. Will Double in 10 Years*

<http://www.diabetesincontrol.com/results.php?storyarticle=4631>

Heart Disease, Diabetes, Depression Increases Risk for Death by 30 Percent*

<http://www.diabetesincontrol.com/results.php?storyarticle=4629>

Even 'High Normal' Fasting Glucose Increases Risk of for Heart Failure*

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Simple Breath Test to Detect Diabetes and Monitor Blood Sugars*

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FDA Okays First Direct Renin Inhibitor for Hypertension*

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Parents Blind to Their Children's Weight and Their Own!*

<http://www.diabetesincontrol.com/results.php?storyarticle=4621>

From the editor's desk

Last week JAMA released the results of a new study comparing 4 diets, and the low-carb diet came out the winner, showing that it is safe and effective compared to 3 other diets **Dr. Richard Bernstein's** philosophy of low-carb diets is unique. Check out his new book that came out last week, Diabetes Solution New and Revised 2007, for more information and a special promotion, and to register for Dr. Bernstein's free live Teleconference calls, go to: <http://www.diabetes911.net/askdrb/index.php>

See this week's Item #1 and then check out the feature: [Low-Carb Diets Vindicated](#)

<http://www.diabetesincontrol.com/results.php?storyarticle=4634>

When we talk about the Diabetes Team, we always mention the doctor, educator, and dietitian. We believe that it should really be the doctor, educator, dietitian, pharmacist, ophthalmologist, podiatrist and dentist. We need to treat the whole patient. So Diabetes in Control.com has teamed up with www.podiatry.com to educate and motivate the podiatrists to participate in not just the care of the patients feet, but to also provide education to the patient about blood glucose control, A1c testing, physical activity, etc. So we welcome all of our new subscribers from podiatry.com

Insurance companies continue to find ways to make it harder to care for our patients. I just received this message from a friend at CCS medical.

There is large health care plan that has now passed a policy for limiting test strips for Type 2 pts (not on insulin or pregnant) to only 50 test strips over 6 months and are telling their pts to use urine glucose test strips, where they can get 200 urine glucose tests per month. They are basing their decision on these articles, and are standing firm with their decision.

Please review these articles and share your opinion

Is Self-Monitoring of Blood Glucose Appropriate for All Type 2 Diabetic Patients? The Fremantle Diabetes Study

Self-Monitoring of Blood Glucose in Patients With Type 2 Diabetes Who Are Not Using Insulin

Click here to read abstracts and offer your opinion

<http://www.diabetesincontrol.com/results.php?storyarticle=4635>

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March 18, 7PM ET on CNBC

Diabetes 911 – what to do when emergencies strike. Plus, remarkable rescues by diabetes dogs, and carb-conscious vegetarian cooking. Tune in for another exciting new episode of dLifeTV on: 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 #4: Treat The Gums, Treat The Heart and Diabetes
- Item #7: Tai Chi Chuan Improves Control for Type 2's
- Item #8: Pioglitazone Lowers Recurrent Stroke Risk in Type 2 Diabetes Patients
- Item #9: Change in Daylight Saving Time May Cause Medical Device Errors for Pump Users
- Item #11: German Diabetes Risk Score May Predict Development of Type 2 Diabetes
- Item #14: Strong Evidence Links Soft Drink Consumption to, Diabetes
- Item #15: Pioglitazone Linked to Drug Interactions With Gemfibrozil and Rifampin

Check out this weeks **“Test Your Knowledge”** question.
<http://www.diabetesincontrol.com/results.php?storyarticle=4636>

Dave Joffe, *Editor-in-Chief*

NEWS FLASH:

Change in Daylight Saving Time May Cause Medical Device Errors for Pump Users The change which started last Sat evening for the beginning and end of daylight saving time (DST) may adversely affect medical equipment that uses date and time information for diagnosis or treatment. The new DST will begin 3 weeks earlier and end one week later this year. See this week's Item #9

The 19th annual American Diabetes Alert® Day is Tuesday March 27, 2007 Check out this weeks Tools for Your Practice and Print out the Take the Test form!

Dr. Richard K. Bernstein's 2007 Edition of **Diabetes Solution** is available now! Check it out at:
<http://www.diabetes911.net>

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Tools for your Practice:

Take the Test: *The 19th annual American Diabetes Alert® Day is Tuesday March 27, 2007.*

Encourage those at risk for developing type 2 diabetes to take the American Diabetes Risk Test and, if they score high, to schedule an appointment to see their doctor. [On line](#) or Print [The Test](#)

<http://www.diabetes.org/risk-test.jsp>

Print the test here

<http://www.diabetesincontrol.com/issues/Issue 355/DiabetesRiskTest.pdf>

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New Product: Tektuma®

FDA Okays First Direct Renin Inhibitor for Hypertension

The FDA has approved aliskiren (Tektuma), the first oral direct renin inhibitor for treatment of hypertension. The drug is the first in a new class of agents known as oral renin inhibitors and is approved for the treatment of high blood pressure as monotherapy or in combination with other antihypertensive medications.

See this week's Item#12

This Week's Items:

1. **New Study Shows That Low Carb Diets Are Healthier Than Critics Contended***
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2. **Risks OF Tight Glucose Control In ICU Outweigh Benefits***
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ITEMS For The Week:

Item 1

New Study Shows That Low Carb Diets Are Healthier Than Critics Contended

Premenopausal women who were assigned to follow the Atkins diet for one year lost more weight and improved their glucose, lipids and blood pressure, when compared to women who were assigned to follow the Zone, Ornish and LEARN diets, according to a study in the March 7 issue of JAMA.

<http://www.diabetesincontrol.com/results.php?storyarticle=4633>

For a more detailed explanation of the study, see this weeks Feature: Low Carb Diets Vindicated

"Concerns about adverse metabolic effects of the Atkins diet were not substantiated within the 12-month study period with over 300 overweight women.

Overweight and obesity are well-documented problems in the United States. National dietary weight loss guidelines (a diet low in calories and fat, high in carbohydrates) have been challenged, particularly by supporters of low-carbohydrate diets. However, limited evidence has been available to effectively evaluate other diets, according to background information in the article.

