

## Clinical Briefs

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#### New Rotavirus Vaccine Approved

A second oral U.S. licensed vaccine for the prevention of rotavirus, an infection that causes gastroenteritis (vomiting and diarrhea) in infants and children was approved last month by the Food and Drug Administration (FDA). The vaccine

Without vaccination, nearly every child in the United States would likely be infected at least once with rotavirus by age 5.

There are many different strains of rotavirus. The vaccine protects against rotavirus gastroenteritis caused by the G1, G3, G4, and G9 strains.

During studies involving nearly 75,000 infants, Rotarix was effective in preventing both severe and mild cases of rotavirus-caused gastroenteritis during the first two years of life. The most common adverse reactions reported during clinical trials were fussiness, irritability, cough, runny nose, fever, loss of appetite and vomiting.

In 1999, a different rotavirus vaccine from another manufacturer was voluntarily withdrawn from the U.S. market because of an association with an increased risk of intussusception, or intestinal folding, which can lead to potentially life-threatening intestinal blockage. Intussusception can occur in children spontaneously in the absence of vaccination, but to help ensure that Rotarix does not increase the risk of intussusception, its manufacturer conducted a study of more than 63,000 infants.

In that study, there was no increase in the risk of intussusception in those who received Rotarix (31,673 infants) compared to those who received placebo (31,552 infants). Increased rates of convulsion and pneumonia-related deaths were observed in the Rotarix recipients in the intussusception study, however these events were not observed in other studies conducted by the manufacturer. Although the FDA has concluded that the available data do not establish that these events are related to the vaccine, the agency has requested the manufacturer to conduct post-marketing safety studies involving more than 40,000 infants to provide additional safety information.

#### FDA Requiring New REMs For Old Drugs

Under the Food and Drug Administration Amendments Act of 2007 (FDAAA), FDA can require manufacturers to submit a risk evaluation and mitigation strategy (REMS) when a drug first comes on the market, or later if FDA becomes aware of new safety data about the drug. Last month, FDA disclosed a list of 25 drugs and biologic products the agency will be requiring manufacturers to develop REMs for.

The manufacturers of the 25 drugs and biologic products identified in last month

REMS by Sept. 21, 2008.

According to FDA, certain drugs present a dilemma. They can provide an important benefit to patients, but they can be especially dangerous if not used properly. For example, certain drugs may be safe and effective for patients, but if taken while pregnant can harm the fetus or cause miscarriage. Rather than deny FDA approval of such drugs, the agency has granted approval and required that the manufacturer develop a safety plan, or REMS, to help ensure that health care professionals prescribe the drug correctly and that patients use it safely. While FDA has previously approved some drugs and biologics with these safety plans, the new law makes explicit FDA's authority to require them and contains specific enforcement authority when violations or noncompliance with the plan's requirements occur.

"These safety plans allow patients to have continued access to certain medicines for which there are safety concerns that can be managed through appropriate use," said Jane Axelrad, associate director for policy, Center for Drug Evaluation and Research, in a statement. "The FDA approved the drugs identified today before the new law was passed, and they will now be brought under the new statutory authority to require and enforce REMS."

In addition to issuing the notice about drugs approved before March 25, 2008, FDA is also implementing the new authority for drugs that will be approved after March 25, 2008, as well as for already marketed drugs for which new risks are identified after March 25. The agency also advised the public to notify the agency if they believe other drugs should be considered to have REMS under the new statutory provisions.

The Federal Register notice, which includes a list of the 25 drugs and biologic products that will be required to submit REMS, is available at

#### Draft Guidelines For Stents Issued

Last month, the Food and Drug Administration (FDA) issued draft guidelines to aid the development, testing and manufacture of coronary drug-eluting stents, devices used to treat blocked heart arteries.

Over the past few years, FDA and the clinical community have been closely monitoring these devices and the complications that have arisen surrounding them, including concerns over clot formation in some patients several years after implantation. The draft guidelines issued last month outline the agency

Each year in the United States, approximately one million patients undergo procedures to treat coronary atherosclerosis, also known as hardening or blockages of the heart arteries, a condition that can cause angina and heart attacks. Some 650,000 of these patients are treated with drug-eluting stents, a scaffolding device that is placed into the arteries to prop them open. Drug-eluting stents have a coating that slowly releases a drug to prevent the growth of scar tissue that may accumulate after the initial procedure opens the artery. Re-accumulation of scar tissue can mean additional procedures to keep arteries open and preserve adequate blood flow.

