

THE CSTE WASHINGTON REPORT

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EDITOR'S NOTE: The Centers for Disease Control and Prevention (CDC) February 17 released results from a survey that indicate physical activity among the nation's youth is increasing as a result of a national youth media campaign launched by the agency in 2002. The award winning multicultural campaign known as VERBTM had one of the largest effects, a 34 percent increase, in weekly free-time physical activity sessions among 8.6 million children ages 9-10 in the United States. A telephone survey of 6,000 youth and their parents was conducted in 2002 prior to launching the VERB? campaign and it was repeated among the same families in 2003. A rigorous analysis of the data collected made it possible to measure changes in physical activity attributed to the VERBTM campaign among youth ages 9-13 in the U.S. population— additional details are provided in this Washington Report.

The CSTE Washington Report is provided as an information resource for members of the Council of State and Territorial Epidemiologists on federal legislation and regulation affecting public health and epidemiology in the U.S. Legislation cited in the report can be accessed via <http://www.thomas.loc.gov> Regulations cited can be accessed via <http://www.gpo.gov>

SENATE BUDGET COMMITTEE TO ACT TO REDUCE DEFICIT – The Senate Budget Committee will mark up its FY 2005 Budget Resolution today. The full Senate is expected to take up the measure next week. The House Budget Committee plans to mark up its version of a budget resolution next week and both Houses are pushing to finish the process before the April Easter Congressional recess. The Senate Budget Committee's Chairman's Mark (Sen. Nickles R-OK), assumes a \$1.6 billion increase in Function 550 – the vast majority of which is comprised of the U.S. Public Health Service agencies and programs, including NIH and CDC. The language further clarifies that fully \$1.7 billion is assumed to be directed for NIH's biodefense activities. An additional \$35 million increase is assumed to be directed for the U.S. Department of Agriculture for BSE (mad cow disease) detection and prevention, as well as bioterrorism preparedness. Furthermore, these discretionary increases are provided, in large or in whole, by cuts in Medicaid spending. The Chairman's mark, in summary, provides zero increase for any other public health activities and programs at the CDC, or nondefense research at the NIH, and may assume cuts to other programs, such as the Health Professions training program at the Health Resources and Services Administration, to finance part of the targeted increases.

Anticipating the worst, public health groups have been coalescing around the budget process and are preparing to support an amendment that Sen. Tom Harkin (D-IA) has agreed to offer on the Senate floor to boost Function 550 health discretionary spending by 12 percent, \$6.1 billion, offset by an increase of \$1.00 in the federal tobacco tax.

HHS ANNOUNCES NEW REQUIREMENTS FOR BAR CODES ON DRUGS AND BLOOD TO REDUCE RISK OF MEDICATION ERRORS -- HHS Secretary Tommy G. Thompson February 25 announced that the Food and Drug Administration is issuing a final rule requiring bar codes on the labels of thousands of human drugs and biological products. The measure will help protect patients from preventable medication errors and reduce the cost of health care and represents a major step forward in the department's efforts to harness information technology to promote higher quality care. "Bar codes can help doctors, nurses and hospitals make sure that they give their patients the right drugs at the appropriate dosage," Secretary Thompson said. "By giving health care providers a way to check medications and dosages quickly, we create an opportunity to reduce the risks of medication errors that can seriously harm patients."

"We're encouraging widespread use of technologies that can help health care providers avoid hundreds of thousands of medication errors," FDA Commissioner Mark B. McClellan, M.D., Ph.D., said. "Bar coding systems have proved their dependability and effectiveness by ensuring the accuracy of a myriad of actions in commerce and industry."

We're now advancing the adoption of these systems in settings where they can help save lives."

The FDA rule calls for the inclusion of linear bar codes -- such as are used on millions of packages of consumer goods -- on most prescription drugs and on certain over-the-counter drugs that are commonly used in hospitals and dispensed pursuant to an order. Each bar code for a drug will have to contain, at a minimum, the drug's National Drug Code number. This information will be encoded within the bar code on the label of the product. Companies also may include information about lot number and product expiration dates.