Christopher D. Gardner, Ph.D., of Stanford University Medical School, Stanford, Calif., and colleagues examined the effects of four diets—3 popular and substantially different diets and 1 diet based on national guidelines—representing a spectrum of carbohydrate intake, on weight loss and related metabolic variables in overweight and obese premenopausal women. The diets were Atkins (very low in carbohydrate), Zone (low in carbohydrate), LEARN (Lifestyle, Exercise, Attitudes, Relationships, and Nutrition; low in fat, high in carbohydrate, based on national guidelines), and Ornish (high in carbohydrate). The study, which included 311 overweight/obese (body mass index, 27-40) nondiabetic, premenopausal women, was conducted from February 2003 to October 2005. Participants were randomly assigned to follow for 12 months the Atkins (n = 77), Zone (n = 79), LEARN (n = 79), or Ornish (n = 76) diets and received weekly instruction for 2 months, then an additional 10-month follow-up.

Besides weight loss, the participants were also measured for lipid profile (low-density lipoprotein, high-density lipoprotein, and non-high-density lipoprotein cholesterol, and triglyceride levels), percentage of body fat, waist-hip ratio, fasting insulin and glucose levels, and blood pressure. Outcomes were assessed at months 0, 2, 6, and 12.

The researchers found that weight loss was greater for women in the Atkins diet group compared with the other diet groups at one year. Average 12-month weight loss was 10.4 lbs for Atkins, 3.5 lbs. for Zone, 5.7 lbs. for LEARN, and 4.8 lbs. for Ornish. At 12 months, measurements for lipids and levels of insulin, glucose and blood pressure for the Atkins group were comparable with or more favorable than the other diet groups.

"Concerns about adverse metabolic effects of the Atkins diet were not substantiated within the 12-month study period. It could not be determined whether the benefits were attributable specifically to the low carbohydrate intake vs. other aspects of the diet (e.g., high protein intake). While questions remain about long-term effects and mechanisms, these findings have important implications for clinical practice and health care policy. Physicians whose patients initiate a low-carbohydrate diet can be reassured that weight loss is likely to be at least as large as for any other dietary pattern and that the lipid effects are unlikely to be of immediate concern. As with any diet, physicians should caution patients that long-term success requires permanent alterations in energy intake and energy expenditure, regardless of macronutrient content," the authors conclude.

JAMA. 2007;297:969-977.

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Advertisement:

Breaking News from the American Diabetes Association 66th Scientific Sessions
Did you miss the ADA Scientific Sessions in Washington, DC? Get up to speed on the latest research and updates to current knowledge on diabetes and dyslipidemia -FREE CME Activities from the ADA Scientific Sessions are now available! Click here to access the interactive CME newsletter summary of several presentations relevant to clinical practice and the CME case-based slide and audio presentations on the real-world management of patients with diabetes and dyslipidemia recorded at the ADA meeting. Don't miss this opportunity to learn the latest clinical updates from one of the year's most critical diabetes events!
<http://www.cemedicus.com/diabetes>

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Item 2

Risks OF Tight Glucose Control In ICU Outweigh Benefits

Intensive care physicians need to "think hard and long" about aiming for tight glycemic control. "We need to be very conservative about starting insulin regimens the minute someone comes into the ICU."

<http://www.diabetesincontrol.com/results.php?storyarticle=4632>

The risks of tight glycemic control for patients in intensive care outweigh the benefits, a Belgian researcher said. That's the clinical message from the aborted European Glucontrol Trial, which was halted prematurely last May when a monitoring committee found an excess of deaths associated with the low-glucose group in the study, according to Jean-Charles Preiser, M.D., Ph.D., of the University Hospital Center in Liège.

The safety signal was premature, however, and when more data were included, overall, patients kept under tight glycemic control were not at greater risk of death than those on a looser regimen, Dr. Preiser told a latebreaker session at the Critical Care Congress of the Society for Critical Care Medicine.

But equally, he said, there was no mortality benefit for the 536 patients randomized to a target of 80 to 110 milligrams per deciliter of glucose over the 546 patients whose blood glucose target was between 140 and 180 mg/dL.

On the other hand, he said, patients in the low glucose group had significantly more incidents of hypoglycemia (at $P < 0.001$). Indeed, if the definition of hypoglycemia was set at 60 mg/dL, being in the low glucose group led to seven-fold greater risk of the condition, compared to those in the other group. "There is no reason to recommend the use of 110 milligrams as a target for insulin therapy," Dr. Preiser said. In fact, aiming for the higher level of 140 or 150 would be "wise," he said.

The insulin regimens used were broadly successful in achieving the study goals:

- ?? Patients in the low glucose group on average had a level of 118 milligrams per deciliter -- slightly above the target -- while those in the other group had an average level of 144.
- ?? The difference between the groups in blood glucose was apparent early and remained significant at $P < 0.001$ through the treatment period.
- ?? The variability in glucose levels was identical in both groups.

Mortality in the ICU, during the hospital stay, and at 28 days was not significantly different between the groups. There was no difference in length of stay on the ICU. Patients in the low glucose group had significantly fewer insulin-free days (at $P < 0.0001$) than those in the other group.

The multi-center international study was intended to extend and verify two single-center Belgian studies published in 2001 and 2006 that showed about a 6% mortality benefit for surgical ICU patients kept under tight glycemic control.

Those studies were widely accepted despite their relatively small size and homogenous northern European patient population, commented Clifford Deutschman, M.D., of the University of Pennsylvania Medical School in Philadelphia, who moderated the late-breaker session.

Whether the results apply in a broader situation was unclear, but Dr. Preiser's data calls the issue into doubt, he said, and intensive care physicians need to "think hard and long" about aiming for tight glycemic control. "We need to be very conservative about starting insulin regimens the minute someone comes into the ICU."

Practice Pearls:

- ~~///~~ Explain to interested patients that two small European studies suggested that keeping blood sugar at normal levels in patients on intensive care could reduce mortality.
- ~~///~~ Note that results from the European Glucontrol Trial -- stopped prematurely last May -- show no mortality benefit and increased risks of hypoglycemia for patients in the tight glucose control group.
- ~~///~~ This study was published as an abstract and presented orally at a conference. These data and conclusions should be considered to be preliminary as they have not yet been reviewed and published in a peer-reviewed publication.

The study was sponsored by the European Society for Intensive Care Medicine, the Communauté Française Wallonie-Bruxelles, and Roche Diagnostics. Dr. Preiser did not report any competing interests

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DID YOU KNOW:

Coffee cuts diabetes risk: Coffee continues to get good and bad press coverage, but a recent study published in the *European Journal of Clinical Nutrition* ([Epub March 7, 2007](#)) details an inverse association between higher coffee intake and incidence of type 2 diabetes. In the trial, 21,826 Finnish men and women 35 to 74 years of age and with no history of diabetes were followed from baseline—1982, 1987, 1992 or 1997—until one of three events occurred: onset of type 2 diabetes, death or the year 2002. Specifically, researchers monitored coffee consumption and serum gamma-glutamyltransferase (GGT), a liver enzyme that is used as a biomarker to indicate damage, especially oxidative. Results showed coffee consumption was significantly and

inversely associated with incident diabetes among both men and women. The inverse association was most significant in those subjects who also had GGT levels higher than the 75th percentile, especially among women and both sexes combined. The researchers concluded, "Habitual coffee consumption is associated with lower incidence of type II diabetes, particularly in those with higher baseline serum GGT levels."