This draft guidance, available online at <http://www.gpoaccess.gov/fr/index.html>

Center for Devices and Radiological Health and the Center for Drug Evaluation and Research. Also included are draft recommendations for engineering tests, biocompatibility tests, and animal studies to assess the device's overall safety.

Currently, FDA has approved three coronary drug-eluting stents.

#### Study May Lead To Better Epilepsy Treatment

Using a rodent model of epilepsy, researchers found one of the body

Researchers say this may explain why approximately 30 per cent of patients with epilepsy do not respond to antiepileptic medications. The study, conducted by researchers at the National Institute of Environmental Health Sciences (NIEHS) and the University of Minnesota College of Pharmacy and Medical School, in collaboration with Ludwig-Maximilians-University in Munich, Germany, is available online and will appear in the May 2008, issue of *Molecular Pharmacology*. "Our work identifies the mechanism by which seizures increase production of a drug transport protein in the blood brain barrier, known as P-glycoprotein, and suggests new therapeutic targets that could reduce resistance," said David Miller, PhD, a principal investigator in the NIEHS Laboratory of Pharmacology and co-author on the paper, in a statement.

The blood-brain barrier (BBB), which resides in brain capillaries, is a limiting factor in treatment of many central nervous system disorders. It is altered in epilepsy so that it no longer permits free passage of administered antiepileptic drugs into the brain. Miller explained that P-glycoprotein forms a functional barrier in the BBB that protects the brain by limiting access of foreign chemicals.

"The problem is that the protein does not distinguish well between neurotoxicants and therapeutic drugs, so it can often be an obstacle to the treatment of a number of diseases, including brain cancer," Dr. Miller said.

Increased levels of P-glycoprotein in the BBB has been suggested as one probable cause of drug resistance in epilepsy.

Using isolated brain capillaries from mice and rats and an animal model of epilepsy, the researchers found that glutamate, a neurotransmitter released when neurons fire during seizures, turns on a signaling pathway that activates cyclooxygenase-2 (COX-2), causing increased synthesis of P-glycoprotein in these experiments. Increased transporter expression was abolished in COX-2 knockout mice or by COX-2 inhibitors. It has yet to be shown in animals or patients that targeting COX-2 will reduce seizure frequency or increase the effectiveness of anti-epileptic drugs.

#### Fat Increases Risk Of Early Death In Women

Women who carry excess fat around their waists were at greater risk of dying early from cancer or heart disease than were women with smaller waistlines, even if they were of normal weight, reported researchers from Harvard and the National Institutes of Health (NIH). Previous studies have shown that the tendency to deposit fat around the waist increases the risk for health problems. The current study is the largest, most comprehensive of its kind undertaken to show that accumulation of abdominal fat can increase the risk of death.

To conduct the study, the researchers analyzed data from more than 44,000 women in the Nurses

Health study, which followed the health history of thousands of registered nurses in 11 states. Researchers followed the women over the course of 16 years to track their medical history and lifestyle. Because the majority of the women who took part in the study were white, the researchers do not know if their findings pertain to other groups of women or to men.

All the women included in the study were registered nurses. At the beginning of the study the women were asked to measure their waists and hips. Every two years, the women completed questionnaires about their health, providing information about their age, activity level, smoking status, diet, blood pressure and cholesterol levels.

The researchers examined the cause of death for all women who died over the course of the study. In total, 3,507 deaths occurred

The researchers discovered that women with greater waist circumferences were more likely to die prematurely, particularly from heart disease, when compared to women with smaller waists. For example, women with waist size equal to or greater than 35 inches were approximately twice as likely to die of heart disease as were women with a waist size less than 28 inches, regardless of their body mass index. Similarly, women with a waist size equal to or greater than 35 inches also were twice as likely to die of cancer as were women with a waist size less than 28 inches.