In addition, the rule requires the use of machine-readable information on container labels of blood and blood components intended for transfusion. These labels, which are already used by most blood establishments, contain FDA-approved, machine-readable symbols identifying the collecting facility, the lot number relating to the donor, the product code and the donor's blood group and type.

The bar code rule is designed to support and encourage widespread adoption of advanced information systems that, in some hospitals, have reduced medication error rates by as much as 85 percent. In these institutions, patients are provided with identification bracelets that bear a bar code, which identifies the patient. The health care professional then scans the patient's bar code and scans the drug's bar code. The information system then compares the patient's drug regimen information to the drug to verify that the right patient is getting the right drug, at the right time, and at the right dose and route of administration. In a study conducted at a Veterans Affairs Medical Center employing such a bar code scanning system, 5.7 million doses of medication were administered to patients with no medication errors.

FDA estimates that the bar code rule, when fully implemented, will help prevent nearly 500,000 adverse events and transfusion errors over 20 years. The economic benefit of reducing health care costs, reducing patient pain and suffering, and reducing lost work time due to adverse events is estimated to be \$93 billion over the same period. FDA first proposed bar code requirements in March 2003. Comments from hospitals, health care professionals, trade and professional associations and others showed widespread support for the approach to improving patient safety and promoting higher quality care.

The final rule applies to most drug manufacturers, repackers, relabelers, private label distributors and blood establishments. New medications covered by the rule will have to include bar codes within 60 days of their approval; most previously approved medicines and all blood and blood products will have to comply with the new requirements within two years.

NATIONAL CAMPAIGN TO GET KIDS PHYSICALLY ACTIVE IS WORKING

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The Centers for Disease Control and Prevention (CDC) February 17 released results from a survey that indicate physical activity among the nation's youth is increasing as a result of a national youth media campaign launched by the agency in 2002. The award winning multicultural campaign known as VERBTM had one of the largest effects, a 34 percent increase, in weekly free-time physical activity sessions among 8.6 million children ages 9-10 in the United States.

A telephone survey of 6,000 youth and their parents was conducted in 2002 prior to launching the VERB? campaign and it was repeated among the same families in 2003. A rigorous analysis of the data collected made it possible to measure changes in physical activity attributed to the VERBTM campaign among youth ages 9-13 in the U.S. population.

"The results of this evaluation are impressive and substantiate that the VERBTM campaign has surpassed expectations and is responsible for improving physical activity levels among youth," said CDC Director Dr. Julie L. Gerberding. "Our national, multicultural efforts are helping young people to realize that physical activity is fun, cool and can be a part of everyday life. This is critical to reducing the epidemic of overweight among today's youth."

The Youth Media Campaign Longitudinal Survey, conducted by an independent research company, also showed that the VERBTM campaign was especially effective in shrinking the gap in physical activity levels between boys and girls. There was a 27 percent increase in free-time physical activity sessions among U.S. girls in the entire 9-13 age range. Likewise, 6 million children from lower-middle income households¹ registered a 25 percent increase in free-time physical activity sessions despite the barriers they faced, which included transportation issues, safety concerns and less access to physical activity resources.

In communities² that received higher levels of VERBTM marketing activity, the increases in physical activity were even more dramatic. The CDC found that the number of least active³ 9-10 year olds was reduced by 33 percent as a result of the VERBTM campaign. The number of least active 9-13 year old girls decreased even more, by 37 percent, in these communities. There was a 38 percent decline among least active 9-13 year olds from lower-middle income households.

“Obesity costs the country \$117 billion dollars a year in medical expenses,” said Dr. James Marks, director, CDC’s National Center for Chronic Disease Prevention and Health Promotion. “Marketing programs like this one are proving to be successful in reducing the health and economic impact of this disease and are encouraging us to adopt similar strategies to address other priority health problems.”