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Item 3

Health Care Spending in the U.S. Will Double in 10 Years

Diabetes will be a primary contributor to the amount of money people spend on health care in the United States, which is likely to double over the next 10 years - from \$2.1 trillion to \$4 trillion - according to a new report published in an online edition of Health Affairs.

<http://www.diabetesincontrol.com/results.php?storyarticle=4631>

Currently, approximately 16 cents of every dollar earned in the U.S. is spent on health care, according to 2006 estimates. The report anticipates that this will rise to 19.6 percent of the Gross Domestic Product (GDP) by 2016. The growth is attributed to an aging population. Also, spending on prescription drugs is expected to grow by approximately 8.6 percent annually, to a level of \$500 billion in 2016. This is more than double the 2006 amount.

U.S. citizens get the worst health care bargain in the world: They spend more on health care (or sick care, actually) than any other nation, yet rates of chronic degenerative disease also remain higher in the U.S. than anywhere in the world. Clearly, the U.S. sick care system does not work.

The real reasons behind rising health care costs in the United States are the continued high prices of new drugs and the utter unwillingness of medical authorities to teach disease prevention to the population. Skyrocketing health care costs are bankrupting the U.S. economy and forcing businesses to shut down or move overseas. Half of all personal bankruptcies in the United States are due to medical bills. The sick care industry seems bent on leaving Americans bankrupt and living in a state of ongoing disease diagnosis and "management" rather than teaching people how to actually prevent disease.

The cost of caring for aging Americans will add 25 percent to the nation's health care bill by 2030 unless people act now to stay healthy, the U.S. Centers for Disease Control and Prevention said on Thursday. Currently, 80 percent of Americans aged 65 and older have at least one chronic disease that could lead to premature death and disability, CDC researchers said.

The report, *The State of Aging and Health in America 2007*, projects that by 2030, 71 million Americans will be over 65, accounting for 20 percent of the U.S. population, up from 10 to 11 percent now. With the cost of caring for older Americans at three to five times greater than care for younger adults, CDC researchers believe policymakers and individuals should take steps to help aging adults forestall chronic disease.

"Given the demographics ... the economic impact on healthcare will be enormous," said Dr. Richard Murray, a vice president at Merck & Co. Inc., whose foundation funded the study. If people adopt healthier lifestyles, they will not develop the expensive, chronic diseases that raise health costs sharply, such as diabetes, cancer and heart disease.

"We are going to see an increase in health care costs, but the goal has to be to restrain the rate of increase. Prevention is the key to that," said Bill Benson, a health care benefits and policy analyst who advised the CDC on the report.

The report noted that three behaviors -- smoking, poor diet and physical inactivity -- caused almost 35 percent of U.S. deaths in 2000. Those three behaviors often lead to the development of the nation's leading chronic diseases: heart disease, cancer, stroke and diabetes, they said. "Having a chronic disease that's well managed doesn't necessarily put a person at risk for functional decline, but when someone starts developing problems, they are much more at risk," said Lynda Anderson, a chronic disease and aging expert at the CDC.

The report looks at how states are faring in terms of elderly health and providing preventive care such as immunizations and health screenings and taking steps to prevent falls, a major risk for the elderly.

"You have some regions that are doing extremely well in a lot of areas and others that are struggling to get these services to older adults," she said. Elderly people in Hawaii, for example, are likely to fare better in many key measures of health. The state ranked best in overall health, mental health, and disability and had the lowest percent of obese elderly. But Hawaii ranked last in terms of screening for colorectal cancer.

West Virginia ranked worst in terms of overall health, oral health and disability, while Kentucky had the highest level of elderly people reporting mental health problems. Louisiana reported the highest levels of obesity, with more than 25 percent of the elderly population considered obese.

She hopes the data will give state policymakers the right tools to start building prevention programs now, before chronic disease begins.

"We have the opportunity for prevention," Merck's Murray said. "We need to be serious about it." The report was authored by a team of economists, statisticians and actuaries from the Centers for Medicare and Medicaid Services.

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Item 4

Treat The Gums, Treat The Heart and Diabetes

Scientists at University College London (UCL) have conducted the first clinical trial to demonstrate that an intensive treatment for periodontitis (gum disease) directly improves the health of blood vessels.
<http://www.diabetesincontrol.com/results.php?storyarticle=4630>

This study, conducted in conjunction with Professor Maurizio Tonetti (University of Connecticut, USA), and reported in the latest edition of the *New England Journal of Medicine*, may have relevance for the prevention of heart attacks and stroke.

Periodontitis is a common inflammatory disease of the gums, affecting up to 40 per cent of the world's adult population. It is a bacterial infection of the tissue that supports the teeth in the mouth. If untreated, it can cause progressive bone loss around the teeth, and eventual tooth loss.

There is already established scientific evidence linking inflammation, the body's natural response to infection or injury, with the arterial changes that underlie stroke and heart attack. However, this is the first clinical trial to demonstrate that relief of inflammation in the mouth, through intensive treatment of periodontitis, results in improved function of the arteries.

Dr Francesco D'Aiuto, project leader and therapist, UCL Eastman Dental Institute, explained the method behind the research: "Middle-aged subjects with severe periodontitis, but no evidence of cardiovascular disease, were randomly allocated to dental treatments of two levels of intensity. After six months, those who received the more intensive periodontitis treatment, which resulted in a marked improvement in their gum disease, also demonstrated a significant restoration of blood vessel function.

"The intensive treatment involved removal of plaque through scaling and root planning techniques, as well as extraction of teeth that could not be saved. This initially resulted in some inflammation and dysfunction of the blood vessels and arteries. However, that was short-lived and six months later the treatment led to an improvement in both oral health and arterial function."

Professor John Deanfield, senior author, UCL Institute of Child Health, added: "Previous studies have shown an association between periodontitis and blood vessel dysfunction, heart attack and stroke. However, a clinical trial was required to test whether these links could be causal. This is the first time that a direct link has been made between treatment for gum disease and improved circulatory function, which is relevant to some of the biggest killers: heart attack and stroke."