Women who had a greater waist circumference and were also obese were at the greatest risk of premature death. Researchers determined if a woman was overweight by calculating her body mass index (BMI), a measure of a person

Waist-to-hip ratio was found to be as strongly associated with risk of early death as the measurement of waist size alone. However, waist-to-hip ratio requires two measurements and therefore may be less convenient to calculate than measuring waist circumference alone.

The study authors wrote that results from previous studies have been inconsistent because of the relatively small number of people who took part and the short duration of the studies. The current study provides the strongest evidence so far regarding the adverse effects of abdominal obesity on the risk of death in women. The authors called for future studies to investigate abdominal obesity and the risk of death in men and other ethnic groups.

#### Six New Gene Variants Linked To Diabetes

An international team that included scientists from the National Human Genome Research Institute (NHGRI) last month reported it has identified six more genetic variants involved in type 2 diabetes, boosting to 16 the total number of genetic risk factors associated with increased risk of the disease. None of the genetic variants uncovered by the new study had previously been suspected of playing a role in type 2 diabetes. Intriguingly, the new variant most strongly associated with type 2 diabetes also was recently implicated in a very different condition: prostate cancer.

The analysis combined genetic data from more than 70,000 people. The work was carried out through the collaborative efforts of more than 90 researchers at more than 40 centers in Europe and North America.

When considered individually, the genetic variants discovered to date account for only small differences in the risk of developing type 2 diabetes. But researchers say when all of the variants are analyzed together, some significant differences in risk are likely to emerge. Researchers said more work is needed to understand the impact of their discovery that a genetic variant called JAZF1 appears to be involved in diabetes as well as prostate cancer.

#### One of the study

The research was conducted by the DIAbetes Genetics Replication And Meta-analysis (DIAGRAM) consortium, which brought together many groups active in the field of diabetes research.

#### Study Finds AEDs Underused In Home

The first study to explore the use of automated external defibrillator (AEDs) in the home has found that although the safe and easy-to-use devices are effective for certain types of cardiac arrest, they were underused. The Home Automated External Defibrillator Trial (HAT), a randomized international clinical trial, was supported by the National Heart, Lung, and Blood Institute (NHLBI).

Researchers followed 7,001 heart attack patients at moderate risk of sudden cardiac arrest who had a spouse or other live-in companion who agreed to take conventional steps to respond to a sudden cardiac arrest

AED before taking conventional life-saving steps. After an average of just over three years of follow-up, researchers found that survival rates were about the same between those who had an AED in the home and those who did not. However, there were relatively few sudden cardiac arrests, and only 39 percent of these events were witnessed at home. The study was conducted in 178 clinical sites in the United States, Canada, Britain, New Zealand, Australia, Germany, and the Netherlands.

AEDs detect the patient

If the AED determines that the problem is caused by ventricular fibrillation, the AED instructs the user to hit a button to deliver an electric shock. The AED transmits the shock through the electrodes, then rereads the heart rhythm to determine if another shock is needed. The machine does not recommend or administer a shock if the cause of the abnormal rhythm cannot be treated by the shock. HAT researchers found no evidence of inappropriate uses of the AED by lay users.

All HAT participants previously had a heart attack and were at moderately increased risk for sudden cardiac arrest. Participants also had to have a family member or other live-in companion who was willing to follow specific steps to immediately help the participant in cardiac arrest; these steps were described in a training video and through discussions with study personnel. One-half of the companions (control group) was asked to call EMS and perform CPR immediately; the other half of the group was asked to use an AED before calling EMS (or at the same time, if there were two bystanders) and performing CPR. Participants were followed for about 3 years (ranging from 20 months to 56 months).

Overall, 450 participants died during the study, with nearly equal numbers of participants in the control group (228 or 6.5 percent) and the AED treatment group (222 or 6.4 per cent). Participants were equally likely to die from sudden cardiac arrest (35.6 percent) as from other causes not related to cardiovascular disease (37.8 per cent), and 160 deaths during the study were due to sudden cardiac arrest. Of the 117 sudden cardiac arrests that occurred at home, only one-half (58) of them were witnessed by another member of the household.

