

THE CSTE WASHINGTON REPORT

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EDITOR'S NOTE: Tuberculosis rates in the United States reached an all-time low in 2006, though progress to eliminate TB continued to slow. Drug-resistant TB, including extensively drug-resistant TB, presents significant challenges to treatment and control of the disease in the United States and abroad, according to articles in today's Morbidity and Mortality Weekly Report (MMWR). "Tuberculosis continues to have a significant and unacceptable impact on minorities and immigrant communities in the United States," said Dr. Kevin Fenton, director of CDC's National Center for HIV, STD and TB Prevention. "Blacks and Hispanics have tuberculosis rates that are about eight times higher than that of whites, and the rate for Asians is more than 21 times that of whites. Foreign-born individuals living in the United States have nearly 10 times the rate of TB as those born in the United States."-- 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>

HOUSE AND SENATE PASS BUDGET RESOLUTIONS THAT INCLUDE INCREASES FOR PUBLIC HEALTH – The Senate narrowly passed its Budget Resolution (S. Con. Res. 21) last week and the House passed its version (H. Con. Res. 99) earlier this week on a vote of 216-210. Both measures contain increases for Function 550 which funds the public health agencies and programs, including CDC. The Senate bill includes \$2.717 billion, 5.2 percent, more than FY 2007, and during the floor debate an amendment offered by Senators Specter (R-PA) and Harkin (D-IA) to add another \$2.2 billion passed on a voice vote. The House includes \$2.1 billion over FY 2007, or 4.1 percent more. The two versions will now be conferenced. The final compromised measure does not require the President's signature. Whether the increased funding for F. 550 actually gets allocated to the House and Senate Labor-HHS-Education Subcommittees is still open to question, but all the trends are in the right direction.

HHS SECRETARY LEAVITT ANNOUNCES STEPS TOWARD A FUTURE OF "PERSONALIZED HEALTH CARE" -- HHS Secretary Mike Leavitt March 23 outlined a course for achieving gene-based medical care combined with health information technology, which he called "Personalized Health Care." He said the initiative has the potential to transform the quality, safety and value of health care for patients in the future.

"Personalized health care will combine the basic scientific breakthroughs of the human genome with computer-age ability to exchange and manage data," Secretary Leavitt said. "Increasingly it will give us the ability to deliver the right treatment to the right patient at the right time -- every time."

In a speech before the annual meetings of the Personalized Medicine Coalition, at the National Press Club, the Secretary outlined steps already under way to develop the needed information, as well as new steps he is undertaking to build the foundation for personalized health care and ensure that gene-based medical data and health information technology are used appropriately.

"Every one of us is biologically unique. We've always known that, but we haven't had the knowledge or the tools to deliver health care at that kind of individual level. That's what's changing," Secretary Leavitt said.

Gene-based medicine can help individuals identify their particular susceptibilities to disease while they are well and take effective preventive steps. In the future, it will help detect the onset of disease much earlier, enabling treatment to prevent disease

progression, and can help bring about medical products that are tailored more precisely to the needs of each individual.

Health information technology, including powerful new tools for managing vast amounts of information, will be needed both to continue building basic scientific knowledge and to make the new knowledge useable and accessible for patient care.

Secretary Leavitt emphasized how much work remains to build a system that can deliver personalized health care. He has identified this issue as one of his priorities for the next two years.

"The Human Genome Project was a dramatic success, but it has correctly been called a race to the starting line," he said. "The work that remains is sweeping, from the most fundamental science to the details of health care practice."

Secretary Leavitt announced new steps that HHS is taking to lay the foundation for a personalized health care future:

- HHS is engaged in a broad review of the implications for privacy protection as health information technology is increasingly adopted, including needs for genetic information, and the anticipated effect on the confidentiality, privacy and security of individually identifiable health information.
- HHS will review existing structures for ensuring that genetic tests are accurate, valid and useful. The objective will be to ensure that responsibilities are clearly and appropriately assigned among HHS agencies to support useful genetic testing for patients.
- HHS will develop consistent policies for its agencies regarding access to and security of federally supported research. The goal will be to ensure open information access for researchers, to support progress, while still rewarding discovery and innovation.
- The President's budget for 2008 includes \$15 million in start-up funding to create a new electronic network that would draw together the nation's major health data repositories. This network of networks would enable researchers to match treatments and outcomes, and in that way learn from the nation's day-to-day medical practice and improve safety and effectiveness of medical treatments.
- The American Health Information Community (AHIC) will develop recommendations to identify health IT standards for including genetic test information on electronic health records. AHIC is charged with developing recommendations for establishing or identifying consensus standards and for other specific actions toward achieving President Bush's goal that most Americans have electronic health records by 2014.