Dr Aron Hingorani, UCL Division of Medicine, a co-author on the study, set the findings in context: "Elevations in blood pressure and cholesterol, as well as smoking and diabetes, are recognized as the main risk factors for

cardiovascular disease, and these can be effectively treated. Nevertheless, heart attacks and stroke remain a major cause of disability and death. Intriguing links have emerged between inflammation and heart disease and so it is important to better understand the nature of this connection, and whether it could lead to the development of new treatments. The current study points to disease of the gums as a potential source of this inflammation."

Professor Deanfield concluded: "This finding therefore has potential implications for public health, but further studies are now required to determine whether the treatment of severe periodontitis could directly contribute to the prevention of disease of the arteries (atherosclerosis), stroke and heart attacks."

The mechanism by which periodontitis affects endothelial function in the body is still uncertain. The gum disease involves a bacterial infection that invades the tissue around the teeth. One possibility is that the bacteria disturb endothelial function directly, since some bacteria can enter the bloodstream. Alternatively, the periodontitis might trigger a low grade inflammatory response throughout the body that has a detrimental effect on the vascular wall.

'Treatment of Periodontitis and Endothelial Function' is published in the March issue of the New England Journal of Medicine. J Am Geriatr Soc 2007;55:182-188.

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DID YOU KNOW:

Treating depression improves diabetes control: - A study of type 2 diabetics with depression confirms that depression has a negative impact on glycemic (blood sugar) control, researchers report, and "affirms the importance of depression management in diabetic patients in its potential to improve glycemic control." Researchers from Missouri treated 93 patients with type 2 diabetes and depression with the antidepressant bupropion (Wellbutrin). "Antidepressant treatment produced benefits beyond just mood improvement," Dr. Patrick J. Lustman from Washington University School of Medicine, St. Louis, stated. "Patients also lost weight, improved self-management of their diabetes, and improved their glucose control (A1C levels)." If these short-term improvements, only depression improvement predicted maintenance of improved blood sugar control in the subsequent 6 months, the researchers found. "This confirms our hypothesis that depression improvement can produce better glycemic control, independent of favorable changes in weight and diabetes self care," Lustman noted. "Improvement in depression was the key to achieving longer term improvements in glucose control." Lustman concludes that the data "point to the importance of weight-independent physiological factors (insulin sensitivity, inflammation) that improve during depression relief and contribute to better long-term control of diabetes." *Diabetes Care, March 2007.*

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Item 5

Heart Disease, Diabetes, Depression Increases Risk for Death by 30 Percent

Heart disease, diabetes and depression can be a lethal triple-play - boosting a patient's death risk by up to 30 percent, new research shows.

<http://www.diabetesincontrol.com/results.php?storyarticle=4629>

"We do not know what this increased risk is due to, but it could either be that depression influences crucial aspects of self-care behaviors needed to manage diabetes or that a more severe disease process is reflected in more depressive symptoms," said lead researcher Anastasia Georgiades, a research associate in the department of psychiatry and behavioral science at Duke University in Durham, N.C.

In their study, the Duke team followed 933 heart patients for more than four years. During that time, there were 135 deaths among patients with type 2 diabetes and/or depression, the researchers found.

Among patients with moderate-to-severe symptoms of depression who were also diabetics, the researchers observed a significant 30 percent greater risk of dying over the four-year period compared with patients with either

depression alone or diabetes alone. These data suggest that diabetes and depression exacerbate each other, but the reasons for this relationship aren't clear.

"Future research will also aim to investigate the mechanisms behind the associations closer. In the meantime, our advice is that physicians monitor these potential high-risk patients carefully," she said.

Co-author Lana Watkins, an assistant research professor, noted that "if you or a loved one has coronary artery disease and diabetes, depression may impact your survival, particularly if it's severe enough to interfere with your daily activities." "This is an interesting study that replicates earlier work showing that symptoms of depression are associated with survival in persons with coronary artery disease," said Robert M. Carney, a professor of psychiatry and director of the Behavioral Medicine Center at Washington University School of Medicine in St. Louis.

Other studies have shown that depression is very common in patients with diabetes, and it is associated with poorer metabolic control and long-term complications in these patients, Carney said. "The researchers also report a possible interaction between depression and diabetes in patients with coronary artery disease, such that having both disorders may more than additively increase the risk for mortality," the expert noted.

"This is potentially a very important finding, as it suggests a possible link between these two risk factors," Carney said. "This could help to identify those individuals at highest risk for dying and possibly lead to novel treatment strategies to improve survival in these patients."

Georgiades presented the findings last Friday at the American Psychosomatic Society annual meeting in Budapest, Hungary.

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Item 6

Even 'High Normal' Fasting Glucose Increases Risk of for Heart Failure

Fasting glucose levels may independently predict the risk of being hospitalized with congestive heart failure in heart attack survivors and others who are at high risk of developing the disorder.

<http://www.diabetesincontrol.com/results.php?storyarticle=4628>

Drawing on data from 31,546 high-risk patients participating in two international trials, researchers found that even small increases in fasting glucose raised the risk of congestive heart failure in both diabetes patients and those whose blood sugar fell within the normal range.

"This illustrates that blood glucose by itself is a continuous risk factor for developing heart failure because all of these patients were free of heart failure when they enrolled in the trials," said Claes Held, MD, PhD, lead author of the study.

"However, these are only associations," said Held, an associate professor of cardiology at the Karolinska Institutet in Stockholm, Sweden. "They do not prove that elevated blood glucose causes heart failure. To demonstrate a causal relationship, you would have to do a study that showed lowering blood glucose levels would reduce the incidence of heart failure."

To examine the relationship between blood glucose levels and congestive heart failure, Held and colleagues performed an interim analysis on the blinded data from the ONgoing Telmisartan Alone and in combination with the Ramipril Global Endpoint Trial (ONTARGET) and Telmisartan Randomized AssessmeNt Study in aCE iNtolerant subjects with cardiovascular Disease (TRANSCEND) trials. Both were randomized, controlled, parallel clinical studies testing drug regimens aimed at reducing fatal and nonfatal cardiovascular events. ONTARGET had 25,620 patients enrolled and TRANSCEND had 5,926, and both included patients with and without diabetes. Researchers obtained fasting blood glucose levels for patients when they entered the trials and periodically

thereafter.

"We know that diabetes is a strong risk factor for cardiovascular disease including heart failure, but these studies included patients with and without diabetes," Held said. "This was a great opportunity to evaluate a broad population of high-risk individuals and study the association between blood glucose and cardiovascular disease, regardless of the diabetic state."