AEDs were used by at-home bystanders on 32 HAT participants, with ventricular fibrillation detected in 15 participants. Fourteen of these participants were shocked, and ventricular fibrillation was terminated in each case. There were no device failures. Overall, among the participants in the AED group who used the AED for ventricular fibrillation in the home, four of the 14 participants defibrillated (28.6 per cent) survived long term

In addition, AEDs were used on seven neighbors or visiting friends, and shock was advised and successfully given in four individuals, of whom two survived long-term.

The AEDs used in the study are the same types of devices that are now available in many airports, fitness centers, and other public places, which have been shown to be safely and easily used by bystanders with little training to perform life-saving treatment on individuals in cardiac arrest.

Anti-Stigma Campaign Targets Colleges

The Substance Abuse and Mental Health Services Administration (SAMHSA), working in collaboration with the Ad Council, announced last month a program that has delivered their National Mental Health Anti-Stigma public service advertising (PSA) campaign for the first time directly to colleges and universities throughout the country. The campaign aims to reach 18-25-year-old adults and is designed to decrease the negative attitudes that surround mental illness by encouraging these young adults to support friends with mental health problems. As an extension of the campaign, new materials created specifically for college students have been distributed to colleges and universities nationwide.

According to SAMHSA, in 2006 there were an estimated 24.9 million adults aged 18 or older living with serious psychological distress, an indicator highly correlated with serious mental illness. Among 18-25-year-olds, the prevalence of serious psychological distress is the highest in the adult population, yet this age group was the least likely to receive treatment or counseling. Young people are more likely to seek help if social acceptance is broadened and they receive support and services early on.

According to fall 2006 data from the National College Health Assessment Report, more than half of all college students in the United States reported feeling "things were hopeless" and more than a third said they have felt during the past school year "so depressed it was difficult to function." Additionally, almost one in 10 students said that they have seriously considered attempting suicide during the past year. Suicide is the second leading cause of death for college students, according to the Centers for Disease Control and Prevention.

In partnership with Alloy Media, the Ad Council and SAMHSA distributed 450,000 campus packs, which included campaign brochures and additional materials for students, to bookstores at more than 200 colleges and universities during the fall 2007 semester. SAMHSA

National Mental Health Anti-Stigma Campaign partners include the Centers for Disease Control and Prevention (CDC), the National Institute of Mental Health (NIMH), state mental health agencies, leading researchers on stigma and a broad coalition of stakeholders, including organizations that represent provider organizations and consumer and family member groups. The Campaign held a series of regional meetings to develop a grassroots network to support the Campaign and provide assistance with anti-stigma efforts to states and local communities. A resource guide entitled, "Developing a Stigma Reduction Initiative," is also a part of the campaign and is based on the evaluation and lessons learned from the Elimination of Barriers Initiative. The guide provides information on how to mount a statewide anti-stigma campaign, examples of outreach materials, reports on the best practices for stigma reduction, and lists important resources for technical assistance. Copies of the guide can be obtained by calling SAMHSA

Some people seem to be in the diet. A week proudly announced that she would lose the 10 pounds, but a few weeks after she painful to admit that weight is restored. But you can not be accused her, accusing the other tens of thousands of people struggle with obesity, accusing those who promote high, people did not believe in the good of dieting methods. Cooper, deputy director of the U.S. Institute for Steve. Farrell said: through diet restriction and weight quickly cut a lot of people, usually always returned the body weight, and some people will lose weight before the fat.

Fashion is the last several decades catering to the latest piracy methods: high-protein diet - a significant reduction in carbohydrates, protein and fat consumption major. Unfortunately, those who appear to cut the miracle of weight, mainly through the role of dehydration the loss of moisture. Such high-protein diet programme is not safe,

University of Illinois, Charles, an associate professor of nutrition and medicine. Baomuboshi pointed out the other two worries: the essential minerals in the bones of the missing, as well as increased fat caused by high lipid content of compounds. And increased lipid compounds may cause heart problems.

So, whether there is a rapid weight loss and maintenance of long-term effects, without damage to healthy way? Yes, but research shows that than you imagine to be much easier - as long as compliance with the following some simple strategies.