Current efforts at HHS agencies supporting personalized health care total \$277 million this year, and are proposed to grow to \$352 million in FY 2008. Current work at HHS agencies includes:

- At the National Institutes of Health (NIH), genome-wide association studies are using information from years of clinical trials to find associations between genetic elements and health outcomes. A milestone event is expected this fall when research from the long-running Framingham Heart Study, involving some 10,000 volunteers who have been followed over two generations, may be posted at NIH's Genotype and Phenotype (dbGaP) Web site.
- At the Food and Drug Administration (FDA), the Critical Path initiative is organizing work across 76 science and regulatory areas to improve product development, especially for gene-oriented drugs and diagnostic tests. Regulatory guidance on the co-development of drugs and diagnostic products, which is an important stepping stone for gene-based medical care, will be published this fall.
- The Centers for Disease Control and Prevention (CDC) has worked with the National Cancer Institute to define the leading 100 genetic variants of public health significance. CDC is using its National Health and Nutrition Examination Survey (NHANES), one of the nation's largest health surveys, to determine how common these variants are in the U.S. population. Results will be released this summer and will be important for researchers.

"In the future, we'll understand diseases at a new level," Secretary Leavitt said. "We'll know them as gene- or molecular-based diseases. And that will give us new kinds of treatments that will be effective for both the very specific condition and the individual patient."

U.S. TUBERCULOSIS CASES AT ALL-TIME LOW; DRUG RESISTANCE REMAINS A THREAT -- Tuberculosis rates in the United States reached an all-time low in 2006, though progress to eliminate TB continued to slow. Drug-resistant TB, including extensively drug-resistant TB, presents significant challenges to treatment and control of the disease in the United States and abroad, according to articles in today's Morbidity and Mortality Weekly Report (MMWR).

"Tuberculosis continues to have a significant and unacceptable impact on minorities and immigrant communities in the United States," said Dr. Kevin Fenton, director of CDC's National Center for HIV, STD and TB Prevention. "Blacks and Hispanics have tuberculosis rates that are about eight times higher than that of whites, and the rate for Asians is more than 21 times that of whites. Foreign-born individuals living in the United States have nearly 10 times the rate of TB as those born in the United States."

A total of 13,767 TB cases were reported in the United States in 2006, down from 14,085

cases in 2005. The 2006 national TB case rate – 4.6 cases per 100,000 persons – was the lowest since reporting began in 1953. However, the decline of 3.2 percent in the national TB case rate from 2005 to 2006 was one of the smallest in more than a decade. Overall the average annual decline in the national TB rate slowed from 7.3 percent per year in the period 1993-2000 to 3.8 percent per year in the period 2000-2006.

Persons living with TB also continue to be severely impacted by HIV. Among TB cases with a documented HIV test result, 12.4 percent were HIV-infected.

Multidrug resistant TB (MDR TB) is TB that is resistant to at least two first line therapies – isoniazid and rifampin. Extensively drug-resistant TB (XDR TB) is TB resistant to at least isoniazid and rifampin among the first-line anti-TB drugs and among second-line drugs, is resistant to any fluoroquinolone and at least one of three injectable drugs. Drug-resistant TB is difficult and costly to treat and can be fatal.

“Tuberculosis that is resistant to many of the standard drugs used to treat the disease challenges our ability to treat and control TB,” Dr. Fenton said. “In the United States, we have made great progress since the early 1990s against TB that is resistant to multiple first line treatments and had seen declines in these cases. Recently however, our success against MDR TB has slowed.”