Patients in the two trials were average age 67 at entry, and 69 percent were men. Thirty-seven percent had been previously diagnosed with diabetes and 3.2% were diagnosed with the disease at the time of entry. Patients were assigned to five groups based on their entry fasting blood glucose levels. The lowest group had an average fasting blood glucose of 83mg/dL and the highest had an average reading of 153mg/dL.

Researchers analyzed data from patients with an average follow-up of 2.4 years. During this time there were:

- 1,067 cardiovascular deaths
- 926 heart attacks
- 823 strokes
- 668 hospitalizations for congestive heart failure

When the researchers examined fasting blood glucose levels alone as a risk factor by adjusting for other known risk factors, they found that, for all patients, an increase of 18 mg/dL above a patient's entry glucose level increased the risk of hospitalization for congestive heart failure by 5%.

Similarly, a 18 mg/dL rise increased the risk of congestive heart failure hospitalization or cardiovascular death by 9% for all patients, by 3% for patients without diabetes and by 5% for patients with diabetes.

"Even in the normal range, our results indicate that elevated blood glucose is associated with the risk of heart failure," Held said. "You can look at blood glucose much like blood pressure or cholesterol. Even if you have normal blood glucose, there is a gradual increase in risk wherever you start on the scale. If the blood sugar is "high normal" there is a higher risk than those with "low normal fasting blood glucose levels."

He and colleagues suggested several potential mechanisms for rising glucose levels which increase the risk of developing congestive heart failure.

"Individuals with disturbances in their glucose regulation usually have more coronary artery disease, which is a well known underlying risk factor for heart failure," Held said. "That is a strong explanation for our findings but the others are more speculative and hypothetical." *Circulation: March 07, Journal of the American Heart Association.*

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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.

<http://www.diabetesincontrol.com/ads/liposcience/dest.php>

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Item 7

Tai Chi Chuan Improves Control for Type 2's

A new study suggests that participation in the Chinese martial art Tai Chi Chuan may help boost immune function and improve blood sugar control in people with type 2 diabetes.

<http://www.diabetesincontrol.com/results.php?storyarticle=4627>

After completing a 12-week Tai Chi exercise program, men and women with the disease had statistically significant reductions in their levels of A1C. The participants also showed increases in regulatory T cells, which help to keep the immune response in check, while their levels of killer T cells, which destroy abnormal cells in the body, decreased.

People with type 2 diabetes experience chronic inflammation, and while exercise has been shown to be beneficial, strenuous exercise may boost inflammation and cause other problems, Dr. Kuender D. Yang of Chang Gung Memorial Hospital in Taiwan and colleagues note.

Tai Chi, in which a person performs a series of poses in a flowing motion, improves balance and heart and lung function, and recently was shown to benefit immune system function in healthy individuals, they add.

To investigate whether Tai Chi might do the same for diabetic patients, Yang and his team had 32 men and women participate in three hour-long sessions of the martial art each week for 12 weeks.

Tai Chi could improve the immune system through its effects on cardiopulmonary health or the martial art might exert its effects by improving glucose metabolism, the researchers note.

They conclude: "An appropriate combination of the Tai Chi Chuan exercise program with diabetic medications may improve both glucose metabolism and immunity of type 2 diabetic patients."

Diabetes Care, March 2007.

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Dr. Philip A. Wood has written a book for healthcare professionals and students of medicine, nursing, pharmacy, and graduate studies, as well lay people interested in understanding the influences of genetics, nutrition, activity level and drugs on diseases associated with excess fat such as obesity, insulin resistance, metabolic syndrome and type 2 diabetes. The book is composed of short, readable chapters with helpful figures to further explain the mechanisms discussed. For further information please click here.

http://www.amazon.com/exec/obidos/tg/detail/-/0674019474/qid=1132176956/sr=8-1/ref=pd_bbs_1/002-7853569-1175265?v=glance&s=books&n=507846

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Item 8

Pioglitazone Lowers Recurrent Stroke Risk in Type 2 Diabetes Patients

Pioglitazone significantly reduces the risk of first-time stroke and recurrent stroke in high-risk patients with type 2 diabetes, a European group reports.

<http://www.diabetesincontrol.com/results.php?storyarticle=4626>

Dr. Robert G. Wilcox, of University Hospital, Nottingham, UK, and colleagues conducted a subgroup analysis of patients in the PROspective pioglitAzone Clinical Trial In microVascular Events 04 (PROactive) trial.

Dr. Wilcox's team compared macrovascular events in 984 patients with a history of stroke and 4254 without a history of stroke who were randomized to pioglitazone or placebo.

All subjects remained on their current medications for dyslipidemia, hypertension, and hyperglycemia, and were followed for an average of 34.5 months.

The primary end point was all-cause mortality, nonfatal MI, stroke, acute coronary syndrome, cardiac interventions, leg revascularization and amputation.

In patients who had had a stroke, the investigators found "a statistically significant beneficial effect of pioglitazone on the end points of fatal or nonfatal stroke ($p = 0.0085$) and cardiovascular death, nonfatal stroke, or nonfatal myocardial infarction ($p = 0.0467$)."

Those with prior stroke also had higher event rates. No treatment effect was observed for a first stroke in patients without prior stroke.

Stroke 2007;38:865-873.

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FACT:

Lipitor® Tablets Has Been Approved for New Indications: The FDA has approved Lipitor to reduce the risk of nonfatal heart attacks, fatal and non-fatal strokes, certain types of heart surgery, hospitalization for heart

failure, and chest pain; **in patients with heart disease**. Lipitor® (previously approved to reduce cardiovascular events in patients **without heart disease**) - is the first cholesterol-lowering medication approved by the USFDA for the reduction of the risk of hospitalization for heart failure. According to Dr. John C. LaRosa, professor of medicine at the State University of New York Downstate Medical Center in Brooklyn, N.Y. and lead investigator: "These new indications are important since many patients who have heart disease remain at risk for another cardiovascular event, and now these indications broaden the means to reduce their risk. The significant reduction in cardiovascular events seen in the TNT trial can now be applied to everyday practice and benefit people with heart disease in the United States." The said FDA approval was based on the positive results from the landmark TNT trial (the longest and largest study of Lipitor 80 mg efficacy and safety) and supported by findings from the Incremental Decrease in Endpoints through Aggressive Lipid Lowering (IDEAL) trial.

