

THE CSTE WASHINGTON REPORT

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EDITOR'S NOTE: -- Scientists supported by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), have identified a defect in the immune response of people with the skin condition atopic dermatitis that puts them at risk of developing serious complications following smallpox vaccination. Led by Donald Y.M. Leung, M.D., Ph.D., of the National Jewish Medical and Research Center in Denver, the researchers used laboratory-grown human skin cells to show that an immune system protein called LL-37 is critical in controlling replication of vaccinia virus, the live virus that is the key component in standard smallpox vaccine – additional information is included 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 TO ACT ON BUDGET – Action on the FY 2007 Budget Resolution has moved to the House after the Senate successfully adopted the Specter-Harkin amendment to add \$7 billion for health and education programs in its Budget Resolution two weeks ago. Moderate House Republicans have been trying to influence the budget process and shift funds towards domestic discretionary priorities. On March 15, they sent a letter requesting a 2 percent increase for all non-defense, non-homeland security domestic discretionary programs in the House FY 2007 Budget Resolution. The letter was signed by 23 Moderate Republican Members. On March 28, Rep. Michael Castle (R-DE) held a rally for health and education groups, and invited the press, to motivate them to keep pressing House Members to also adopt the Specter-Harkin amendment in the House Budget Resolution. An estimated 300 representatives of health and education groups attended and were energized by Rep. Castle's message. However, the first legislative step in the House Budget process took place on Wednesday, March 29th when the Budget Committee voted down the Specter-Harkin amendment offered by Rep. Rosa DeLauro's (D-CT). The vote was 22-14 strictly along party lines. Rep. DeLauro is a cancer survivor and spoke passionately about the need for additional resources for cancer research and cancer prevention programs. Rep. Lois Capps (D-CA), speaking in favor of Rep. DeLauro's amendment, also shared that her daughter had died of cancer.

The next step is the House floor where a vote on the Budget Resolution is planned for April 5th or 6th next week. No amendments are allowed on Budget Resolutions in the House, so the only option available to health advocacy groups is to urge the Members to vote against the measure. If enough pressure is applied, it will be evident there are not enough votes to pass the Budget Resolution until and unless more funding for health and education programs is made available.

HHS BUYS MORE ANTIVIRAL MEDICATION FOR THE STRATEGIC NATIONAL STOCKPILE -- HHS Secretary Mike Leavitt March 22 announced additional purchases of antiviral drugs that could be used in the event of a potential influenza pandemic. The department has ordered 2.2 million more treatment courses of antiviral drug zanamivir (Relenza®) from GlaxoSmithKline and 3.8 million more treatment courses of oseltamivir phosphate (Tamiflu®) from Roche. With these purchases, the Strategic National Stockpile will have a total of 26 million treatment courses of antiviral drugs for distribution to the states when an influenza pandemic is deemed to be imminent.

"Our ultimate goal is to stockpile sufficient quantities of antiviral drugs to treat 25 percent of the U.S. population," Secretary Leavitt said. "We also hope these purchases will stimulate development of expanded domestic production capacity in order to accommodate subsequent needs through normal commercial transactions."

President Bush has outlined a coordinated government strategy that includes the establishing the new International Partnership on Avian and Pandemic Influenza, stockpiling antiviral medications, enhancing domestic capacity to develop and manufacture influenza vaccines and dose-sparing technology, expanding early-warning systems domestically and abroad and new funding and initiatives for local and state level preparedness.

As part of the Administration's goal to enhance state and local pandemic preparedness, HHS senior officials now have participated at summits in 26 states and the District of Columbia. To date, pandemic preparedness planning summits have been held in Alabama, Arizona, Connecticut, Delaware, District of Columbia, Florida, Georgia, Kentucky, Illinois, Iowa, Maryland, Massachusetts, Minnesota, Missouri, Nebraska, Nevada, North Carolina, North Dakota, Ohio, Pennsylvania, Rhode Island, South Carolina, South Dakota, Vermont, West Virginia, Wisconsin and Wyoming.

More information on pandemic preparedness, including a list of 12 summits planned through March 31 is available on the newly revised www.pandemicflu.gov.

U.S. TUBERCULOSIS CASES AT AN ALL-TIME LOW IN 2005, BUT DRUG RESISTANCE INCREASING -- The latest national surveillance data show that tuberculosis (TB) rates reached an all-time low in the United States in 2005, but progress to eliminate TB is slowing.¹ Furthermore, the increasing occurrence of drug-resistant TB, including extensively drug-resistant cases, presents significant challenges to treatment and control of the disease both in the United States and abroad.