XDR TB renders patients virtually untreatable with available drugs, particularly those in areas with less access to the full range of effective drugs. CDC’s new analysis, which includes provisional data for 2006, found that between 1993 and 2006, there were 49 XDR TB cases in the United States reported to the CDC.

XDR TB continues to be widely distributed geographically in the United States and abroad, causing public health concern. The risk of XDR TB appears to be low in the United States. However, due to the ease with which TB can spread, XDR TB will continue to pose a serious risk to the United States as long as it exists anywhere else in the world.

“CDC and its domestic and international partners are taking many steps to prevent further spread of drug-resistant TB and to reduce the overall burden of the disease,” said Dr. Ken Castro, director of CDC’s Division of Tuberculosis Elimination. “These efforts include developing new treatment regimens, increasing the capacity of health professionals to provide effective treatment, and issuing new recommendations for improved screening and treatment for U.S. immigrants.”

For more information about the reports in today’s MMWR, visit www.cdc.gov/mmwr. For information about tuberculosis, visit <http://www.cdc.gov/nchstp/tb/default.htm>.

CDC RELEASES SAFETY DATA ON ROTAVIRUS VACCINE REPORTED INTUSSUSCEPTION CASES FALL WITHIN EXPECTED RANGE -- The Centers for Disease Control and Prevention (CDC) released March 15 new safety data on a recently licensed rotavirus vaccine given to infants that indicate the vaccine does not

pose an elevated risk for intussusception, the most common cause of bowel obstruction in infants.

The vaccine, sold by Merck and Company under the brand name RotaTeq, was licensed by the U.S. Food and Drug Administration (FDA) in February 2006. The Advisory Committee on Immunization Practices (ACIP) recommends RotaTeq for routine vaccination of U.S. infants to protect against rotavirus, which causes severe diarrhea, vomiting, fever and dehydration (gastroenteritis) in children.

Each year in the United States, rotavirus is responsible for more than 400,000 doctor visits; more than 200,000 emergency room visits; and 55,000 to 70,000 hospitalizations. In developing countries, rotavirus is a major cause of childhood deaths, estimated to cause more than half a million deaths each year in children younger than 5 years of age.

Last month, FDA notified healthcare providers and consumers that it had received reports of intussusception following RotaTeq vaccination. Since then, FDA, ACIP and CDC have concluded that the number of intussusception reports after administration of RotaTeq has not exceeded the number expected to occur without vaccination and that the vaccine does not appear to be associated with intussusception.

"Monitoring the safety of a new vaccine is very important," said Anne Schuchat, M.D., director of CDC's National Center for Immunization and Respiratory Diseases. "The data we have reviewed are reassuring, and we continue to recommend the RotaTeq vaccine. However, we will continue to carefully monitor reports of possible adverse effects associated with the vaccine and will take appropriate action if there proves to be a problem in the future."

Based on ACIP recommendations, CDC policy calls for routine immunization of all U.S. infants with three doses of RotaTeq administered orally at 2, 4 and 6 months.

RotaTeq is the only vaccine approved in the United States for prevention of rotavirus disease. Studies indicate RotaTeq will prevent about 74 percent of all rotavirus cases and about 98 percent of the most severe cases, including 96 percent of cases requiring hospitalization.

Intussusception is a serious, life-threatening condition that occurs when the intestine or bowel becomes blocked. The condition can occur spontaneously in the absence of vaccination. It is most common among infants in the first year of life, causing about 1,400 infant hospitalizations annually. These cases occurred before use of any rotavirus vaccines in the United States.

The reported intussusception cases were detected through routine monitoring of new vaccines using the Vaccine Adverse Event Reporting System (VAERS). Following licensure and general use of all vaccines in the United States, CDC and FDA closely monitor VAERS reports of potential health problems after vaccination submitted by a variety of sources. Reports to VAERS may be submitted by anyone, including healthcare providers, patients and family members. Physicians and scientists at both agencies review

all reports of serious side effects reported to VAERS.

CDC and FDA continue to closely monitor RotaTeq for problems in vaccine recipients. They encourage all healthcare providers and other individuals to report any cases of intussusception or other serious adverse events to VAERS.