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Richard K. Bernstein's New Book, Diabetes Solution 2007 is now shipping, plus Dr. Bernstein will be doing another live teleconference on Tuesday March 27 at 7:00 P.M. CST 8:00 P.M. EST. If you would like to ask a question or just register for the free teleconference call, just go to <http://www.diabetes911.net/askdrb/index.php> and register. There were over 600 people on the last call. More info at <http://www.diabetes911.net/askdrb/index.php>

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Item 9

Change in Daylight Saving Time May Cause Medical Device Errors for Pump Users

The change which started last Sat evening for the beginning and end of daylight saving time (DST) may adversely affect medical equipment that uses date and time information for diagnosis or treatment. The new DST will begin 3 weeks earlier and end one week later this year.

<http://www.diabetesincontrol.com/results.php?storyarticle=4625>

Medical equipment that uses, creates, or records time or date information about a patient's diagnosis or treatment may register the wrong dates for the start and end of DST when the changes are implemented, according to an alert sent Friday from MedWatch, the FDA's safety information and adverse event reporting program.

The FDA notes that most devices currently in use are likely to be affected, unless they were manufactured after the DST change was approved (Energy Policy Act of 2005) or have been updated by the manufacturer.

Adverse effects associated with their use might include incorrect dose prescribing, dose administration at the wrong time, missed doses, extra doses, unintended increased/decreased duration of therapy, and incorrectly recorded treatment/diagnostic results.

Healthcare professionals are advised to check with manufacturers for available patches/fixes for medical devices, hospital networks, and associated information technology systems; the time on these products should be verified on each of the critical DST dates: March 11 (new start date), April 1 (old start date), October 28 (old end date), and November 4 (new end date). Vigilance should be exercised when making clinical decisions or using medical devices on these days.

Unpredictable medical device events or medical device-related problems related to DST should be reported to the manufacturer and to the FDA's MedWatch reporting program by phone at 1-800-FDA-1088, by fax at 1-800-FDA-0178, online at <http://www.fda.gov/medwatch>, or by mail to 5600 Fishers Lane, Rockville, MD 20852-9787.

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Item 10

Simple Breath Test to Detect Diabetes and Monitor Blood Sugars

Researchers have developed a simple breath test for detecting Type 1 diabetes, and say that the new non-invasive tool could possibly be an economical method for tracking day-to-day glucose levels.

<http://www.diabetesincontrol.com/results.php?storyarticle=4624>

At present, Type 1 diabetes or juvenile diabetes is detected by directly drawing a small amount of blood and assessing the amount of glucose it contains. But it may be possible to sense diabetes on the breath, according to Armstrong Mbi, a graduate student at Mississippi State University.

Mbi and his advisor Chuji Wang have developed a new technique to detect acetone, one of the chemicals whose presence in the lungs rises when blood-sugar levels are high. The team injected acetone-laden water vapour into

a small chamber with mirrors. They then sent an infrared laser sensitive to the acetone into the hollow. By detecting the amount of time it took the light to completely dissolve as it went back and forth between the mirrors, they were able to perceive amounts of acetone to concentrations of 0.45 parts per million by volume (ppmv).

Mbi says that initial tests show that typical diabetics have acetone levels greater than 1.4 ppmv. Based on the new test, they could tell if the person is diabetic or not.

The new technique sounds helpful to Matt Petersen, director of information resources for the American Diabetes Association in Alexandria, Virginia. Current tests are highly accurate but require blood samples.

"Non-invasive techniques are always better. If the technique could be extended to test daily blood-sugar levels, then it would be "extremely interesting," Nature quoted Peterson, as saying.

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Is your neuropathy getting worse? Recent research has shown that many cases of neuropathy are related to a deficiency of available oxygen, either chronic or acute. This phenomenon can occur when the individual suffers from chronic sleep apnea, excess levels of glucose displacing the oxygen, free radicals adhering to the Oxygen thus making the oxygen metabolically unavailable, or peripheral artery or vascular disease.

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Item 11

German Diabetes Risk Score May Predict Development of Type 2 Diabetes

The German Diabetes Risk Score which is based on anthropometric, dietary, and lifestyle factors, was an effective tool to identify patients at high risk or with undiagnosed diabetes, according to the results of a study. <http://www.diabetesincontrol.com/results.php?storyarticle=4623>

"We aimed to develop a precise risk score for the screening of large populations for individuals at high risk of developing type 2 diabetes based on noninvasive measurements of major risk factors in German study populations," write Matthias B. Schulze, DrPH, of the German Institute of Human Nutrition Potsdam-Rehbruecke in Nuthetal, Germany, and colleagues. "In contrast to the Finrisk score, we did not use broad categories for age and anthropometric risk factors in order to use the full information from these continuous variables."

The European Prospective Investigation into Cancer and Nutrition (EPIC-Potsdam) study is a prospective cohort study of 9729 men and 15,438 women aged 35 to 65 years. The investigators used data from this cohort to weigh each variable and to derive a risk score predicting incident type 2 diabetes. The German Diabetes Risk Score included information on age, waist circumference, height, history of hypertension, physical activity, smoking, and consumption of red meat, whole-grain bread, coffee, and alcohol. The mean score was 446 points (range, 118 - 983).

The probability of developing diabetes within 5 years in the EPIC-Potsdam study increased from 0.3% for a score of 300 to 23.2% for a score of 750

"The German Diabetes Risk Score (available at <http://drs.dife.de/en>) is an accurate tool to identify individuals at high risk for or with undiagnosed type 2 diabetes," the authors write.

"The measurements and the deduced German Diabetes Risk Score performed similarly well in the two EPIC cohorts and predicted insulin resistance in two other cohorts with acceptable accuracy," the authors conclude.

Practice Pearls

- ?? A previous clinical screening tool was useful in predicting the risk for incident type 2 diabetes but was even more useful when data regarding fasting glucose and lipid levels were added to the algorithm.
- ?? The German Diabetes Risk Score uses waist circumference, height, age, the presence of hypertension, consumption of red meat, consumption of whole-grain bread, consumption of coffee, alcohol intake, physical activity, and smoking history to predict the risk of developing type 2 diabetes.

Diabetes Care. 2007;30:510-515.

DID YOU KNOW:

New Information Shows Actos Shows Increased Incidence of Fractures: *The results of an analysis of the trial database showed an increase in fractures in female patients.* The results of an analysis of the manufacturer's clinical trial database of pioglitazone showed more reports of fractures in female patients taking pioglitazone than those taking a comparator (either placebo or active). The majority of fractures observed in female patients were in the distal upper limb (forearm, hand and wrist) or distal lower limb (foot, ankle, fibula and tibia). There were more than 8100 patients in the pioglitazone-treated groups and over 7400 patients in the comparator-treated groups. The duration of pioglitazone treatment was up to 3.5 years. Healthcare professionals should consider the risk of fracture when initiating or treating female patients with type 2 diabetes mellitus with pioglitazone-containing products.