TREADMILL TESTING, EKG, AND CT SCANS NOT RECOMMENDED FOR SCREENING PATIENTS AT LOW RISK FOR HEART DISEASE --

The U.S. Preventive Services Task Force said February 16 that it does not recommend using treadmill exercise testing, resting electrocardiograms, or electron beam computerized tomography to screen for heart disease in low-risk adults who don't have any symptoms of heart disease. For adults at increased risk for heart disease, the Task Force found insufficient evidence for or against using these three tests for screening.

The recommendations are published in the February 17 issue of *Annals of Internal Medicine*, and further information about the three screening tests can be found on the AHRQ Web site at <http://www.ahrq.gov/clinic/uspstf/uspacad.htm>.

An estimated 22 million Americans have heart disease, and more than 700,000 die from it each year. Heart disease is the leading killer of both men and women and is estimated to cost more than \$350 billion annually in medical care, time lost from work and other expenses.

Men under age 50 and women under age 60 who have normal blood pressure and cholesterol levels, do not smoke, and do not have diabetes are at low risk of heart disease. A simple calculator to estimate risk of heart disease can be found at <http://hin.nhlbi.nih.gov/atpiii/calculator.asp?usertype=pub>.

The Task Force recommends screening for many of the risks for heart disease, such as high blood pressure, obesity, diabetes, and high cholesterol. The Task Force found that while treadmill testing, EKG, and EBCT could identify persons at higher risk of heart disease, no studies to date have examined whether or not using these tests to screen adults improves health outcomes. Furthermore, the Task Force concluded that using these three technologies to screen for heart disease in low-risk adults could cause more harm than good because of the frequency of false-positive and false-negative results.

False-positive results, in addition to causing a patient psychological stress and anxiety, often lead to invasive tests, such as coronary angiography or treatment with unnecessary medications. Although coronary angiography—a test in which a catheter is inserted into the patient and a dye injected—is considered generally safe, complications, such as internal bleeding, stroke or infection, and even death, can occur. False-negative results can mislead those with heart disease and result in delayed treatment.

The Task Force said that the evidence is inadequate to determine how test results would change the course of treating patients and noted concern that potential harms, such as false-positive findings, unnecessary invasive procedures, and over-treatment could outweigh any benefit of the tests in lower risk persons.

"These recommendations can help clinicians and their patients make more informed decisions about use of these tests to screen for heart disease and may help guide employers and insurers as well," said Task Force chair, Ned Calonge, M.D., Chief Medical Officer and State Epidemiologist for the Colorado Department of Public Health and Environment. "The most important thing individuals at low risk can do is to work with their clinician to monitor their blood pressure, cholesterol, and weight, and to be physically active."

The Task Force, sponsored by the Agency for Healthcare Research and Quality, is the leading independent panel of private-sector experts in prevention and primary care and conducts rigorous, impartial assessments of the scientific evidence for a broad range of preventive services. Its recommendations are considered the gold standard for clinical preventive services. The Task Force based its conclusions on a report from a research team led by Michael Pignone, M.D., M.P.H., Assistant Professor of Medicine at the University of North Carolina-Chapel Hill School of Medicine and the RTI International-University of North Carolina Evidence-based Practice Center.

The Task Force grades the strength of the evidence as "A" (strongly recommends), "B" (recommends), "C" (no recommendation for or against), "D" (recommends against), or "I" (insufficient evidence to recommend for or against screening). The Task Force recommends against routine screening with resting electrocardiogram, exercise treadmill test, or electron beam computerized tomography scanning for coronary calcium, for either the presence of severe coronary artery stenosis or the prediction of coronary heart disease events in adults at low risk for CHD events ("D" recommendation). For adults at increased risk for CHD events, the Task Force found insufficient evidence to recommend for or against routine screening with EKG, treadmill testing, or EBCT scanning for coronary calcium, for either the presence of severe coronary artery disease or the prediction of CHD events ("I" recommendation).