Adverse reactions and other potential health problems related to RotaTeq can be reported to VAERS by calling 1-800-822-7967 or online at www.vaers.hhs.gov.

ACUTE VIRAL HEPATITIS CASES DOWN; HEPATITIS A AND HEPATITIS B AT LOWEST LEVELS EVER REPORTED --The three most common forms of acute viral hepatitis in the United States – hepatitis A, B and C – declined dramatically between 1995 and 2005, with hepatitis A and B at the lowest levels ever recorded since the government began collecting surveillance data more than 40 years ago, according to the Centers for Disease Control and Prevention (CDC). Hepatitis B and C are diseases that can lead to liver cancer and death.

The main factor behind the declines in new cases of hepatitis A and B were the availability of vaccines and strong federally supported immunization programs. Declines in new cases of hepatitis A were greater among children in the 17 states where routine vaccination of children has been recommended since 1999. The declines in hepatitis B were greatest among children and teens age 15 and younger, likely the result of high vaccination coverage in this age group. The CDC recommends three doses of hepatitis B vaccine beginning at birth. Declines in reported new cases of hepatitis C were likely due to reductions in high-risk behaviors among injection drug users, as well as efforts to diagnose individuals infected with hepatitis C and the promotion of health behaviors to reduce person-to-person transmission of the virus.

Since 1995, new cases of reported acute hepatitis A have declined by 88 percent, to an incidence of 1.5 per 100,000 population, the lowest rate ever reported, according to the *Morbidity and Mortality Weekly Report (MMWR) Surveillance Summary*, “Surveillance for Acute Viral Hepatitis – United States, 2005.”

“The sharp declines in rates of hepatitis A and B are one of the big public health success stories of the last 10 years. The drops in new cases of hepatitis A and hepatitis B are evidence that our prevention strategies have been successful, particularly the widespread use of vaccines for hepatitis A and hepatitis B. In order for these declines to continue, our prevention efforts must be sustained,” said Dr. Kevin Fenton, director of CDC’s National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention.

The CDC recommends that all children 12 months to 23 months be vaccinated against hepatitis A. In addition, hepatitis A vaccine is also recommended for persons at risk for infection, including international travelers, men who have sex with men, injection- and non-injection drug users, and children living in communities with high rates of the disease.

The reported cases of acute hepatitis B also dropped to the lowest rate ever recorded in

2005 (1.8 per 100,000), a decline of 79 percent from 1990. In addition to the declines noted in children, hepatitis B rates also declined among adults but remained highest among those 25 to 44 years of age and among people with behavioral risk factors such as high-risk sexual activity and injection drug use.

Cases of hepatitis C have also declined steadily since the late 1980s. However, this trend should be viewed with caution since surveillance for acute hepatitis C is limited because many individuals do not immediately develop symptoms and do not know they are infected with the virus.

Despite the declines, there were more than 100,000 people infected with viral hepatitis in 2005. “Although the declines in acute viral hepatitis are promising, the number of new infections remains high particularly among unvaccinated adults,” said Dr. John Ward, director of CDC’s division of viral hepatitis. “By vaccinating infants against hepatitis B, we have made great progress in reducing infections in children.

In 2006, CDC issued new guidelines to increase vaccination coverage among adults at risk for hepatitis B. “We need to encourage vaccination of adults at high risk for hepatitis B, particularly those with multiple sex partners or whose sex partners are already infected, men who have sex with men, and injection drug users,” Dr. Ward said.

More than 4.5 million Americans are living with chronic hepatitis B and hepatitis C and are at serious risk for liver cirrhosis and cancer. “In addition to strengthening our efforts to prevent new cases of viral hepatitis we must also ensure that people with chronic hepatitis are aware of their infection and know how to protect their health and prevent transmission to others,” Dr. Ward added.

Morbidity and Mortality Weekly Report (MMWR), “Surveillance for Acute Viral Hepatitis – United States, 2005,” is available at www.cdc.gov/mmwr.

For information about viral hepatitis visit <http://www.cdc.gov/ncidod/diseases/hepatitis/>.