TB Rate Declines Nationwide

A total of 14,093 TB cases were reported in the United States in 2005, down from 14,516 cases in 2004. The 2005 national TB case rate – 4.8 cases per 100,000 persons – was the lowest since reporting began in 1953. However, the decline of 3.8 percent in the national TB case rate from 2004 to 2005 was one of the smallest declines in more than a decade.

Increase in Multi-Drug Resistant TB Presents Serious Challenges

At the same time, persons with multi-drug-resistant (MDR) TB – TB that is resistant to at least two first-line therapies (isoniazid and rifampin) -- increased 13.3 percent in the United States from 2003 to 2004, the most recent years for which those data are available. This was the largest single-year increase in MDR TB since 1993.

MDR TB, which is difficult and costly to treat, and can be fatal, now accounts for 1.2 percent of all TB cases for which drug-susceptibility data are available. Closely following MDR TB trends in the coming years will be critical in determining whether the 2005 increase represents a nationwide trend, and in understanding the implications of resistance for TB treatment and control.

Other new CDC research reports for the first time on the worldwide emergence of extensively drug-resistant (XDR) TB – or TB that is resistant to at least two main first-line drugs and additionally to three or more of the six classes of second-line drugs.² From 2000 to 2004, 2 percent of TB patients whose isolates were tested in a survey of a worldwide laboratory network were classified as XDR TB. Over the five-year period in this survey, XDR TB increased from 5 percent of MDR TB cases in 2000 to 6.5 percent in 2004 (excluding South Korea). In the industrialized nations in this survey (including

the United States), XDR TB increased from 3 percent of MDR TB cases in 2000 to 11 percent in 2004.

The emergence of XDR TB is cause for concern because it is widely distributed geographically, including in the United States, and renders patients virtually untreatable with available drugs.

Importantly, the emergence of MDR TB 15 years ago was a harbinger of a pandemic; this scenario must be prevented from happening with XDR TB.

Addressing the Threat of TB Drug-Resistance Worldwide

TB is a serious threat both in the United States and abroad. Globally, more than one-third of the world's population is infected with the bacteria that cause TB, and each year approximately 9 million people become ill with the disease, and 2 million of those die. The ability of the disease to develop resistance to treatments and to travel easily across borders makes worldwide TB control efforts critical.

CDC is working with partners around the world to ensure that adequate resources and tools are in place to prevent further drug resistance. These efforts include strengthening national TB programs and health care professionals to diagnose and ensure completion of TB treatment, developing global policy recommendations, improving standards for second-line drug testing, designing new treatment regimens, and improving tests to diagnose the disease.

CDC's global efforts also include working with officials in Mexico and other countries to improve TB control on the U.S. borders, improving overseas screening for immigrants and refugees and providing diagnoses and care to recent arrivals from countries that have a high incidence of TB.

For more information about CDC's TB elimination program or World TB Day activities, visit www.cdc.gov/nchstp/tb/WorldTBDay/2006.

AHRQ LAUNCHES NEW WEB-BASED TOOL FOR STATES TO MEASURE PERFORMANCE ON THE QUALITY OF HEALTH CARE ACROSS AMERICA

-- HHS' Agency for Healthcare Research and Quality March 17 released a new interactive Web-based tool for States to use in measuring health care quality. The new *State Snapshot* Web tool is based on the *2005 National Healthcare Quality Report* (NHQR) and the *2005 National Healthcare Disparities Report* (NHDR), originally released on January 9, and provides quick and easy access to the many measures and tables of the NHQR from each State's perspective.

"We developed the new *State Snapshot* tool because it is important for States and other health care policymakers to know how their State is doing in providing care," said AHRQ Director Carolyn M. Clancy, M.D. "The need to improve quality of care for all

Americans continues to be great, and this tool can help States target their very significant quality improvement efforts.”

The *State Snapshot* tool provides a multitude of valuable information for each individual State, including:

- * State ranking tables that rank the 50 States and the District of Columbia on 15 representative measures of health care quality culled from 179 measures contained in the 2005 NHQR.
- * Summary measures of the quality of types of care (prevention, acute, chronic) and settings of care (hospital, ambulatory, nursing home, and home health) for each State.
- * Comparisons of each State’s summary measures to regional and national performance relative to the region or nation.
- * Performance meters that show at a glance a State’s performance relative to the region or nation.
- * Data tables for each State’s summary measures that show the NHQR detailed measures and numbers behind the performance meters.

Also, the *State Snapshot* tool features a special focus on each State’s performance in the treatment of diabetes across three areas:

- * Quality of diabetes care.
- * Disparities in diabetes treatment.
- * Cost savings that States might accrue by implementing disease management for diabetes for State government employees.

During 2005, AHRQ released several resources to help States target their quality improvement efforts such as *Diabetes Care Quality Improvement: A Resource Guide for State Action* and its companion Workbook and several online tools for States developed from the 2004 NHQR (go to <http://www.ahrq.gov/qual/diabqualoc.htm>).