Read the complete MedWatch 2007 Safety summary, including links to the Manufacturer's Dear Healthcare Provider Letter regarding this issue at: <http://www.fda.gov/medwatch/safety/2007/safety07.htm#Actos>

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<http://ad.doubleclick.net/clk;62999853;15154955;d>

Item 12

FDA Okays First Direct Renin Inhibitor for Hypertension

The FDA has approved aliskiren (Tekturna), the first oral direct renin inhibitor for treatment of hypertension. The drug is the first in a new class of agents known as oral renin inhibitors and is approved for the treatment of high blood pressure as monotherapy or in combination with other antihypertensive medications

<http://www.diabetesincontrol.com/results.php?storyarticle=4622>

Unlike angiotensin converting enzyme inhibitors that attack the middle of the renin-angiotensin cascade, or angiotensin receptor blockers (ARBs) that target the bottom of the cascade, aliskiren interferes at the top of the renin-angiotensin cascade -- before any disruption of blood pressure regulation.

A once-daily oral tablet, aliskiren blocks the action of renin at the top of the renin-angiotensin-system cascade. A pooled data analysis of antihypertensive treatment with the drug in more than 8000 patients, presented by Dr Matthew R Weir (University of Maryland School of Medicine, Baltimore) at the World Congress of Cardiology in Barcelona in September, suggested that it reduces blood pressure effectively regardless of age or gender, is well tolerated, and appears to be additive to most other antihypertensive agents, with the exception of angiotensin-receptor blockers.

In clinical trials reported at the American Society of Hypertension meeting in 2006, the drug was also touted for its ability to smooth out the daily peaks and troughs of blood pressure. Variations in blood pressure during the day are thought to increase the risk of end organ damage.

In clinical trials, the drug demonstrated efficacy across all demographic groups, but African Americans reported smaller reductions in blood pressure. As with other blood pressure medications, the drug was most effective when used in combination with a thiazide diuretic.

"Clearly, a new drug with a unique mechanism of action is a welcome addition," Dr Franz Messerli (St Luke's-Roosevelt Hospital, New York, NY) stated that, "However, there are several questions coming to mind. Is there a need for triple blockade of the renin angiotensin system, and if so, what is the risk/benefit ratio? If the prorenin story plays out--and that's a big if--conceivably aliskiren will have distinct advantages in the diabetic patient. From a purely antihypertensive point of view, I cannot conceive that a drug that has a very similar shallow dose-response curve as the angiotensin-receptor inhibitors but seems to have more adverse effects will confer a distinct advantage."

Where aliskiren might be advantageous, said Messerli, is in patients who cannot take ACE inhibitors because of cough or angioedema or those who need a double blockade of the renin angiotensin system, such as diabetic patients with albuminuria. He added that while there seem to be many unanswered questions, "this is not unusual when a new compound is introduced, because our vision of efficacy and safety is still narrow because of the lack of data."

The FDA said aliskiren was evaluated for safety in more than 6,460 patients, including 1,740 who were treated longer than six months, and more than 1,250 for over one year. Side effects were usually mild and brief. The most common side effect experienced by patients taking aliskiren was diarrhea, which was reported by about 2% of patients randomized to it.

Rarely patients experienced allergic reactions characterized by swelling of the face, lips, or tongue and difficulty breathing.

Aliskiren and other drugs that act directly on the renin-angiotensin system should not be used during pregnancy, said the FDA, because they can cause injury and even death to the developing fetus. It will be sold in the United States in March in doses of 150 milligram and 300 mg. *Aliskiren was developed by Novartis.*

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Item 13

Parents Blind to Their Children's Weight and Their Own!

Researchers with Deakin's Center for Physical Activity and Nutrition Research surveyed more than 1200 families to find out if parents had concerns about their children's weight and if they took any preventative action to avoid obesity in their children.

<http://www.diabetesincontrol.com/results.php?storyarticle=4621>

The study of more than 1100 families found that 89 per cent of parents of overweight 5 & 6 year-olds and 63 per cent of parents of overweight 10 to 12 year-olds were unaware their child was overweight. It also revealed that 71 per cent of parents of overweight 5 or 6 year-olds and 43 per cent of parents with overweight 10 to 12 year-olds did not think their child's weight was a problem.

"These are quite troubling results and suggest that current obesity prevention campaigns are not hitting the mark with parents," said head of the Centre, Professor David Crawford.

"Parents are part of the front line in the battle to reverse the trend of obesity in children, it is therefore essential that they are armed with information and practical strategies that they understand and can easily build into their daily lives."

Professor Crawford said it was not altogether surprising that many parents were unaware their child was overweight given that "many adults are not able to recognize overweight in themselves."

He suggested that some reasons for the lack of recognition of childhood overweight could be that some parents, particularly mothers, tend to judge overweight by whether or not their child is teased about their weight at school or has developed limitations in physical activity; or that, with childhood obesity becoming increasingly normative, that some excess weight simply goes unnoticed.

Despite parents' inability to recognize problem weight in their children, Professor Crawford said a substantial proportion of parents reported they employed various strategies to help prevent their child from gaining too much weight.

The most common strategies included: promoting a balanced diet; promoting physical activity; reducing junk food; limiting the amount of fat and sugar; promoting more fruit.

While this is encouraging, Professor Crawford said that less than 10 per cent of parents increased consumption of fruit and vegetables as a potential weight-control strategy, and few reported that they tried to limit or reduce their child's intake of high-energy drinks and limit television viewing. *Research Australia*

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FACT:

Small Classes Improve Outcomes in Diabetic Foot Care: *Data shows the benefit of group education about foot care for patients with diabetes.* Diabetic patients have a 12% to 25% lifetime risk of developing foot complications leading to significant morbidity and mortality. The objective of this study was to assess the effectiveness of group education in improving patient awareness of foot care. Patients attending a 2-hour teaching session filled in an 18-part questionnaire before and after the teaching session to assess knowledge. Fifty-nine patients recently diagnosed with diabetes mellitus or foot complications were recruited for 7 sessions. Analysis of the data showed a statistically significant improvement in foot care knowledge after the teaching session compared with before (69% to 85%, $P < .001$). Patients in the smaller group ($n < 10$) had significantly higher scores compared with the bigger groups ($n > 10$; $P < .025$). These data show the benefit of group education about foot care for patients with diabetes. Smaller groups benefited more than larger ones did, which could be attributed to the sizes allowing for better interaction between the tutor and patient. As patient knowledge is variable from individual to individual, smaller teaching sessions may allow patients to address specific concerns. *The International Journal of Lower Extremity Wounds, Vol. 6, No. 1, 28-33 (2007)*

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Item 14

Strong Evidence Links Soft Drink Consumption to, Diabetes

Those who consumed one or more soft drinks per day were twice as likely as those who consumed less than one per month to develop diabetes

<http://www.diabetesincontrol.com/results.php?storyarticle=4620>

The case against swigging soda just got stronger. A review of 88 studies finds strong evidence to reduce population consumption of soft drinks

This supported evidence becomes available, while the American Beverage Association says the U.S. obesity problem can't be linked to any one food product or beverage.