HIGH BLOOD PRESSURE IN THE LUNGS A MAJOR RISK FOR DEATH IN ADULTS WITH SICKLE CELL DISEASE -- A new study reveals that nearly one third of adults with sickle cell disease develop high blood pressure in their lungs and that the condition, known as pulmonary hypertension, causes a much higher death rate in patients with the complication than those without it. The findings, according to researchers from the Warren Grant Magnuson Clinical Center at the National Institutes of Health (NIH), demonstrate an urgent need to diagnose this complication in adults with sickle cell disease as it is a major risk factor for death. The study was conducted as a multi-center collaboration between NIH and the Howard University Center for Sickle Cell Disease. A complete report was published in the February 26 edition of the *New England Journal of Medicine*.

Sickle cell disease is a chronic, often fatal anemia that is classically characterized by severe attacks of pain from blood vessels being blocked by red blood cells that become rigid and form a sickle shape when deoxygenated. In the United States this genetic disease occurs predominantly in people of African descent, and is accompanied by

episodic severe pain in the joints, leg ulcers, jaundice and multi-organ failure. A serious complication of sickle cell disease is pulmonary hypertension.

Pulmonary hypertension is high blood pressure (not related to the pressure measured by cuff on the arm) in the arteries that supply the lungs. The blood vessels that supply the lungs narrow and their walls thicken, so they can't carry as much blood. Like a kinked garden hose, pressure builds up and backs up. The heart works harder, trying to force the blood through. If the pressure is high enough, eventually the heart can't keep up, and is unable to pump enough blood through the lungs to pick up adequate amounts of oxygen. Patients become tired, dizzy and short of breath. When an underlying cause can't be found, the condition is called primary pulmonary hypertension. When a pre-existing disease such as sickle cell triggers high blood pressure in the lungs, doctors call it secondary pulmonary hypertension because it is secondary to another problem. This is the type of pulmonary hypertension evaluated in the NIH project.

“Secondary pulmonary hypertension develops in most types of hereditary and chronic anemias that are caused by hemolysis, the destruction of red blood cells. This suggests that there is a distinct syndrome of hemolysis-associated pulmonary hypertension, a complication that has been reported with increasing frequency in sickle cell patients,” said Dr. Mark Gladwin, pulmonary specialist, NIH Clinical Center and lead investigator of this current research. He pointed out that retrospective studies show a prevalence of pulmonary hypertension ranging from 20-to-40 percent in patients with sickle cell disease.

The research project followed 195 patients, 82 men and 113 women, with an average age of 37, over two years. Doppler echocardiography, a test that uses sound waves to ‘see’ the heart, was performed on each person to assess their pulmonary-artery pressures. Doppler-defined pulmonary hypertension occurred in 32 percent of the patients. “The ‘echo’ is a test that is reasonably priced, non-invasive and should be recommended screening for adults with sickle cell disease just as the colonoscopy, cholesterol panel, mammogram, and other tests are. This would save lives and help to minimize a public health problem.” said co-investigator Dr. Griffin Rodgers, chief, Clinical Hematology, National Institute of Diabetes and Digestive and Kidney Diseases.

“This is similar to what occurred in the mid-nineties. We saw that use of a transcranial Doppler exam changed the screening and management of pediatric patients with sickle cell disease in that it defined important clinical decision points that successfully led to preventing — or at least improving — the odds of reducing strokes in children and adolescents,” added Dr. Rodgers.

Of the 195 individuals evaluated in the current study, 20 percent with pulmonary hypertension died and all but two of the patients without the condition survived. Even patients with mild arterial pressure in the lungs had a high rate of fatality. Sickle cell treatment continues to improve and people with the disease are living longer. “This,” said co-investigator Dr. Oswaldo Castro, Acting Director, Howard University Center for Sickle Cell Disease, “may be why we are seeing such a high prevalence of pulmonary hypertension in sickle cell patients.”

Since the study identified those sickle cell patients at the highest risk of death certain therapies targeting pulmonary hypertension could improve survival rates. "Several types of interventional therapies are now available but so far have been tried in only a few sickle cell patients," said Dr. Castro. He referenced inhalants such as oxygen and nitric oxide; blood exchanges through transfusions; and use of vaso-dilator drugs such as Viagra that open the blood vessels or arteries.