#### Security

Strategy 1: Gao Qian Wei Baomu, Farrell and other researchers believe that reduction in daily calories should not exceed 250 to 500 cards, but there should be no special diet, the feeling of hunger. Head of the Department of Nutritional Sciences University of Alabama Roland. Wen Seerboshi recommended diet, eat as much - as long as it is the right thing.

According to the study Wensel, if people want to eat the number of take a number of high-fiber foods, such as vegetables, fresh fruits, cereals and not the refined starch, they were the only choice heat sugar, meat, cheese and fried foods Half. May be partly due to high fiber foods can easily feed, but higher than other foods contain fewer calories. This means the long-term, healthy diet is necessary.

The U.S. Department of Agriculture guidance of the existing proposals, the daily intake of total calories, carbohydrates (vegetables, cereals, fruits) should account for 55-60 percent of protein accounted for 12 to 15 percent, not more than 30 percent fat . University of California, director of the Center for Human Nutrition David. Xiboboshi said that in order to lose weight and maintain weight loss effects, can further reduce total fat intake to 20 percent of total calories. In his book On the new diet , Shppe proposed lean meat does not exceed 1 / 3, in order to Eat more vegetables, grains and starch.

Remember, the brain needs a little time to have recognized your stomach full of food, and prove that you are no longer hungry. If eating too fast, recognized this point in the brain before you eat too much. Nelson used to eat fast suggested that the two tips: one on each lay down their forks to eat with other people eat together, in Xijiaomanyan in the conversation, rather than continuously Langtunhuyan.

#### Safety

Strategy 2: In addition to the regular walk every day reduced in the diet of 250 cards, sports and other physical activities have to consume 250 calories.

Like the movement of people, walking 30 minutes a day is the best activities. According to the middle of obese middle-aged women, dance like Manbu Cycling and the like so that you reduce weight quickly. Another study found that the low-fat diet obese women, an increase of the daily activities of the rules (for example, to do more yard work, choose the stairs instead of elevators sit, walk more, etc.), special arrangements than those of the women s movement more To maintain weight loss results. Perhaps this is because of lifestyle changes than the time devoted to the campaign

plans more easily adhere to. Nelson recalled that: There are many ways that can be consumed 20 or 50 cards. Walking, station stop, gently patted shoes, in the breaks when walking five minutes, these small changes can really help you.

## Security

The two groups are reduced by an average of 13 pounds. But more important is that they have lost weight categories: strength training at the same time the group has cut fat, and has increased an average of 1.5 pounds muscles, and that only restricted diet group and cut the fat with muscle almost three pounds.

Why is this important? Nelson said, We have the muscle by the body of the decision of our metabolic rate, weight loss, retain muscle, we will maintain the metabolic rate at a higher level, which will help the long-term weight control.

The number of muscle weight control how important it Shppe dieting new theory, wrote: Each daily consumption of 14 pounds of muscle calories. After a long period, which is really very effective.

As you can see, in order to reduce weight, you do not have to starve, do not have to reject many of cuisine, there is no need to become a competitive athletes. To focus on some minor changes, the effect than you imagine to be much faster, much more.

## About the Author

From [www.usmedicine.com](http://www.usmedicine.com):

Physician supervision means you get stronger, not weaker Fastest safe weight loss program available You lose as quickly.

Weight Loss Wand provides variety of tips related to weight loss diets, pills, and advice on choosing right weight.

Postpartum weight loss, losing weight after baby and weight loss after baby. Fast, safe postpartum weight loss. Weightloss.

Simple steps designed to help you improve your health and acheive permanent weight loss. Discover the secrets to successful.

The attraction of diet pills and there appealing weight loss claims can be hard to pass up. But are all diet pills as safe and effective as they claim to be.

A safe plan is to eat 300 to 500 fewer calories a day to lose 1 to 2 pounds a week. Watch Out for Promises of Quick And Easy Weight.

We offer you safe weight loss options through proper diet and weight loss pills. Attain weight loss through diet weight loss packages.

Just place a new adhesive skin patch on your body, each day for continuous, safe, and effective weight loss. Much like a Nicotine Patch which takes away.

Source: <http://www.productsherbal.com>