The case against swigging soda just got stronger. A large systematic review reveals clear associations between consumption of nondiet soft drinks and increased calorie intake and body weight.

Full-calorie soft drinks are also linked with reduced intake of milk and fruit and increased risk of type 2 diabetes. "Recommendations to reduce population soft drink consumption are strongly supported by the available science," concludes the review of 88 studies.

The American Beverage Association, however, presents a different view on its Web site. "It is not feasible to blame any one food product or beverage as being a sole contributor to obesity No science supports such a claim."

Carbonated soft drinks are the single largest source of calories in the American diet, according to a 2005 report called "Liquid Candy," produced by the nonprofit Center for Science in the Public Interest (CSPI). Companies annually manufacture enough soda pop to provide more than 52 gallons to every man, woman and child in the United States.

"Nobody claims there is a single cause to the obesity problem, but the existing science certainly puts soft drinks in the list of leading contributors," said review co-author Kelly Brownell, Ph.D. He is director of the Rudd Center for Food Policy and Obesity at Yale University.

"These conditions now exist, and several clear conclusions are apparent," they say. One of the most "powerful" findings is the link between soft drink intake and increased calorie consumption.

Of 21 studies, 19 showed that as people drink more soda pop, the number of calories they consume rises. Moreover, the studies using the most reliable statistical methods showed the largest effects.

Instead of satisfying a sweet tooth, soft drinks may do just the opposite. Several studies found that the caloric increase is actually greater than that contained in the soda, raising "the possibility that soft drinks increase

hunger, decrease satiety or simply calibrate people to a high level of sweetness that generalizes to preferences in other foods," the authors say.

"These results, taken together, provide clear and consistent evidence that people do not compensate for the added calories they consume in soft drinks by reducing their intake of other foods," the reviewers say.

The authors anticipated a weaker relationship between soft drink consumption and body weight, because there are many other calorie sources in the diet. Yet in the highest-quality studies, which controlled for a number of unrelated variables, a moderate relationship existed. The review also showed a slight correlation between soft drink consumption and lower intakes of milk, calcium, fruit and fiber.

The "most striking link" was between soft drink consumption and the incidence of type 2 diabetes, according to the reviewers. In a study of 91,249 women followed for eight years, those who consumed one or more soft drinks per day were twice as likely as those who consumed less than one per month to develop diabetes

"This result alone warrants serious concern about soft drink intake, particularly in light of the unprecedented rise in type 2 diabetes among children," the review says.

CSPI, on the other hand, is satisfied with the research to date. "There's so much damning evidence," says Michael F. Jacobson, Ph.D., executive director. "This is just sugar water. The real need is for laws and regulations that would help rein in soft drink consumption."

The consumer advocacy group calls for clearly presented calorie information at vending machines, convenience stores and restaurants. The group urges schools to stop selling full-calorie soft drinks. CSPI has also petitioned the federal government to require health notices on all nondiet sodas warning that they may promote obesity, diabetes, tooth decay, osteoporosis and other health problems.

Vartanian LR, Schwartz MB, Brownell KD. Effects of soft drink consumption on nutrition and health: a systematic review and meta-analysis. Am J Public Health 97(4), 2007. The systematic review appears in the April issue of the American Journal of Public Health.

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Item 15

Pioglitazone Linked to Drug Interactions With Gemfibrozil, Rifampin

Te FDA approved safety labeling revisions for the antidiabetic agents pioglitazone and pioglitazone/metformin to warn of interactions associated with concomitant use of the pioglitazone component and drugs known to induce or inhibit the cytochrome P (CYP) 450 isoenzyme 2C8 (CYP 2C8).

<http://www.diabetesincontrol.com/results.php?storyarticle=4619>

The metabolism of pioglitazone involves multiple cytochrome P450 (CYP) isoforms, of which CYP 2C8 (and to lesser degrees, CYP 3A4 and CYP 1A1) have the highest activity. Use of a CYP 2C8 inhibitor (eg, gemfibrozil) may therefore significantly increase the area under the curve (AUC) of pioglitazone; use of a CYP 2C8 inducer (eg, rifampin) may cause a significant decrease.

In a clinical study of 10 healthy volunteers, the addition of oral gemfibrozil (600 mg twice daily) to pioglitazone (30 mg) yielded a 226% increase in pioglitazone exposure (AUC₀₋₂₄) compared with pioglitazone alone.

A similar study (n = 10) showed that concomitant administration of oral rifampin (600 mg once daily) and pioglitazone (30 mg) resulted in a decrease in the AUC of pioglitazone by 54%.

The FDA notes that if an inhibitor or inducer of CYP 2C8 is started or stopped during treatment with pioglitazone, changes in diabetes treatment may be required based on clinical response.

Pioglitazone tablets are indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus. Treatment with pioglitazone/metformin combination tablets is warranted for patients who are inadequately controlled with either component alone or already are receiving both.

Gemfibrozil tablets (*Lopid*, Pfizer Inc) are indicated as adjunctive therapy for the treatment of adult patients with types 4 and 5 hyperlipidemias who present a risk for pancreatitis and do not respond adequately to diet, and for reducing the risk for de novo coronary heart disease in type 2b patients with lipid abnormalities who have demonstrated inadequate response to weight loss, dietary therapy, exercise, and other pharmacologic agents (eg, bile acid sequestrants and nicotinic acid).

Rifampin capsules and injection (*Rifadin and Rifadin IV*, Sanofi-Aventis US) are indicated for use as part of a treatment regimen for tuberculosis and for the treatment of asymptomatic carriers of *Neisseria meningitidis* to eliminate meningococci from the nasopharynx.

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Quote of the Week!

"When they discover the center of the universe, a lot of people will be disappointed to discover they are not it."

.....Bernard Bailey

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