AHRQ will partner with four States in 2006 to develop a complementary guide to the *State Snapshot* Web tool that will help States use the information from the tool for priority setting and quality improvement.

To view the *State Snapshot* tool, go to <http://www.qualitytools.ahrq.gov/qualityreport/2005/state>. The *2005 National Healthcare Quality Report* and the *2005 National Healthcare Disparities Report* are available online at <http://www.qualitytools.ahrq.gov>, by calling 1-800-358-9295, or by sending an E-mail to ahrqpubs@ahrq.gov.

**DEFECTIVE IMMUNE SYSTEM RESPONSE TO SMALLPOX VACCINE
DETAILED IN NEW STUDY** -- Scientists supported by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), have identified a defect in the immune response of people with the skin condition atopic dermatitis that puts them at risk of developing serious complications following smallpox

vaccination. Led by Donald Y.M. Leung, M.D., Ph.D., of the National Jewish Medical and Research Center in Denver, the researchers used laboratory-grown human skin cells to show that an immune system protein called LL-37 is critical in controlling replication of vaccinia virus, the live virus that is the key component in standard smallpox vaccine.

The investigators are part of NIAID's Atopic Dermatitis and Vaccinia Network, which was created in 2004 to integrate clinical and animal research aimed at reducing the risk of eczema vaccinatum, a potentially deadly complication of smallpox vaccination. Eczema vaccinatum occurs almost exclusively in people who have a history of atopic dermatitis, a common, non-contagious skin disorder also known as eczema.

"This new research, the first to be published by Atopic Dermatitis and Vaccinia Network scientists, illuminates one potential mechanism leading to eczema vaccinatum and improves our understanding of the immune responses to smallpox vaccine of people with atopic dermatitis," says NIAID Director Anthony S. Fauci, M.D.

Published in this month's issue of *Immunity*, the study details how the overproduction in skin cells of inflammation-promoting molecules called interleukin-4 and interleukin-13 (IL-4 and IL-13) hampers LL-37 activity in people with atopic dermatitis. LL-37, a small protein produced in skin cells, is part of the body's first line of defense against invaders. Earlier research by Dr. Leung and his colleagues suggested that LL-37 is critical in controlling the spread of vaccinia virus.

In the current study, the investigators used skin samples taken from people with atopic dermatitis (as well as samples taken from healthy volunteers without skin disease and from people with another skin condition called psoriasis) to further investigate how dysfunctions in the immune response of people with eczema set the stage for eczema vaccinatum. When exposed to vaccinia virus, the skin samples from healthy volunteers and from those with psoriasis reacted by producing more LL-37. As a result, the replication of the virus was controlled and eventually halted. In contrast, LL-37 production was minimal in skin samples from people with atopic dermatitis and vaccinia replication was poorly controlled. Next, the scientists exposed skin samples from people with atopic dermatitis to vaccinia, and then added LL-37. With the LL-37 supplement, the skin cells successfully controlled the viral replication.

Dr. Leung and his group then looked more closely at why vaccinia infection fails to induce LL-37 production in atopic dermatitis skin. Comparing immune responses of skin cells grown in the lab from healthy volunteers and from people with atopic dermatitis, the researchers found that the latter skin samples produced excessive amounts of IL-4 and IL-13. Adding IL-4 and IL-13 to skin cells from healthy volunteers prior to vaccinia exposure reduced levels of LL-37 production. Conversely, when the scientists applied IL-4- and IL-13-neutralizing antibodies to skin samples from people with atopic dermatitis, LL-37 production increased significantly.

Together, these findings suggest a rationale for new treatment approaches to eczema vaccinatum, notes Dr. Leung. One approach involves developing drugs to mimic the

action of LL-37 or developing LL-37-containing creams that could be applied to the skin in order to boost its ability to contain vaccinia virus infection. Another approach could be to develop agents to neutralize IL-4 and IL-13. Although no such drugs are currently marketed, compounds that can neutralize IL-4 and IL-13 are under study as possible asthma and allergy treatments, Dr. Leung says, and might also be applied to eczema vaccinatum treatment.

Smallpox vaccine, which is made with live vaccinia virus (a close relative of the virus that causes smallpox), has not been routinely given in the United States since the early 1970s. But recent concerns about the possibility of a bioterrorist attack using smallpox virus prompted authorities to reinstate voluntary smallpox vaccination for specific groups, such as military personnel. In the first five months of 2003, the U.S. Department of Defense vaccinated more than 450,000 personnel against smallpox. During this period, the majority of those who deferred vaccination cited atopic dermatitis or other skin conditions as the main reason.