Detection of high blood pressure in the lungs may also account for the unexplained or mistakenly explained sudden deaths in adult patients with sickle cell disease. "We see a high frequency of sudden death in those with sickle cell and this study helps to clarify what is causing those fatalities; particularly in the absence of coronary artery disease (hardening of the arteries) as the cause," explained lead investigator Dr. Gladwin. The co-authors agree that this study's findings represent an opportunity to address a major cause of disability and death in the adult sickle cell disease population — pulmonary hypertension. They believe the research data supports universal screening of individuals with sickle cell disease for this condition and clearly shows the immediate need for clinical trials to further investigate therapies that may combat a serious complication of sickle cell disease that is associated with an ominous outcome.

REPORT SETS DIETARY INTAKE LEVELS FOR WATER, SALT, AND POTASSIUM TO MAINTAIN HEALTH AND REDUCE CHRONIC DISEASE RISK -- The vast majority of healthy people adequately meet their daily hydration needs by letting thirst be their guide, says the newest report on nutrient recommendations from the Institute of Medicine of the National Academies. The report set general recommendations for water intake based on detailed national data, which showed that women who appear to be adequately hydrated consume an average of approximately 2.7 liters (91 ounces) of total water -- from all beverages and foods -- each day, and men average approximately 3.7 liters (125 ounces) daily. These values represent adequate intake levels, the panel said; those who are very physically active or who live in hot climates may need to consume more water. About 80 percent of people's total water comes from drinking water and beverages -- including caffeinated beverages -- and the other 20 percent is derived from food.

"We don't offer any rule of thumb based on how many glasses of water people should drink each day because our hydration needs can be met through a variety of sources in addition to drinking water," said Lawrence Appel, chair of the panel that wrote the report and professor of medicine, epidemiology, and international health, Johns Hopkins University, Baltimore. "While drinking water is a frequent choice for hydration, people also get water from juice, milk, coffee, tea, soda, fruits, vegetables, and other foods and beverages as well. Moreover, we concluded that on a daily basis, people get adequate amounts of water from normal drinking behavior -- consumption of beverages at meals and in other social situations -- and by letting their thirst guide them."

Regarding salt, healthy 19- to 50-year-old adults should consume 1.5 grams of sodium and 2.3 grams of chloride each day -- or 3.8 grams of salt -- to replace the amount lost daily on average through perspiration and to achieve a diet that provides sufficient

amounts of other essential nutrients. Elevated blood pressure, which may lead to stroke, coronary heart disease, and kidney disease, is associated with sodium intake. On average, blood pressure rises progressively as salt intake increases. A tolerable upper intake level (UL) -- a maximum amount that people should not exceed -- is set at 5.8 grams of salt (2.3 grams of sodium) per day. Older individuals, African Americans, and people with chronic diseases including hypertension, diabetes, and kidney disease are especially sensitive to the blood pressure-raising effects of salt and should consume less than the UL. More than 95 percent of American men and 90 percent of Canadian men ages 31 to 50, and 75 percent of American women and 50 percent of Canadian women in this age range regularly consume salt in excess of the UL.

To lower blood pressure, blunt the effects of salt, and reduce the risk of kidney stones and bone loss, adults should consume 4.7 grams of potassium per day. However, most American women 31 to 50 years old consume no more than half of the recommended amount of potassium, and men's intake is only moderately higher. Canadians typically eat more potassium than their American counterparts. African Americans in the United States generally get less potassium than non-Hispanic whites, and because they have a higher prevalence of elevated blood pressure, increased potassium intake may have particularly significant benefits for them.

The typical Western diet is high in salt and low in potassium -- the opposite of what evidence shows is optimal for good health and reducing the risks of chronic disease, the report says. "Research is needed to find ways to help people select better food choices to reduce their salt intake and boost their potassium consumption," Appel said. In addition, because Americans and Canadians get the majority of their salt -- 77 percent, according to one study -- from prepared and processed foods, research should be done to help food processors develop alternative technologies that can reduce the amount of salt added during processing without impairing taste, shelf-life, or product qualities at an affordable cost.